

INTEGRA LIFESCIENCES HOLDINGS CORP  
Form 10-K  
February 27, 2012  
Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**Form 10-K**

(Mark One)

**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**  
*(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)*

**311 Enterprise Drive**

**PLAINSBORO, NEW JERSEY**  
*(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)*

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

**51-0317849**  
*(I.R.S. EMPLOYER  
IDENTIFICATION NO.)*

**08536**  
*(ZIP CODE)*

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

**Title of Each Class**

**Name of Exchange on Which Registered**

# Edgar Filing: INTEGRA LIFESCIENCES HOLDINGS CORP - Form 10-K

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  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

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

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a 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

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.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1.	<u>Business</u> 1
Item 1A.	<u>Risk Factors</u> 15
Item 1B.	<u>Unresolved Staff Comments</u> 30
Item 2.	<u>Properties</u> 30
Item 3.	<u>Legal Proceedings</u> 30
Item 4.	<u>Mine Safety Disclosures</u> 31
<b><u>PART II</u></b>	
Item 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 32
Item 6.	<u>Selected Financial Data</u> 33
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 35
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 54
Item 8.	<u>Financial Statements and Supplementary Data</u> 55
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> 55
Item 9A.	<u>Controls and Procedures</u> 55
Item 9B.	<u>Other Information</u> 56
<b><u>PART III</u></b>	
Item 10.	<u>Directors, Executive Officers and Corporate Governance</u> 57
Item 11.	<u>Executive Compensation</u> 57
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> 57
Item 13.	<u>Certain Relationships, Related Transactions, and Director Independence</u> 57
Item 14.	<u>Principal Accountant Fees and Services</u> 57
<b><u>PART IV</u></b>	
Item 15.	<u>Exhibit and Financial Statements Schedules</u> 58
<u>Signatures</u>	69
<u>EX-10.16(c)</u>	
<u>EX-10.39(n)</u>	
<u>EX-21</u>	
<u>EX-23</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	
<u>EX-101 INSTANCE DOCUMENT</u>	
<u>EX-101 SCHEMA DOCUMENT</u>	
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>	
<u>EX-101 DEFINITION LINKBASE DOCUMENT</u>	
<u>EX-101 LABELS LINKBASE DOCUMENT</u>	
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>	

**Table of Contents**

**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 subsidiaries 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.

## **Table of Contents**

*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.

## **Table of Contents**

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 carpal 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.

## **Table of Contents**

***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.

## **Table of Contents**

**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.



## **Table of Contents**

**Tissue Ablation Equipment.** Our tissue ablation equipment uses high frequency acoustic pulses to selectively dissect soft tissues according to their density. Integra's CUSA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> NXT Extended Length Tip for Integra's CUSA<sup>®</sup> NXT and CUSA<sup>®</sup> Selector<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Miltex<sup>®</sup> 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.

## **Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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.

## **Table of Contents**

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

---

## **Table of Contents**

Manta Ray , Miltex<sup>®</sup>, Movement<sup>®</sup>, NeuraGen<sup>®</sup>, NeuraWrap , NewPort , NuGrip , Omni-Tract<sup>®</sup>, OrthoBlast<sup>®</sup> II, OSV II<sup>®</sup>, Qwix<sup>®</sup>, Panta<sup>®</sup>, Redmond , Ruggles , SafeGuard<sup>®</sup>, SeaSpine<sup>®</sup>, Selector<sup>®</sup>, Sonoma , Subtalar MBA<sup>®</sup>, TenoGlide<sup>®</sup>, Titan , Trel-X , Trel-XC<sup>®</sup>, Tibiaxys<sup>®</sup>, Uni-CP , Uni-Clip<sup>®</sup>, Universal2 , Ventrix<sup>®</sup>, XKknife<sup>®</sup>, Zuma , and the Integra logo are some of the material trademarks of Integra LifeSciences Corporation and its subsidiaries. MAYFIELD<sup>®</sup> is a registered trademark of SM USA, Inc., and is used by Integra under license.

## **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.

**Table of Contents**

**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](http://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](http://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.



**Table of Contents**

**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.

## Edgar Filing: INTEGRA LIFESCIENCES HOLDINGS CORP - Form 10-K

You can identify these forward-looking statements by forward-looking words such as believe, may, could, might, will, estimate, continue, anticipate, intend, seek, plan, expect, should, would and similar expressions in this report. We undertake no obligation to publicly update or 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.

**Table of Contents**

**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.

## **Table of Contents**

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

## **Table of Contents**

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.

## Table of Contents

*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

## **Table of Contents**

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



## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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,

## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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.

## **Table of Contents**

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;

## **Table of Contents**

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

## **Table of Contents**

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.

**Table of Contents**

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.

**Table of Contents**

**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.

**Table of Contents**

**ITEM 4. MINE SAFETY DISCLOSURES**  
Not applicable.

**Table of Contents****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.

**Table of Contents**

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	\$ 49.84	42	\$ 72,884
March 1, 2011 to March 31, 2011	44	\$ 50.14	44	\$ 70,680
June 1, 2011 to June 30, 2011	1,127(1)	\$ 46.79	322	\$ 55,561
August 1, 2011 to August 31, 2011	200	\$ 42.00	200	\$ 47,161
September 1, 2011 to September 30, 2011	96	\$ 37.22	96	\$ 43,559
October 1, 2011 to October 31, 2011	400	\$ 36.13	400	\$ 29,106
	1,909		1,104	

- (1) On June 15, 2011 the Company purchased approximately 0.8 million shares at an average price of \$46.70 in connection with the issuance of its 2016 Notes.

**ITEM 6. SELECTED FINANCIAL DATA**

The information set forth below should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this report. We have acquired numerous businesses and product lines during the previous five years. As a result of these acquisitions, the consolidated financial results and balance sheet data for certain of the periods presented below may not be directly comparable.

	2011	Years Ended December 31,			2007
		2010	2009	2008	
		(In thousands, except per share data)			
<b>Operating Results:</b>					
Total revenues, net	\$ 780,078	\$ 732,068	\$ 682,487	\$ 654,604	\$ 550,459
Costs and expenses(1)	725,166	633,374	584,663	607,193	483,171
Operating income	54,912	98,694	97,824	47,411	67,288
Interest income (expense), net(3)	(27,175)	(18,131)	(22,596)	(27,971)	(23,561)
Other income (expense), net	757	1,551	(2,076)	(905)	2,971
Income before income taxes	28,494	82,114	73,152	18,535	46,698
Provision for (benefit from) income taxes	505	16,445	22,197	(9,192)	20,949
Net income	\$ 27,989	\$ 65,669	\$ 50,955	\$ 27,727	\$ 25,749
Diluted net income per share	\$ 0.95	\$ 2.17	\$ 1.74	\$ 0.96	\$ 0.86
	29,495	30,149	29,292	28,378	29,373

Weighted average common shares outstanding for diluted net  
income per share

33



**Table of Contents**

	2011	2010	December 31, 2009 (In thousands)	2008	2007
<b>Financial Position:</b>					
Cash, cash equivalents	\$ 100,808	\$ 128,763	\$ 71,891	\$ 183,546	\$ 57,339
Total assets	1,144,109	1,017,308	940,102	1,026,014	819,788
Long-term borrowings under the revolving portion of the senior credit facility(2)	179,688		160,000	160,000	
Long-term debt(3)	352,576	294,842	148,754	299,480	286,742
Retained earnings	260,819	232,830	167,161	116,206	89,368
Stockholders' equity	492,638	499,963	444,885	372,309	287,594

- (1) In 2008, we recorded an in-process research and development charge of \$25.2 million in connection with the Integra Spine (as hereinafter defined) acquisition and, we also recorded an \$18.0 million stock-based compensation charge related to restricted stock units that were vested on the date of grant. In 2009 and 2007 we recorded similar in-process research and development charges of \$0.3 million for the Innovative Spinal Technologies, Inc. acquisition, and \$4.6 million for the IsoTis, Inc. acquisition, respectively. In 2011, we recorded a total of \$13.3 million in stock-based compensation charges related to our former chief executive officer's employment agreement extension, accelerated vesting of his outstanding shares upon the appointment of the new chief executive officer, and his minimum annual stock-based compensation award which was fully vested on the date of grant.
- (2) In 2011, 2009 and 2008 we classified \$179.7 million, \$160.0 million and \$160.0 million, respectively, of the revolving portion of our senior credit facility borrowings as long-term debt based on our current intent and ability to repay the borrowings outside of the following twelve-month periods. In 2010 we converted \$150.0 million of our revolving loan balance to a term loan as part of our amended and restated senior credit facility that is due at various dates through August 2015. At December 31, 2011, we have a total of \$179.7 million outstanding on our senior credit facility and \$420.3 million available for future borrowings.
- (3) In 2003, we issued \$120.0 million of 2.5% contingent convertible subordinated notes due 2008. In March 2008, these notes matured and we repaid the principal amount in cash and issued approximately 768,000 shares of our common stock.
- In 2007, we issued \$165.0 million of 2.75% senior convertible notes due 2010 (the 2010 Notes) and \$165.0 million of 2.375% senior convertible notes due 2012 (the 2012 Notes). The 2010 Notes were paid off in June 2010 in accordance with their terms. We expect to satisfy any conversion of the 2012 Notes with cash up to their principal amount pursuant to the net share settlement mechanism set forth in the indenture and, with respect to any excess conversion value, with shares of our common stock.

In 2011, we issued \$230.0 million of 1.625% convertible senior notes due in 2016 (the 2016 Notes). We expect to satisfy any conversion of the 2016 Notes with cash up to their principal amount pursuant to the net share settlement mechanism set forth in the indenture and, with respect to any excess conversion value, with shares of common stock.

## **Table of Contents**

### ***ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

The following discussion and analysis of our financial condition and results of operations should be read together with the selected consolidated financial data and our financial statements and the related notes appearing elsewhere in this report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those under the heading Risk Factors.

#### **GENERAL**

Integra is a world leader in medical devices focused on limiting uncertainty for surgeons so they can concentrate on providing the best patient care. Integra provides customers with clinically relevant, innovative and cost-effective products that improve the quality of life for patients. We focus on cranial and spinal procedures, small bone and joint injuries, the repair and reconstruction of soft tissue, and instruments for surgery.

We present revenues in three product categories: Orthopedics, Neurosurgery and Instruments. Our orthopedics products group includes specialty metal implants for surgery of the extremities and spine, orthobiologics products for repair and grafting of bone, dermal regeneration products and tissue-engineered wound dressings and nerve and tendon repair products. Our neurosurgery products group includes, among other things, dural grafts that are indicated for the repair of the dura mater, ultrasonic surgery systems for tissue ablation, cranial stabilization and brain retraction systems, systems for measurement of various brain parameters and devices used to gain access to the cranial cavity and to drain excess cerebrospinal fluid from the ventricles of the brain. Our instruments products group includes a wide range of specialty and general surgical and dental instruments and surgical lighting for sale to hospitals, outpatient surgery centers, and physician, veterinarian and dental practices.

We manage these product groups and distribution channels on a centralized basis, and accordingly, we report our financial results under a single operating segment—the development, manufacturing, and marketing of medical devices.

We manufacture many of our products in plants located in the United States, Puerto Rico, France, Germany, Ireland, the United Kingdom and Mexico. We also source most of our handheld surgical instruments and specialty metal implants through specialized third-party vendors.

In the United States, we have several sales channels. Orthopedics products are sold through a large direct sales organization and through specialty distributors focused on their respective surgical specialties. Neurosurgery products are sold through directly employed sales representatives. Instruments products are sold through two sales channels, both directly and through distributors and wholesalers, depending on the customer call point.

We also market certain products through strategic partners.

Our objective is to become a diversified global medical device company that helps patients by limiting uncertainty for medical professionals, and become 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. Our strategy includes the following key elements: geographic expansion, margin expansion, leveraging platform synergies, disciplined focus and execution, global quality assurance and acquiring or in-licensing products that fit existing sales channels.

We aim to achieve this growth in revenues while maintaining strong financial results. While we pay attention to any meaningful trend in our financial results, we pay particular attention to measurements that are

## Table of Contents

indicative of long-term profitable growth. These measurements include (1) revenue growth (derived through acquisitions and products developed internally), (2) gross margins on total revenues, (3) operating margins (which we aim to continually expand as we leverage our existing infrastructure), (4) earnings before interest, taxes, depreciation, and amortization, and (5) earnings per diluted share of common stock.

We believe that we are particularly effective in the following aspects of our business:

*Regenerative Medicine Platform.* We have developed numerous product lines through our proprietary collagen matrix and demineralized bone matrix technologies that are sold through every one of our sales channels.

