INTEGRA LIFESCIENCES HOLDINGS CORP Form 10-K March 03, 2009

#### 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 þ **EXCHANGE ACT OF 1934**

to

For the fiscal year ended December 31, 2008

#### TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 0 **EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_

#### **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

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

**Title of Each Class** 

Name of Exchange on Which Registered The Nasdaq Stock Market LLC Common Stock, Par Value \$.01 Per Share 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 o No b

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 o No b

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 b No o 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. o

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 b Accelerated filer o

Smaller reporting company o

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(I.R.S. EMPLOYER **IDENTIFICATION NO.)** 

51-0317849

08536 (ZIP CODE)

Non-accelerated filer o

(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 o No þ

As of June 30, 2008, the aggregate market value of the registrant s common stock held by non-affiliates was approximately \$859.9 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 25, 2009 was 28,142,997.

#### DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant s definitive proxy statement relating to its scheduled May 20, 2009 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

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#### PART I

#### ITEM 1. BUSINESS OVERVIEW

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

Integra, headquartered in Plainsboro, New Jersey, is a world leader in regenerative medicine. We employ over 2,800 people around the world who are dedicated to improving patient quality of life through the development, manufacturing and marketing of clinically relevant, innovative, and cost-effective surgical implants and medical instruments. Our products are used to treat millions of patients every year, primarily in neurosurgery, orthopedics and general surgery. Revenues grew to \$654.6 million in 2008, an increase of 19% from \$550.5 million in 2007. Founded in 1989, Integra has grown to be a leader in developing medical devices, particularly for neurosurgery, spinal surgery, and extremity reconstruction, and is one of the largest surgical instrument companies in the United States. We had several developments in 2008 that we expect will contribute to growing our business in the foreseeable future. In August 2008, we acquired Theken Spine, LLC, Theken Disc, LLC and Therics, LLC (collectively, Theken ), based in Akron, Ohio. Theken specializes in pioneering spinal implant technologies that seek to improve spinal surgical techniques, thereby benefiting patients as well as surgeons. Theken provides comprehensive product lines that offer steadfast product reliability and easy-to-use instrumentation. Products include cervical plates, pedicle screws, spacers, degenerative/deformity products, trauma devices, and synthetic bone substitute products. Theken Disc is a development stage company focused on next generation artificial disc replacement technology. We have begun marketing Theken s products as Integra Spine, which will align the spinal implant business more closely with the Integra corporate brand and build on our mutual strengths.

In November 2008, we acquired our longstanding Australia and New Zealand distributors, which will provide us with both direct access to these markets and the ability to provide enhanced service and support in Southeast Asia.

In December 2008, we acquired Minnesota Scientific, Inc., which does business as Omni-Tract Surgical (Omni-Tract), based in St. Paul, Minnesota. It is a global leader in the development and manufacture of table-mounted retractors and sells these systems for use in vascular, bariatric, general, urologic, orthopedic, spine, pediatric and laparoscopic surgery. We will integrate Omni-Tract s retractor products into our other lines of surgical instruments and illumination systems sold by the Integra Surgical sales team.

In the third quarter of 2008, we revised the presentation of our revenue results to reflect the markets into which we sell our products: neurosciences, orthopedics and medical instruments. These replace the previously reported revenue categories.

#### STRATEGY

Our goal is to become a global leader in the development, manufacturing and marketing of medical devices, implants and instruments for surgery, particularly neurosurgery, spine surgery, and orthopedics. Key elements of our strategy include:

*Marketing innovative medical devices in underserved markets.* We develop innovative medical devices for neurosurgery, spine surgery, extremity reconstructive surgery and general surgery.

*Investing in sales distribution channels to increase market penetration.* We have built a large neurosurgical sales team of approximately 150 sales professionals in the U.S. who sell products to operating rooms and intensive care units. We have also built one of the largest direct extremity reconstruction sales forces of approximately 90 sales professionals in the U.S. Our European sales force consists of approximately 75 professionals, our Canadian sales force consists of approximately 10 professionals, and our newly acquired New Zealand and Australia sales force consists of approximately 5 professionals.

Developing innovative products based on core technologies. We are a leader in regenerative technology. We sell a number of regenerative products through both our own sales network and through alliances with other companies in private-label arrangements. Our proprietary highly purified collagen scaffold technology provides the foundation of our products for duraplasty, dermal regeneration, nerve and tendon repair, and bone repair and regeneration.

Acquiring products that fit existing sales channels or establish new sales channels. We acquire new products and businesses to increase the efficiency and size of our sales force, stimulate the development of new products, and extend the commercial lives of existing products. We have completed 18 acquisitions since the beginning of 2004, have demonstrated that we can quickly and profitably integrate new products and businesses and have an active program to evaluate more such 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

In the U.S., we have three sales channels. The largest, Integra NeuroSciences, sells products through directly employed sales representatives. Within our Integra Orthopedics sales channel, there are three sales organizations: Integra Extremity Reconstruction, which sells through a large direct sales organization, Integra OrthoBiologics and Integra Spine. Integra OrthoBiologics and Integra Spine sell through specialty distributors focused on their respective surgical specialties. The Integra Medical Instruments market sales channel sells through three main sales organizations: Integra Surgical, which sells both directly and through distributors; Miltex, which sells through distributors and wholesalers; and Integra Pain Management, which sells through independent sales people and specialty distributors.

Integra NeuroSciences. Integra NeuroSciences direct sales effort in the U.S. involves approximately 150 professionals, including direct sales representatives, product specialists, sales management, and clinical educators who educate and train our salespeople and customers in the use of our products. Our direct sales representatives focus on products used in operating rooms and intensive care units. Integra NeuroSciences sales representatives call on neurosurgeons, intensivists, other physicians, nurses, hospitals and surgery centers. Outside the U.S., we sell neurosurgical products directly in Canada, Australia, New Zealand and major European markets. In all other markets, Integra NeuroSciences products are sold through a network of distributors.

Integra Extremity Reconstruction. Our Integra Extremity Reconstruction sales organization in the U.S. consists of approximately 90 direct salespeople, sales managers and clinical educators. Integra Extremity Reconstruction sells medical devices to orthopedic surgeons, podiatric surgeons, trauma and reconstructive surgeons, burn surgeons and other physicians who practice in hospitals and surgery centers. The Integra Extremity Reconstruction team sells both metal implants for internal fixation and joint reconstruction and regenerative biomaterials for the repair of soft tissue, including the skin, peripheral nerves and tendons. Outside the U.S., we sell devices for extremity reconstruction directly through sales representatives in Canada, Australia, New Zealand and major European markets, and elsewhere through a network of distributors.

Integra OrthoBiologics. Integra OrthoBiologics supports a distributor network of more than 45 dealer organizations, which retain over 300 sales representatives. The Integra OrthoBiologics distributor network receives additional marketing support from a team of approximately 20 Integra OrthoBiologics sales representatives who work in tandem with the dealers representatives to deliver a solution of bone regenerative products to spine and orthopedic surgeons. Outside the U.S., we sell orthobiologics products through a network of distributors.

Integra Spine. Our Integra Spine sales network consists of approximately 50 independent U.S. distributor organizations that retain over 170 sales representatives who distribute our products in 33 states. They market our spinal implant and biologics products to neurosurgeons and orthopedic surgeons who specialize in spine surgery. We have nine additional sales specialists who support our field efforts and work closely with our customers. Integra Spine is not currently represented outside the U.S., and we view this market outside the U.S. as a long-term opportunity for growth.

Integra Medical Instruments. Integra Medical Instruments includes three sales organizations. Integra Surgical sells specialty and general instruments and surgical lighting to hospitals through approximately 50 directly employed sales representatives and a network of distributors. Miltex sells hand-held surgical and dental instruments in the

alternate-site market (outpatient surgical clinics, physician offices, podiatry practices, dental offices and veterinary clinics) through a large network of distributors and wholesalers. Integra Pain Management sells customized pain management kits and devices through independent sales people or specialty distributors.

*Strategic Alliances.* We market certain products through strategic partners or original equipment manufacturer customers. Because these products generally address large and diverse markets, it is more cost-effective for us to leverage the product development and distribution systems of our strategic partners. We have these relationships with Johnson & Johnson, Medtronic, Wyeth and Zimmer, among others.

#### PRODUCTS OVERVIEW

Integra is a fully integrated medical device company with thousands of products for the medical specialties that we target. Our objective is to develop, or otherwise provide, any product that will improve our service to our customers. These products include implants for neurosurgery, spinal surgery and extremity reconstructive surgery, and medical surgical equipment, which includes hand-held instruments, powered instruments, image-guided surgery systems and monitors that measure brain parameters. We distinguish ourselves by emphasizing the importance of the relatively new field of regenerative medicine.

In 2008, approximately 22% of our revenues came from surgical implants derived from our proprietary collagen matrix technology. 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 lay down new native extracellular matrix. In their interaction with the patient s body, our collagen matrices inhibit the formation of scar tissue, so in the end the implant disappears leaving healthy native tissue in its place. This basic technology can be applied to many different procedures. We sell regenerative medicine products through most of our sales channels.

#### NEUROSCIENCES PRODUCT PORTFOLIO

Our Integra NeuroSciences sales organization sells a full line of instruments and other equipment for neurosurgery. We have products for each step of cranial procedure and the care of the patient after the operation. We sell equipment used in the neurosurgery operating room and neurosurgery intensive care unit (ICU). We also offer a wide array of implants for neurosurgery and spine surgery, including a complete set of duraplasty products and biomaterials for spine surgery. Highlights include:

*Duraplasty Products.* In the U.S., over 225,000 craniotomy procedures are performed each year. Most of these surgeries breach the dura mater, which is the tough, fibrous membrane that surrounds and protects the tissue of the brain and spinal cord. The breach must be repaired, either by suturing or applying a dural graft to prevent cerebrospinal fluid leaks and facilitate wound healing. Since the introduction of the DuraGen<sup>®</sup> 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 U.S. We subsequently launched DuraGen Plus<sup>®</sup> Dural Regeneration Matrix in 2003, Suturable DuraGen Dural Regeneration Matrix in 2005, and DuraGen XS Dural Regeneration Matrix in 2007, demonstrating our sustained commitment to providing the neurosurgical community with innovative technology and materials for the management of dural defects. These products are alternatives to autologous tissue grafts taken from elsewhere in the patient s body.

*Collagen for Spine.* Over 450,000 patients undergo lumbar surgery in the U.S. each year. Adhesions, a painful condition that occurs when internal scar tissue causes nerves, organs and other structures to adhere to each other, are a frequent complication of the procedure. Our collagen matrix technology has the potential to inhibit the formation of scar tissue, so we believe it is well-suited to address this problem. Outside the U.S., we sell the DuraGen Plus<sup>®</sup> Adhesion Barrier Matrix as a barrier against the formation of adhesions following spine surgery and for the repair and restoration of the dura mater following spinal and cranial surgery.

In 2008, we continued to make progress in our multi-center clinical trial, designed to evaluate the safety and effectiveness of DuraGen Plus<sup>®</sup> Adhesion Barrier Matrix, for use in spinal surgery in the U.S., as a barrier against the formation of adhesions following such surgery. If the trial is completed in accordance with our expectations and achieves results acceptable to the Food and Drug Administration (FDA) (of which there can be no assurance), we expect to file a Premarket Approval (PMA) application for DuraGen PfuAdhesion Barrier Matrix with the FDA in 2011 for use as an adhesion barrier in spinal surgery.

*Cerebral Spinal Fluid* (*CSF*) *Management Devices*. CSF drainage is an important component of managing the intracranial pressure of a neuro-compromised patient or a patient undergoing abdominal aortic aneurysm surgery. In 2007, over 300,000 procedures in the U.S. were performed using lumbar or ventricular drainage systems, representing an estimated \$100 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 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 valve to maintain a normal level of CSF within the ventricles. Each year there are 40,000 new implants and revision cases to treat hydrocephalus. The total U.S. market for hydrocephalus management is over \$100 million. Integra currently offers a diverse line of hydrocephalus management products, including a wide variety of valves and ventricular, lumbar, peritoneal and cardiac catheters.

Normal Pressure Hydrocephalus ( NPH ) is an abnormal increase of CSF in the brain s ventricles, or cavities. The majority of cases of NPH are idiopathic. The accumulation causes the ventricles to enlarge, putting pressure on the brain. However, due to the normal atrophy of the brain associated with aging, there is usually little or no increase in intracranial pressure. NPH is characterized by many of the same symptoms associated with other conditions that occur more often in the elderly, such as memory loss, dementia, gait disorder, urinary incontinence and a general slowing of activity. It may result from a subarachnoid hemorrhage, head trauma, infection, tumor, complications of surgery or for unknown reasons. Treatment for NPH involves surgical placement of a shunt in the brain to drain excess CSF into the abdomen where it can be absorbed. This allows the brain ventricles to decrease in size, alleviating the pressure of the brain. There are about 13,200 cases of NPH a year. It is estimated that 10% of the 7.5 million patients who think they have Alzheimer s actually have NPH.

*Cranial Stabilization Equipment.* Most neurosurgery procedures require that the head is held rigidly during the operation. The MAYFIELD<sup>®</sup> line of cranial stabilization equipment fixes the head in an orientation determined by the surgeon; the device contacts 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.

The MAYFIELD<sup>®</sup> system is used worldwide in over 200,000 brain procedures annually. Treatments using MAYFIELD<sup>®</sup> include head trauma injuries, pediatric disorders such as hydrocephalus, biopsies, cancer removal, and treatments for cerebrovascular disorders such as aneurysms, and neurodegenerative disorders such as Parkinson s disease or epilepsy.

*Image-Guided Surgery Equipment.* Our Radionics<sup>®</sup> OmniSight<sup>®</sup> EXcel image-guided surgery system provides neurosurgeons and orthopedic surgeons with enhanced three-dimensional visualization of critical anatomy and the ability to perform less invasive surgical procedures.

*Stereotactic Equipment.* Stereotactic radiosurgery is a minimally invasive technique used to deliver a single high dose of radiation to small, well-defined target volumes, while avoiding nearby normal tissue and critical structures. The targeted volumes are primarily brain tumors and vascular malformations. Integra NeuroSciences has a strong portfolio of stereotactic products, with the Radionics CRW<sup>®</sup> stereotactic system for neurosurgery, and the Radionics XKnife<sup>®</sup> system for stereotactic radiosurgery. Certain intracranial brain lesions may not be good candidates for surgical resection, and neurosurgeons may use our Radionics XKnife<sup>®</sup> system in the non-invasive treatment of these lesions.

*Tissue Ablation Equipment.* Ultrasonic surgery uses high frequency acoustic pulses to selectively dissect soft tissues according to their density, leaving fibrous tissues, such as nerves and blood vessels, relatively unaffected. It therefore facilitates the ablation of unwanted tissue adjacent or attached to vital structures. Integra s CUSA has been a leading ultrasonic surgical aspirator for over 25 years. The product offering includes the CUSA Excel<sup>®</sup>, CUSA<sup>®</sup> Selector<sup>®</sup> and CUSA<sup>®</sup> Dissectron<sup>®</sup> (sold internationally). In 2009, we plan to launch the CUSA<sup>®</sup> NXT. Its new features, which will include revolutionary digital architecture and an advanced aspiration system, will enhance clinical performance and simplify system set up and control.

Our market-leading CUSA tissue ablation systems are used on over 100,000 procedures annually, at over 2,000 centers around the world, for the removal of brain tumors, epilepsy foci, as well as gynecological and liver tumors. According to industry sources, the total U.S. market for ultrasonic tissue ablation products is 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, such as new tips and handpieces, to meet these new clinical applications. We expect the market to continue to grow.

*Intracranial Monitoring Equipment.* The neurosurgical ICU monitors a patient s post-operative condition, following most neurosurgical procedures involving craniotomy. We offer the leading products for monitoring intracranial

pressure (the Camino<sup>®</sup> ICP monitor) and metabolic activity (LICOX<sup>®</sup> brain tissue monitoring system) and equipment for the drainage of excess CSF (the AccuDrain<sup>®</sup> External Ventricular Drainage Systems).

Our Camino<sup>®</sup> and LICOX<sup>®</sup> monitoring systems are also used in the treatment of Traumatic Brain Injury (TBI). TBI is a major public health problem and costs the U.S. an estimated \$56 billion a year. More than 5 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 monitoring and managing intracranial pressure and brain tissue oxygen.

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#### **ORTHOPEDICS PRODUCT PORTFOLIO**

Our orthopedics market category includes products sold by our Integra Extremity Reconstruction, Integra OrthoBiologics and Integra Spine sales organizations.

#### **Integra Extremity Reconstruction Product Portfolio**

Extremity reconstruction is a growing area of the orthopedic market. It is attractive to us because larger orthopedic medical device companies have not traditionally concentrated on this niche 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 arm below the shoulder.

*Dermal Regeneration and Engineered Wound Dressings.* Our dermal repair and regeneration products (INTEGRA<sup>®</sup> Dermal Regeneration Template, Integra Bilayer Matrix Wound Dressing, Integra Matrix Wound Dressing, and Integra Flowable Wound Matrix) are used to treat the chronic wounds that can form on the foot, ankle and lower leg, severe burns, and scar contractures.

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 U.S. is approximately \$800 million.

There are currently 18 million people with diabetes in the U.S. 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 U.S.

*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 the NeuraGen<sup>®</sup> Nerve Guide and the NeuraWrap Nerve Protector for peripheral nerve repair and protection, and the TenoGlide<sup>®</sup> Tendon Protector Sheet, all of which are based on our regenerative matrix technology platform.