*Diversification and Platform Synergies.* Each of our three selling platforms contributes a different strength to our core business. Orthopedics enables us to grow our top line and increase marginal gross profit. Neurosurgery provides stable growth as a market with few elective procedures. Instruments has a strong capacity to generate cash flows. We have unique synergies among these platforms, such as our regenerative medicine technology, instrument sourcing capabilities, and Group Purchasing Organization ( GPO ) contract management.

*Unique Sales Footprint.* Our sales footprint provides us with a unique set of customer call-points and synergies. Each of our sales channels can benefit from the GPO and Integrated Delivery Network ( IDN ) relationships that our Instruments group manages. We have market leading products among neurosurgeons, many of whom also perform spine surgeries, and we have yet to fully leverage those relationships to sell our spine products. We also have clinical expertise across all of our channels in the United States, and have an opportunity to expand and leverage this expertise in markets worldwide.

*Ability to Change and Adapt.* Our corporate culture is truly what enables us to adapt and reinvent ourself. We have demonstrated that we can quickly and profitably integrate new products and businesses. This core strength has made it possible for us to double our size over the years, and is key to our ability to grow into a multi-billion dollar company.

## **ACQUISITIONS**

Our strategy for growing our business includes the acquisition of complementary product lines and companies. Our recent acquisitions of businesses, assets and product lines may make our financial results for the year ended December 31, 2011 not directly comparable to those of the corresponding prior-year periods. See Note 3, Acquisitions, to our consolidated financial statements for a further discussion.

From January 2009 through December 2011, we have acquired the following businesses, assets and product lines:

In September 2011, we acquired Ascension Orthopedics, Inc. ( Ascension ) for \$66.5 million, subject to working capital adjustments. Ascension, based in Austin, Texas, develops and distributes a range of implants for the shoulder, elbow, wrist, hand, foot and ankle. In particular, Ascension adds a significant number of new and differentiated products to our extremities portfolio and access to the shoulder market.

In May 2011, we acquired SeaSpine, Inc. ( SeaSpine ) for approximately \$89.0 million, subject to working capital adjustments. SeaSpine, based in Vista, California, offers spinal fusion products to customers across the U.S. and in select markets in Europe. The addition of the SeaSpine business effectively doubled our distribution footprint and customer base in the U.S. spine hardware market.

In September 2010, we acquired certain assets as well as the distribution rights for our extremity reconstruction product lines in Australia from Culley Investments Pty. Ltd. ( Culley ) for approximately \$1.6 million (1.7 million Australian dollars) in cash. For eight years, Culley had been our distributor of these products in Australia. The acquisition provides us with the ability to sell orthopedic products directly to our Australian customers.

## **Table of Contents**

In May 2010, we acquired certain assets and liabilities of the surgical headlight business of Welch Allyn, Inc. ( Welch ) for approximately \$2.4 million in cash and \$0.2 million of working capital adjustments. We believe that the assets acquired will further our goal of expanding our reach into the surgical headlight market.

In December 2009, we acquired certain assets as well as the distribution rights for our Newdeal® product lines in the United Kingdom from Athrodax Healthcare International Ltd. ( Athrodax ), for approximately \$3.3 million (2.0 million British Pounds) in cash, subject to certain working capital adjustments. For the previous 10 years Athrodax had been our distributor of extremity reconstruction products in the United Kingdom. The acquisition provides us with the opportunity to become closer to our United Kingdom customers and includes an experienced sales team in the foot and ankle surgery market that had successfully developed our brand in the United Kingdom.

In August 2009, we acquired certain assets and liabilities of Innovative Spinal Technologies, Inc. ( IST ) for approximately \$9.3 million in cash and \$0.2 million in acquisition expenses. IST had filed for Chapter 7 bankruptcy protection in May 2009 and the acquisition resulted from an auction process that the bankruptcy trustee conducted and that a United States Bankruptcy Judge for the District of Massachusetts approved. IST s focus was on spinal implant products related to minimally invasive surgery and motion preservation techniques. We acquired three product lines, various product development assets for posterior dynamic stabilization, various patents and trademarks, inventory, and we assumed certain of IST s patent license agreements and related obligations. The assets and liabilities acquired did not meet the definition of a business under the authoritative guidance for business combinations. Accordingly, we recognized the assets and liabilities at cost and charged the acquired in-process research and development immediately to expense.

## **FACILITY CONSOLIDATION, MANUFACTURING AND DISTRIBUTION TRANSFER ACTIVITIES**

As a result of our ongoing acquisition strategy and significant growth in recent years, we have undertaken cost-saving initiatives to consolidate manufacturing and distribution facilities and activities, implement a global enterprise resource planning system, eliminate duplicative positions, and realign various sales and marketing activities, and to expand and upgrade production capacity for our regenerative medicine products.

While we expect a positive impact from ongoing restructuring, integration and manufacturing transfer and expansion activities, such results remain uncertain.

## **MANAGEMENT CHANGES**

On December 20, 2011, the Company s Board of Directors approved the following changes effective January 3, 2012: (i) Peter Arduini would be promoted from the role of President and Chief Operating Officer to the role of President and Chief Executive Officer, and was appointed to a newly created seat on the Board of Directors, (ii) Stuart Essig would be appointed Executive Chairman of the Board of Directors, and (iii) Richard Caruso, the former Chairman of the Board of Directors, would remain as a director of the Company.

## **RESULTS OF OPERATIONS**

Net income in 2011 was \$28.0 million, or \$0.95 per diluted share, as compared to \$65.7 million, or \$2.17 per diluted share in 2010, and \$51.0 million, or \$1.74 per diluted share in 2009.

**Table of Contents****Special Charges**

Income before taxes includes the following special charges:

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
<b>SPECIAL CHARGES</b>			
Acquisition-related charges	\$ 5,253	\$ 2,509	\$ 5,322
Certain employee termination and related charges	2,705	1,498	674
Intangible asset impairment charges	2,648	856	1,519
Charges associated with discontinued product lines	3,926	506	246
Systems implementation charges	17,068	3,462	
Facility consolidation, acquisition integration, manufacturing and distribution transfer charges	2,956	1,676	768
Charges related to restructuring our European entities (1)	378	1,329	1,876
Charges related to the accelerated vesting of stock-based compensation and the minimum annual stock-based compensation award for our former Chief Executive Officer	4,912		
Charges related to extending our former Chief Executive Officer's employment contract	8,379		
Expenses related to the refinancing of our senior credit facility	790		
Expenses related to our Chief Executive Officer joining the Company	100	2,188	
Expenses associated with remediation and related unplanned idle time and underutilization at our Plainsboro, New Jersey manufacturing facility	5,830		
Non-cash amortization of imputed interest for convertible debt	10,521	7,125	9,900
Incremental professional and bank fees related to the possibility of obtaining a waiver under our revolving credit facility			350
Acquired in-process research and development			277
Litigation settlement (gain) and related charges			(253)
Gain related to early extinguishment of convertible notes			(469)
<b>Total</b>	<b>\$ 65,466</b>	<b>\$ 21,149</b>	<b>\$ 20,210</b>

- (1) The foreign exchange loss in 2009 of \$1.9 million is associated with our intercompany loan set up in connection with the restructuring of a German subsidiary in the fourth quarter of 2008. Net income for 2011, 2010 and 2009 includes foreign exchange gains and losses associated with intercompany loans not related to any restructuring.

The items reported above are reflected in the consolidated statements of operations as follows:

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
Cost of product revenues	\$ 13,418	\$ 3,642	\$ 7,200
Research and development	669	102	570
Selling, general and administrative	37,420	9,424	1,236
Intangible asset amortization	2,648	856	
Interest expense	11,311	7,125	10,050
Other income (expense), net			1,154
<b>Total</b>	<b>\$ 65,466</b>	<b>\$ 21,149</b>	<b>\$ 20,210</b>



**Table of Contents**

We typically define special charges as items for which the amounts and/or timing of such expenses may vary significantly from period-to-period, depending upon our acquisition, integration and restructuring activities, and for which the amounts are non-cash in nature, or for which the amounts are not expected to recur at the same magnitude as we implement certain tax planning strategies. We believe that, given our ongoing strategy of seeking acquisitions, our continuing focus on rationalizing our existing manufacturing and distribution infrastructure and our continuing review of various product lines in relation to our current business strategy, certain of the special charges discussed above could recur with similar materiality in the future. In 2010 we began investing significant resources in the global implementation of a single enterprise resource planning system. Once the project reaches the application development stage, we will begin to capitalize the related expenditures.

We believe that the separate identification of these special charges provides important supplemental information to investors regarding financial and business trends relating to our financial condition and results of operations. Investors may find this information useful in assessing comparability of our operating performance from period to period, against the business model objectives established by management, and against other companies in our industry. We provide this information to investors so that they can analyze our operating results in the same way that management does and to use this information in their assessment of our core business and their valuation of Integra.

**Total Revenues and Gross Margin**

	Years Ended December 31,		
	2011	2010	2009
	(In thousands)		
Orthopedics	\$ 328,782	\$ 290,050	\$ 262,170
Neurosurgery	285,341	275,046	256,544
Instruments	165,955	166,972	163,773
Total revenues	780,078	732,068	682,487
Cost of product revenues	299,150	268,188	244,918
Gross margin	\$ 480,928	\$ 463,880	\$ 437,569
Gross margin as a percentage of revenues	61.7%	63.4%	64.1%

For the year ended December 31, 2011, total revenues increased by \$48.0 million or 7%, to \$780.1 million from \$732.1 million during the prior-year. Domestic revenues increased by 6% to \$593.0 million and were 76% of total revenues for the year ended December 31, 2011. International revenues increased \$16.2 million to \$187.0 million, an increase of 9% compared to 2010. Foreign exchange fluctuations, arising primarily from a stronger euro during the second and third quarters of 2011 and a stronger Australian dollar throughout the year compared to the U.S. dollar than in 2010, accounted for a net \$7.9 million increase in revenues for the year ended December 31, 2011. On a constant currency basis, our overall revenues increased 5.5% compared to 2010.

Orthopedics revenues were \$328.8 million, an increase of 13% over the prior-year period. The impact of our acquisitions of SeaSpine and Ascension drove most of this increase in revenue, and sales of engineered regenerative medicine products for skin and wound repair and orthobiologics products also increased over the full year 2010. However, the overall spine market is experiencing reductions in both the average selling price of products, and procedure volumes. These trends may put pressure on spine revenues in the future. Additionally, the remediation work in our Plainsboro, New Jersey facility (discussed further below) has resulted in shortages of our regenerative medicine products because the part of the plant that manufactures these products has been out of production longer than initially anticipated. We expect to resume production at normal levels in the first quarter of 2012, complete the remediation work in the first half of 2012, and resolve shortages of dermal wound products in the second quarter of 2012. Our extremity reconstruction business, especially foot and ankle products, grew more slowly in 2011 than in recent years. Forefoot procedures in particular tend to be elective in nature and

---

**Table of Contents**

sensitive to local economic conditions. Furthermore, our sales force has been devoting significant attention to learning the Ascension product lines and customer base, which is something we expect will continue through the first quarter of 2012, but will be resolved in the second quarter of 2012. Finally, we have seen a decrease in our private-label product revenue as the sales volume of the underlying products by our strategic partners has declined. This decline also has resulted in decreased royalty revenues.

Neurosurgery revenues were \$285.3 million, an increase of 4% over the prior-year period, resulting primarily from increases in sales of neuromonitoring devices used in the critical care setting, ultrasonic tissue ablation systems, duraplasty products, and instrumentation. Neurosurgery revenues also benefited from changes in exchange rates during the year. During 2010, we had higher than normal sales levels in neurosurgery as the rebound from the early stages of the global economic slowdown in 2009 was realized. The strong comparable from 2010 muted some of the 2011 increases in revenues.

Instruments revenues were \$166.0 million, a 1% decrease from the prior-year period. Strong sales growth in surgical lighting was offset by weakness in both hospital and alternate site instruments. In the alternate site channel, our largest distributors purchased fewer instruments in the fourth quarter in order to reduce their inventories at year-end. That said, our distributors are selling our instruments to their final customers at consistent levels and as a result, we believe that we are not losing market share and that normal buying patterns will return during the first half of 2012 once our distributors attain their desired inventory levels. On the acute care side of the category, new ambulatory surgery centers and hospital starts during 2011 had a smaller impact when compared to 2010.