The NeuraGen<sup>®</sup> Nerve Guide has been used in many procedures, including peripheral nerve repair in the upper and lower extremities, cranial and facial nerves, as well as procedures for brachial plexus reconstruction. We estimate that the worldwide market for the repair of severed peripheral nerves is approximately \$40 million.

The NeuraWrap Nerve Protector is a collagen implant designed for the management of injured, compressed or scarred nerves, NeuraWrap provides a protective environment for nerve healing and serves as an interface between damaged nerves and surrounding tissue. We estimate that the worldwide market for the repair of injured, compressed and scarred peripheral nerves is approximately \$70 million.

*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 reconstruction, including orthopedic implants and surgical devices for small bone and joint procedures involving the foot, ankle, hand, wrist and elbow. Our products address both the trauma and reconstructive segments of the extremities market, an approximately \$900 million market in the U.S.

We are a leading developer and manufacturer of specialty implants and instruments specifically designed for foot and ankle surgery. In reconstruction of the lower extremities, our leading brands include Newdeal<sup>®</sup>, the Uni-CP Compression Plate, the Bold<sup>®</sup> Cannulated Compression Screw, the Uni-Clip<sup>®</sup>, the AdvansysMid and Hind Foot Plating Systems, the Hallu<sup>®</sup>-Fix System, the PANTA<sup>®</sup> Nail, and Qwix<sup>®</sup> and Large Qwix<sup>®</sup> stabilization screws, the HINTEGRA<sup>®</sup> total ankle prosthesis (sold outside the U.S.), and the Subtalar MBA<sup>®</sup> Implant System (Maxwell-Brancheau Arthroereisis System), a market leading product that provides a simple and effective means of correcting debilitating flatfoot for both pediatric and adult patients. Customers include orthopedic surgeons specializing in injuries of the foot, ankle and extremities, as well as podiatric surgeons, of which there are 2,300 and 6,200, respectively, in the U.S.

For upper extremity reconstruction, we offer the Universal2 Total Wrist Implant System, which is recognized as the premier implant for wrist arthroplasty, a procedure that restores the function of the arthritic wrist. Other leading products offered include the Katalyst Bipolar Radial Head System for elbow reconstruction, the Spider Limited Wrist Fusion System for intercarpal arthrodesis, the Viper Distal Radius Plate for fracture fixation, the Kompressor Compression Screw System for small bone fixation, the SafeGuard<sup>®</sup> Mini Carpal Tunnel Release System for treatment of carpal tunnel syndrome, and the EndoRelease Endoscopic Cubital Tunnel System for treatment of cubital tunnel syndrome.

Extremity fixation is an increasingly large segment of the orthopedic market. Over 700,000 extremity fusion and osteotomy procedures were performed in the U.S. in 2008. In March 2008, we introduced the Large Qwix<sup>®</sup> Fixation and Positioning Screw System, which is designed for correction and fixation of osteotomies, a surgical procedure where a bone is cut to shorten, lengthen or change its alignment, and fractures of the mid and hind foot. The combination of the Large Qwix<sup>®</sup> screws, with our existing 3mm and 4.3mm Qwix<sup>®</sup> screws and the Bold<sup>®</sup> screw, gives Integra s extremity sales organization a comprehensive line of cannulated screws for lower extremity fixation.

In June 2008, Integra introduced the Tibiaxys Plating System, which is designed specifically to address ankle arthritis and deformity, and is manufactured from titanium alloy for strength and biocompatibility.

The use of plating systems is becoming an increasingly popular technique for the treatment of ankle fractures. Plating is also being used extensively in arthrodesis procedures for the treatment of degenerative diseases of the ankle joint, a technique by which the joint is fused to reduce pain and aid walking. Based on available procedural data, Integra estimates that there are over 20,000 ankle fusion procedures performed annually in the U.S., with an estimated market value of \$10-\$20 million.

**Bone Graft Substitutes for Extremity Reconstruction.** In March 2008, Integra introduced its line of extremity focused bone graft substitutes to leverage the strength of its bone and joint fixation products. Integra s comprehensive line of synthetic bone graft substitutes and demineralized bone matrix products includes three distinct product lines: Integra OS Osteoconductive Scaffold, bone void filler manufactured from beta tri-calcium phosphate and type I bovine collagen; Trel-X a demineralized bone matrix; and Trel-XC, a 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 U.S.

#### **Integra Spine Product Portfolio**

In 2008, the U.S. spinal implant market, consisting of thoracolumbar fusion devices, cervical fusion devices, interbody fusion devices, and motion preservation technologies, was valued at approximately \$4.2 billion, representing one of the most dynamic and growing segments of the orthopedic industry. Integra Spine provides comprehensive spinal solutions from the occiput to the sacrum, and has 13 spinal fusion systems, a full line of synthetic orthobiologics, and motion preservation devices in development. Our design philosophy is fewer parts, fewer steps, which benefits both the surgeon and patient by decreasing time in the operating room and limiting the number of surgical implants.

*Spinal Fusion Devices.* Many people suffer from chronic back pain, which may be alleviated surgically with a spinal fusion, the process of removing the disc material and fusing two vertebrae together. However, the vertebrae cannot fuse unless bone touches bone. To create this union, surgeons utilize two types of fusion devices: supplemental fixation systems and interbody/vertebral body replacements.

Supplemental fixation devices are plate and rod systems used to keep the vertebra in place, securing the bone to bone union. Interbody/vertebral body replacements are shaped like a cage and used to hold the bone graft in place. They are placed in the disc space and filled with bone graft or bone type material. Successful spinal fusion requires the combination of supplemental fixation and interbody/vertebral body replacement devices. Integra Spine offers each type of device for the different areas of the spine and specific types of diseases.

Supplemental Fixation Systems. According to industry sources, in 2008 the cervical market was valued at more than \$700 million. The market consists of posterior and anterior fixation devices, which include plating and rod systems. Integra Spine offers several supplemental fixation systems for cervical procedures. We offer the Tether anterior cervical plating system for the anterior side, and the Atoll Cervico-Thoracic system for the posterior side. In May 2008, we introduced the Manta Ray System in the U.S., a new anterior cervical plate. This system provides a unique locking ring on the screw, which eliminates the need for a secondary locking mechanism.

The degenerative market is the largest market segment within the spinal implant market. The majority of the procedures are patients with degenerative disc disease requiring fusion in the lower lumbar region of the spine. Lower back pain affects approximately 80% of Americans at some point in their lives. When back pain is severe, a pedicle screw system may be used to alleviate the chronic back pain and limited mobility caused by various spinal disorders, including spinal tumors. The Coral Spinal System is a pedicle screw fusion system used for the correction and stabilization of the lumbar or lower region of the spine. Components of the system incorporate a number of features that make it unique, enabling a lumbar surgery to require fewer implants and fewer surgical steps.

Our Coral Spinal System may also be used for surgical procedures to help correct spinal deformities. The unique feature of this system is the semi-malleable titanium rod, which allows for *in situ* correction techniques. This correction technique is less invasive and allows for a gradual curvature correction of the spine through a specialized segmental bending technique. Further development and focus on the deformity market segment is planned for 2009. In 2008, the deformity market was valued at approximately \$475 million.

*Interbody/vertebral body replacements.* Integra Spine offers a number of interbody/vertebral body replacement devices. These include Vu e POD, Vu L POD, L POD, Vu c POD and Vu Mesh. Each of these devices is a small with a unique shape. They are used to hold the graft in place to ensure a successful fusion. In 2008, Integra Spine released the Vu aPOD, the first anterior lumbar intervertebral fusion (ALIF) device with an optional internal SpinPlate to receive FDA clearance. The SpinPlate provides further security against risk of implant expulsion.

*Synthetic Orthobiologics.* Synthetic bone substitute is a growing market because of the need for a second incision if harvesting the patient s own bone for the procedure. Our synthetic bone product line consists of beta-tricalcium phosphate (TCP) grafts and putty and is manufactured with the patented Theriforntechnology, which controls the porosity and structure of the product, makes the product unique, and enhances its performance. The controlled porosity and structure allows for the synthetic bone to resorb back into the body more slowly, which enables it to stay in place long enough to allow the bones to grow together and create a successful fusion. Studies show that beta-TCP maintains high levels of bone in-growth, while maintaining controlled graft resorption rates, resulting in high quality bone with mechanical properties comparable to native tissue.

*Motion Preservation Devices.* The spinal fixation market is evolving toward motion preservation. Motion preservation devices are utilized in place of fixation devices, in efforts to maintain some of the patient s natural motion. Total disc replacement ( TDR ) for the cervical and lumbar market is the leading technology in this area. Integra Spine is developing the eDisc, a lumbar TDR, which incorporates proprietary polymer and embedded microelectronics. The eDisc is the first artificial disc to incorporate microelectronics.

#### Integra OrthoBiologics Product Portfolio

Integra offers a comprehensive family of orthobiologic products and deploys an established network of distributors focusing on orthopedic surgeons. We market and sell a range of innovative bone graft substitutes and other related medical devices that are used to enhance the repair and regeneration of bone in spinal and trauma surgery, total joint replacements and dental applications. Integra is one of the largest companies in the world focused on advanced technology in orthobiologics. We have a product portfolio encompassing some of the largest and most trusted orthobiologic brands, such as Integra Mozaik Osteoconductive Scaffold, the Accefl family of demineralized bone matrix products, and DynaGraft<sup>®</sup> II and OrthoBlast<sup>®</sup> II.

Degenerative disease of the spine is increasingly prevalent in the aging population. Patients who experience severe pain and who do not respond to conservative therapies may require fusion of one or more vertebrae (spinal fusion). A spinal fusion is successful when the bones grow together biologically and form a solid mass. Surgeons frequently use bone grafts or other materials to aid and promote bone growth to achieve fusion. The use of bone graft substitutes in spinal procedures, excluding recombinant bone morphogenetic proteins, represents an estimated \$400 million market.

In 2008, an estimated 500,000 spinal fusion procedures were performed in the U.S, including over 200,000 cervical spinal fusions. Additional opportunity exists in orthopedic reconstructive applications.

#### MEDICAL INSTRUMENTS PRODUCT PORTFOLIO

We are one of the leading surgical instrument companies in the U.S., providing more than 60,000 instrument patterns and surgical products to hospitals, surgery centers, and dental, podiatry, veterinarian and physician offices.

#### **Integra Surgical**

Integra Surgical is a leading supplier of innovative, high quality operating room instrumentation and surgical lighting. For over 35 years, the Jarit<sup>®</sup> instrument line has offered a comprehensive selection of reusable surgical instruments that provides a complete solution for laparoscopic, general, cardiovascular, neuro, gynecological, and orthopedic surgical specialties. For over 25 years, Luxtec<sup>®</sup> products have led the surgical illumination market. Today these products include market leading Xenon illumination systems, digital video recording systems, fiber optic cables and surgical loupes. For over 35 years, innovative market leading Omni-Tract<sup>®</sup> Surgical table retractor systems have offered surgeons and operating rooms the benefits of light weight, fewer parts, and fast, easy set up. Our CIMS<sup>®</sup> Consulting services and software offers comprehensive, integrated instrument solutions for managing surgical instrument assets.

In October 2008, we introduced the Luxtec<sup>®</sup> MLX 300W Xenon light source for use in surgical procedures, the latest addition to Luxtec s extensive line of illumination systems. Most surgical procedures require directed white light to visualize blood vessels, muscle tissue and specific anatomical features. Over 60,000 surgeons worldwide use Luxtec<sup>®</sup> light sources for optimal surgical site visualization.

#### Miltex

For more than 50 years, Miltex, Inc. has established itself as one of the largest and most respected suppliers of hand-held surgical instruments in the alternate site market, which includes surgical, dental, podiatry and veterinarian markets.

#### Integra Pain Management

Integra Pain Management is one of the preferred choices in disposable products for interventional and chronic pain management. The product line offers quality disposable devices for steroid injections, discography, and radiofrequency procedures. Integra Pain Management specializes in custom designed trays for steroid injections within the spine. These custom trays focus on patient safety and effective treatment, while reducing costly facility waste. Injecting steroid products into the spine, with the use of Integra Pain Management s instruments, can reduce nerve inflammation, effectively reducing or eliminating back pain.

#### **RESEARCH AND DEVELOPMENT STRATEGY**

We spent \$60.5 million, \$30.7 million and \$25.7 million in 2008, 2007 and 2006, respectively, on research and development activities. The 2008 amount includes \$25.2 million in-process research and development charges recorded in connection with the Theken acquisition. The 2007 amount includes \$4.6 million in-process research and development charges recorded in connection with the IsoTis acquisition. The 2006 amount includes a \$5.9 million in-process research and development charge recorded in connection with the KMI acquisition. Increases in research and development expenditures will accelerate the development of new devices for neurosurgery, extremity reconstruction and orthobiologics.

Our research and development activities focus on identifying and evaluating unmet surgical needs and product improvement opportunities to drive the development of innovative solutions and products. We apply our technological and developmental core competencies to develop regenerative products for neurosurgical, orthopedic and spinal applications, neuro-monitoring and CSF management, cranial stabilization and closure, tissue ablation, surgical instruments and spine, soft tissue, extremity small bone, and joint fixation. Our activities include both internal product development initiatives and the acquisition of proprietary rights to strategic technological platforms.

**Regenerative Products.** Because implants represent a fast-growing, high-margin segment for us, a large portion of our research and development expenditure is allocated to the development of these products. Our regenerative product development portfolio focuses on applying our expertise in biomaterials and collagen matrices to support the development of innovative products targeted at neurosurgical, orthopedic and spinal surgery applications, as well as dermal regeneration, nerve repair, and wound dressing applications. Our focus on technological advancement, product segmentation and differentiation activities will continue to drive our activities in each of these areas. We are committed to investing in, and proving the safety and efficacy of, our regenerative products.

*Neurosurgery.* With a focus on our neurosurgery customers and distribution channel, our 2009 research and product development activities will be directed toward the development of new systems and tips for ultrasonic removal of tumors and bone, next generation cranial stabilization systems for surgical procedures with intraoperative imaging, regenerative solutions for dural closure, shunt product improvements, next generation stereotaxy products and expanded applications in radiation therapy. For neuro critical care customers, our 2009 development activities will be focused on improvements in Integra s advanced neuromonitoring technology.

We continue to invest in clinical research and will continue enrolling patients in our DuraGen Plus<sup>®</sup> Adhesion Barrier Matrix multi-center clinical trial in the U.S. being conducted under an FDA Investigational Device Exemption (IDE). This study is designed to demonstrate the safety and effectiveness of the DuraGen Plus<sup>®</sup> product as an adhesion barrier in spine surgery.

*Extremity Reconstruction.* We continue to build and expand the capabilities of our product development team, focusing on the development of fixation devices for upper and lower extremity reconstruction, skin and soft tissue products, and have structured a robust product development program that will advance our product offerings. This program includes the development of devices for both the upper and lower extremities. In 2008, we launched six significant extremities products; five for use in lower extremity procedures and one novel endoscopic system for upper extremity ulnar nerve release procedures.

*Orthobiologics.* We have built a strong orthobiologic product development capability that leverages our Accell family of demineralized bone matrix product lines and our Integra Mozaik Osteoconductive Scaffold, resorbable bone void filler product line. We are pursuing product development synergies and opportunities in both of these areas. In 2008, we launched our third generation demineralized bone matrix, Accell Evo3 . We also launched additional sizes of Integra Mozaik Putty and Accell TBM (Total Bone Matrix) to address a wider variety of orthopedic procedures requiring bone grafting materials.

*Spine.* The recent acquisition of Theken expands Integra s product development engine with a strong engineering team, prototyping and mechanical testing capabilities and a portfolio of active spine implant product developments. Included are exciting new projects in synthetic orthobiologic scaffolding for bone and tissue regeneration, and projects in the rapidly growing spine segment of motion preservation. In 2008, Integra Spine received FDA clearance for four products. The most significant product launches were the Vu aPOD Intervertebral Body Fusion Device and the Manta Ray Anterior Cervical Plate.

#### COMPETITION

Our largest competitors in the neurosurgery markets are the Medtronic Neurologic Technologies division of Medtronic, Inc., the Codman division of Johnson & Johnson, the Stryker Craniomaxillofacial division of Stryker Corporation and the Aesculap division of B. Braun. In addition, many of our neurosurgery product lines compete with smaller specialized companies and larger companies that do not otherwise focus on neurosurgery.

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

Competitors for our newly launched Integra Spine business include Medtronic, Inc., the DePuy division of Johnson & Johnson, Synthes, Inc., Stryker Corporation, Zimmer, NuVasive, Inc., Globus Medical Inc., Alphatec Spine, Inc., and Orthofix.

The competitors in our orthobiologics business include such well-established companies as Medtronic, Inc., Synthes, Inc. and Johnson & Johnson and also include several smaller, biologic-focused companies, such as Osteotech and Orthovita.

We believe that we are the second largest reusable surgical instrument company in the U.S. We compete with the largest reusable instrument company, V. Mueller, a division of Cardinal Healthcare, as well as the Aesculap division of B. Braun. In addition, we compete with the Codman division of 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.

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 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 marketing partner, 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 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.

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 U.S., that we secure a Premarket Notification clearance pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (the FFDCA ), an approved Premarket Approval application (or supplemental PMA application) or an approved Product Development Protocol. Obtaining these approvals and clearances can take up to several years and involves preclinical studies and clinical testing. The FDA has announced that it is reviewing the 510(k) Premarket Notification process which may result in more extensive testing and clinical trial requirements. To perform clinical trials for significant risk devices in the U.S. 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 U.S. that have not been approved by the FDA for distribution in the U.S., we are required to provide notices to the FDA, maintain certain records relating to exports and make these records available to the FDA for inspection, if required.

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. There may be increases in user fees on an annual basis as well as additional user fees established by the FDA.

#### Human Cells, Tissues and Cellular and Tissue-Based Products

Integra, through the acquisition of IsoTis OrthoBiologics, 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 FFDCA. 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 distribution HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting.

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

*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. 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.

*Postmarket Requirements.* After a device is cleared or approved for commercial distribution, numerous regulatory requirements apply. These include the FDA Quality System Regulation which covers 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 FFDCA.

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 U.S. 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. CE Mark Certification requires a comprehensive Quality System program, comprehensive technical documentation and data on the product, which a Notified Body (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) in Europe reviews. 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. A recognized Notified Body audits our facilities annually to verify our compliance with these standards. As a result of an amendment to Japan s Pharmaceutical Affairs Law that went into effect on April 1, 2005, new regulations and requirements for obtaining approval of medical devices, including new requirements governing the conduct of clinical trials, the manufacturing of products and the distribution of products in Japan became law. Australia, China and other countries have issued new regulations on the approval and registration process for Medical Devices with which we must comply with in order to sell our products in those countries. In the European Union (the EU ), our products that contain human derived tissue, including those containing DBM, 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. Due to 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 European Union, 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 Regulatory Oversight Of The Medical Device Industry Might Affect The Manner In Which We May Sell Medical Devices.

Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries and the U.S. Foreign Corrupt Practices Act. 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.

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 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 payers, including the Medicare and Medicaid programs and private payers, 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 payers. The manner in which reimbursement is sought and obtained varies based upon the type of payer involved and the setting in which the product is furnished and utilized. Reimbursement from Medicare, Medicaid and other third-party payers 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 payers 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.

#### PATENTS AND INTELLECTUAL PROPERTY

We seek patent protection for our key technology, products and product improvements, both in the U.S. and in selected foreign countries. When determined appropriate, we have enforced and plan to continue to enforce and defend our patent rights. In general, however, we do not rely on our patent estate to provide us with any significant competitive advantages as it relates to our existing product lines. We 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.

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AccuDrain<sup>®</sup>, Accell<sup>®</sup>, Atoll , Bol<sup>®</sup>, Camino<sup>®</sup>, CRW<sup>®</sup>, Coral , CUS<sup>®</sup>, CUSA Excel<sup>®</sup>, DenLite<sup>®</sup>, Dissectron<sup>®</sup>, DuraGen<sup>®</sup>, DuraGen Plus<sup>®</sup>, DynaGraft<sup>®</sup> II, Hallu<sup>®</sup>-Fix, HINTEGRA<sup>®</sup>, ICOS , Integra Mozaik , Integra OS , Jarit<sup>®</sup>, LICOX<sup>®</sup>, Luxtec<sup>®</sup>, Manta Ray , Milte<sup>®</sup>, Mobius<sup>®</sup>, NeuraGen<sup>®</sup>, NeuraWrap , Newde<sup>®</sup>, OmniSight<sup>®</sup>, OmniTract<sup>®</sup>, OrthoBlast<sup>®</sup> II, Qwix<sup>®</sup>, Padgett , Radionic<sup>®</sup>, Selector<sup>®</sup>, Subtalar MBA<sup>®</sup>, TenoGlide<sup>®</sup>, Tether<sup>tm</sup>, Trel-X , Trel-XC , Tibiaxys , Uni-C<sup>®</sup>lipVentrix and XKnif<sup>®</sup> 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, 2008, we had approximately 2,800 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 are 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 15, 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, sole source 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 case of bovine spongiform encephalopathy, or from the U.S. We are also qualifying sources of collagen from another country 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 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 Integra OrthoBiologics 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 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 OrthoBiologics 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 a careful screening of the incoming bone and serology test records by our staff of QA microbiologists. During our manufacturing process, the bone particles are subjected to our proprietary process and terminally sterilized. This type of rigorous processing has been demonstrated through our testing to further enhance the safety and effectiveness of our DBM products. To date, our demineralized bone matrix products have a good safety record and are widely distributed in the United States and in over 40 countries.

#### SEASONALITY

Revenues during our second and fourth quarters tend to be stronger than the first and third quarters because many hospitals increase their purchases of our products during the second and fourth quarters, which coincides 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.Integra-LS.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 at the SEC-0330 for further information on the operation of the public reference facilities.

#### 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 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;

work stoppages at our facilities; and

other risk factors described in the section entitled Risk Factors in this report.

You can identify these forward-looking statements by forward-looking words such as believe, could, might, may, continue. anticipate, intend. seek. would and similar expressions estimate. plan. expect. should. 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.

#### 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:

current economic conditions, which could affect the ability of hospitals and other customers to purchase our products;

the impact of acquisitions;

the impact of our restructuring activities;

the timing of significant customer orders, which tend to increase in the second and fourth quarters 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 corrections 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;
- the timing of our research and development expenditures; and

reimbursement for our products by third-party payors such as Medicare, Medicaid and private health insurers.

### 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 services and other resources than we do. Our competitors may be more effective at implementing their technologies to develop 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.

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. For example, two of our largest competitors introduced an onlay dural graft matrix during 2004, a large company introduced a duraplasty product in 2006 and others may introduce similar products. The introduction and market acceptance of such products could reduce the sales, growth in sales and profitability of our duraplasty products. Competitors have also been developing products to compete with our extremity reconstruction implants, neuro critical care monitors and ultrasonic tissue ablation devices, among others.

Our largest competitors in the neurosurgery markets are the Medtronic Neurosurgery division of Medtronic, Inc., the Codman division of Johnson & Johnson, the Stryker Craniomaxillofacial division of Stryker Corporation and the Aesculap division of B. Braun Medical Inc. 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 the DePuy division of 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 business include Medtronic, Inc., the DePuy division of Johnson & Johnson, Synthes, Inc., Stryker Corporation, Zimmer, NuVasive, Inc., Globus Medical, Inc., Alphatec Spine, Inc. and Orthofix. In surgical instruments, we compete with V. Mueller, a division of Cardinal Healthcare, as well as Aesculap. In addition, we compete with Codman and many smaller instrument companies in the reusable and disposable specialty instruments markets. The competitors in our orthobiologics business include such well-established companies as Medtronic, Inc., Synthes Inc. and Johnson & Johnson and also include several smaller, biologic-focused companies, such as Osteotech and Orthovita. 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 2006, we have acquired 12 businesses or product lines at a total cost of approximately \$443 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 can result in material transaction expenses, increased interest and amortization expense, increased depreciation expense and increased operating expense, 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 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 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 had \$212.1 million of goodwill and \$50.0 million of indefinite-lived intangible assets as of December 31, 2008. Under Statement of Financial Accounting Standards (SFAS) No. 142,

*Goodwill and Other 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

or circumstances change that would more likely than not reduce our enterprise fair value below its book value. See Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and the Use of Estimates Valuation of Identifiable Intangible Assets, In-Process Research and Development Charges, and Goodwill of this report.

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SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* requires that we assess the impairment of our long-lived assets, including definite-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, 2008, we had \$176.0 million of other intangible assets.

The value of biotechnology and medical device businesses is often volatile, and the assumptions underlying our estimates made in connection with our assessments under SFAS No. 142 or 144 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 under SFAS No. 142 or 144 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.

Current economic conditions 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, 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.

## The disruption in the global financial markets and the economic downturn may adversely impact the availability and cost of credit.

Our ability to refinance our indebtedness and to obtain financing for acquisitions or other general corporate and commercial purposes will depend on our operating and financial performance and is also subject to prevailing economic conditions and to financial, business and other factors beyond our control. Recently, global credit markets and the financial services industry have been experiencing a period of unprecedented turmoil characterized by the bankruptcy, failure or sale of various financial institutions, a general tightening of credit, and an unprecedented level of market intervention from the United States and other governments. These events have adversely affected the U.S. and world economy, and may adversely affect the availability and cost of financing. There can be no assurances as to the length or severity of this period of disruption and the related economic downturn.

# 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 are 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 announced that it is reviewing the 510(k) Premarket Notification process, and there may be requirements for more extensive testing and/or clinical trials required for products cleared to market under the 510(k) process. The FDA may also require the more extensive PMA process for certain products. 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 could adversely impact our ability to compete against alternative products or technologies, which could affect our sales. 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 product. We are also seeing third-party intermediaries 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. If the FDA does not approve the additional indications for use, this could affect our ability to obtain reimbursement for these products and adversely affect our ability to compete against alternative products and adversely affect our ability to compete against alternative and adversely affect our ability to compete against alternative products and adversely affect our ability to compete against alternative products and adversely affect our ability to compete against alternative products or technologies, which could affect our sales.

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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.

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 American Association of Tissue Banks, or 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. Manufacturing facilities, both international and domestic, are also subject to inspections by or under the authority of the FDA. In addition, failure to comply with applicable regulatory requirements could subject us to enforcement action, including product seizures, recalls, withdrawal of clearances or approvals, restrictions on or injunctions against marketing our product or products based on our technology, cessation of operations and civil and criminal penalties.

We are also subject to the regulatory requirements of countries outside the U.S. where we do business. For example, under the European Union Medical Device Directive, all medical devices must meet the Medical Device Directive standards and receive CE Mark Certification prior to marketing in the European Union. CE Mark Certification requires a comprehensive Quality System program, comprehensive technical documentation and data on the product, which a Notified Body in Europe 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 European Union, Canada, Japan, Latin America, Asia-Pacific and most other countries outside the U.S. As a result of an amendment to Japan s Pharmaceutical Affairs Law that went into effect on April 1, 2005, new regulations and requirements exist for obtaining approval of medical devices, including new requirements governing the conduct of clinical trials, the manufacturing of products and the distribution of products in Japan. Significant resources may be needed to comply with the extensive auditing of and requests for documentation relating to all manufacturing facilities of our company and our vendors by the Pharmaceutical Medical Device Agency and the Ministry of Health, Labor and Welfare in Japan to comply with the amendment to the Pharmaceutical Affairs Law. These new regulations may affect our ability to obtain approvals of new products for sale in Japan. Additionally, the European Union as well as many other countries outside the U.S. have or may be considering implementing new or amended medical device regulations that require extensive documentation, including clinical trial data, as well as may require audits of our manufacturing facilities. There are also associated fees with these new regulations. These regulations are required for all new products and re-registration of our medical devices.

Our products that contain human derived tissue, including those containing de-mineralized bone matrices, are not medical devices in the European Union 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. Due to 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 European Union 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 European Union 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.

# 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 increasingly 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 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 U.S. have increased awareness of the issue in North America.

We take great care to provide that our products are safe and free of agents that can cause disease. In particular, we have qualified our source of collagen from a country outside the U.S. 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 are 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 prion transmission. 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 European Union has requested that our dural replacement products be sourced from bovine tendon sourced from a country where no cases of BSE have occurred. In addition, Japan has issued new regulations regarding medical devices that contain tissue of animal origin. Among other regulations, Japan requires that the tendon used in the manufacture of medical devices sold in Japan originate in a country that has never had a case of BSE. Currently, we purchase our tendon from the U.S. and New Zealand. We received approval in Japan for the use of New Zealand-sourced tendon in the manufacturing of our products sold in Japan. 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 Japan.

*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 FFDCA. 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.

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 American Association of Tissue Banks, or 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.

In the European Union, regulations, if applicable, are different from one EU member state to the next. Due to 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 European Union 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 European Union 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 can be treated by our devices 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 the Integra<sup>®</sup> Dermal Regeneration Template.

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 existing 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 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 insurance, 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, among other things, consolidation, technological improvements and the pressure on third-party payors and providers to reduce healthcare costs. 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. However, our patents 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 U.S. 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 usually takes approximately three 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 proprietary information 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 product 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. For example, Codman & Shurtleff, Inc., a division of Johnson & Johnson, commenced an action in May 2006 seeking declaratory relief that its DURAFORM<sup>®</sup> product does not infringe our patent covering our duraplasty products and that our patent is invalid and unenforceable. In addition, we may have to 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. In addition, 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<sup>®</sup> Dermal Regeneration Template and wound dressing products, the DuraGen<sup>®</sup> family of products, and our Absorbable Collagen Sponges;
- our products made from silicone, such as our neurosurgical shunts and drainage systems and hemodynamic shunts; and
- products which use many different electronic parts from numerous suppliers, such as our intracranial monitors and catheters.

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.

We manufacture our products in a limited number of facilities. Damage to our manufacturing, development or research facilities because of fire, natural disaster, power loss, communications failure, unauthorized entry or other events 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 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 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 pass along additional costs to our customers.

We are planning on a phased deployment of a global enterprise business system in all facilities. This system, the hosting and maintenance of which we outsource, will replace the legacy enterprise resource planning applications currently in place in the facilities. The new system has already been deployed in some facilities. 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 U.S. 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 U.S. and we generate revenues and incur operating expenses in multiple foreign currencies including euros, British pounds, Swiss francs, Canadian dollars, Mexican pesos, Japanese yen, Australian dollars and New Zealand dollars, we experience currency exchange risk with respect to those foreign currency-denominated revenues and expenses.

Currently, we do not use derivative financial instruments to manage operating foreign currency risk. As the volume of our business transacted in foreign currencies increases, we expect to continue to assess the potential effects that changes in foreign currency exchange rates could have on our business. If we believe that this potential impact presents a significant risk to our business, we may enter into derivative financial instruments to mitigate this risk.

In general, 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.

Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries and the U.S. Foreign Corrupt Practices Act. 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, 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 U.S.

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 U.S. 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:

major 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;

recently effected 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;

potential legislative proposals have been considered that would result in major reforms in the U.S. healthcare system that could have an adverse effect on our business;

there has been a consolidation among healthcare facilities and purchasers of medical devices in the U.S. 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 that will permit hospitals to provide financial incentives to doctors for reducing hospital costs (known as gainsharing) and to award physician efficiency (known as physician profiling) could reduce prices; 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 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.

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, and state law equivalents to these federal laws that are meant to protect against fraud and abuse. 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

government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation.

In January 2004, ADVAMED, the principal U.S. trade association for the medical device industry, put in place 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 ADVAMED Code, and we provide routine training to our sales and marketing personnel on our policies regarding sales and marketing practices. 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, proposed federal legislation and recent 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. We have in place policies to govern how we may retain healthcare professionals as consultants that reflect the current climate on this issue and provide training on these policies. Finally, 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 business depends 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. Our most important alliance is our agreement with the Wyeth BioPharma division of Wyeth for the development of collagen matrices to be used in conjunction with Wyeth BioPharma s recombinant bone protein, a protein that stimulates the growth of bone in humans. 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 any of our alliances would require us to develop other means to distribute the affected products and 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 U.S., 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. 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 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.

#### The loss of key personnel could harm our business.

We believe our success depends on the contributions of a number of our key personnel, including Stuart M. Essig, our President and Chief Executive Officer. If we lose the services of key personnel, those losses could materially harm our business. We maintain key person life insurance on Mr. Essig and two other members of management.

## We have had material weaknesses in our internal control over financial reporting and cannot assure you that additional material weaknesses will not be identified in the future.

In 2007, management identified material weaknesses in our internal controls over financial reporting related to (1) the complement of its personnel; (2) accounts reconciliation; (3) intercompany transactions; (4) income tax accounts; and (5) the configuration, segregation of duties and access to key financial reporting applications. Remediation of these weaknesses has been completed as of December 31, 2008. We will continue to take further steps in an attempt to strengthen our control processes and procedures.

While we aim to work diligently to ensure a robust accounting system that is devoid of material weaknesses, given the growth of our business through acquisitions and the complexity of the accounting rules, we may, in the future, identify additional material weaknesses in our disclosure controls and procedures and internal control over financial reporting. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, cause us to fail to meet our periodic reporting obligations or certain covenants related to our outstanding revolving credit facility, or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting are under Section 404 of the Sarbanes-Oxley Act of 2002 and the rules promulgated under Section 404. The existence of a material weakness could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations or certain covenants related to our outstanding revolving credit facility, and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price. See Part I. Item 4 Controls and Procedures for a further discussion of our assessment of our internal controls over financial reporting.

## Access to the capital markets may be more expensive or subject to delays until such time as we qualify to file short-form registration statements.

Currently we are ineligible to use a short-form registration statement, which would allow us to incorporate by reference future reports on Form 10-K, Form 10-Q and other SEC reports into our registration statements, until we have filed all of our periodic reports with the SEC in a timely manner for a period of twelve consecutive months. Additionally, we currently do not qualify as a well-known seasoned issuer which previously enabled us to, among other things, file shelf registration statements and have them declared effectively immediately by the SEC without risk of SEC review. As a result, any attempt by us to access the capital markets while we are unable to use a short-form registration statement could be more expensive or subject to delays.

### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### **ITEM 2.** *PROPERTIES*

Our principal executive offices are located in Plainsboro, New Jersey. Principal manufacturing and research facilities are located in New Jersey, Massachusetts, Ohio, California, Pennsylvania, Puerto Rico, United Kingdom, Ireland, France and Mexico. Our instrument procurement operations are located in Germany. Our primary distribution centers are located in Nevada, New York, Ohio, Pennsylvania and Belgium. 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 lease all of our facilities other than certain facilities in Ohio, and our facilities in Pennsylvania, United Kingdom, and Biot, France, which we own.

Our manufacturing facilities are registered with the FDA. Our facilities are subject to FDA inspection to assure compliance with Quality System regulations. We believe that 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. Some capacity of the plants is being converted, with any needed modification, 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 those are described below.

In May 2006, Codman & Shurtleff, Inc., a division of Johnson & Johnson, commenced an action in the U.S. District Court for the District of New Jersey for declaratory judgment against us with respect to our U.S. Patent No. 5,997,895 (the 895 Patent). This patent covers dural repair technology related to our Dura Gamily of duraplasty products.