In 2010, total revenues increased by \$49.6 million or 7%, to \$732.1 million from \$682.5 million during 2009. Foreign exchange fluctuations, arising primarily from a weaker euro and a stronger Australian dollar compared to the U.S. dollar than in 2009, accounted for a net unfavorable effect of \$0.7 million on 2010 revenues. Orthopedics revenues were \$290.1 million in 2010, an increase of 11% over 2009. Our extremities reconstruction products led the dollar growth in this category, followed by our private-label products. Most of the increase in extremities products came from sales of regenerative medicine products for skin and wound repair and from metal implants for the forefoot, mid- and hindfoot. Sales of metal spinal implants were up only slightly compared to 2009 as we were facing new competition, particularly from physician-owned distributorships. Neurosurgery revenues were \$275.0 million in 2010, an increase of 7% over 2009. Sales of ultrasonic tissue ablation products led the growth in neurosurgery, followed by stereotaxy and cranial stabilization systems, since capital spending at hospitals improved over 2009 we recognized pent-up demand. Sales of implants, including duraplasty products and shunts, grew more slowly than the capital equipment products. Instruments revenues were \$167.0 million for 2010, an increase of 2% over 2009. This growth principally came from increases in hospital-based instrument sales and surgical lighting systems, while sales to physician, dental, and veterinary offices lagged.

With our global reach, we generate revenues in multiple foreign currencies, including euros, British pounds, Swiss francs, Canadian dollars, Japanese yen and Australian dollars. Accordingly, we will experience currency exchange risk with respect to those foreign currency denominated revenues.

Gross margin as a percentage of revenues was 61.7% in 2011, 63.4% in 2010, and 64.1% in 2009. Cost of product revenues in 2011, 2010, and 2009 included \$3.3 million, \$1.8 million, and \$4.6 million, respectively, in fair value inventory purchase accounting adjustments recorded in connection with acquisitions, and \$8.2 million, \$5.9 million, and \$6.6 million, respectively, of amortization for technology-based intangible assets inclusive of impairments.

The decrease in gross margin from 2010 to 2011 resulted primarily from higher write-offs and reserves for excess and obsolete inventory in our orthopedics products, fair value inventory adjustments on our SeaSpine and Ascension acquisitions, and higher costs of manufacturing than in the prior-year period. The FDA inspected our Plainsboro, New Jersey regenerative medicine manufacturing facility during the third quarter of 2011, at the



**Table of Contents**

conclusion of which it issued FDA Form 483 observations that described violations of quality system regulations. We subsequently received a warning letter from the FDA dated December 21, 2011 which did not identify any new observations that were not provided in the Form 483 observations 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 all of the issues that the FDA identified. We have completed remediation-related construction activities at the facility at the end of December 2011, but continue to remediate processes and quality systems. In 2011 we incurred \$5.8 million of costs related to remediation and related unplanned idle time and underutilization at this facility. In 2012, we expect to incur expenses of \$1.5 million specifically related to completing the remediation of the findings from our Plainsboro, New Jersey inspection. Finally, we incurred the following charges which had a further negative impact on our gross margins in 2011: \$2.3 million related to manufacturing transitions and severance, \$2.1 million of technology-related intangible asset impairments, and \$2.0 million related to discontinued products.

The decrease in gross margin percentage from 2009 to 2010 resulted from higher overall production costs and engineering expenses associated with manufacturing improvement projects, which offset an improvement in the mix of sales toward higher margin products. In 2010 we incurred \$1.9 million related to manufacturing transitions costs and severance, which further affected our gross margins.

In 2012, we expect our consolidated gross margin to be flat compared to 2011. We expect to complete the remediation work at our Plainsboro, New Jersey regenerative medicine manufacturing facility and accordingly, expect to return to normal levels of production in 2012, and we expect to have fewer inventory write-offs. However, our consolidated gross margin will be negatively impacted by higher costs resulting from the amortization of the Ascension and SeaSpine inventory to cost of product revenues at acquisition value, costs related to the expansion of our regenerative medicine activities, and continued downward pressure on our private-label sales volumes.

**Other Operating Expenses**

The following is a summary of other operating expenses as a percent of total revenues:

	Years Ended December 31,		
	2011	2010	2009
Research and development	6.6%	6.6%	6.4%
Selling, general and administrative	45.9%	41.7%	41.1%
Intangible asset amortization	2.1%	1.6%	2.1%

**RESEARCH AND DEVELOPMENT.** Research and development expenses increased to \$51.5 million in 2011, compared to \$48.1 million in 2010 and \$44.3 million in 2009. The increase in research and development from 2010 to 2011 resulted primarily from our SeaSpine and Ascension acquisitions, and to a lesser extent, headcount increases to focus on projects in our neurosurgery and extremity reconstruction product lines. The increased research and development expense in 2010 resulted primarily from additional headcount in product development personnel.

Excluding acquisition-related and other special charges, we target future spending on research and development to be about 6.5% to 7.0% of total revenues. In order to focus our research and development on high growth, high margin products, we are concentrating most of our planned spending for 2012 on product development efforts for our spine, neurosurgery and extremity reconstruction product lines. We do not generally invest in product development for the majority of our hand-held surgical instruments.

---

**Table of Contents**

*SELLING, GENERAL AND ADMINISTRATIVE.* Selling, general and administrative expenses in the year ended December 31, 2011 increased by \$53.0 million to \$358.1 million compared to \$305.1 million in the same period last year. Selling expenses increased by \$20.5 million primarily because of an increase in revenues and the corresponding commission costs, as well as the impact of our SeaSpine and Ascension acquisitions. General and administrative costs increased \$32.6 million because of charges related to the implementation of our global enterprise resource planning system of \$17.1 million, incremental stock-based compensation charges of \$13.3 million related to the renewal of our former Chief Executive Officer's employment agreement in May 2011, the accelerated vesting of awards upon the appointment of a new chief executive officer in December 2011 and the minimum annual equity award for 2011 for our former Chief Executive Officer, acquisition related costs of \$1.7 million, severance costs, and to a lesser extent, increases in compensation costs brought on by increased headcount.

In 2010, selling, general and administrative expenses increased by \$24.0 million to \$305.1 million compared to \$281.1 million in 2009. Selling expenses increased by \$9.2 million primarily because of an increase in revenues and the corresponding commission costs. General and administrative costs increased \$11.6 million to \$132.2 million compared to \$120.5 million in the same period last year resulting from increases in compensation, resulting in part from increases in headcount for our enterprise resource planning system implementation, and also the impact of \$2.2 million of signing bonus and other expenses related to the hiring of our Chief Executive Officer when he initially joined the Company as Chief Operating Officer.

We reported stock-based compensation charges in selling, general and administrative expenses of \$26.3 million in 2011 (inclusive of stock-compensation charges of \$13.3 million relating to grants made in connection with the extension of our former Chief Executive Officer's employment agreement in May 2011, the accelerated vesting of awards upon the appointment of a new chief executive officer in December 2011 and the minimum annual equity award for 2011 for our former Chief Executive Officer), \$16.7 million in 2010 (inclusive of a stock-compensation charge of \$1.5 million stock-based compensation charges relating to grants made in connection with the hiring of our Chief Executive Officer), and \$15.0 million in 2009.

For 2012, we expect general and administrative expenses to be flat compared to 2011; however, we expect to grow the sales team, resulting in similar overall costs as a percentage of revenue. We also expect to incur significant costs related to upgrading our enterprise resource planning system, which will be characterized as special charges. Excluding all special charges, we target future selling, general and administrative expenses to be approximately 41% of revenues.

*INTANGIBLE ASSET AMORTIZATION.* In 2011, amortization expense (excluding amounts reported in cost of product revenues for technology-based intangible assets) increased by \$4.4 million to \$16.4 million compared to \$12.0 million in 2010. The increase primarily resulted from accelerated amortization of \$1.5 million for several trade names that we will phase out through the end of 2012 as part of our rebranding strategy, the impairment of trade names totaling \$1.1 million, and incremental amortization on intangible assets acquired through business combinations that occurred in 2011.

In 2010, amortization expense (excluding amounts reported in cost of product revenues for technology-based intangible assets) decreased by \$2.3 million to \$12.0 million compared to \$14.4 million in 2009. The decrease resulted mainly from the completion of the amortization period for certain intangible assets and impairments recorded in 2009, partially offset by \$0.8 million for impairment of several trade names in connection with our re-branding strategy in 2010.

The change in useful lives in connection with our rebranding strategy will result in incremental amortization expense of \$2.7 million in the full year of 2012 when compared to historical trends. Additionally, we may discontinue certain products in the future as we continue to assess the profitability of our product lines. As our re-branding strategy and profitability assessment evolve, we may make further decisions about our trade names and incur additional impairment charges or accelerated amortization. We expect total annual amortization expense (including amounts reported in cost of product revenues) to be approximately \$25.0 million in 2012, \$19.1 million in 2013, \$18.1 million in 2014, \$16.2 million in 2015 and \$14.0 million in 2016.

## **Table of Contents**

### **Non-Operating Income and Expenses**

We recorded interest income on our invested cash of \$0.5 million, \$0.2 million and \$0.6 million in 2011, 2010 and 2009, respectively. Interest income varies from one year to the next due to changes in the average cash balance throughout a given year.

Interest expense was \$27.6 million, \$18.4 million and \$23.2 million in 2011, 2010 and 2009, respectively. The expense was primarily associated with the principal amount of the outstanding 2010 Notes, the 2012 Notes, 2016 Notes and interest and fees related to our \$600.0 million senior secured credit facility. Interest expense included in these amounts from the non-cash amortization of imputed interest for convertible debt for the years ended December 31, 2011, 2010, and 2009 was \$10.6 million, \$7.6 million and \$10.4 million, respectively.

Interest expense increased for the year ended December 31, 2011 compared to the same period last year primarily because of increased average borrowings under our Senior Credit Facility during the period and interest related to our 2016 Notes issued in June 2011. Although overall borrowings increased, we refinanced our Senior Credit Facility in June 2011 and as a result, the applicable rates used for borrowings decreased by 75 basis points, which was accompanied by a decrease in the annual commitment fee by an average 13.8 basis points. Furthermore, the coupon interest rate on the 2016 Notes is 75 basis points lower than the 2012 Notes. Finally, the impact of our interest rate swap resulted in additional interest expense of \$2.3 million during the period.

Interest expense decreased for the year ended December 31, 2010 primarily because of repurchases of our 2010 Notes throughout 2009 and their settlement in June 2010, and our non-cash interest expense decreased for the same reason. A higher interest rate paid on borrowings from our amended and restated senior credit facility beginning in August 2010 partially offset these decreases.

Our reported interest expense for the years ended December 31, 2011, 2010 and 2009 included \$3.4 million, \$1.6 million and \$1.8 million, respectively, of non-cash amortization of debt issuance costs. The 2011 amount includes approximately \$0.8 million of fees expensed in connection with our refinancing in June 2011.

In 2011, net other income of \$0.8 million consisted of research and development reimbursements from third-party partners and foreign governments, partially offset by foreign exchange losses. In 2010, net other income was \$1.6 million consisting primarily of foreign exchange gains of \$1.1 million, and other gains of \$0.5 million.

### **Income Taxes**

Our effective income tax rate was 1.8%, 20.0% and 30.3% of income before income taxes in 2011, 2010 and 2009, respectively. See Note 10, Income Taxes, in our consolidated financial statements for a reconciliation of the United States Federal statutory rate to our effective tax rate.

In 2011, our full-year worldwide income decreased significantly, primarily due to the decrease of earnings generated in the United States. As income in the United States tends to be taxed at higher rates, the shift in the mix of earnings caused a significant decline in our overall effective tax rate. Also, during 2011 we recorded a reversal of \$2.5 million of accruals, which includes interest, for uncertain tax positions due to matters that were considered effectively settled. We recorded additional tax expense of \$1.7 million for a correction to a state deferred tax asset relating to 2009 and recorded a tax benefit of \$2.2 million relating to the correction of various deferred tax items for periods prior to 2011 that largely impacted foreign operations. These amounts were not material to the current or prior periods and were therefore recorded in 2011.

In 2010, we recorded a tax benefit of \$4.5 million related to the settlement of several uncertain tax positions and a benefit related to the passing of the Tax Relief, Unemployment Insurance Reauthorization and Job Creation Act of 2010 (the TRUIJ Act). Since the TRUIJ Act was passed during the fourth quarter of 2010, we recorded the tax impact for the entire year at that time.

**Table of Contents**

Our effective tax rate could vary from year to year depending on, among other factors, the geographic and business mix of taxable earnings and losses. We consider these factors and others, including our history of generating taxable earnings, in assessing our ability to realize deferred tax assets. We expect our effective income tax rate for 2012 to be between 16% and 18%.

We have recorded a valuation allowance of \$32.3 million against the remaining \$125.9 million of gross deferred tax assets recorded at December 31, 2011. This valuation allowance relates to deferred tax assets for which the Company does not believe it has satisfied the more likely than not threshold for realization. We do not anticipate additional income tax benefits through future reductions in the valuation allowance. However, if we determine that we would be able to realize more or less than the recorded amount of net deferred tax assets, we will record an adjustment to the deferred tax asset valuation allowance in the period such a determination is made. Our deferred tax asset valuation allowance decreased \$4.3 million in 2011, and increased \$0.5 million in 2010 and \$0.1 million in 2009.