The action seeks declaratory relief that Codman s DURAFOR<sup>®</sup> product does not infringe our patent and that our patent is invalid. Codman does not seek either damages from us or injunctive relief to prevent us from selling the DuraGen<sup>®</sup> Dural Graft Matrix. We have filed a counterclaim against Codman, alleging that Codman s DURAFOR<sup>®</sup> product infringes the 895 Patent, seeking injunctive relief preventing the sale and use of DURAFOR<sup>®</sup>, and seeking damages, including treble damages, for past infringement.

In addition to these matters, we are subject to various claims, lawsuits and proceedings in the ordinary course of our 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.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

#### 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:

	2008				2007			
	]	High Low		Low	High		Low	
Fourth Quarter	\$	46.27	\$	26.03	\$	49.74	\$	39.44
Third Quarter	\$	49.89	\$	42.76	\$	51.46	\$	46.08
Second Quarter	\$	46.29	\$	39.21	\$	52.85	\$	44.99
First Quarter	\$	45.97	\$	39.50	\$	46.08	\$	40.15

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 Senior Secured Revolving Credit Facility. 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 25, 2009 was approximately 920, which includes stockholders whose shares were held in nominee name.

#### Sales of Unregistered Securities

The Company committed 310,000 unregistered shares of the Company s common stock (of which 135,000 were issued on December 22, 2008, with the remainder issued in January 2009), valued at \$10.7 million, as part of the price for the acquisition of Omni-Tract. The shares of common stock issued were offered and issued pursuant to a private placement in reliance upon the exemption from registration pursuant to Rule 506 under the Securities Act. Each person to whom shares were issued (each, an Investor ), is an accredited investor as defined in Rule 501(a) and each Investor has represented to the Company that such Investor is acquiring the securities for investment purposes for such Investor s own account and not with a view toward distribution of the securities. The Company advised each Investor that the securities issued to them have not been registered under the Securities Act and may not be sold unless they are registered under the Securities Act or sold pursuant to a valid exemption from registration under the Securities Act. The certificates representing the shares of common stock issued to the Investors contain a legend that such shares of common stock have not been registered under the Securities Act and state the restrictions on transfer and resale as described above. Additionally, the Company did not engage in any general solicitation or advertisement in connection with the issuance of the above described shares of common stock.

#### **Issuer Purchases of Equity Securities**

On October 30, 2007, 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, 2008. We purchased 500,000 shares of our common stock under this repurchase program during the three months ended December 31, 2007, See Note 7, Treasury Stock. On October 30, 2008, our Board of Directors terminated the repurchase authorization it adopted in October 2007 and authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed \$75.0 million through December 31, 2010. Shares may be purchased either in the open market or in privately negotiated transactions. We did not repurchase any shares of our common stock in 2008. As of December 31, 2008, there remained \$75.0 million available for share repurchases under this authorization.

The following table summarizes our repurchases of our common stock during the quarter ended December 31, 2008 under the repurchase program authorized on October 30, 2008:

Total Number Approximate

	Total Number	Average Price	of Shares Purchased as Part of Publicly	Dollar Value of Shares that May Yet be Purchased			
October 1, 2008October 31, 2008November 1, 2008November 30, 2008December 1, 2008December 31, 2008	of Shares Purchased	Paid per Share	Announced Program	Under the Program \$ 75,000,000 75,000,000 75,000,000			
Total				\$ 75,000,000			

### 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.

	Years Ended December 31,									
		2008		2007	_	2006	_	2005		2004
	(In thousands, except per share data)									
Operating Results: Total revenues, net	\$	654,604	\$	550,459	\$	419,297	\$	277,935	\$	229,825
Costs and expenses(1)	φ	607,193	φ	483,171	φ	360,553	φ	277,933	φ	229,823
costs and expenses(1)		007,175		405,171		500,555		221,030		203,040
Operating income		47,411		67,288		58,744		56,105		24,779
Interest income (expense), net		(15,500)		(10,197)		(8,426)		(265)		555
Other income (expense), net(2)		(905)		2,971		(2,010)		(739)		2,674
Income before income taxes (Benefit from) provision for		31,006		60,062		48,308		55,101		28,008
income taxes		(3,927)		26,591		18,901		17,907		10,811
Net income	\$	34,933	\$	33,471	\$	29,407	\$	37,194	\$	17,197
Diluted net income per share	\$	1.22	\$	1.13	\$	0.97	\$	1.15	\$	0.55
Weighted average shares outstanding		28,703		29,578		32,747		34,565		31,102
		2008		2007		cember 31, 2006		2005		2004
Financial Position:					( <b>In</b> 1	thousands)				
Cash, cash equivalents	\$	183,546	\$	57,339	\$	22,697	\$	46,889	\$	69,855
Marketable securities(3)	Ψ	105,540	Ψ	51,555	Ψ	22,077	Ψ	96,495	Ψ	126,127
Total assets		1,034,431		818,012		613,618		448,432		456,713
Long-term borrowings under		) ) -		) -		,		- , -		) · -
senior credit facility(4)		160,000								
Long-term debt(4)		330,000		330,000		508		118,378		118,900
Retained earnings/(accumulated										
deficit)		132,219		98,175		66,336		36,929		(265)
Stockholders equity		350,206		260,429		296,162		289,818		307,823

 In 2004, we recorded
 \$23.9 million in share-based compensation charges incurred in connection with the extension of the employment agreement of our President and Chief Executive Officer. In 2008, we recorded an \$18.0 million share-based compensation charge incurred in connection with the extension of the employment agreement of our President and Chief Executive Officer. In 2008, we recorded an in-process research and development charge of \$25.2 million in connection with the Theken acquisition. In 2007, 2006 and 2005, we recorded similar charges of \$4.6 million for the IsoTis acquisition, \$5.9 million for the KMI acquisition and \$0.5 million for the Eunoe, Inc. acquisition,

### (2)

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respectively.

In 2004, we recorded a \$1.4 million gain in other income related to an unrealized gain on a foreign currency collar which was used to reduce our exposure to fluctuations in the exchange rate between the euro and the U.S. dollar as a result of our commitment to acquire Newdeal Technologies SAS for 38.5 million euros. The collar contract expired on January 3, 2005, concurrent with our acquisition of Newdeal Technologies. (3) In 2006, all marketable securities were liquidated.

(4) In 2003, we issued
\$120.0 million of 2.5% contingent convertible subordinated notes due 2008. The net proceeds generated by the notes, after expenses, were

\$115.9 million. In 2006, we exchanged \$119.5 million of these notes for the equivalent amount of new notes. Because the closing price of our stock at the issuance date was higher than the market price trigger of the new notes, the new notes were classified as a current liability. In March 2008, these notes matured and we repaid the principal amount in cash and issued approximately 768,000 shares of our common stock. Additionally in 2008, we classified \$160.0 million of our senior credit facility borrowings as long-term debt based on our current intent and ability.

In 2007, we issued \$165 million of 2.75% senior convertible notes due 2010 and \$165 million of 2.375% senior convertible notes due 2012. We expect to satisfy any conversion of the notes with cash up to the principal amount of the applicable series of notes pursuant to the net share settlement mechanism set forth in the applicable indenture and, with respect to any excess conversion value, with shares of our common stock.

In 2008, we were required to make interest payments on our \$120 million contingent convertible subordinated notes (the 2008 Notes ) at an annual rate of 2.5% each September 15 and March 15. We paid contingent interest on the 2008 Notes approximating \$1.8 million during the quarter ended March 31, 2008. The contingent interest paid was for each of the last three years the 2008 Notes remained outstanding in an amount equal to the greater of (1) 0.50% of the face amount of the 2008 Notes and (2) the amount of regular cash dividends paid during each such year on the number of shares of common stock into which each 2008 Note was convertible. Holders of the 2008 Notes could convert the 2008 Notes under certain circumstances, including when the market price of our common stock on the previous trading day was more than \$37.56 per share, based on an initial conversion price of \$34.15 per share. All of the 2008 Notes were converted to common stock or cash. In March 2008, we borrowed \$120 million under our senior secured revolving credit facility to repay the 2008 Notes upon conversion or maturity. As a result of the conversions, we issued 768,221 shares of our common stock. There were no financial covenants associated with the 2008 Notes.

At December 31, 2008, we have \$260 million outstanding on our senior credit facility of which we borrowed \$120 million in March 2008 for the repayment of our 2008 Notes, \$80 million in July 2008 for the Theken acquisition and \$60 million in October 2008 for general corporate purposes.

# 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 market-leading, innovative medical device company focused on helping the medical professional enhance the standard of care for patients. 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 market categories: neurosciences, orthopedics and medical instruments. Our neurosurgical 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 orthopedics products include 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 medical instruments products include 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. Accordingly, we report our financial results under a single operating segment the development, manufacture and distribution of medical devices. We manufacture many of our products in plants located in the U.S., Puerto Rico, France, Germany, Ireland, the United Kingdom and Mexico. We also source most of our handheld surgical instruments through specialized third-party vendors.

In the U.S., we have three sales channels. The largest, Integra NeuroSciences, sells products through directly employed sales representatives. Within our Integra Orthopedics sales channel, there are three sales organizations: Integra Extremity Reconstruction, which sells through a large direct sales organization; Integra OrthoBiologics and Integra Spine, which sell through specialty distributors focused on their respective surgical specialties. The Integra Medical Instruments market sales channel sells through two main sales organizations: Integra Surgical, which sells

both directly and through distributors and Miltex, which sells through distributors and wholesalers.

We also market certain products through strategic partners or original equipment manufacturer customers. Our objective is to continue to build a customer-focused and profitable medical device company by developing or acquiring innovative medical devices and other products to sell through our sales channels. Our strategy therefore entails substantial growth in revenues through both internal means through launching new and innovative products and selling existing products more intensively and by acquiring existing businesses or already successful product lines.

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 indicative of long-term profitable growth. These measurements include revenue growth (derived through acquisitions and products developed internally), gross margins on total revenues, operating margins (which we aim to continually expand on as we leverage our existing infrastructure), operating cash flows (which we aim to increase through improved working capital management), and earnings per diluted share of common stock.

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

*Developing, manufacturing and selling specialty regenerative technology products.* We have a broad technology platform for developing products that regenerate or repair soft tissue and bone. We believe that we have a particular advantage in developing, manufacturing and selling tissue repair products derived from bovine collagen. These products comprised 22%, 24%, and 26% of revenues in the years ended December 31, 2008, 2007 and 2006, respectively. Products that contain materials derived from animal sources, including food, pharmaceuticals and medical devices, have been subject to scrutiny from the media and regulatory authorities. Accordingly, widespread public controversy concerning collagen products, new regulations, or a ban of our products containing material derived from bovine tissue, could have a material adverse effect on our current business and our ability to expand.

*Developing metal implants for bone and joint repair, fixation and fusion.* Through acquisitions, particularly those of Theken in 2008 and Newdeal Technologies SAS in 2005, we have acquired significant expertise in developing metal implants for use in bone and joint repair, fixation and fusion and in successfully bringing those products to market.

Acquiring and integrating new product lines and complementary businesses. Since 1999, we have acquired and integrated more than 30 product lines or businesses through a disciplined acquisition program that focuses on acquiring companies or product lines at reasonable valuations which complement our existing product lines or can be used to leverage our broad technology platform in tissue regeneration and metal implants. We also employ a seasoned team of managers and executives who are quite adept at successfully integrating the acquired product lines and businesses.

## 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, 2008 not directly comparable to those of the corresponding prior year periods. See Note 3 to the financial statements for a further discussion. Additionally, our implementation of Statement of Financial Accounting Standards No. 141(R) on January 1, 2009 significantly changes the accounting for business combinations by requiring that we expense most transaction and restructuring costs as they are incurred, whereas we previously capitalized such costs if certain criteria were met, and capitalize the fair value of acquired research and development assets separately from goodwill, whereas we previously determined the acquisition-date fair value and then immediately charged the value to expense.

From January 2006 through December 2008, we have acquired the following businesses, assets and product lines: In December 2008, we acquired Minnesota Scientific, Inc., doing business as Omni-Tract Surgical (Omni-Tract), for \$6.4 million in cash paid at closing, 310,000 unregistered shares of our common stock valued at \$10.7 million (of which 135,000 shares were issued at closing, with the remainder issued in January 2009), and \$0.3 million in transaction related costs, subject to certain adjustments. Omni-Tract is a global leader in the development and manufacture of table mounted retractors and is based in St. Paul, Minnesota. Omni-Tract markets and sells these retractor systems for use in vascular, bariatric, general, urologic, orthopedic, spine, pediatric, and laparoscopic surgery. We will integrate Omni-Tract s product lines into our combined offering of JARI $\hat{T}$ , Padgett , R&B Redmond , and Luxtec<sup>®</sup> lines of surgical instruments and illumination systems sold by the Integra Medical Instruments sales organization.

In October 2008, we acquired Integra Neurosciences Pty Ltd. in Australia and Integra Neurosciences Pty Ltd. in New Zealand for \$4.0 million (6.0 million Australian Dollars) in cash at closing, \$0.3 million in acquisition expenses and working capital adjustments, and up to \$2.1 million (3.1 million Australian Dollars) in future payments based on the performance of business in the three years after closing. With this acquisition of the Company s long-standing distributor, the Company now has a direct selling presence in Australia and New Zealand.

In August 2008, we acquired Theken Spine, LLC, Theken Disc, LLC and Therics, LLC (collectively, Theken ) for \$75.0 million in cash, subject to certain adjustments, acquisition expenses of \$2.4 million, working capital adjustments of \$3.9 million, and up to \$125.0 million in future payments based on the revenue performance of the business in the two years after closing. Theken, based in Akron, Ohio, designs, develops and manufactures spinal fixation products, synthetic bone substitute products and spinal arthroplasty products. With Theken, we acquired a unique and comprehensive portfolio of spinal implant products and a robust technology pipeline and demonstrated product development capacity, an established network of spinal hardware distributors with established access to the orthopedic spine market, and a strong management team with extensive experience in the orthopedic spine market. Theken does not currently sell its products outside of the U.S. Accordingly, we expect that the business will benefit from Integra s large international presence. The Theken products are now being marketed under the name Integra Spine .

In December 2007, we acquired all of the outstanding stock of the Precise Dental family of companies (Precise) for \$10.5 million in cash, subject to certain adjustments and acquisition expenses of \$0.6 million. The Precise Dental family of companies develops, manufactures, procures, markets and sells endodontic materials and dental accessories, including the manufacture of absorbable paper points, gutta percha and dental mirrors. Together these companies had procurement and distribution operations in Canoga Park, California and manufacturing operations at multiple locations in Mexico. In 2008, we integrated the acquired Canoga Park procurement and distribution functions into our York, Pennsylvania dental operations. We continue to manage the manufacturing operations in Mexico.

In October 2007, we acquired all of the outstanding stock of IsoTis, Inc. and its subsidiaries ( IsoTis ), a well-respected leader in regenerative medicine, for \$64.0 million in cash, subject to certain adjustments and acquisition expenses of \$4.7 million. IsoTis, based in Irvine, California, brought to Integra a comprehensive family of orthobiologic products and an established network of distributors focusing on orthopedic surgeons. IsoTis develops, manufacturers and markets proprietary products for the treatment of musculoskeletal diseases and disorders. IsoTis current orthobiologics products are bone graft substitutes that promote the regeneration of bone and are used to repair natural, trauma-related and surgically-created defects common in orthopedic procedures, including spinal fusions. The Accell<sup>®</sup> line of products represents the next generation in bone graft substitution. By integrating the IsoTis products with Integra s own osteoconductive scaffold product line and integrating the Integra spine specialist sales team into the IsoTis distributor network, we created a single unified selling organization, now known as Integra OrthoBiologics. The combined activity strengthens our position as a global leader in orthobiologics.

In May 2007, we acquired certain assets of the pain management business of Physician Industries, Inc. (Physician Industries) for approximately \$4.0 million in cash, subject to certain adjustments and acquisition expenses of \$0.1 million. In addition, we may pay additional amounts over the next four years depending on the performance of the business. Physician Industries, located in Salt Lake City, Utah, assembles, markets, and sells a comprehensive line of pain management products for acute and chronic pain, including customized trays for spinal, epidural, nerve block, and biopsy procedures. The Physician Industries business has been combined with our similar Spinal Specialties product line and the products are sold under the name Integra Pain Management.

In May 2007, we acquired the shares of LXU Healthcare, Inc. (LXU) for \$30.0 million in cash paid at closing and \$0.5 million of acquisition-related expenses. LXU, based in West Boylston, Massachusetts, was comprised of three distinct businesses:

*Luxtec* The market-leading manufacturer of fiber optic headlight systems for the medical industry through its Luxtec<sup>®</sup> brand. The Luxtec<sup>®</sup> products are manufactured in a 31,000 square foot leased facility in West Boylston.

*LXU Medical* A leading specialty surgical products distributor with a sales force calling on surgeons and key clinical decision makers, covering 18,000 operating rooms in the southeastern, midwestern and

mid-Atlantic regions of the U.S. LXU Medical is the exclusive distributor of the Luxtec fiber optic headlight systems in these territories.

*Bimeco* A critical care products distributor with direct sales coverage in the southeastern U.S.

We have integrated the LXU Medical sales force and distributor network with the Integra Medical Instruments sales and distribution organization. As was the intention at the time of the acquisition, we subsequently wound down the Bimeco business and discontinued many of the LXU Medical distributed product lines, which were not aligned with our core strategy.

In January 2007 we acquired the DenLite<sup>®</sup> product line from Welch Allyn in an asset purchase for \$2.2 million in cash paid at closing and approximately \$35,000 of acquisition-related expenses. DenLite<sup>®</sup> is a lighted mouth mirror used in dental procedures.

In July 2006 we acquired all of the outstanding shares of Kinetikos Medical, Inc. (KMI) for \$39.5 million in cash paid at closing and \$2.2 million in adjustments and transaction-related costs, subject to certain adjustments, and additional contingent future payments totaling up to \$20 million based on the post-acquisition performance of the KMI business for the two year period ended June 30, 2008. We did not pay out any contingent consideration. KMI, based in Carlsbad, California, was a leading developer and manufacturer of innovative orthopedic implants and surgical devices for small bone and joint procedures involving the foot, ankle, hand, wrist and elbow. KMI marketed products that addressed both the trauma and reconstructive segments of the extremities market. KMI s reconstructive products are largely focused on treating deformities and arthritis in small joints of the upper and lower extremity, while its trauma products are focused on the treatment of fractures of small bones most commonly found in the extremities. KMI was a strategic fit for our growing extremity business and strengthened our presence in the orthopedic hand market. We integrated the KMI product line into our U.S. Extremity Reconstructive in Europe.

In July 2006, we acquired a direct sales force in Canada through the acquisition of our longstanding distributor, Canada Microsurgical Ltd. (Canada Microsurgical). Canada Microsurgical has ten sales professionals who cover all of the provinces in Canada. The sales and distribution operations have enhanced our expanding Canadian business. We paid \$5.8 million (6.4 million Canadian dollars) for Canada Microsurgical at closing, and \$0.3 million in adjustments and transaction-related costs. In addition, we contracted to pay additional contingent future payments up to an additional \$1.9 million (2.1 million Canadian dollars) over the three years following the date of acquisition, depending on the performance of the business. Pursuant to our agreement, we paid \$1.4 million for 2007 and 2008.

In May 2006 we acquired all of the outstanding capital stock of Miltex Holdings, Inc. (Miltex) for \$102.7 million in cash paid at closing, subject to certain adjustments, and \$0.6 million of transaction-related costs. Miltex, based in York, Pennsylvania, is a leading provider of surgical and dental hand instruments to alternate site facilities, which includes physician and dental offices and ambulatory surgery care sectors. Miltex sells products under the Miltex<sup>®</sup>, Meisterhand<sup>®</sup>, Vantage<sup>®</sup>, Moyco, Union Borach<sup>®</sup> and Thompson trademarks in over 65 countries, using a network of independent distributors. Miltex operates a manufacturing and distribution facility in York, Pennsylvania and also operates a leased facility in Tuttlingen, Germany, where Miltex s staff coordinates design, production and delivery of instruments. Miltex also provides a broader platform to grow our business as it participates in the dental and veterinary markets.

In March 2006 we acquired the assets of the Radionics Division of Tyco Healthcare Group, L.P. for approximately \$74.5 million in cash, subject to certain adjustments, including a \$2.1 million reduction received in 2007, and \$3.2 million of acquisition-related expenses. Radionics, based in Burlington, Massachusetts, is a leader in the design, manufacture and sale of advanced minimally invasive medical instruments in the fields of neurosurgery and radiation therapy. Radionics products include the CUSA Excellultrasonic surgical aspiration system, the CRW<sup>®</sup> stereotactic system, the XKnife<sup>®</sup> stereotactic radiosurgery system, and the OmniSight<sup>®</sup> EXcel image guided surgery system. This acquisition increased our global neurosurgery product offering, positioned us to offer new stereotactic surgery products, and secured our entry into the radiosurgery/radiotherapy and image-guided surgery device business.

# RESTRUCTURING, INTEGRATION, AND MANUFACTURING AND DISTRIBUTION TRANSFER AND EXPANSION ACTIVITIES

Because of our ongoing acquisition strategy and significant growth in recent years, we have undertaken many cost-saving initiatives to consolidate manufacturing and distribution facilities and activities, eliminate duplicative positions, and realign various sales and marketing activities, and to expand and upgrade production capacity for our collagen-based products.

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During 2007, we expanded our collagen manufacturing capacity in our Puerto Rico plant and, in 2008 we transferred certain manufacturing processes of some of our collagen-based product lines from our Plainsboro plant to the Puerto Rico plant. In connection with the acquisition of IsoTis, we closed the IsoTis facilities in Lausanne, Switzerland and Bilthoven, Netherlands, eliminated various sales, marketing and administrative positions in Europe and reduced various duplicative positions in Irvine, California. In connection with the acquisition of Precise Dental, we closed its facility in Canoga Park, California and integrated Precise s procurement and distribution operations into our York, Pennsylvania dental operations. In 2007 we also closed the Alabama distribution facility acquired in the LXU Healthcare acquisition.

In 2008, we transferred the assembly of our Spinal Specialties brand of customized pain management kits from our San Diego, California manufacturing facility to our pain management kit assembly facility in Salt Lake City, Utah that was included in the assets acquired from Physician Industries, Inc. in May 2007. Additionally, in January 2008, we completed the integration of the LXU Healthcare acquisition and closed its administrative facility in Tucson, Arizona. In connection with these restructuring activities, we recorded \$0.5 million and \$1.0 million in 2008 and 2006, respectively, for the estimated costs of employee termination benefits to be provided to the affected employees and related facility exit costs. In 2007 we reversed \$0.5 million of previously recorded employee termination costs because our initial estimates exceeded actual costs.

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

#### **RESULTS OF OPERATIONS**

Net income in 2008 was \$34.9 million, or \$1.22 per diluted share, as compared to net income of \$33.5 million, or \$1.13 per diluted share, in 2007 and net income of \$29.4 million, or \$0.97 per diluted share, in 2006.

#### **Special Charges**

Income before taxes for 2008, 2007 and 2006 include the following special charges:

	2008		2007 (In thousands)		2006
SPECIAL CHARGES					
Acquired in-process research and development	\$	25,240	\$	4,600	\$ 5,875
Stock-based compensation charge from renewal of Chief Executive					
Officer s employment agreement and other related charges		18,356			
Inventory fair market value purchase accounting adjustments		6,667		4,238	4,640
Impairment of inventory and other assets related to discontinued or					
withdrawn product lines		1,207		2,806	1,578
Incremental professional and bank fees related to delayed filing of					
the 2007 Annual Report on Form 10-K		1,041		1,389	
Facility consolidation, manufacturing and distribution transfer, and					
System integration costs		1,035		1,106	936
Involuntary employee termination costs				(388)	1,035
Other acquisition-related costs		346			
Charges related to litigation matters or disputes		437			
Charges recorded in connection with terminating defined benefit					
plans		372			
Intangible asset impairment charges				1,688	
Charges associated with convertible debt exchange offer					1,879
Charges associated with termination of interest rate swap					1,425
Total	\$	54,701	\$	15,439	\$ 17,368

Of these amounts, \$8.8 million, \$8.7 million, and \$5.9 million were charged to cost of product revenues for the years ended December 31, 2008, 2007, and 2006, respectively, \$25.2 million, \$4.6 million, and \$7.5 million were charged to research and development expense for the same periods, and \$20.7 million, \$1.7 million, and \$1.1 million were charged to selling, general and administrative expenses for the same periods. The remaining amounts were primarily charged to benefit from income taxes, amortization expense, interest expense and other expense.

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 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.

Special charges are typically defined as charges 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, or for which the amounts are not expected to recur at the same magnitude as we further expand our finance department and 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.

## **Total Revenues and Gross Margin**

	2008			2007 thousands)	2006
Integra NeuroSciences Integra Orthopedics Integra Medical Instruments	\$	256,869 217,953 179,782	\$	242,631 143,917 163,911	\$ 200,808 110,209 108,280
Total revenues Cost of product revenues		654,604 252,826		550,459 214,674	419,297 168,314
Gross margin	\$	401,778	\$	335,785	\$ 250,983

Gross margin as a percentage of revenues In 2008, total revenues increased \$104.1 million, or 19%, over 2007 to \$654.6 million. Sales of products acquired since the beginning of 2007 comprised approximately \$86.2 million of this increase, and changes in foreign currency exchange rates had a \$5.6 million favorable effect on 2008 revenues. Sales of our extremity reconstruction implants, Integra dermal repair products and Integra Mozaik osteoconductive scaffold for spinal fusion contributed significantly to revenue growth in 2008 and increased in excess of 20% over 2007. This growth resulted primarily from the continued expansion in our direct sales force. Modest increases in our intracranial monitoring systems, DuraGen<sup>®</sup> family of dural repair products, MAYFIELD<sup>®</sup> cranial stabilization systems, Jarit<sup>®</sup> line of handheld surgical instruments, and Radionics<sup>®</sup> image-guided surgery and stereotactic radio surgery system primarily drove the remainder of the growth in revenues in 2008.

In 2007, total revenues increased \$131.2 million, or 31%, over 2006 to \$550.5 million. Sales of products acquired since the beginning of 2006 constituted approximately \$90.9 million of this increase, and changes in foreign currency exchange rates had a \$7.4 million favorable effect on 2007 revenues. Sales of our extremity reconstruction implants, MAYFIELD<sup>®</sup> cranial stabilization systems, Integra Mozaik osteoconductive scaffold for spinal fusion, and private label products contributed significantly to revenue growth in 2007 and all increased in excess of 20% over 2006. Modest increases in our intracranial monitoring systems, DuraGen<sup>®</sup> family of dural repair products, Integra dermal

repair products, and the Jarit<sup>®</sup> line of handheld surgical instruments primarily drove the remainder of our growth in revenues in 2007.

In 2006, total revenues increased \$141.4 million, or 51%, over 2005 to \$419.3 million. Sales of products acquired since the beginning of 2005 constituted approximately \$104.1 million of this increase, and changes in foreign currency exchange rates had a \$0.6 million favorable effect on 2006 revenues. Sales of our extremity reconstruction implants, Integra dermal repair products, and private label products contributed significantly to revenue growth in 2007, and all increased in excess of 30% over 2005. Modest increases in our cranial access and external drainage systems and the Jarit line of handheld surgical instruments primarily drove the remainder of our growth in revenues in 2006.

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.

We have generated our revenue growth primarily through acquisitions, new product launches, market share gains achieved through increased direct sales and marketing efforts worldwide and annual price increases. We expect to drive future revenue growth by continuing to launch new products and acquire businesses and products that can be sold through our existing sales organizations and by gaining additional market share through the expansion of our Integra Extremity Reconstruction and Integra Spine sales organizations in the U.S. and leveraging the distribution channels in our Integra Spine, Integra NeuroSciences, and Integra OrthoBiologics sales organizations to broaden each organization s access to spine surgeons. We believe that the biggest opportunities for revenue growth exist in the extremity reconstruction and spine markets.

We expect that the following factors will temper sales growth in the short term: reduced spending by hospitals on capital equipment, the occurrence of fewer elective surgical procedures in the current global recessionary economic environment, the recent strengthening of the U.S. dollar against the foreign currencies in which certain of our revenues are denominated, and our recent elimination of many of the product lines that we distributed for third parties. However, we do expect these factors to produce a benefit in our gross margin as a percentage of revenue because most of our capital equipment products and products distributed for third parties tend to generate lower gross margins as compared to our other products and, over time, because the U.S. dollar cost of products that we manufacture outside the U.S. or procure in foreign currencies will also be reduced as the U.S. dollar strengthens against those foreign currencies.

While most of our products are not used in elective surgical procedures, approximately 10% of our revenues in 2008 consisted of sales of capital equipment. Given the current economic conditions, hospital spending on capital equipment is widely expected to decrease in 2009 and potentially beyond. With our large installed base of capital equipment, such as Camino<sup>®</sup> intracranial pressure monitors, CUSA<sup>®</sup> ultrasonic surgical systems, and Radionics<sup>®</sup> image-guided surgery and stereotactic radio surgery systems, we expect to continue to generate revenue growth from the related disposable products. In addition, we plan to focus on generating more revenues from service and repair agreements on the installed base of capital equipment, as hospitals reduce spending on new capital equipment. We are also exploring other revenue generating alternatives with respect to our capital equipment, such as leasing programs.

Because our business is focused on developing, manufacturing and marketing products developed internally or acquired, we have eliminated distributed product lines that represent approximately 54% of the original revenues of the LXU Healthcare business that we acquired in May 2007. One of our main objectives is to increase the gross margin as a percentage of our revenues. Because we did not own the rights to the products that the LXU Healthcare business distributed for third parties, the gross margins on those products were generally lower than those earned on products that we develop internally or acquire.

Gross margin as a percentage of revenues was 61% in 2008, 61% in 2007, and 60% in 2006. Cost of product revenues in 2008, 2007 and 2006, respectively, included \$6.7 million, \$4.2 million, and \$4.6 million in fair value inventory purchase accounting adjustments recorded in connection with acquisitions. The following charges negatively affected our gross margin: in 2008, \$1.2 million associated with discontinued or withdrawn product lines; and, in 2007, \$2.8 million associated with discontinued or withdrawn product lines and \$0.8 million technology-related intangible asset impairments. In 2008, 2007, and 2006, respectively, cost of product revenues included \$4.8 million, \$4.2 million, and \$2.8 million of intangible asset amortization for technology-based intangible assets.

In 2009, we expect our consolidated gross margin to increase because sales of our higher gross margin implant products, particularly those from the recently acquired Theken business, are expected to continue to increase as a proportion of total revenues. Additionally, we expect that our gross margin as a percentage of sales will improve over time if the U.S. dollar continues to strengthen against the euro and British pound, as such a strengthening would lower the U.S. dollar cost of products we manufacture at our European plants and the large proportion of the handheld surgical instruments that we procure in euros. Although we continuously identify and implement programs to reduce costs at our manufacturing plants and to manage our inventory more efficiently, gross margin improvements in our business are expected to continued to result primarily from changes in sales mix to a larger proportion of sales of our

higher gross margin implant products.

#### **Other Operating Expenses**

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

	2008	2007	2006
Research and development	9%	6%	6%
Selling, general and administrative	43%	41%	38%
Intangible asset amortization	2%	2%	2%

RESEARCH AND DEVELOPMENT. Research and development expenses increased to \$60.5 million in 2008, compared to \$30.7 million in 2007. Research and development expenses in 2008, 2007 and 2006, respectively, included \$25.2 million, \$4.6 million, and \$5.9 million of in-process research and development charge related to the Theken, IsoTis, and KMI acquisitions, respectively. To date, we have successfully launched one-half of the products underlying the in-process research and development charge from the IsoTis acquisition, while others are still in development. We have terminated the projects underlying the in-process research and development charge from the KMI acquisition. Additionally, in 2006 we recognized a \$1.6 million impairment of inventory and fixed assets associated with a discontinued project for the development of an ultrasonic aspirator system. We discontinued this project in June 2006 following our review of our existing technology and the ultrasonic aspirator technology acquired in the Radionics acquisition. We determined that there was no future, alternative use for the inventory or fixed assets in any other development project.

Excluding acquisition-related and other special charges, we target future spending on research and development to be between 5% and 6% of total revenues. Most of this planned spending for 2009 is concentrated on product development efforts for our spine, neurosurgery and extremity reconstruction product lines, for which we have more than 50 active development projects planned. Additionally, we are continuing the multi-center clinical trial being conducted under an FDA IDE, initiated in 2006 to support FDA approval of the DuraGen Plus<sup>®</sup> Adhesion Barrier Matrix product in the U.S. and the clinical trial initiated in 2008 to support FDA approval of expanded claims for our Integra<sup>®</sup> Dermal Regeneration Template product.

In 2008, research and development expenses as a percentage of revenue increased three percentage points to 9%. The \$29.8 million increase to \$60.5 million resulted largely from the \$25.2 million (approximately 4% of revenue) in-process research and development charge recorded in connection with the Theken acquisition. The remaining increase is primarily related to ongoing expenses from the recently acquired Theken businesses, and from owning the IsoTis business for a full year in 2008, and from increased spending on our DuraGen Plus<sup>®</sup> Adhesion Barrier Matrix clinical trial.

The \$25.2 million in-process research and development charge recorded in connection with the Theken acquisition represents the estimated fair value of acquired development projects that had not yet reached technological feasibility and had no alternative future use. The fair value of this in-process research and development was determined by estimating the costs to develop the acquired technology into commercially viable products and estimating the net present value of the resulting net cash flows from these projects. These cash flows were based on our best estimates of revenue, cost of sales, research and development costs, selling, general and administrative costs and income taxes from the development projects. A summary of the estimates used to calculate the net cash flows for the projects is as follows:

	Year net cash In-flows expected	Discount rat including factor to accou for uncertainty o	unt		Acquired In-Process Research and
Project	to begin	success		Ľ	Development
eDisc artificial lumbar disc	2013		23%	\$	13.0 million
eDisc artificial cervical disc	2016		23%		7.2 million
Spinal fixation implants	2009		15%		4.7 million

All other 2009 15% 0.3 million The eDisc is a unique elastomer disc is intended to restore disc height while maintaining motion over the long term. An electrical version of the eDisc will add the functionality of force sensing in the implant to improve patient recovery by providing alerts postoperatively to the patient via a pager. The spinal fixation implants are structural fixation devices to immobilize the spine in order to promote fusion. Fusion has been shown to reduce pain due to degenerative disc disease and other conditions of the spine. The products are made of either implant grade titanium or implant grade polyetherethereketone and are designed for ease of use to reduce operating room time through fewer parts and fewer steps. The function of the implants is to stabilize the spine to a degree and time period necessary for the growth of bone to occur and provide biologic stability for the long term. There are thirteen different implant systems currently in various stages of development.

We continuously monitor our research and development projects. We believe that the assumptions used in the valuation of these acquired development projects represent a reasonably reliable estimate of the future benefits attributable to the acquired in-process research and development. No assurance can be given that actual results will not deviate from those assumptions in future periods.