At December 31, 2011 we had net operating loss carryforwards of \$61.3 million for federal income tax purposes, \$73.1 million for foreign income tax purposes and \$31.7 million for state income tax purposes to offset future taxable income. The federal net operating loss carryforwards expire through 2030, \$66.7 million of the foreign net operating loss carryforwards expire through 2020 with the remaining \$6.3 million having an indefinite carryforward period. The state net operating loss carry forwards expire through 2030.

At December 31, 2011, certain of our subsidiaries had unused net operating loss carryforwards and tax credit carryforwards arising from periods prior to our ownership which expire through 2030. The Internal Revenue Code limits the timing and manner in which we may use any acquired net operating losses or tax credits.

Income taxes are not provided on certain undistributed earnings of non-U.S. subsidiaries because such earnings are expected to be permanently reinvested. Undistributed earnings of such foreign subsidiaries totaled \$168.8 million, \$142.2 million and \$101.4 million at December 31, 2011, 2010 and 2009, respectively.

**INTERNATIONAL REVENUES AND OPERATIONS**

Revenues by major geographic area are summarized below:

	For Years Ended December 31		
	2011	2010	2009
	(In thousands)		
United States	\$ 593,036	\$ 561,240	\$ 519,203
Europe	94,772	89,381	93,414
Asia Pacific	44,445	40,584	32,788
Other Foreign*	47,825	40,863	37,082
Consolidated	\$ 780,078	\$ 732,068	\$ 682,487

\* Consists of: Canada, Latin America, Africa and the Middle East

Most of our revenues came from customers within the United States. In 2011 sales to U.S. customers increased approximately 6% compared to the prior year, primarily resulting from the incremental impact of the SeaSpine and Ascension acquisitions, with neurosurgery sales increasing and instrument sales decreasing. Over the past few years, the austerity measures of certain European governments, which have reduced expenditures on healthcare, have negatively affected revenues from our European customers. While the economic downturn has not significantly affected our ability to collect receivables, the macro-economic conditions and liquidity issues in certain countries continue to hamper our sales volumes. That said, European sales grew approximately 6% in 2011

## **Table of Contents**

compared to the prior year resulting primarily from changes in foreign exchange rates, which had an impact on our neurosurgery and orthopedics products, and to a lesser extent, instruments. Sales to customers in the Asia Pacific region increased approximately 10% for the year ended December 31, 2011 mainly in neurosurgery and orthopedics. Sales to our other foreign customers increased approximately 17% in 2011 compared to the prior year; we experienced this increase in all product lines across all other foreign geographies.

In 2010 sales to U.S. customers increased approximately 8% compared to 2009 primarily from sales in extremities reconstruction and private-label, and to a lesser extent, neurosurgery and instruments. European sales decreased approximately 4% in 2010 compared to 2009. The effects of European austerity measures had a negative impact on our sales during that period. Sales to customers in the Asia Pacific region increased approximately 24% in 2010 compared to 2009, driven primarily by neurosurgery products. Sales to our other foreign customers increased approximately 10% in 2010 compared to 2009; this increase was seen in all product lines across all other foreign geographies as we were expanding our sales efforts in these areas.

With our global reach, we generate revenues and incur operating expenses in multiple foreign currencies, including euros, British pounds, Swiss francs, Canadian dollars, Japanese yen and Australian dollars. Accordingly, we will experience currency exchange risk with respect to those foreign currency denominated revenues and operating expenses. The Company generated revenues denominated in foreign currencies of \$141.4 million, \$125.8 million and \$124.8 million during the years ended December 31, 2011, 2010 and 2009, respectively.

We will continue to assess the potential effects that changes in foreign currency exchange rates could have on our business. However, either a strengthening or a weakening of the dollar against individual foreign currencies could reduce future revenues and gross margins. If we believe this potential impact presents a significant risk to our business, we may enter into derivative financial instruments to mitigate this risk.

Additionally, we generate significant revenues outside the United States, a portion of which are U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. As a result, currency fluctuations between the U.S. dollar and the currencies in which those customers do business may have an impact on the demand for our products in foreign countries.

Local economic conditions, regulatory, legal or political considerations, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice all could combine to affect our sales into markets outside the United States.

Relationships with customers and effective terms of sale frequently vary by country, often with longer-term receivables than are typical in the United States.

Economic conditions in certain European countries, especially Greece, Ireland, Italy, Portugal and Spain, continued to deteriorate throughout 2011. Accounts receivable from customers in these countries represented approximately \$5.8 million of our total accounts receivable balance at December 31, 2011, of which \$0.8 million was reserved. We continually evaluate receivables for potential collection risks associated with our customers. If the financial condition of customers or their respective countries' healthcare systems continue to deteriorate it may negatively impact our results in future periods.

**Table of Contents****LIQUIDITY AND CAPITAL RESOURCES**

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(In millions)</b>	
Cash and cash equivalents	\$ 100.8	\$ 128.8
Borrowings under senior credit facility	(179.7)	(248.1)
Convertible securities	(352.6)	(155.2)
 Net cash position	 \$ (431.5)	 \$ (274.5)

The decrease in our net cash position at December 31, 2011 primarily resulted from cash paid for our acquisitions of SeaSpine and Ascension of \$146.3 million, \$38.4 million of capital expenditures and \$83.4 million of stock repurchases. Our cash flows from operation of \$104.3 million and other items partially offset these decreases. We believe that our existing cash, future cash expected to be generated from operations, and our remaining \$420.3 million of borrowing capacity under our senior secured revolving credit facility, if needed, will satisfy our foreseeable working capital, debt repayment, capital expenditure requirements and acquisition hold-back payments for at least the next twelve months.

In 2012, we anticipate that our principal uses of cash will include the repayment of our convertible 2012 Notes of \$165 million, of which approximately \$134 million will be classified as a financing use of cash for the repayment of the debt component, and approximately \$31 million will be classified as an operating use of cash for the repayment of accreted interest. Additionally, we plan to spend between \$65 million and \$75 million on capital expenditures primarily for the expansion of regenerative medicine manufacturing capacity, our enterprise resource planning system implementation, and additions to our instrument kits used in sales of orthopedic products.

Our non-U.S. subsidiaries hold approximately \$86.3 million of cash and cash equivalents that are available for use by all of our operations around the world. However, if these funds were repatriated to the United States or used for United States operations, certain amounts could be subject to United States tax for the incremental amount in excess of the foreign tax paid.

**Cash Flows**

We generated positive operating cash flows of \$104.3 million, \$105.6 million and \$143.2 million in 2011, 2010 and 2009, respectively. Net income for the year ended December 31, 2011, plus items included in those earnings that did not result in a change to our cash balance, amounted to \$119.4 million. In 2011, the impact of net working capital items on operating cash flows excluding the impact of acquisitions was a decrease of \$12.3 million. Increases in accounts receivable used \$1.9 million of cash, increases in prepaid expenses and other current assets used \$0.4 million of cash, which includes a tax refund of \$10.0 million, and decreases in accounts payable, accrued expenses, and other current liabilities used \$11.8 million of cash. Decreases in inventory provided \$1.7 million of cash. Net income for the year ended December 31, 2010, plus items included in those earnings that did not result in a change to our cash balance, amounted to approximately \$131.2 million. Additionally, we paid \$6.6 million in accreted interest related to the repurchase of our 2010 Notes at their maturity. In 2010, the net impact of working capital items on operating cash flows was a decrease of \$11.3 million. Increases in both accounts receivable and inventory resulted in a use of cash; however, those increases resulted from higher overall sales, and accounts receivable was lower as a percentage of sales compared to 2009. Additionally, increases in our prepaid expenses and other current assets used \$6.5 million of cash. Increases in accounts payable and accrued expenses primarily offset these uses of cash. The change in other liabilities resulted in part from \$4.5 million in reversals of income tax reserves for audits that were concluded during the year. In 2009, changes in working capital items increased operating cash flows by \$30.5 million. In 2009, prepaid expenses and other current assets includes a tax refund that provided \$11.3 million, improvements in our accounts receivable provided \$9.8 million, and reductions in inventory provided another \$9.4 million of operating cash flows.

---

## **Table of Contents**

Our principal uses of funds for the year ended December 31, 2011 were \$152.0 million for business acquisitions, \$83.5 million for repurchases of stock, \$68.4 million for net repayments under our senior credit facility, \$38.4 million for capital expenditures, and \$42.9 million for the purchase of the option hedge on our convertible notes. In addition to the \$104.3 million we generated in operating cash flows, we received a total of \$230.0 million related to the issuance of our 2016 Notes, proceeds of \$28.5 million from the sales of stock purchase warrants related to our 2016 Notes and approximately \$4.5 million related to the issuance of stock options and the related excess tax benefits.

Our principal uses of funds for the year ended December 31, 2010 were \$5.2 million for acquisitions of businesses, \$31.3 million in repurchases of our common stock, \$37.1 million in capital expenditures, and \$6.8 million in debt issuance costs. In addition to the \$105.6 million in operating cash flows we generated in 2010, our net outstanding borrowings increased by \$16.8 million, and we received \$16.1 million from the issuance of common stock through the exercise of stock options during the period.

Our principal uses of funds for the year ended December 31, 2009 were approximately \$52.0 million in earnout payments in connection with the Integra Spine acquisition, \$27.6 million in capital expenditures and intangible asset purchases, \$78.0 million in repurchases of the liability component of our 2010 Notes, and \$100.0 million in repayments on our revolving credit facility. In addition to the \$143.2 million in operating cash flows we generated in 2009, we received \$6.6 million from the issuance of common stock through the exercise of stock options during the year.

### ***Working Capital***

At December 31, 2011 and 2010, working capital was \$350.4 million and \$243.0 million, respectively. Most of the \$107.4 million increase in working capital resulted from a decrease in borrowings classified as short term, increased accounts receivable balances and inventory from our acquisitions during the year which we funded using cash and long-term borrowings under our Senior Credit Facility.

### ***Convertible Debt and Related Hedging Activities***

We pay interest each June 1 and December 1 on our \$165.0 million senior convertible notes due June 2012 ( 2012 Notes ) at an annual rate of 2.375%, and each June 15 and December 15 on our \$230.0 million senior convertible notes due December 2016 ( 2016 Notes ) at an annual interest rate of 1.625% (the 2012 Notes and 2016 Notes are collectively referred to as, the Notes ). We paid interest on our \$165.0 million senior convertible notes due June 2010 ( 2010 Notes ) at an annual rate of 2.75% and we repaid the 2010 Notes in full during June 2010 in accordance with their terms.

The 2012 Notes and 2016 Notes are senior, unsecured obligations of Integra, and are convertible into cash and, if applicable, shares of our common stock based on an initial conversion rate, subject to adjustment, of 15.3935 shares and 17.4092 shares, respectively, per \$1,000 principal amount of notes (which represents an initial conversion price of approximately \$64.96 per share and \$57.44 per share, respectively). We expect to satisfy any conversion of the Notes with cash up to the principal amount pursuant to the net share settlement mechanism set forth in the respective indenture and, with respect to any excess conversion value, with shares of our common stock. The 2012 Notes and 2016 Notes are convertible only in the following circumstances: (1) if the closing sale price of our common stock exceeds 130% and 150%, respectively, of the conversion price during a period as defined in the applicable indenture; (2) if the average trading price per \$1,000 principal amount of the Notes is less than or equal to 97% or 98%, respectively, of the average conversion value of the Notes during a period as defined in the applicable indenture; (3) at any time on or after December 15, 2011, or June 15, 2016, respectively; or (4) if specified corporate transactions occur. The issue price of the Notes was equal to their face amounts, which is also the amount holders are entitled to receive at maturity if the Notes are not converted. None of these conditions existed with respect to the Notes; therefore the 2016 Notes are classified as long-term. The 2012 Notes are classified as long-term based on our intent and ability to settle the obligation with long-term borrowings from our Senior Credit Facility.

## **Table of Contents**

The Notes, under the terms of the applicable private placement agreement, are guaranteed fully by Integra LifeSciences Corporation, a subsidiary of Integra. The Notes are Integra's direct senior unsecured obligations and will rank equal in right of payment to all of our existing and future unsecured and unsubordinated indebtedness.

In connection with the issuance of the Notes, we entered into call transactions and warrant transactions, primarily with affiliates of the initial purchasers of the Notes (the "hedge participants"). The cost of the call transactions to us was approximately \$30.4 million for the 2012 Notes and \$42.9 million for the 2016 Notes. We received approximately \$12.2 million and \$28.5 million of proceeds from the warrant transactions for the 2012 Notes and 2016 Notes, respectively. The call transactions involved our purchasing call options from the hedge participants, and the warrant transactions involved us selling call options to the hedge participants with a higher strike price than the purchased call options. The initial strike price of the call transactions is approximately \$64.96 for the 2012 Notes and \$57.44 for the 2016 Notes, subject to anti-dilution adjustments substantially similar to those in the Notes. The initial strike price of the warrant transactions is approximately \$90.95 for the 2012 Notes and \$70.05 for the 2016 Notes, in each case subject to customary anti-dilution adjustments.