Research and development expenses in each of 2007 and 2006 remained consistent at 6% of revenues.

SELLING, GENERAL AND ADMINISTRATIVE. Excluding special charges, we target future selling, general and administrative expenses at between 39% and 41% of revenues. In 2008, selling, general and administrative expenses as a percentage of revenue increased two percentage points to 43%. The \$55.8 million increase in 2008 to \$281.0 million included an \$18.0 million (approximately 3% of revenue) non-cash, stock-based compensation charge recorded in connection with the renewal of our chief executive officer s employment agreement. Additional increases in 2008 resulted from a significant expansion of our corporate staff, particularly in our finance department, to address multiple material weaknesses in our internal controls over financial reporting, \$11.3 million of ongoing operating expenses from the recently acquired Theken businesses, from owning the businesses acquired in 2007 for a full year in 2008, increased expenses associated with headcount expansion in our European headquarters in Lyon, France and from a higher sales commission structure applicable to the Integra Spine distribution channel that was acquired through the Theken acquisition. In the fourth quarter of 2008, we reduced approximately \$4.6 million of cash bonuses that had been accrued through the first three quarters of the year because we decided not to pay cash bonuses for 2008 to most of our employees. We had previously accrued these bonuses because, based on the financial results for the first three guarters of the year, it was probable at that time that such bonuses would be earned and paid. Based on our reduced revenue forecast and particularly the lack of capital product orders, the disruption in the credit markets and the uncertainty of its duration, we currently do not anticipate accruing or paying cash bonuses for most of our employees in 2009.

In 2007, the three percentage point increase in selling, general and administrative expenses as a percentage of revenues to 41% resulted primarily from substantial increases in the size of our selling organizations, particularly for spine and extremity reconstruction, higher expenses for corporate staff, consulting, and professional fees arising from the delayed completion of our financial reporting process, and higher costs in connection with our recent investments in our infrastructure, including the continued implementation of an enterprise business system. The increase in selling, general and administrative expenses in 2007 included \$12.1 million of expenses from businesses acquired in 2007 and increases resulting from reporting a full year of expenses for businesses that were acquired in 2006.

For 2008, 2007 and 2006, respectively, we reported \$31.7 million (inclusive of a stock-compensation charge and related expenses of \$18.4 million relating to grants made in connection with the renewal of our CEO s employment agreement), \$14.3 million and \$13.1 million of stock-based compensation charges in selling, general and administrative expenses.

For 2009, we expect that the increase from a full year of expenses related to the recent expansion of our corporate staff will grow at a slower rate than revenues. Additionally, we plan to decrease expenses from reduced participation in certain trade shows and mass print advertising campaigns and focus more on direct marketing. We expect, however, that additional selling expenses related to the higher sales commission structure of the Integra Spine sales organization and further expansion of the Integra Extremity Reconstruction and Integra Spine sales organizations will largely offset these decreased expenses.

Additionally, the implementation of FASB Statement No. 141(R), *Business Combinations* (Statement 141(R)) on January 1, 2009 could result in an increase or decrease in future selling, general and administrative and other operating expenses, depending upon the extent of our acquisition-related activities going forward. Statement 141(R) changes the practice for accounting for business combinations, such as requiring that we (1) expense transaction costs as incurred, rather than capitalizing them as part of the purchase price; (2) record contingent consideration arrangements and pre-acquisition contingencies, such as legal issues, at fair value at the acquisition date, with subsequent changes in fair value recorded in the income statement; (3) capitalize the fair value of acquired research and development assets separately from goodwill, whereas we previously determined the acquisition-date fair value and then immediately charged the value to expense; and (4) limit the conditions under which restructuring expenses can be accrued in the opening balance sheet of a target to only those where the requirements in FASB Statement No. 146, *Accounting for* 

Costs Associated with Exit or Disposal Activities, would have been met at the acquisition date.

INTANGIBLE ASSET AMORTIZATION. In 2008, amortization expense (excluding amounts reported in cost of product revenues for technology-based intangible assets) increased to \$12.9 million because of amortization on intangible assets acquired through our business acquisitions. In 2007, amortization expense (excluding amounts reported in cost of product revenues) increased to \$12.6 million because of amortization on intangible assets acquisitions and \$0.9 million of impairment charges recorded against certain tradename intangible assets.

Including the impact of intangible assets acquired in 2008, we expect total annual amortization expense (including amounts reported in cost of product revenues) to be approximately \$19.0 million in 2009, \$16.6 million in 2010, \$16.4 million in 2011, \$16.1 million in 2012, \$13.4 million in 2013 and \$94.5 million thereafter.

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

We recorded interest income on our invested cash and marketable debt securities of \$2.1 million, \$3.6 million, and \$2.2 million in 2008, 2007, and 2006, respectively. Interest income decreased in 2008 because of lower yields on invested cash and cash equivalents.

Interest expense primarily relates to the \$165 million of outstanding convertible notes due June 2010, \$165 million of outstanding convertible notes due June 2012, \$120 million of convertible notes that matured or were converted in March 2008, a related interest rate swap agreement, which was terminated in September 2006, and interest and fees relating to our \$300 million senior secured credit facility. In 2008, 2007, and 2006, we recorded interest expense to be paid in cash of \$9.1 million, \$7.7 million, and \$3.0 million, respectively, in connection with our convertible notes, and interest expense to be paid in cash of \$5.5 million, \$3.7 million, and \$4.0 million, respectively, in connection with the credit facility.

The increase in interest expense in 2008 is related to a full year of interest expense associated with the \$330 million of senior convertible notes that we issued in June 2007 and increased borrowings under our credit facility, which were offset by a decrease in interest expense associated with the \$120 million of convertible notes that matured or were converted in March 2008. In 2008, we made borrowings of \$260 million under our credit facility primarily to pay down the \$120 million of convertible notes that matured or were converted in March and April 2008, to finance acquisitions and for general corporate purposes.

The increase in interest expense for 2007 is related to the interest expense associated with the \$330 million of senior convertible notes we issued in June 2007, which was offset by a decrease in interest expense associated with lower borrowings under our credit facility, which was paid down in full in June 2007.

Interest expense for 2006 included a \$1.2 million write-off of unamortized debt issuance costs related to the old convertible notes discussed below and interest associated with increased borrowings under our credit facility. In 2006, we made additional net borrowings of \$100 million under our credit facility.

In September and October 2006, we exchanged \$119.5 million (out of a total of \$120.0 million) of our old 2.5% contingent convertible subordinated notes that matured in March 2008 for the equivalent amount of new notes. See Note 5 to the financial statements for a further discussion. In connection with the exchange of these convertible notes, we recorded a \$1.2 million write-off of the unamortized debt issuance costs and \$0.3 million of fees associated with the old contingent convertible notes that were exchanged.

We recorded a \$0.4 million liability related to the estimated fair value of the additional interest ( contingent interest ) on these convertible notes that matured in March 2008 at the time the notes were issued in 2003. At each balance sheet date, we marked the contingent interest obligation to its estimated fair value, which was the same under the old and new notes, with changes in the fair value recorded to interest expense. In 2007 and 2006, we recorded \$0.7 million and \$0.4 million, respectively, of interest expense associated with changes in the estimated fair value of the contingent interest obligation. In 2008, we did not record any interest expense associated the contingent interest obligation, because at December 31, 2007 we had marked it to a fair value of \$1.8 million, which was the amount of additional interest we paid in March 2008 upon maturity of the notes.

Our reported interest expense for the years ended December 31, 2008, 2007, and 2006 included \$2.4 million, \$1.8 million, and \$0.6 million, respectively, of non-cash amortization of debt issuance costs.

In August 2003, we entered into an interest rate swap agreement with a \$50.0 million notional amount to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of our fixed-rate convertible

notes that matured in March 2008. The interest rate swap agreement was scheduled to terminate in March 2008, subject to early termination upon the occurrence of certain events, including redemption or conversion of the convertible notes. In September 2006, we terminated this interest rate swap agreement in connection with the exchange of our convertible notes. The interest rate swap agreement qualified as a fair value hedge under SFAS No. 133, as amended *Accounting for Derivative Instruments and Hedging Activities*. The net amount to be paid or received under the interest rate swap agreement was recorded as a component of interest expense.

We paid the counterparty approximately \$2.2 million in connection with the termination of the swap, consisting of a \$0.6 million payment of accrued interest and a \$1.6 million payment representing the fair market value of the interest rate swap on the termination date, which we had already accrued. Historically, the net difference between changes in the fair value of the interest rate swap and the contingent convertible notes represented the ineffective portion of the hedging relationship, and this amount was recorded in other income/(expense), net. In 2006, we recorded a \$0.1 million benefit from the ineffective portion of the hedging relationship.

The implementation of FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments that May be Settled in Cash Upon Conversion* (FSP APB 14-1) on January 1, 2009 will increase the amount of interest expense we report. FSP APB 14-1 requires that the liability and equity components of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) be separately accounted for in a manner that reflects an issuer s nonconvertible debt borrowing rate. FSP APB 14-1 applies to all of the convertible notes that we have had outstanding. Upon adoption in our 2009 financial statements, FSP APB 14-1 requires retrospective application back to 2007. Accordingly, we expect that the implementation of FSP APB 14-1 will increase our currently reported interest expense for 2007 and 2008 by \$13.4 million and \$12.5 million, respectively, and by \$11.5 million for 2009, \$8.7 million for 2010, \$6.7 million for 2011, and \$2.9 million for 2012. Early adoption of FSP APB 14-1 is not permitted.

Our net other income (expense) decreased in 2008 by (\$3.9) million of expense to (\$0.9) million of net expense. This change includes a decrease in foreign exchange net gains of \$2.6 million and asset disposals of \$0.5 million. Our net other income (expense) increased in 2007 by \$5.0 million to \$3.0 million of income. In 2006, we recognized \$1.4 million in other expense related to the interest rate swap termination (see Note 6, Derivative Instruments, for a further discussion) and \$1.1 million in losses on the sale of assets. In 2007, we recognized \$2.2 million in income related to currency transaction and translation gains at foreign affiliates.

#### **Income Taxes**

Our effective income tax rate was (12.7)%, 44.3% and 39.1% of income before income taxes in 2008, 2007 and 2006, respectively. The decrease in 2008 resulted primarily from a tax benefit of \$10.0 million associated with the restructuring of our German operations, as well as, the additional deferral in 2008 of income earned in low tax jurisdictions. The 2007 and 2006 effective income tax rates, respectively, include a \$4.6 million and \$2.1 million charge for the write-off of in-process research and development related to acquisitions, which are non-deductible for tax purposes.

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 2009 to increase as compared to 2008 and to be between 30% and 35%.

The net decrease in our tax asset valuation allowance was \$2.8 million in 2008. Our tax asset valuation allowance increased by \$42.1 million in 2007 and decreased \$3.5 million in 2006.

A valuation allowance of \$40.8 million is recorded against the remaining \$114.4 million of net deferred tax assets recorded at December 31, 2008. This valuation allowance relates to deferred tax assets for certain expenses which will be deductible for tax purposes in very limited circumstances and for which we believe it is unlikely that we will recognize the associated tax benefit. 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.

At December 31, 2008 we had net operating loss carryforwards of \$21.2 million for federal income tax purposes, \$152.8 million for foreign income tax purposes and \$62.0 million for state income tax purposes to offset future taxable income. The federal net operating loss carryforwards expire through 2027, \$98.4 million of the foreign net operating loss carryforwards expire through \$54.4 million having an indefinite carry forward period. The state net operating loss carry forwards expire through 2028.

At December 31, 2008, certain of our subsidiaries had unused net operating loss carryforwards and tax credit carryforwards arising from periods prior to our ownership which expire through 2027. The Internal Revenue Code limits the timing and manner in which we may use any acquired net operating losses or tax credits.

We do not provide income taxes on undistributed earnings of non-U.S. subsidiaries because such earnings are expected to be permanently reinvested. Undistributed earnings of foreign subsidiaries totaled \$72.7 million, \$40.1 million, and \$21.9 million at December 31, 2008, 2007, and 2006, respectively.

#### INTERNATIONAL REVENUES AND OPERATIONS

Revenues by major geographic area are summarized below:

					Asia		Other		
	United States	Europe		Pacific (In thousands)		Foreign		Consolidated	
2008	\$ 494,459	\$	98,848	\$	28,509	\$	32,788	\$	654,604
2007	417,035		85,764		21,399		26,261		550,459
2006	317,503		77,100		12,315		12,379		419,297

In 2008, revenues from customers outside the U.S. totaled \$160.1 million or 24% of consolidated revenues, of which approximately 62% were sales to European customers. Revenues from customers outside the U.S. included \$116.7 million of revenues generated in foreign currencies.

In 2007, revenues from customers outside the U.S. totaled \$133.4 million or 24% of consolidated revenues, of which approximately 64% were sales to European customers. Revenues from customers outside the U.S. included \$94.5 million of revenues generated in foreign currencies.

In 2006, revenues from customers outside the U.S. totaled \$101.8 million or 24% of consolidated revenues, of which approximately 76% were sales to European customers. Revenues from customers outside the U.S. included \$57.6 million of revenues generated in foreign currencies.

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

We currently do not hedge our exposure to operating foreign currency risk. Accordingly, either a strengthening or a weakening of the dollar against individual foreign currencies could reduce future gross margins and operating margins. We will continue to assess the potential effects that changes in foreign currency exchange rates could have on our business. 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 U.S., 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 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 U.S.

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

# LIQUIDITY AND CAPITAL RESOURCES

	December 31,			
	2008 2007			
		(in mil	lions)	)
Cash and cash equivalents	\$	183.5	\$	57.3
Short term borrowings and long-term debt		(590.0)		(450.0)
Net cash position	\$	(406.5)	\$	(392.7)

We believe that our liquidity remains strong. We believe that our existing cash, future cash expected to be generated from operations, and our remaining \$40.0 million of borrowing capacity under our senior secured revolving credit facility, if needed, will satisfy our foreseeable working capital and capital expenditure requirements for at least the next twelve months. The decrease in our net cash position at December 31, 2008 primarily results from the \$86.9 million in cash that we paid for acquisitions in 2008 that exceeded the \$72.6 million of cash generated from operations. The largest of these acquisitions, Theken, which was acquired for \$75.0 million in cash paid at closing in July 2008, was financed through additional borrowings under our revolving credit facility. We do not expect to invest as much cash for acquisitions in 2009 as we did in 2008, unless we are able to obtain alternate sources of financing to fund such future acquisitions at the same levels we did in 2008.

Our non-U.S. subsidiaries hold 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 U.S. or used for U.S. operations, the amounts could be subject to U.S. tax for the incremental amount in excess of the foreign tax paid.

We currently do not have any investments in marketable securities with purchased maturities greater than three months. Our current investment strategy seeks to preserve capital and maintain an adequate level of liquidity at all times.

## Cash Flows

We generated positive operating cash flows of \$72.6 million, \$47.0 million, and \$71.7 million in 2008, 2007, and 2006, respectively. Operating cash flows increased in 2008 primarily from higher net income, as adjusted for the \$25.2 million in-process research and development charge from the Theken acquisition, for which the related cash paid is reported as an investing activity, and the \$18.0 million non-cash, stock-based compensation charge recorded in connection with the renewal of our chief executive officer s employment agreement. Operating cash flows in 2007 were lower primarily as a result of higher cash payments for income taxes in 2007 following the utilization of substantially all of our net operating loss carryforwards in 2006 and higher levels of working capital in 2007, particularly from substantial investments in inventory. In 2008, 2007, and 2006, changes in working capital items reduced operating cash flows by \$26.4 million, \$22.5 million, and \$1.2 million, respectively. In 2008, operating cash flows included non-cash charges of \$25.2 million and \$32.6 million relating to in-process research and development and stock-based compensation, respectively. Additionally, the reduction of inventory provided \$10.8 million of net cash flows while the payment of income taxes used \$41.2 million and the reduction of other operating liabilities, including those acquired through acquisitions, used \$17.3 million. In 2007, we invested significantly in inventory because of the commencement of our manufacturing plant in Ireland and to support greater extremity reconstruction and surgical instrument sales. In 2008, we took actions to reduce our inventories to levels more consistent with prior trends and we are continuing these efforts in 2009.

Our principal uses of funds for the year ended December 31, 2008 were \$119.6 million in repayment on our  $2^{1/2\%}$  contingent convertible notes that matured in March 2008, \$86.9 million for acquisition consideration, and \$13.4 million in capital expenditures. In addition to the \$72.6 million in operating cash flows we generated in 2008, we borrowed \$260.0 million under our revolving credit facility, and we received \$11.5 million from the issuance of common stock through the exercise of stock options during the period. The borrowings under our revolving credit facility were used to repay the contingent convertible notes that matured in March 2008, to finance acquisitions and for general corporate purposes.

Our principal uses of funds for the year ended December 31, 2007 were \$100.0 million in net repayments on our credit facility, \$100.8 million for acquisition consideration, \$106.5 million paid for the purchase of 2.2 million shares for our common stock, and \$22.6 million in capital expenditures. In addition to the \$47.0 million in operating cash flows that we generated in 2007, we received \$295.1 million in net cash proceeds from the issuance of senior convertible notes, which is net of the purchase of call options and sale of warrants, and \$18.8 million from the issuance of common stock through the exercise of stock options during the period.

In 2006, we used \$228.7 million for acquisition consideration, \$70 million for the purchase of 1.8 million shares for our common stock and \$11.5 million in capital expenditures. We received \$109.9 million in cash from sales and maturities of available for sale securities, net of purchases. In addition to the \$71.7 million in operating cash flows that we generated in 2006, we received \$15.9 million from the issuance of common stock through the exercise of stock options during the period and \$98.5 million from net borrowings under our credit facility.