We may from time to time seek to retire or purchase a portion of our outstanding Notes through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. Under certain circumstances, the call options associated with any repurchased Notes may be terminated early, but only with respect to the number of Notes that cease to be outstanding. The amounts involved may be material.

See Note 4, "Debt," of our consolidated financial statements for additional information.

### ***Amended and Restated Senior Credit Agreement***

In December 2005, we established a \$200.0 million, five-year, senior secured revolving credit facility (the "Senior Credit Facility"). In February 2007 we amended the Senior Credit Facility to increase its size to \$300.0 million, which we had the ability to increase further to \$400.0 million under certain circumstances. On August 10, 2010, we entered into an amended and restated credit agreement (the "First Amendment") with a syndicate of lending banks and further amended the agreement on June 8, 2011 (the "Second Amendment").

The First Amendment increased the size of the Senior Credit Facility from \$300.0 million to \$450.0 million, provided for a \$150.0 million term loan component and allowed us to further increase the size of either the term loan or the revolving credit facility, or a combination thereof, by an aggregate of \$150.0 million with additional commitments. The First Amendment extended the prior revolving credit facility's maturity date from December 21, 2011 to August 10, 2015.

The Second Amendment increased the revolving credit component from \$450.0 million to \$600.0 million and eliminated the \$150.0 million term loan component that existed under the First Amendment. It allows us to further increase the size of the revolving credit component by an aggregate of \$200.0 million with additional commitments, provides us with decreased borrowing rates and annual commitment fees, and provides more favorable financial covenants. The Second Amendment extended the Senior Credit Facility's maturity date from August 10, 2015 to June 8, 2016. The Senior Credit Facility is collateralized by substantially all of the assets of our U.S. subsidiaries, excluding intangible assets. We capitalized \$1.3 million of incremental financing costs, expensed \$0.4 million of incremental financing costs, and expensed \$0.4 million of previously capitalized financing costs in connection with the Second Amendment. The Senior Credit Facility is subject to various financial and negative covenants at December 31, 2011. The most notable covenant is the maximum consolidated total leverage ratio that we are allowed to have at any time during any four consecutive fiscal quarter period can be no greater than (i) 3.75 to 1.00 during any such period ending on or before March 31, 2012, or (ii) 3.50 to 1.00



## **Table of Contents**

during any period thereafter. The maximum Consolidated Total Leverage Ratio is the ratio of (a) Consolidated Funded Indebtedness less cash in excess of \$40 million that is not subject to any restriction of the use or investment thereof to (b) consolidated EBITDA (all capitalized terms as defined under the agreement). We were in compliance with all covenants at December 31, 2011.

Borrowings under the Senior Credit Facility bear interest, at our option, at a rate equal to (i) the Eurodollar Rate (as defined in the Senior Credit Facility, which definition has not changed) in effect from time to time plus the applicable rate (ranging from 1.00% to 1.75% under the Second Amendment and from 1.75% to 2.50% under the First Amendment) or (ii) the highest of (x) the weighted average overnight Federal funds rate, as published by the Federal Reserve Bank of New York, plus 0.5%, (y) the prime lending rate of Bank of America, N.A. or (z) the one-month Eurodollar Rate plus 1.0%. The applicable rates are based on our consolidated total leverage ratio at the time of the applicable borrowing.

We also pay an annual commitment fee (ranging from 0.15% to 0.3% under the Second Amendment, and from 0.2% to 0.5% under the First Amendment, based on our consolidated total leverage ratio) on the daily amount by which the revolving credit facility exceeds the outstanding loans and letters of credit under the credit facility.

We plan to utilize the Senior Credit Facility for working capital, capital expenditures, share repurchases, acquisitions, repayments of our 2012 Notes and other general corporate purposes. In June and August 2009, we repaid \$60.0 million and \$40.0 million, respectively, of our outstanding borrowings. Prior to the First Amendment of the Senior Credit Facility in 2010, we borrowed \$75.0 million in connection with the maturity of our 2010 Notes and also repaid \$15.0 million of outstanding borrowings. Subsequent to the First Amendment, we borrowed an additional \$30.0 million in October 2010 to repay certain intercompany loans and made the scheduled repayments under our term loan. In 2011, we repaid \$40.0 million in January, and borrowed \$85.0 million during May in connection with the SeaSpine acquisition. In June, we repaid \$145.0 million when we entered into the Second Amendment. We borrowed \$50.0 million in September 2011 in connection with the Ascension acquisition, and we borrowed \$10.0 million in October for general corporate purposes. In November 2011, we repaid \$20.0 million, and made various other repayments throughout the year totaling \$8.4 million. As a result, we have \$179.7 million outstanding under our Senior Credit Facility at December 31, 2011.

### ***Share Repurchase Plans***

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 in connection with that offering. See Note 6, Treasury Stock, in our consolidated financial statements for further details.

### ***Dividend Policy***

We have not paid any cash dividends on our common stock since our formation. Our revolving credit facility limits the amount of dividends that we may pay. Any future determinations to pay cash dividends on our common stock will be at the discretion of our Board of Directors and will depend upon our financial condition, results of operations, cash flows and other factors that the Board of Directors deems relevant.

**Table of Contents****Contractual Obligations and Commitments**

As of December 31, 2011, we were obligated to pay the following amounts under various agreements:

	Total	Less than 1 Year	1-3 Years (In millions)	3-5 Years	More than 5 Years
Convertible Securities(1)	\$ 395.0	\$ 165.0	\$	\$ 230.0	\$
Revolving Credit Facility(2)	179.7			179.7	
Interest(3)	18.4	5.4	7.5	5.5	
Employment Agreements(4)	3.6	1.9	1.7		
Operating Leases	48.2	12.1	21.0	9.7	5.4
Acquisition Consideration (5)	7.7	7.7			
Purchase Obligations	14.5	5.2	4.2	5.1	
Other	3.3	1.5	1.1	0.4	0.3
<b>Total</b>	<b>\$ 670.4</b>	<b>\$ 198.8</b>	<b>\$ 35.5</b>	<b>\$ 430.4</b>	<b>\$ 5.7</b>

- (1) The estimated debt service obligation of the senior convertible securities includes interest expense representing the amortization of the discount on the liability component of the senior convertible notes in accordance with the authoritative guidance. See Note 4, Debt, of our consolidated financial statements for additional information.
- (2) The Company may borrow and make payments against the credit facility from time to time and considers all of the outstanding amounts to be long term based on its current intent and ability to repay the borrowing outside of the next twelve-month period.
- (3) Interest is calculated on the convertible securities based on current interest rates paid by the Company. As the revolving credit facility can be repaid at any time, no interest has been included in the calculation.
- (4) Amounts shown under Employment Agreements do not include compensation resulting from a change in control.
- (5) The acquisition consideration is comprised of amounts that may be due to the sellers of SeaSpine, Inc. upon the finalization of the working capital adjustment and indemnification holdback releases, the sellers of Ascension, Inc. upon the finalization of the working capital adjustment and certain other matters.

Excluded from the contractual obligations table is the liability for uncertain tax benefits, including interest and penalties, totaling \$5.3 million. This liability for uncertain tax benefits has been excluded because we cannot make a reliable estimate of the period in which the uncertain tax benefits may be realized.

**CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES**

Our discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities, and the reported amounts of revenues and expenses. Significant estimates affecting amounts reported or disclosed in the consolidated financial statements include allowances for doubtful accounts receivable and sales returns and allowances, net realizable value of inventories, valuation of intangible assets including in-process research and development, amortization periods for acquired intangible assets, estimates of projected cash flows and discount rates used to value intangible assets and test goodwill and intangible assets for impairment, estimates of projected cash flows and depreciation and amortization periods for long-lived assets, computation of taxes, computation of valuation allowances recorded against deferred tax assets, valuation of stock-based compensation, valuation of pension assets and liabilities, valuation of derivative instruments, valuation of the equity component of convertible debt instruments, valuation of debt instruments and loss contingencies. These estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the current circumstances. Actual results could differ from these estimates.

## **Table of Contents**

We believe that the following accounting policies, which form the basis for developing these estimates, are those that are most critical to the presentation of our financial statements and require the most difficult, subjective and complex judgments:

### ***Allowances For Doubtful Accounts Receivable and Sales Returns and Allowances***

We evaluate the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to us, we record an allowance against amounts due to reduce the net recognized receivable to the amount that we reasonably expect to collect. For all other customers, we record allowances for doubtful accounts based on the length of time the receivables are past due, the current business environment and our historical experience. If the financial condition of customers or the length of time that receivables are past due were to change, we may change the recorded amount of allowances for doubtful accounts in the future through charges or reductions to selling, general and administrative expense.

We record a provision for estimated sales returns and allowances on revenues in the same period as the related revenues are recorded. We base these estimates on historical sales returns and allowances and other known factors. If actual returns or allowances differ from our estimates and the related provisions for sales returns and allowances, we may change the sales returns and allowances provision in the future through an increase or decrease in revenues.

### ***Inventories***

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost (determined by the first-in, first-out method) or market. At each balance sheet date, we evaluate ending inventories for excess quantities, obsolescence or shelf-life expiration. Our evaluation includes an analysis of historical sales levels by product, projections of future demand by product, the risk of technological or competitive obsolescence for our products, general market conditions, a review of the shelf-life expiration dates for our products, and the feasibility of reworking or using excess or obsolete products or components in the production or assembly of other products that are not obsolete or for which we do not have excess quantities in inventory. To the extent that we determine there are excess or obsolete quantities or quantities with a shelf life that is too near its expiration for us to reasonably expect that we can sell those products prior to their expiration, we adjust their carrying value to estimated net realizable value. If future demand or market conditions are lower than our projections, or if we are unable to rework excess or obsolete quantities into other products, we may record further adjustments to the carrying value of inventory through a charge to cost of product revenues in the period the revision is made.

### ***Valuation of Identifiable Intangible Assets, In-Process Research and Development Charges, and Goodwill***

We allocate the purchase price of acquired businesses and product lines between tangible and intangible assets (including in-process research and development) and goodwill, as applicable. In-process research and development is defined as the value assigned to those acquired technologies or projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to in-process research and development and other intangible assets requires us to make significant estimates. We allocate the purchase price to in-process research and development and other identifiable intangible assets by estimating the future cash flows of each project, technology, customer relationship, trade name, or other applicable asset and discounting those net cash flows back to their present values. The discount rate used is determined at the time of acquisition in accordance with accepted valuation methods. For in-process research and development, these methodologies include consideration of the risk of the project not achieving commercial feasibility.

We review goodwill, identifiable intangible assets with indefinite lives and capitalized in-process research and development for impairment annually, and whenever events or changes indicate that the carrying value of an

## **Table of Contents**

asset may not be recoverable. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, sale or disposition of significant assets or products, or the termination of development programs. Application of these impairment tests requires significant judgments, including estimation of future cash flows, which is dependent on internal forecasts, estimation of the long-term rate of growth for our business, the useful life over which cash flows will occur and determination of our weighted-average cost of capital.

Changes in the projected cash flows and discount rate estimates and assumptions underlying the valuation of identifiable intangible assets, in-process research and development, and goodwill could materially affect the determination of fair value at acquisition or during subsequent periods when tested for impairment.

Our finite-lived assets are reviewed for impairment and to ensure their useful lives are appropriate whenever events or changes indicate that the carrying value of the assets may not be recoverable.

### ***Derivatives***

We develop, manufacture, and sell medical devices globally. Our earnings and cash flows are exposed to market risk from changes in interest rates and currency exchange rates. We address these risks through a risk management program that includes the use of derivative financial instruments, and operate the program pursuant to documented corporate risk management policies. All derivative financial instruments are recognized in the financial statements at fair value in accordance with the authoritative guidance. Under the guidance, for those instruments that are designated and qualify as hedging instruments, the hedging instrument must be designated as a fair value hedge, cash flow hedge, or a hedge of a net investment in a foreign operation, based on the exposure being hedged. The accounting for changes in the fair value of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and, further, on the type of hedging relationship. Our derivative instruments do not subject our earnings or cash flows to material risk, and gains and losses on these derivatives generally offset losses and gains on the item being hedged. We have not entered into derivative transactions for speculative purposes and all of our derivatives are designated as hedges.