## Working Capital

At December 31, 2008 and 2007, working capital was \$322.6 million and \$148.3 million, respectively.

#### Convertible Debt and Related Hedging Activities

We pay interest each June 1 and December 1 on our \$165 million senior convertible notes due June 2010 (2010 Notes) at an annual rate of 2.75% and on our \$165 million senior convertible notes due June 2012 (2012 Notes) and, collectively with the 2010 Notes, the Notes) at an annual rate of 2.375%. In 2008, we paid an aggregate amount of \$0.1 million to holders of the Notes as liquidated damages for failure to maintain the effectiveness of the registration statements that permit resales of the common stock issuable upon conversion of the Notes, which failure was caused by our inability to timely file our Annual Report on Form 10-K for the year ended December 31, 2007. Payments of the liquidated damages amount were made at the same time that ordinary interest payments were made to the holders of the Notes.

The 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 15.0917 shares per \$1,000 principal amount of notes for the 2010 Notes and 15.3935 shares per \$1,000 principal amount of notes for the 2012 Notes (which represents an initial conversion price of approximately \$66.26 per share and approximately \$64.96 per share for the 2010 Notes and the 2012 Notes, respectively.) We expect to satisfy any conversion of the Notes with cash up to the principal amount of the applicable series of Notes pursuant to the net share settlement mechanism set forth in the applicable indenture and, with respect to any excess conversion value, with shares of our common stock. The Notes are convertible only in the following circumstances: (1) if the closing sale price of our common stock exceeds 130% of the conversion price during a period as defined in the indenture; (2) if the average trading price per \$1,000 principal amount of the Notes is less than or equal to 97% of the average conversion value of the Notes during a period as defined in the 2012 Notes); or (4) if specified corporate transactions occur. The issue price of the Notes was equal to their face amount, which is also the amount holders are entitled to receive at maturity if the Notes are not converted. As of December 31, 2008, none of these conditions existed and, as a result, the \$330 million aggregate balance of the 2010 Notes and the 2012 Notes is classified as long-term.

The Notes, under the terms of the private placement agreement, are guaranteed fully by Integra LifeSciences Corporation, a subsidiary of Integra. The 2010 Notes rank equal in right of payment to the 2012 Notes. The Notes are Integra s direct senior unsecured obligations and rank equal in right of payment to all of our existing and future unsecured and unsubordinated indebtedness.

On March 19, 2008 and April 9, 2008, we received notices of default from the trustee related to the failure to timely provide the trustee with a copy of our Annual Report on Form 10-K for the year ended December 31, 2007. The default under the indentures was cured by May 18, 2008 (60 days from the date of the earlier notice of default) without penalty.

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 ), in connection with each series of Notes. The cost of the call transactions to us was approximately \$46.8 million. We received approximately \$21.7 million of proceeds from the warrant transactions. 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 (1) for the 2010 Notes, approximately \$66.26 per share of Common Stock, and (2) for the 2012 Notes, approximately \$64.96, in each case subject to anti-dilution adjustments substantially similar to those in the Notes. The initial strike price of the warrant transactions is (i) for the 2010 Notes, approximately \$77.96 per share of Common Stock and (ii) for the 2012 Notes, approximately \$90.95, in each case subject to customary anti-dilution adjustments.

We may from time to time seek to retire or purchase 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 terminate early, but only with respect to the number of Notes that cease to be outstanding. The amounts involved may be material.

Neither the 2010 Notes nor the 2012 Notes are rated by any credit rating agency.

We paid interest on our \$120 million contingent convertible subordinated notes that matured in March 2008 (2008 Notes) at an annual rate of 22%. Upon maturity of the 2008 Notes, we also paid \$1.8 million of contingent interest because our common stock price was greater than \$37.56 at thirty days prior to their maturity. Because the market price of our common stock was greater than \$37.56 per share, holders of the 2008 Notes were able to convert the notes prior to maturity. In March 2008, we repaid the 2008 Notes upon conversion or maturity by issuing approximately 768,000 shares of our common stock and paying \$119.6 million in cash. There were no financial covenants associated with the 2008 Notes.

In conjunction with the 2008 Notes, we had previously recognized a deferred tax liability related to the conversion feature of the debt. Due to the repayment of the 2008 Notes, we reversed the remaining balance of the deferred tax liability which resulted in the recognition of a \$2.4 million valuation allowance on a deferred tax asset, a \$4.8 million increase to current income taxes payable and \$11.5 million of additional paid-in capital.

In 2006, we exchanged \$119.5 million principal amount of new notes with a net share settlement mechanism for \$119.5 million of our then outstanding 2008 Notes. The terms of the new notes were substantially similar to those of the old notes, except that the new notes had a net share settlement feature and included takeover protection, whereby we would pay a premium to holders who had converted their notes upon the occurrence of designated events, including a change in control. The net share settlement feature of the new notes required that, upon conversion of the new notes, we would pay holders in cash for up to the principal amount of the converted new notes, with any amount in excess of the cash amount settled, at our election, in cash or shares of our common stock.

Holders who exchanged their old notes in the exchange offer received an exchange fee of \$2.50 per \$1,000 principal amount of their old notes. We paid approximately \$299,000 of exchange fees to tendering holders of the existing notes plus expenses totaling approximately \$332,000 in connection with the offer.

In September 2006, we terminated our interest rate swap agreement with a \$50 million notional amount to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of the March 2008 Notes. See Results of Operations Non-Operating Income and Expenses.

## Senior Secured Revolving Credit Facility

In December 2005, we established a \$200 million, five-year, senior secured revolving credit facility, which runs through December 2011. We amended the credit facility in February 2007 to increase the size of the credit facility to \$300 million, which can be increased to \$400 million should additional financing be required in the future. We plan to utilize the credit facility for working capital, capital expenditures, share repurchases, acquisitions, debt repayments and other general corporate purposes. In 2008, we borrowed an aggregate of \$260.0 million against this facility, including \$120.0 million borrowed in March 2008 to finance the \$119.4 million pay down of our 2008 Notes upon their conversion or maturity, \$80.0 million borrowed in July 2008 to fund the acquisition of Theken and for other general corporate purposes, and \$60.0 million borrowed in October 2008 for general corporate purposes. As a result, we have \$260.0 million of outstanding borrowings under our credit facility as of December 31, 2008.

We borrowed \$98.5 million in 2006 for acquisition-related purposes and paid down the entire outstanding balance in June 2007 with a portion of the proceeds from the issuance of our \$330 million of senior convertible notes.

The indebtedness under the credit facility is guaranteed by all but one of our domestic subsidiaries. Our obligations under the credit facility and the guarantees of the guarantors are secured by a first-priority security interest in all present and future capital stock of (or other ownership or profit interest in) each guarantor and substantially all of ours and the guarantors other assets, other than real estate, intellectual property and capital stock of foreign subsidiaries. Borrowings under the credit facility bear interest, at our option, at a rate equal to (i) the Eurodollar Rate in effect from time to time plus an applicable rate (ranging from 0.375% to 1.25%) or (ii) the higher of (x) the weighted average overnight Federal funds rate, as published by the Federal Reserve Bank of New York, plus 0.5%, and (y) the prime commercial lending rate of Bank of America, N.A. plus an applicable rate (ranging from 0% to 0.25%). The applicable rates are based on a financial ratio at the time of the applicable borrowing.

We will also pay an annual commitment fee (ranging from 0.10% to 0.20%) on the daily amount by which the commitments under the credit facility exceed the outstanding loans and letters of credit under the credit facility.

The credit facility requires us to maintain various financial covenants, including leverage ratios, a minimum fixed charge coverage ratio and a minimum liquidity ratio. The credit facility also contains customary affirmative and negative covenants, including those that limit our and our subsidiaries ability to incur additional debt, incur liens, make investments, enter into mergers and acquisitions, liquidate or dissolve, sell or dispose of assets, repurchase stock and pay dividends, engage in transactions with affiliates, engage in certain lines of business and enter into sale and leaseback transactions. We amended the credit facility in September 2007 to accommodate the acquisition of IsoTis as well as other acquisitions. The amendment modified certain financial and negative covenants which include the addition of up to \$14.7 million of cost savings to the calculation of our Consolidated EBITDA as well as an increase in the Total Leverage ratio from 4.0 to 4.5 to 1 through June 30, 2008. We were in compliance with all covenants at each balance sheet date.

In March and April 2008 we received waivers from the lenders under our credit facility related to the late completion of our audited financial statements for the year ended December 31, 2007. We included such financial statements in our Annual Report on Form 10-K filed on May 16, 2008. We also received an extension of the delivery date under the credit facility of our financial statements for the quarter ended March 31, 2008. We included such financial statements in our Quarterly Report on Form 10-Q filed on June 4, 2008. In addition, we obtained a waiver regarding a representation and warranty in the credit agreement relating to material weaknesses in our internal controls through November 15, 2008. We have since remediated the material weaknesses in our internal controls. Accordingly, we are now able to make additional borrowings under the revolving credit facility.

## Share Repurchase Plans

In October 2007, our Board of Directors adopted a program that authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed \$75.0 million through December 31, 2008. On October 30, 2008, our Board of Directors terminated the repurchase authorization it adopted in October 2007 and authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed \$75.0 million through December 31, 2010. Shares may be purchased either in the open market or in privately negotiated transactions. We did not repurchase any shares of our common stock in 2008 under either of these programs.

During 2007 and 2006, we repurchased 2.2 million and 1.8 million shares, respectively, of our common stock under authorized share repurchase programs. We hold repurchased shares as treasury shares and may use them for general corporate purposes, including acquisitions and for issuance upon exercise of outstanding stock options and stock awards.

# **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.

## **Contractual Obligations and Commitments**

As of December 31, 2008, we were obligated to pay the following amounts under various agreements:

	,	Total	ss than year	1-3 Zears nillions)	,	3-5 Years	1	More than years
Convertible Securities Long Term	\$	330.0	\$	\$ 165.0	\$	165.0	\$	
Revolving Credit Facility (1)		260.0	100.0	160.0				
Interest on Convertible Securities		23.6	8.5	10.2		4.9		
Employment Agreements (2)		5.5	3.1	2.4				
Operating Leases		22.8	4.3	9.8		2.8		5.9
Purchase Obligations		15.3	7.7	2.9		0.5		4.2
Minimum Royalty		1.0	0.6	0.2		0.2		
Warranty Obligations		0.7	0.7					
Pension Contributions		0.2		0.1				0.1
Total	\$	659.1	\$ 124.9	\$ 350.6	\$	173.4	\$	10.2

(1) The Company makes regular borrowing and payments each month against the credit facility and considers \$100 million of the outstanding amounts to be short-term in nature based on its current intent and ability. If additional borrowings are made in connection with, for instance, future acquisitions, this could impact the timing of when the Company intends to repay amounts under this credit

facility which runs through December 2011.

(2) Amounts shown

under Employment Agreements do not include executive compensation or compensation resulting from a change in control relating to our executive officers.

In addition, the terms of the purchase agreements executed in connection with certain acquisitions we closed in the last several years require us to make payments to the sellers of those businesses based on the performance of such businesses after the acquisition. The purchase agreements could require payments up to a total of approximately \$128 million in 2009 and 2010, the actual amounts to depend primarily on the revenues attributable to the Theken Spine, LLC acquisition.

Excluded from the contractual obligations table is the liability for unrecognized tax benefits totaling \$11.6 million. This liability for unrecognized tax benefits has been excluded because we cannot make a reliable estimate of the period in which the unrecognized tax benefits will 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, estimates of projected cash flows and discount rates used to value intangible assets and in-process research and development charges and test goodwill and intangible assets for impairment, computation of valuation allowances recorded against deferred tax assets 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.

We believe 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 are different 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 quantities or quantities with a shelf life that is too near its expiration for us to reasonably expect that we can sell those products to adjust their carrying value to estimated net realizable value. If future demand or market conditions are different from our projections, or if we are unable to rework excess or obsolete quantities into other products, we may change the recorded amount of inventory valuation reserves through a charge or reduction in cost of products, we may change 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, goodwill and in-process research and development charges, 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 and identifiable intangible assets with indefinite lives for impairment annually and whenever events or changes indicate that the carrying value of an asset may not be recoverable in accordance with the Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, or sale or disposition of significant assets or products. 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.

#### Income Taxes

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 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.

## 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 in accordance with SFAS 5; that is, 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, as permitted by EITF Topic D-77. 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.

# **OTHER MATTERS**

## **Recently Issued Accounting Standards**

In May 2008, the FASB issued Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments that May be Settled in Cash Upon Conversion* (FSP APB 14-1). FSP APB 14-1 requires that the liability and equity components of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) be separately accounted for in a manner that reflects an issuer s nonconvertible debt borrowing rate. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. FSP APB 14-1 applies to all of the convertible notes that we have had outstanding. Accordingly, the implementation of FSP APB 14-1 on January 1, 2009 will increase the amount of interest expense we report. Upon adoption in our 2009 financial statements, FSP APB 14-1 will increase our currently reported interest expense for 2007 and 2008 by \$13.4 million and \$12.5 million, respectively, and by \$11.5 million for 2009, \$8.7 million for 2011, and \$2.9 million for 2012. Early adoption of FSP APB 14-1 is not permitted.

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (FAS 161), which is effective January 1, 2009. FAS 161 requires enhanced disclosures about derivative instruments and hedging activities to allow for a better understanding of their effects on an entity s financial position, financial performance, and cash flows. Among other things, FAS 161 requires disclosure of the fair values of derivative instruments and associated gains and losses in a tabular format. Since FAS 161 requires only additional disclosures about our derivatives and hedging activities, the adoption of FAS 161 is not expected to affect our financial position or results of operations.

In December 2007, the FASB issued Statement No. 141(R), *Business Combinations* (Statement 141(R)), a replacement of FASB Statement No. 141. Statement 141(R) is effective for fiscal years beginning on or after December 15, 2008 and applies to all business combinations. Statement 141(R) changes the practice for accounting for business combinations, such as requiring that we (1) expense transaction costs as incurred, rather than capitalizing them as part of the purchase price; (2) record contingent consideration arrangements and pre-acquisition contingencies, such as legal issues, at fair value at the acquisition date, with subsequent changes in fair value recorded in the income statement; (3) capitalize the fair value of acquired research and development assets separately from goodwill, whereas we previously determined the acquisition-date fair value and then immediately charged the value to expense; and (4) limit the conditions under which restructuring expenses can be accrued in the opening balance sheet of a target to only those where the requirements in FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, would have been met at the acquisition date. Additionally, Statement 141(R) provides that, upon initially obtaining control, an acquirer shall recognize 100 percent of the fair values of acquired assets, including goodwill, and assumed liabilities, with only limited exceptions, even if the acquirer has not acquired 100 percent of its target. The implementation of Statement 141(R) on January 1, 2009 could result in an increase or decrease in future selling, general and administrative and other operating expenses, depending upon the extent of our acquisition related

activities going forward.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under Statement 141(R), and other generally accepted accounting principles. This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We are required to adopt this FSP for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of this FSP will have a material impact on our financial statements.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the U.S. Any effect of applying the provisions of SFAS 162 shall be reported as a change in accounting principle in accordance with Statement of Financial Accounting Standards No. 154, *Accounting Changes and Error Corrections*. SFAS 162 is effective 60 days following approval by the Securities and Exchange Commission of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles. Management does not anticipate that the adoption of SFAS 162 will have a material impact on our financial statements.

In June 2008, the FASB issued Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (FSP EITF 03-6-1), which is effective January 1, 2009. FSP EITF 03-6-1 clarifies that share-based payment awards that entitle holders to receive non-forfeitable dividends before they vest will be considered participating securities and included in the basic earnings per share calculation. Management is assessing the impact of adoption of FSP EITF 03-6-1 on our results of operations.

# 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 Rate Risk

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

We currently do not hedge our exposure to operating foreign currency risk. Accordingly, a weakening of the dollar against any of these foreign currencies could reduce future gross margins and operating margins. We will continue to assess the potential effects that changes in foreign currency exchange rates could have on our business. If we believe this potential impact presents a significant risk to our business, we may enter into derivative financial instruments to mitigate this risk.

# Interest Rate Risk

*Marketable Debt Securities.* We are exposed to the risk of interest rate fluctuations on the fair value and interest income earned on our cash and cash equivalents. A hypothetical 100 basis point movement in interest rates applicable to our cash and cash equivalents outstanding at December 31, 2008 would increase or decrease interest income by approximately \$1.8 million on an annual basis. We are subject to foreign currency exchange risk with respect to cash balances maintained in foreign currencies.

Senior Secured Credit Facility. We are exposed to the risk of interest rate fluctuations on the interest paid under the terms of our senior secured credit facility. Based on our outstanding borrowings as of December 31, 2008, a hypothetical 100 basis point movement in interest rates applicable to this credit facility would increase or decrease interest expense by approximately \$2.6 million on an annual basis. The primary reference rate under this credit facility is the London Interbank Offered Rate (LIBOR) for the applicable duration.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and the financial statement schedules specified by this Item, together with the reports 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 16, 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.

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, 2008. 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, 2008 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, 2008.

In conducting our evaluation of the effectiveness of our internal control over financial reporting, we have excluded Theken Spine, LLC, Theken Disc, LLC and Therics, LLC (collectively, Theken ) and Minnesota Scientific, Inc., from our assessment of internal control over financial reporting as of December 31, 2008 because they were acquired by the Company in purchase business combinations during 2008. Theken and Minnesota Scientific, Inc., are wholly owned entities of the Company whose total assets and total revenues represent approximately 6.7% and 3.0%, and 1.7% and 0.1%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2008.