All derivative instruments are recognized at their fair values as either assets or liabilities on the balance sheet. We determine the fair value of our derivative instruments, using the framework prescribed by the authoritative guidance, by considering the estimated amount we would receive to sell or transfer these instruments at the reporting date and by taking into account expected forward interest rates, currency exchange rates, the creditworthiness of the counterparty for assets, and our creditworthiness for liabilities. In certain instances, we may utilize a discounted cash flow model to measure fair value. Generally, we use inputs that include quoted prices for similar assets or liabilities in active markets; other observable inputs for the asset or liability; and inputs that are derived principally from, or corroborated by, observable market data by correlation or other means. As of December 31, 2011, observable inputs are available for substantially the full term of our derivative instruments.

### ***Income Taxes***

Since we conduct operations on a global basis, our effective tax rate has and will depend upon the geographic distribution of our pre-tax earnings among locations with varying tax rates. Changes in the tax rates of the various jurisdictions in which we operate affect our profits. In addition, we maintain a reserve for uncertain tax benefits, changes to which could impact our effective tax rate in the period such changes are made. The effective tax rate can also be impacted by changes in valuation allowances of deferred tax assets, and tax law changes.

We recognize a tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrual for which an exposure exists is measured by determining the amount that has a greater than 50 percent likelihood of being realized upon ultimate settlement of the position. Components of the reserve are classified as a long-term liability in the consolidated balance sheets. We record interest and penalties accrued in relation to uncertain tax benefits as a component of income tax expense.

## **Table of Contents**

We believe we have identified all reasonably identifiable exposures and the reserve we have established for identifiable exposures is appropriate under the circumstances; however, it is possible that additional exposures exist and that exposures will be settled at amounts different than the amounts reserved. It is also possible that changes in facts and circumstances could cause us to either materially increase or reduce the carrying amount of our tax reserves.

Our deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their basis for income tax purposes, and also the temporary differences created by the tax effects of capital loss, net operating loss and tax credit carryforwards. We record valuation allowances to reduce deferred tax assets to the amounts that are more likely than not to be realized. We could recognize no benefit from our deferred tax assets or we could recognize some or all of the future benefit depending on the amount and timing of taxable income we generate in the future.

Our policy is to provide income taxes on earnings of certain foreign subsidiaries only to the extent those earnings are taxable or are expected to be remitted.

### ***Loss Contingencies***

We are subject to claims and lawsuits in the ordinary course of our business, including claims by employees or former employees, with respect to our products and involving commercial disputes. We accrue for loss contingencies when it is deemed probable that a loss has been incurred and that loss is estimable. The amounts accrued are based on the full amount of the estimated loss before considering insurance proceeds, if applicable, and do not include an estimate for legal fees expected to be incurred in connection with the loss contingency. We consistently accrue legal fees expected to be incurred in connection with loss contingencies as those fees are incurred by outside counsel as a period cost. Our financial statements do not reflect any material amounts related to possible unfavorable outcomes of claims and lawsuits to which we are currently a party because we currently believe that such claims and lawsuits are not expected, individually or in the aggregate, to result in a material adverse effect on our financial condition. However, it is possible that these contingencies could materially affect our results of operations, financial position and cash flows in a particular period if we change our assessment of the likely outcome of these matters.

### ***Recently Issued Accounting Standards***

On September 15, 2011 the Financial Accounting Standards Board issued *Accounting Standards Update No. 2011-08, Intangibles – Goodwill and Other (Topic 350), Testing Goodwill for Impairment*. The revised standard is intended to reduce the cost and complexity of the annual goodwill impairment test by providing the option of performing a qualitative assessment to determine whether further impairment testing is necessary. Under this standard, we have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, we determine it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, performing the two-step impairment test under Topic 350 is unnecessary. However, if we conclude otherwise, we are required to perform the first step of the two-step impairment test, as described in Topic 350. If the carrying amount of a reporting unit exceeds its fair value under the first step, we are required to perform the second step of the goodwill impairment test to measure the amount of the impairment loss, if any. We also have the option to bypass the qualitative assessment for any reporting unit in any period and to proceed directly to performing the first step of the two-step goodwill impairment test. We may resume performing the qualitative assessment in any subsequent period. This standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, and early adoption is permitted. We believe that the adoption of this standard will not have a material impact on our financial statements.

On June 16, 2011 the Financial Accounting Standards Board issued *Accounting Standards Update No. 2011-05, Presentation of Comprehensive Income*. This standard eliminates the option to report other

## **Table of Contents**

comprehensive income and its components in the statement of changes in equity. We may elect to present items of net income and other comprehensive income in one continuous statement or in two consecutive statements. Each component of net income and each component of other comprehensive income, together with totals for comprehensive income and its two parts – net income and other comprehensive income – would need to be displayed under either alternative, and the statements would need to be presented with equal prominence as the other primary financial statements. This standard does not change 1) the items that constitute net income and other comprehensive income, 2) when an item of other comprehensive income must be reclassified to net income, or 3) the computation for earnings per share – which will continue to be based on net income. This standard is effective for fiscal years beginning after December 15, 2011, and will not have an impact on our operating results as it impacts presentation only.

On May 12, 2011 the Financial Accounting Standards Board issued *Accounting Standards Update No. 2011-04 - Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS*. This standard merges many aspects of fair value measurement guidance by amending U.S. GAAP and creating a new standard under International Financial Reporting Standards. The primary changes to U.S. GAAP include 1) clarifying the valuation premise of highest and best use, 2) clarifying how portfolios of financial instruments are measured, 3) clarifying the use of blockage factors and other premiums and discounts, and 4) increasing the disclosure requirements in a number of circumstances. This standard is effective for fiscal years beginning after December 15, 2011, and we believe the standard will not have a material impact on our results.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to various market risks, including changes in foreign currency exchange rates and interest rates that could adversely affect our results of operations and financial condition. To manage the volatility relating to these typical business exposures, we may enter into various derivative transactions when appropriate. We do not hold or issue derivative instruments for trading or other speculative purposes.

#### ***Foreign Currency Exchange and Other Rate Risks***

We operate on a global basis and are exposed to the risk that changes in foreign currency exchange rates could adversely affect our financial condition, results of operations and cash flows. We are primarily exposed to foreign currency exchange rate risk with respect to transactions and net assets denominated in euros, Swiss francs, British pounds, Canadian dollars, and Australian dollars. We manage the foreign currency exposure centrally, on a combined basis, which allows us to net exposures and to take advantage of any natural offsets. To mitigate the impact of currency fluctuations on transactions denominated in nonfunctional currencies, from time to time we enter into derivative financial instruments in the form of foreign currency forward contracts with major financial institutions. Realized and unrealized gains and losses on these contracts that qualify as cash flow hedges are temporarily recorded in other comprehensive income, then recognized in other income or expense when the hedged item affects net earnings.

From time to time, we enter into foreign currency forward contracts with terms of up to 12 months to manage currency exposures for liabilities denominated in a currency other than an entity's functional currency. Some of these contracts are designated and accounted for as hedges while others are not. As a result, the impact of foreign currency gains/losses recognized in earnings are partially offset by gains/losses on the related foreign currency forward contracts in the same reporting period. At December 31, 2011, the notional amount of foreign currency forward contracts outstanding that were designated as hedges was equivalent to \$1.6 million, and the amount not designated as hedges was equivalent to \$3.3 million. There were no foreign currency forward contracts outstanding at December 31, 2010.

We maintain written policies and procedures governing our risk management activities. With respect to cash flow hedges, changes in cash flows attributable to hedged transactions are generally expected to be completely

## **Table of Contents**

offset by changes in the fair value of hedge instruments. Consequently, foreign currency forward contracts would not subject us to material risk due to exchange rate movements, because gains and losses on these contracts offset gains and losses on the assets, liabilities and transactions being hedged.

The results of operations for the periods discussed herein have not been materially affected by inflation.

### ***Interest Rate Risk***

*Cash and Cash Equivalents.* We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash and cash equivalents. A hypothetical 100 basis point increase in interest rates applicable to our cash and cash equivalents outstanding at December 31, 2011 would increase interest income by approximately \$1.0 million on an annual basis. No significant decrease in interest income would be expected as our cash balances are earning interest at rates close to zero. We are subject to foreign currency exchange risk with respect to cash balances maintained in foreign currencies.

*Senior Credit Facility.* Our interest rate risk relates primarily to U.S. dollar LIBOR-indexed borrowings. We have used an interest rate derivative instrument to manage our earnings and cash flow exposure to changes in interest rates by utilizing a forward-starting interest rate swap that began to offset a portion of our interest payments in the first quarter of 2011. This interest rate derivative instrument fixed the interest rate on a portion of our expected LIBOR-indexed floating-rate borrowings beginning on December 31, 2010. The interest rate swap had a notional amount of \$139.7 million outstanding as of December 31, 2011. We recognized additional interest expense related to this derivative of \$2.3 million during 2011. We recorded a \$4.1 million liability at December 31, 2011 to recognize the fair value of our interest rate derivative instrument.

Based on our outstanding borrowings at December 31, 2011, a one-percentage point change in interest rates would have impacted interest expense on the unhedged portion of our debt by \$0.4 million on an annualized basis.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Financial statements and the financial statement schedules specified by this Item, together with the report thereon of PricewaterhouseCoopers LLP, are presented following Item 15 of this report.

Information on quarterly results of operations is set forth in our financial statements under Note 14, Selected Quarterly Information Unaudited, to the Consolidated Financial Statements.

### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### ***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Management has designed our disclosure controls and procedures to provide reasonable assurance of achieving the desired control objectives.

## **Table of Contents**

As required by Exchange Act Rule 13a-15(b), we have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2011. Based upon this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2011 to provide such reasonable assurance.

### ***Management's Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934, as amended. Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America ( GAAP ). We recognize that because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies and procedures may deteriorate.

To evaluate the effectiveness of our internal control over financial reporting, management used the criteria described in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ). Based upon this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2011.

In conducting our evaluation of the effectiveness of internal control over financial reporting, we have excluded SeaSpine, Inc. and Ascension Orthopedics, Inc. from our assessment of internal control over financial reporting as of December 31, 2011 because they were acquired by the Company in a purchase combination during 2011. SeaSpine, Inc. and Ascension Orthopedics, Inc. are wholly owned entities of the Company whose total assets and total revenues represent approximately 2.9% and 1.5%, and 3.8% and 0.6%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2011.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 9B. OTHER INFORMATION**

Not applicable.



**Table of Contents**

**PART III**

**INCORPORATION BY REFERENCE**

The information called for by Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities relating to equity compensation plans, Item 10. Directors, Executive Officers and Corporate Governance, Item 11. Executive Compensation, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, Item 13. Certain Relationships and Related Transactions, and Director Independence and Item 14. Principal Accountant Fees and Services is incorporated herein by reference to the Company's definitive proxy statement for its Annual Meeting of Stockholders scheduled to be held on May 17, 2012, which definitive proxy statement is expected to be filed with the Commission not later than 120 days after the end of the fiscal year to which this report relates.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) Documents filed as a part of this report.

**1. Financial Statements.**

The following financial statements and financial statement schedules are filed as a part of this report:

<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2011 and 2010</u>	F-3
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009</u>	F-4
<u>Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2011, 2010 and 2009</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6

**2. Financial Statement Schedules.**

<u>Schedule II Valuation and Qualifying Accounts</u>	F-42
--	------

All other schedules not listed above have been omitted, because they are not applicable or are not required, or because the required information is included in the consolidated financial statements or notes thereto.

**3. Exhibits required to be filed by Item 601 of Regulation S-K.**

- 3.1(a) Amended and Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3.1(a) to the Company's Annual Report on Form 10-K for the year ended December 31, 2005)
- 3.1(b) Certificate of Amendment to Amended and Restated Certificate of Incorporation dated May 22, 1998 (Incorporated by reference to Exhibit 3.1(b) to the Company's Annual Report on Form 10-K for the year ended December 31, 1998)
- 3.1(c) Certificate of Amendment to Amended and Restated Certificate of Incorporation dated May 17, 1999 (Incorporated by reference to Exhibit 3.1(c) to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)
- 3.2(a) Amended and Restated Bylaws of the Company (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 3, 2006)
- 3.2(b) Amended and Restated Bylaws of the Company (Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on November 3, 2009)
- 4.1 Purchase Agreement, dated June 9, 2011, by and between Integra LifeSciences Holdings Corporation and J.P. Morgan Securities LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. LLC, Deutsche Bank Securities Inc., RBC Capital Markets, LLC and Wells Fargo Securities, LLC (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 15, 2011)
- 4.2 Indenture, dated June 15, 2011, by and between Integra LifeSciences Holdings Corporation and Wells Fargo Bank, National Association, as trustee (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 15, 2011)
- 4.3(a) Credit Agreement, dated as of December 22, 2005, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, Citibank FSB and SunTrust Bank, as Co-Syndication Agents, and Royal Bank of Canada and Wachovia Bank, National Association, as Co-Documentation Agents (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 29, 2005)



**Table of Contents**

- 4.3(b) First Amendment, dated as of February 15, 2006, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, Citibank FSB and SunTrust Bank, as Co-Syndication Agents, and Royal Bank of Canada and Wachovia Bank, National Association, as Co-Documentation Agents (Incorporated by reference to Exhibit 4.3(b) to the Company's Annual Report on Form 10-K for the year ended December 31, 2005)
- 4.3(c) Second Amendment, dated as of February 23, 2007, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, Citibank FSB and SunTrust Bank, as Co-Syndication Agents, and Royal Bank of Canada and Wachovia Bank, National Association, as Co-Documentation Agents (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 27, 2007)
- 4.3(d) Third Amendment, dated as of June 4, 2007, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, Citibank, N.A., successor by merger to Citibank, FSB, as Syndication Agent and JPMorgan Chase Bank, N.A., Deutsche Bank Trust Company Americas and Royal Bank of Canada, as Co-Documentation Agents (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 6, 2007)
- 4.3(e) Fourth Amendment, dated as of September 5, 2007, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, Citibank, N.A., successor by merger to Citibank FSB, as Syndication Agent and JPMorgan Chase Bank, N.A., Deutsche Bank Trust Company Americas and Royal Bank of Canada, as Co-Documentation Agents (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 6, 2007)
- 4.3(f) Amended and Restated Credit Agreement, dated as of August 10, 2010, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, JP Morgan Chase Bank, as Syndication Agent, and HSBC Bank USA, NA, RBC Capital Markets, Wells Fargo Bank, N.A., Fifth Third Bank, DNB NOR Bank ASA and TD Bank, N.A., as Co-Documentation Agents (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 10, 2010)
- 4.3(g) Second Amended and Restated Credit Agreement, dated as of June 8, 2011, among Integra LifeSciences Holdings Corporation, the lenders party thereto, Bank of America, N.A. as Administrative Agent, Swing Line Lender and L/C Issuer, JPMorgan Chase Bank N.A. as Syndication Agent, and, HSBC Bank USA, NA, Royal Bank of Canada, Wells Fargo Bank, N.A., Fifth Third Bank, DNB NOR Bank ASA, and TD Bank, N.A., as Co-Documentation Agents (Incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on July 29, 2011)
- 4.4 Security Agreement, dated as of December 22, 2005, among Integra LifeSciences Holdings Corporation and the additional grantors party thereto in favor of Bank of America, N.A., as administrative and collateral agent (Incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005)
- 4.5 Pledge Agreement, dated as of December 22, 2005, among Integra LifeSciences Holdings Corporation and the additional grantors party thereto in favor of Bank of America, N.A., as administrative and collateral agent (Incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005)
- 4.6 Subsidiary Guaranty Agreement, dated as of December 22, 2005, among the guarantors party thereto and individually as a Guarantor ), in favor of Bank of America, N.A., as administrative and collateral agent (Incorporated by reference to Exhibit 4.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005)

**Table of Contents**

- 4.7 Indenture, dated as of September 29, 2006, between the Company and Wells Fargo Bank, N.A. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 5, 2006)
- 4.8 Indenture, dated June 11, 2007, among Integra LifeSciences Holdings Corporation, Integra LifeSciences Corporation and Wells Fargo Bank, N.A., as trustee (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 12, 2007)
- 4.9 Form of 2.75% Senior Convertible Note due 2010 (included in Exhibit 4.8) (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on June 12, 2007)
- 4.10 Indenture, dated June 11, 2007, among Integra LifeSciences Holdings Corporation, Integra LifeSciences Corporation and Wells Fargo Bank, N.A., as trustee (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on June 12, 2007)
- 4.11 Form of 2.375% Senior Convertible Note due 2012 (included in Exhibit 4.10) (Incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on June 12, 2007)
- 4.12 Registration Rights Agreement, dated June 11, 2007, among Integra LifeSciences Holdings Corporation, Banc of America Securities LLC, J.P. Morgan Securities Inc. and Morgan Stanley & Co., Incorporated, as representatives of the several initial purchasers (Incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K filed on June 12, 2007)
- 4.13 Registration Rights Agreement, dated June 11, 2007, among Integra LifeSciences Holdings Corporation, Banc of America Securities LLC, J.P. Morgan Securities Inc. and Morgan Stanley & Co., Incorporated, as representatives of the several initial purchasers (Incorporated by reference to Exhibit 4.6 to the Company's Current Report on Form 8-K filed on June 12, 2007)
- 10.1(a) Lease between Plainsboro Associates and American Biomaterials Corporation dated as of April 16, 1985, as assigned to Colla-Tec, Inc. on October 24, 1989 and as amended through November 1, 1992 (Incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form 10/A (File No. 0-26224) which became effective on August 8, 1995)
- 10.1(b) Lease Modification #2 entered into as of the 28th day of October, 2005, by and between Plainsboro Associates and Integra LifeSciences Corporation (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 2, 2005)
- 10.1(c) Lease Modification #3 entered into as of the 2<sup>nd</sup> day of March, 2011, by and between Plainsboro Associates and Integra LifeSciences Corporation (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 3, 2011)
- 10.2 (a) Equipment Lease Agreement between Medicus Corporation and the Company, dated as of June 1, 2000 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000)
- 10.2(b) First Amendment to Equipment Lease Agreement between Medicus Corporation and the Company, dated as of June 29, 2010 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010)
- 10.3 Form of Indemnification Agreement between the Company and [ ] dated August 16, 1995, including a schedule identifying the individuals that are a party to such Indemnification Agreements (Incorporated by reference to Exhibit 10.37 to the Company's Registration Statement on Form S-1 (File No. 33-98698) which became effective on January 24, 1996)\*
- 10.4 1996 Incentive Stock Option and Non-Qualified Stock Option Plan (as amended through December 27, 1997) (Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on February 3, 1998)\*

**Table of Contents**

10.5	1998 Stock Option Plan (amended and restated as of July 26, 2005) (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005)*
10.6	1999 Stock Option Plan (amended and restated as of July 26, 2005) (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005)*
10.7(a)	Employee Stock Purchase Plan (as amended on May 17, 2004) (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-127488) filed on August 12, 2005)*
10.7(b)	First Amendment to the Company's Employee Stock Purchase Plan, dated October 26, 2005 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 1, 2005)*
10.8	2000 Equity Incentive Plan (amended and restated as of July 26, 2005) (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005)*
10.9	2001 Equity Incentive Plan (amended and restated as of July 26, 2005) (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005)*
10.10(a)	Integra LifeSciences Holdings Corporation Second Amended and Restated 2003 Equity Incentive Plan effective May 19, 2010 (Incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed May 21, 2010)*
10.10(b)	Integra LifeSciences Holdings Corporation Amended and Restated 2003 Equity Incentive Plan effective July 9, 2008 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 11, 2008)*
10.10(c)	Amendment to the Integra LifeSciences Holdings Corporation 2003 Equity Incentive Plan dated July 9, 2008 (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 11, 2008)*
10.11(a)	Second Amended and Restated Employment Agreement dated July 27, 2004 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004)*
10.11(b)	Amendment 2006-1, dated as of December 19, 2006, to the Second Amended and Restated Employment Agreement, between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 22, 2006)*
10.11(c)	Amendment 2008-1, dated as of March 6, 2008, to the Second Amended and Restated Employment Agreement, between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.12(c) to the Company's Annual Report on Form 10-K for the year ended December 31, 2007)*
10.11(d)	Amendment 2008-2, dated as of August 6, 2008, to the Second Amended and Restated Employment Agreement between Stuart M. Essig and the Company (Incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008)*
10.11(e)	Amendment 2009-1, dated as of April 13, 2009, to the Second Amended and Restated Employment Agreement between Stuart M. Essig and the Company (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on April 13, 2009)*
10.11(f)	Letter Agreement dated May 17, 2011 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 23, 2011)

**Table of Contents**

10.11(g)	Letter dated December 20, 2011 from Stuart M. Essig to Integra LifeSciences Holdings Corporation (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed December 23, 2011)
10.12	Indemnity letter agreement dated December 27, 1997 from the Company to Stuart M. Essig (Incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on February 3, 1998)*
10.13(a)	Registration Rights Provisions for Stuart M. Essig (Incorporated by reference to Exhibit B of Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 3, 1998)*
10.13(b)	Registration Rights Provisions for Stuart M. Essig (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 8, 2001)*
10.13(c)	Registration Rights Provisions for Stuart M. Essig (Incorporated by reference to Exhibit B of Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004)*
10.14(a)	Amended and Restated 2005 Employment Agreement between John B. Henneman, III and the Company dated December 19, 2005 (Incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005)*
10.14(b)	Amendment 2008-1, dated as of January 2, 2008, to the Amended and Restated 2005 Employment Agreement between John B. Henneman, III and the Company (Incorporated by reference to Exhibit 10.15(b) to the Company's Annual Report on Form 10-K for the year ended December 31, 2007)*
10.14(c)	Amendment 2008-2, dated as of December 18, 2008, to the Amended and Restated 2005 Employment Agreement between John B. Henneman, III and the Company (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 24, 2008)*
10.14(d)	Amendment 2009-1, dated as of April 13, 2009, to the Amended and Restated 2005 Employment Agreement between John B. Henneman, III and the Company (Incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on April 13, 2009)*
10.14(e)	Amendment 2010-1, dated as of October 12, 2010, to the Amended and Restated 2005 Employment Agreement between John B. Henneman, III and the Company (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed October 12, 2010)*
10.14(f)	Letter dated as of February 22, 2012 from John B. Henneman, III to the Company (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 22, 2012)*
10.15	Consulting Agreement, dated October 12, 2010, between Integra LifeSciences Holdings Corporation and Inception Surgical (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 12, 2010)*
10.16(a)	Severance Agreement between Judith O. Grady and the Company dated as of January 4, 2010 (Incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009)*
10.16(b)	Severance Agreement between Judith O. Grady and the Company dated as of January 3, 2011 (Incorporated by reference to Exhibit 10.17(a) to the Company's Annual Report on Form 10-K for the year ended December 31, 2010)*
10.16(c)	Severance Agreement between Judith O. Grady and the Company dated as of January 3, 2012*+
10.17(a)	Employment Agreement, dated as of October 12, 2010, between Peter J. Arduini and Integra LifeSciences Holdings Corporation (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed October 12, 2010)*
10.17(b)	Amended and Restated Employment Agreement dated December 20, 2011 between Peter J. Arduini and Integra LifeSciences Holdings Corporation (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 23, 2011)*

**Table of Contents**

10.18	Form of Notice of Stock Option Grant with Eight-Year Term for Peter J. Arduini (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 23, 2011)*
10.19(a)	Lease Contract, dated April 1, 2005, between the Puerto Rico Industrial Development Company and Integra CI, Inc. (executed on September 15, 2006) (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006)
10.19(b)	Amendment to Lease Contract dated as of November 2, 2011, between Integra CI, Inc. and Puerto Rico Industrial Development Company (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 7, 2011)
10.20	Restricted Units Agreement dated December 27, 1997 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on February 3, 1998)*
10.21	Stock Option Grant and Agreement dated December 22, 2000 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 8, 2001)*
10.21	Stock Option Grant and Agreement dated December 22, 2000 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on January 8, 2001)*
10.23(a)	Restricted Units Agreement dated December 22, 2000 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on January 8, 2001)*
10.23(b)	Amendment 2006-1, dated as of October 30, 2006, to the Stuart M. Essig Restricted Units Agreement dated as of December 22, 2000 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 3, 2006)*
10.24	Stock Option Grant and Agreement dated July 27, 2004 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)*
10.25(a)	Contract Stock/Restricted Units Agreement dated July 27, 2004 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)*
10.25(b)	Amendment 2006-1, dated as of October 30, 2006, to the Stuart M. Essig Contract Stock/Restricted Units Agreement dated as of July 27, 2004 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 3, 2006)*
10.25(c)	Amendment 2008-1, dated as of March 6, 2008, to the Stuart M. Essig Contract Stock/Restricted Units Agreement dated as of July 27, 2004 (Incorporated by reference to Exhibit 10.25(c) to the Company's Annual Report on Form 10-K for the year ended December 31, 2007)*
10.25(d)	Amendment 2011-1, dated as of May 17, 2011, to the Stuart M. Essig Contract Stock/Restricted Units Agreement dated as of July 24, 2004 (Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed July 29, 2011)*
10.26	Form of Amendment 2011-1 to Contract Stock/Restricted Units Agreements between the Company and Mr. Essig (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed July 29, 2011)*
10.27	Contract Stock/Units Agreement dated as of May 17, 2011 between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 23, 2011)



**Table of Contents**

10.28	Form of Stock Option Grant and Agreement between the Company and Stuart M. Essig (Incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)*
10.29(a)	Form of Contract Stock/Restricted Units Agreement for Stuart M. Essig (Incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008)*
10.29(b)	New Form of Contract Stock/Restricted Units Agreement (for Annual Equity Awards) for Stuart M. Essig (Incorporated by reference to Exhibit 10.28(b) to the Company's Annual Report on Form 10-K for the year ended December 31, 2010)*
10.29(c)	Form of Amendment 2011-1 to Contract Stock/Restricted Units Agreement between the Company and Mr. Essig (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed July 29, 2011)*
10.30	Form of Performance Stock Agreement for Stuart M. Essig (Incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008)*
10.31	Form of Restricted Stock Agreement for Stuart M. Essig for 2009 (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed April 13, 2009)*
10.32	New Form of Contract Stock/Restricted Units Agreement (for 2011) Annual Equity Award for Stuart M. Essig (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed July 29, 2011)*
10.33	Form of Notice of Grant of Stock Option and Stock Option Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 29, 2005)*
10.34	Form of Non-Qualified Stock Option Agreement (Non-Directors) (Incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)*
10.35	Form of Incentive Stock Option Agreement (Incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)*
10.36	Form of Non-Qualified Stock Option Agreement (Directors) (Incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)*
10.37(a)	Compensation of Directors of the Company effective July 9, 2008 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 11, 2008)*
10.37(b)	Compensation of Directors of the Company effective May 17, 2011 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 16, 2010)*
10.38(a)	Form of Restricted Stock Agreement for Non-Employee Directors under the Integra LifeSciences Holdings Corporation 2003 Equity Incentive Plan (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 17, 2005)*
10.38(b)	Form of Restricted Stock Agreement for Non-Employee Directors under the Integra LifeSciences Holdings Corporation 2003 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008)*
10.38(c)	New Form of Restricted Stock Agreement for Non-Employee Directors under the Integra LifeSciences Holdings Corporation 2003 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 13, 2009)*

**Table of Contents**

10.39(a)	Form of Restricted Stock Agreement for Executive Officers – Cliff Vesting (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on January 9, 2006)*
10.39(b)	New Form of Restricted Stock Agreement for Executive Officers – Annual Vesting (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 25, 2009)*
10.39(c)	New Form of Restricted Stock Agreement with Cliff Vesting for Executive Officers (Incorporated by reference to Exhibit 10.8 to the Company’s Quarter Report on Form 10-Q for the quarter ended March 31, 2009)*
10.39(d)	Form of Restricted Stock Agreement for Mr. Henneman for 2008 and 2009 (Incorporated by reference to Exhibit 10.6 to the Company’s Current Report on Form 8-K filed on April 13, 2009)*
10.39(e)	Form of Contract Stock/Restricted Units Agreement for Mr. Henneman (Incorporated by reference to Exhibit 10.4 to the Company’s Current Report on Form 8-K filed on December 24, 2008)*
10.39(f)	Form of Option Agreement among Integra LifeSciences Holdings Corporation and John B. Henneman, III (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on June 6, 2008)*
10.39(g)	Form of Restricted Stock Agreement for John B. Henneman, III (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 27, 2007)*
10.39(h)	Form of Performance Stock Agreement for John B. Henneman, III (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on March 21, 2007)*
10.39(i)	Form of Performance Stock Agreement for John B. Henneman, III (Incorporated by reference to Exhibit 10.37(b) to the Company’s Annual Report on Form 10-K for the year ended December 31, 2007)*
10.39(j)	Form of Contract Stock/Restricted Units Agreement (for Signing Grant) for Mr. Arduini (Incorporated by reference to Exhibit 10.4 to the Company’s Current Report on Form 8-K filed on October 12, 2010)*
10.39(k)	Form of Contract Stock/Restricted Units Agreement (for Annual Equity Awards) for Mr. Arduini (Incorporated by reference to Exhibit 10.5 to the Company’s Current Report on Form 8-K filed on October 12, 2010)*
10.39(l)	Form of Non-Qualified Stock Option Agreement for Mr. Arduini (Incorporated by reference to Exhibit 10.6 to the Company’s Current Report on Form 8-K filed on October 12, 2010)*
10.39(m)	Form of Restricted Stock Agreement for Mr. Henneman (Incorporated by reference to Exhibit 10.7 to the Company’s Current Report on Form 8-K filed on October 12, 2010)*
10.39(n)	Form of Restricted Stock Agreement (Annual Vesting) for Mr. Henneman *+
10.40	Asset Purchase Agreement, dated as of September 7, 2005, by and between Tyco Healthcare Group LP and Sherwood Services, AG and Integra LifeSciences Corporation and Integra LifeSciences (Ireland) Limited (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on September 13, 2005)
10.41	Performance Stock Agreement by and between John B. Henneman, III and the Company dated January 3, 2006 (Incorporated by reference to Exhibit 10.42 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2005)*
10.42	Stock Purchase Agreement, dated as of April 19, 2006, by and between ASP/Miltex LLC and Integra LifeSciences Corporation (Incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on April 25, 2006)

**Table of Contents**

10.43	Stock Agreement and Plan of Merger, dated as of June 30, 2006, by and between Integra LifeSciences Corporation, Integra California, Inc., Kinetikos Medical, Inc., Telegraph Hill Partners Management LLC, as Shareholders Representative, and the Shareholders party thereto (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 7, 2006)
10.44(a)	Integra LifeSciences Holdings Corporation Management Incentive Compensation Plan (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006)*
10.44(b)	First Amendment to Integra LifeSciences Holdings Corporation Management Incentive Compensation Plan (Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007)*
10.44(c)	Integra LifeSciences Holdings Corporation Management Incentive Compensation Plan, as amended and restated as of January 1, 2008 (Incorporated by reference to Exhibit 10.43(c) to the Company's Annual Report on Form 10-K for the year ended December 31, 2007)*
10.45	Form of 2010 Convertible Bond Hedge Transaction Confirmation, dated June 6, 2007, between Integra LifeSciences Holdings Corporation and dealer (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 12, 2007)
10.46	Form of 2012 Convertible Bond Hedge Transaction Confirmation, dated June 6, 2007, between Integra LifeSciences Holdings Corporation and dealer (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 12, 2007)
10.47	Form of 2010 Amended and Restated Issuer Warrant Transaction Confirmation, dated June 6, 2007, between Integra LifeSciences Holdings Corporation and dealer (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on June 12, 2007)
10.48	Form of 2012 Amended and Restated Issuer Warrant Transaction Confirmation, dated June 6, 2007, between Integra LifeSciences Holdings Corporation and dealer (Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on June 12, 2007)
10.49	Letter Agreement, dated June 9, 2011, between Deutsche Bank AG, London Branch and Integra LifeSciences Holdings Corporation, regarding the Base Call Option Transaction (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on June 15, 2011)
10.50	Letter Agreement, dated June 9, 2011, between Royal Bank of Canada and Integra LifeSciences Holdings Corporation, regarding the Base Call Option Transaction (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on June 15, 2011)
10.51	Letter Agreement, dated June 9, 2011, between The Royal Bank of Scotland plc and Integra LifeSciences Holdings Corporation, regarding the Base Call Option Transaction (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on June 15, 2011)
10.52	Letter Agreement, dated June 9, 2011, between Wells Fargo Bank, National Association and Integra LifeSciences Holdings Corporation, regarding the Base Call Option Transaction (Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on June 15, 2011)
10.53	Letter Agreement, dated June 9, 2011, between Deutsche Bank AG, London Branch and Integra LifeSciences Holdings Corporation, regarding the Base Warrant Transaction (Incorporated by reference to Exhibit 10.5 to the Company's Form 8-K filed on June 15, 2011)
10.54	Letter Agreement, dated June 9, 2011, between Royal Bank of Canada and Integra LifeSciences Holdings Corporation, regarding the Base Warrant Transaction (Incorporated by reference to Exhibit 10.6 to the Company's Form 8-K filed on June 15, 2011)
10.55	Letter Agreement, dated June 9, 2011, between The Royal Bank of Scotland plc and Integra LifeSciences Holdings Corporation, regarding the Base Warrant Transaction (Incorporated by reference to Exhibit 10.7 to the Company's Form 8-K filed on June 15, 2011)

**Table of Contents**

10.56	Letter Agreement, dated June 9, 2011, between Wells Fargo Bank, National Association and Integra LifeSciences Holdings Corporation, regarding the Base Warrant Transaction (Incorporated by reference to Exhibit 10.8 to the Company's Form 8-K filed on June 15, 2011)
10.57	Letter Agreement, dated June 14, 2011, between Deutsche Bank AG, London Branch and Integra LifeSciences Holdings Corporation, regarding the Additional Call Option Transaction (Incorporated by reference to Exhibit 10.9 to the Company's Form 8-K filed on June 15, 2011)
10.58	Letter Agreement, dated June 14, 2011, between Royal Bank of Canada and Integra LifeSciences Holdings Corporation, regarding the Additional Call Option Transaction (Incorporated by reference to Exhibit 10.10 to the Company's Form 8-K filed on June 15, 2011)
10.59	Letter Agreement, dated June 14, 2011, between The Royal Bank of Scotland plc and Integra LifeSciences Holdings Corporation, regarding the Additional Call Option Transaction (Incorporated by reference to Exhibit 10.11 to the Company's Form 8-K filed on June 15, 2011)
10.60	Letter Agreement, dated June 14, 2011, between Wells Fargo Bank, National Association and Integra LifeSciences Holdings Corporation, regarding the Additional Call Option Transaction (Incorporated by reference to Exhibit 10.12 to the Company's Form 8-K filed on June 15, 2011)
10.61	Letter Agreement, dated June 14, 2011, between Deutsche Bank AG, London Branch and Integra LifeSciences Holdings Corporation, regarding the Additional Warrant Transaction (Incorporated by reference to Exhibit 10.13 to the Company's Form 8-K filed on June 15, 2011)
10.62	Letter Agreement, dated June 14, 2011, between Royal Bank of Canada and Integra LifeSciences Holdings Corporation, regarding the Additional Warrant Transaction (Incorporated by reference to Exhibit 10.14 to the Company's Form 8-K filed on June 15, 2011)
10.63	Letter Agreement, dated June 14, 2011, between The Royal Bank of Scotland plc and Integra LifeSciences Holdings Corporation, regarding the Additional Warrant Transaction (Incorporated by reference to Exhibit 10.15 to the Company's Form 8-K filed on June 15, 2011)
10.64	Letter Agreement, dated June 14, 2011, between Wells Fargo Bank, National Association and Integra LifeSciences Holdings Corporation, regarding the Additional Warrant Transaction (Incorporated by reference to Exhibit 10.16 to the Company's Form 8-K filed on June 15, 2011)
10.65	Unit Purchase Agreement, dated as of July 23, 2008, by and among Integra LifeSciences Holdings Corporation, Theken Spine LLC, Randall R. Theken and the other members of Theken Spine, LLC party thereto (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 24, 2008)
10.66	Form of Indemnification Agreement for Non-Employee Directors and Officers (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 24, 2008)*
10.67	Piggyback Registration Rights Agreement dated December 22, 2008 between Integra LifeSciences Holdings Corporation and George Heenan, Thomas Gilliam and Michael Evers, as trustees of The Bruce A. LeVahn 2008 Trust and Steven M. LeVahn (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 29, 2008)
10.68(a)	Lease Agreement between 109 Morgan Lane, LLC and Integra LifeSciences Corporation, dated May 15, 2008 (Incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008)
10.68(b)	First Amendment to Lease Agreement between 109 Morgan Lane, LLC and Integra LifeSciences Corporation, dated March 9, 2009 (Incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009)
21	Subsidiaries of the Company+

**Table of Contents**

23	Consent of Pricewaterhouse Coopers LLP+
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002+
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002+
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002+
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002+
99.1	Letter, dated December 21, 2011, from the United States Federal Drug Administration to Integra LifeSciences Corporation (Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on January 5, 2012)
101.INS	XBRL Instance Document+#
101.SCH	XBRL Taxonomy Extension Schema Document+#
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document+#
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document+#
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document+#

\* Indicates a management contract or compensatory plan or arrangement.

+ Indicates this document is filed as an exhibit herewith.

# The financial information of Integra LifeSciences Holdings Corporation Annual Report on Form 10-K for the year ended December 31, 2011 filed on February 27, 2012 formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Operations, (ii) the Consolidated Balance Sheets, (iii) Parenthetical Data to the Consolidated Balance Sheets, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Changes in Stockholders' Equity, and (vi) Notes to Consolidated Financial Statements, is furnished electronically herewith.

The Company's Commission File Number for Reports on Form 10-K, Form 10-Q and Form 8-K is 0-26224.

**Table of Contents**

**SIGNATURES**

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

**INTEGRA LIFESCIENCES HOLDINGS  
CORPORATION**

By: /s/ Peter J. Arduini  
Peter J. Arduini