The effectiveness of the Company s internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

## **Remediation of Material Weaknesses**

A material weakness in internal control over financial reporting is a deficiency, or a combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis. In connection with management s assessment of our internal control over financial reporting, we had identified the following material weaknesses in our internal control over financial reporting as of September 30, 2008. For the reasons set forth below, these material weaknesses have been remediated as of December 31, 2008.

We strengthened our control processes and procedures with the objective of remediating the material weaknesses as soon as practicable. The steps we took in general with respect to each enumerated material weakness are set forth below.

*Remediation In General.* We established a dedicated team, including both employees and consultants, to manage our internal control compliance program. This team is responsible for identifying and testing all of the Company s key controls, assigning a process owner to each key control, determining which ones are deficient in either design or application, and monitoring remediation progress via an online assessment tool. The team has reviewed its progress with management regularly. This team has also raised awareness and accountability for internal controls compliance throughout all departments and levels in the organization. These efforts substantially remediated the internal controls deficiencies that aggregated into our material weaknesses. Specifically:

# Personnel and management.

<u>Previously reported material weakness</u>: The Company did not maintain a sufficient complement of personnel with the appropriate skills, training and experience to identify and address the application of generally accepted accounting principles and effective controls with respect to locations undergoing change or experiencing staff turnover. Specifically, the Company did not maintain a sufficient complement of personnel to completely and accurately record and review the inventory, accrued liabilities, intercompany accounts, accounts receivable and income tax accounts as of and for the year ended December 31, 2007 and interim periods through September 30, 2008. Further, effective communication was not designed and in place for sharing of information within and between our finance department and other operating departments. This control deficiency contributed to the following control deficiencies which are individually considered to be material weaknesses.

<u>Remediation efforts:</u> In the last year, we substantially increased our accounting, financial planning, information technology, business process management and tax departments, adding more than 25 employees in the United States and Europe, and significantly reduced staff turnover. We also reorganized our financial functions in Europe. We assigned an experienced executive to manage and develop the European finance organization, and we significantly increased the number and experience of the accountants overseeing our Tullamore, Ireland manufacturing operation. As these new employees gained experience with our systems, processes, accounts, and substantive business, we improved system utilization, streamlined business processes, and improved our ability to maintain and review inventory, accrued liabilities, intercompany accounts, accounts receivable and income tax accounts. We also improved the communication between our finance department and other operating departments, as well as within the finance department. These improvements also contributed toward the remediation of our other control deficiencies. *Financial statement accounts reconciliation*.

<u>Previously reported material weakness:</u> The Company did not maintain effective controls over certain financial statement accounts reconciliation. Specifically, accounts reconciliation involving inventory, accrued liabilities, intercompany accounts, accounts receivable and income taxes were not designed for proper preparation and timely review and reconciling items were not timely resolved and adjusted. This control deficiency resulted in audit adjustments to the aforementioned accounts and disclosures in the Company s consolidated financial statements as of and for the year ended December 31, 2007.

<u>Remediation efforts:</u> Our material weakness in the analysis, reconciliation, and review of accounts was exacerbated by the aggregate effect of deficiencies in various key controls throughout the organization that have an impact on the enumerated accounts (inventory, accrued liabilities, intercompany, accounts receivable, and income taxes). We have remediated many, but not all, of these underlying control deficiencies through a combination of better training, more experienced employees, better processes, the implementation of additional software and systems, and a company-wide

initiative to improve the quality of systems data. We have also adopted formal policies requiring the reconciliation of key accounts and have substantially increased the quality and review of account reconciliations. *Intercompany accounting.* 

<u>Previously reported material weakness:</u> The Company did not maintain effective controls over the recording and elimination of intercompany transactions. Specifically, controls were not appropriately designed for completeness and accuracy of intercompany accounts and to reconcile and review intercompany transactions between the Company s subsidiaries on a timely basis. This control deficiency resulted in improper intercompany profit eliminations and audit adjustments to intercompany sales and cost of goods sold for the year ended December 31, 2007.

<u>Remediation efforts:</u> We have made substantial improvements in both the process for reconciling intercompany accounts and in the disposition of items identified through these reconciliations. We implemented better procedures for ensuring consistency of transactions and data between our subsidiaries, system configuration changes made to support proper accounting for intercompany sales transactions, and improved documentation of intercompany loans and settlements initiated by the treasury group.

#### Income tax.

<u>Previously reported material weakness</u>: The Company did not maintain effective controls over the completeness and accuracy of its income tax provision. Specifically, controls were not appropriately designed to ensure its income tax provision and related income taxes payable and deferred income tax assets and liabilities were properly calculated. This control deficiency resulted in audit adjustments to the aforementioned accounts and disclosures in the Company s consolidated financial statements as of and for the year ended December 31, 2007.

<u>Remediation efforts:</u> We have increased our staff and engaged an outside firm to assist with the preparation of our tax returns and quarterly tax provision. We have improved the process itself through better forecasting, faster completion of pre-tax financial results (which allows for more time to complete and review the tax provision), more accurate transfer pricing analyses, and more and better supervision of the tax provision process, including additional review of accounting for current and deferred income tax accounts. We continue to recruit for experienced tax accounting professionals.

## Implementation, configuration, access and usage of financial reporting systems.

<u>Previously reported material weakness</u>: The Company did not maintain effective controls over the system configuration, segregation of duties and access to key financial reporting systems, particularly with respect to locations undergoing systems implementations. Specifically, key financial reporting systems were not appropriately configured to ensure that certain transactions were properly processed, to segregate duties amongst personnel and to ensure that unauthorized individuals did not have access to add, change or delete key financial data. Further, the Company lacked adequate internal access security policies and procedures.

<u>Remediation efforts:</u> We have implemented software that enables us to monitor and assess both access to systems and segregation of duties within and between business processes. As a result we have revised business processes and individual responsibilities to resolve those conflicts, and have implemented software that will prevent such conflicts in the future. We have increased the size of our business process management and information technology departments, which have improved the quality of system data, trained and provided additional support to users, and have made significant changes in the configuration of systems that have already been implemented in order to more efficiently use our financial systems and to improve financial reporting and controls. Finally, we have changed our procedures around the implementation of systems in new locations and for new business processes.

Remediation of the weaknesses described above have been completed and, therefore, these material weaknesses did not exist as of December 31, 2008.

The effectiveness of any system of controls and procedures is subject to certain limitations, and, as a result, there can be no assurance that our controls and procedures will detect all errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be attained.

We will continue to develop new policies and procedures as well as educate and train our financial reporting department regarding our existing policies and procedures in a continual effort to improve our internal control over financial reporting, and will be taking further actions as appropriate. We view this as an ongoing effort to which we will devote significant resources.

We believe that the foregoing actions have improved and will continue to improve our internal control over financial reporting, as well as our disclosure controls and procedures.

## Changes in Internal Control Over Financial Reporting

We have completed the implementation of the changes, as described above in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended December 31, 2008 (and prior periods) that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

#### PART III

#### **INCORPORATION BY REFERENCE**

The information called for by 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 20, 2009, 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.

## 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:	
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006	F-2
Consolidated Balance Sheets as of December 31, 2008 and 2007	F-3
Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006	F-4
Consolidated Statements of Changes in Stockholders Equity for the years ended December 31, 2008, 2007 and 2006	F-5
Notes to Consolidated Financial Statements	F-6

## 2. Financial Statement Schedules.

#### Financial Statement Schedule

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	Amended and Restated By-laws 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)
4.1	Indenture, dated as of March 31, 2003, between the Company and Wells Fargo Bank Minnesota, National Association (Incorporated by reference to Exhibit 4.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003)
4.2	Registration Rights Agreement, dated as of March 31, 2003, between the Company and Credit Suisse First Boston, LLC, Banc of America Securities LLC and U.S. Bancorp Piper Jaffray Inc. (Incorporated by reference to Exhibit 4.3 to the Company s Registration Statement on Form S-3 filed on June 30, 2003 (File No. 333-106625))
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

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Current Report on Form 8-K filed on December 29, 2005)

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)
- 4.4 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)
- 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	Inne	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)
- 10.2 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)

10.3	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. 22, 08608) which become effective on January 24, 1006)*
10.4	Statement on Form S-1 (File No. 33-98698) which became effective on January 24, 1996)* 1993 Incentive Stock Option and Non-Qualified Stock Option Plan (Incorporated by reference to Exhibit 10.32 to the Company s Registration Statement on Form 10/A (File No. 0-26224) which became effective on August 8, 1995)*
10.5	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)*
10.6	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)*
10.7	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)*
10.8(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)*
10.8(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)*
10.9	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)*
10.10	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)*
10.11(a)	2003 Equity Incentive Plan (amended and restated as of July 26, 2005) (Incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005)*
10.11(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)*
10.11(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)*
10.12(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)*
10.12(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)*
10.12(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)*

- 10.12(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)\*
- 10.13 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)\*
- 10.14(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)\*
- 10.14(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)\*
- 10.14(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)\*
- 10.15(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)\*
- 10.15(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)\*

10.15(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)*
10.16(a)	Amended and Restated 2005 Employment Agreement between Gerard S. Carlozzi and the
	Company dated December 19, 2005 (Incorporated by reference to Exhibit 10.17 to the
	Company s Annual Report on Form 10-K for the year ended December 31, 2005)*
10.16(b)	Amendment 2008-1, dated as of January 2, 2008, to the Amended and Restated 2005
	Employment Agreement between Gerard S. Carlozzi and the Company (Incorporated by
	reference to Exhibit 10.16(b) to the Company s Annual Report on Form 10-K for the year
10.16(a)	ended December 31, 2007)*
10.16(c)	Amendment 2008-2, dated as of December 18, 2008, to the Amended and Restated 2005
	Employment Agreement between Gerard S. Carlozzi and the Company (Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on
	December 24, 2008)*
10.17	Severance Agreement between Judith O Grady and the Company dated as of January 1,
10.17	2008 (Incorporated by reference to Exhibit 10.17(b) to the Company's Annual Report on
	Form 10-K for the year ended December 31, 2007)*
10.18	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(a)	Industrial Real Estate Triple Net Sublease dated July 1, 2001 between Sorrento Montana,
	L.P. and Camino NeuroCare, Inc. (Incorporated by reference to Exhibit 10.24(a) to the
	Company s Annual Report on Form 10-K for the year ended December 31, 2004)
10.19(b)	First Amendment to Sublease dated as of July 1, 2003 by and between Sorrento Montana,
	L.P. and Camino NeuroCare, Inc. (Incorporated by reference to Exhibit 10.24(b) to the
10.10()	Company s Annual Report on Form 10-K for the year ended December 31, 2004)
10.19(c)	Second Amendment to Sublease dated as of June 1, 2004 by and between Sorrento Montana, L. B. and Camina Naura Cara, Inc. (Incompared by references to Exhibit 10.24(a))
	Montana, L.P. and Camino NeuroCare, Inc. (Incorporated by reference to Exhibit 10.24(c) to the Company s Annual Report on Form 10-K for the year ended December 31, 2004)
10.19(d)	Third Amendment to Sublease dated as of June 15, 2004 by and between Sorrento
10.17(0)	Montana, L.P. and Integra LifeSciences Corporation (Incorporated by reference to
	Exhibit 10.24(d) to the Company s Annual Report on Form 10-K for the year ended
	December 31, 2004)
10.19(e)	Fourth Amendment to Sublease, dated as of August 15, 2006, by and between Sorrento
	Montana, L.P. and Integra LifeSciences Corporation (Incorporated by reference to
	Exhibit 10.1 to the Company s Current Report on Form 8-K filed on August 17, 2006)
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
10.00	on Form 8-K filed on January 8, 2001)*
10.22	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)*
10.00()	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)\*

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10.26	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)*
10.27	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)*
10.28	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)*
10.29	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)*
10.30	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)*
10.31	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)*
10.32	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)*
10.33(a)	Compensation of Directors of the Company (Incorporated by reference to Exhibit 10.33 to the Company s Annual Report on Form 10-K for the year ended December 31, 2006)*
10.33(b)	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)*
10.34(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)*
10.34(b)	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 10.4 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008*
10.35(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)*
10.35(b)	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)*
10.36	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)
10.37	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)*
10.38	Performance Stock Agreement by and between Gerard S. Carlozzi and the Company dated January 3, 2006 (Incorporated by reference to Exhibit 10.43 to the Company s Annual Report on Form 10-K for the year ended December 31, 2005)*

- 10.39(a) Form of Performance Stock Agreement for Gerard S. Carlozzi and 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(b) Form of Performance Stock Agreement for Gerard S. Carlozzi and 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)\*
- 10.40 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)
- 10.41 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)
- 10.42(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)\*
- 10.42(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)\*

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10.42(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 Composite of Annual Persent on Form 10 K for the user on ded December 21, 2007)*
10.43	to the Company s Annual Report on Form 10-K for the year ended December 31, 2007)* Form of Restricted Stock Agreement for Gerard S. Carlozzi and 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)*
10.44	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)
10.45	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)
10.46	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)
10.47	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)
10.48	Agreement and Plan of Merger among Integra LifeSciences Holdings Corporation, ICE Mergercorp, Inc. and IsoTis, Inc., dated as of August 6, 2007 (Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on August 7, 2007)
10.49	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)*
10.50	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)
10.51	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)*
10.52	Form of Contract Stock/Restricted Units Agreement for Mr. Carlozzi and Mr. Henneman (Incorporated by reference to Exhibit 10.4 to the Company s Current Report on Form 8-K filed on December 24, 2008)*
10.53	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)
10.54	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)
21 23	Subsidiaries of the Company+ Consent of Pricewaterhouse Coopers LLP+
31.1	Consent of Pricewaterhouse Coopers LLP+ 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+
- \* Indicates a management contract or compensatory plan or arrangement.
- + Indicates this document is filed as an exhibit herewith.

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

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# 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/ Stuart M. Essig Stuart M. Essig President and Chief Executive Officer

Date: March 2, 2009

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

Signature	Title	Date
/s/ Stuart M. Essig	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2009
Stuart M. Essig		
/s/ John B. Henneman, III	Executive Vice President, Finance and Administration, and Chief Financial Officer	March 2, 2009
John B. Henneman, III	(Principal Financial Officer)	
/s/ Jerry E. Corbin	Vice President and Corporate Controller (Principal Accounting Officer)	March 2, 2009
Jerry E. Corbin	(Thielpar Accounting Officer)	
/s/ Richard E. Caruso, Ph.D.	Chairman of the Board	March 2, 2009
Richard E. Caruso, Ph.D.		
/s/ Thomas J. Baltimore, Jr.	Director	March 2, 2009
Thomas J. Baltimore, Jr.		
/s/ Keith Bradley, Ph.D.	Director	March 2, 2009
Keith Bradley, Ph.D.		
/s/ Neal Moszkowski	Director	March 2, 2009
Neal Moszkowski		
/s/ Christian Schade	Director	March 2, 2009
Christian Schade		
/s/ James M. Sullivan	Director	March 2, 2009
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James M. Sullivan		
/s/ Anne M. VanLent	Director	March 2, 2009
Anne M. VanLent		
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#### **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Integra LifeSciences Holdings Corporation:

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Integra LifeSciences Holdings Corporation and its subsidiaries at December 31, 2008 and December 31, 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management s Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company s internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for uncertain income tax positions in 2007.

A company s internal control over financial reporting is a process 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. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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 or procedures may deteriorate.

As described in Management s Report of Internal Control Over Financial Reporting, management has excluded Theken Spine, LLC, Theken Disc, LLC and Therics, LLC (collectively, Theken ) and Minnesota Scientific, Inc., from its assessment of internal control over financial reporting as of December 31, 2008 because they were acquired by the Company in purchase business combinations during 2008. Theken and Minnesota Scientific, Inc., are wholly owned entities of the Company whose total assets and total revenues represent approximately 6.7% and 3.0%, and 1.7% and

0.1%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2008. /s/ PricewaterhouseCoopers LLP Florham Park, New Jersey March 2, 2009

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS

		Year	End	ed Decembe	er 31	,
		2008		2007		2006
	]	are a	e amounts			
Total revenue, net	\$	654,604	\$	550,459	\$	419,297
COSTS AND EXPENSES						
Cost of product revenues		252,826		214,674		168,314
Research and development		60,495		30,658		25,732
Selling, general and administrative		280,997		225,187		157,706
Intangible asset amortization		12,875		12,652		8,801
Total costs and expenses		607,193		483,171		360,553
Operating income		47,411		67,288		58,744
Interest income		2,114		3,552		2,194
Interest expense		(17,614)		(13,749)		(10,620)
Other income (expense), net		(905)		2,971		(2,010)
Income before income taxes		31,006		60,062		48,308
(Benefit from) provision for income taxes		(3,927)		26,591		18,901
Net income	\$	34,933	\$	33,471	\$	29,407
Basic net income per share	\$	1.26	\$	1.21	\$	1.00
Diluted net income per share	\$	1.22	\$	1.13	\$	0.97
Weighted average common shares outstanding:						
Basic		27,781		27,712		29,300
Diluted		28,703		29,578		32,747
The accompanying notes are an integral part of the	se cons	olidated fina	ncia	l statements		

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED BALANCE SHEETS

	Year Ended 1 2008 In tho	2007
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 183,546	\$ 57,339
Trade accounts receivable, net of allowances of \$10,052 and \$7,816	112,417	103,539
Inventories, net	146,103	144,535
Deferred tax assets	24,135	22,254
Prepaid expenses and other current assets	31,191	12,264
	01,171	
Total current assets	497,392	339,931
Property, plant, and equipment, net	70,382	61,730
Intangible assets, net	225,998	195,766
Goodwill	212,094	207,438
Other assets	28,565	13,147
	20,000	10,117
Total assets	\$ 1,034,431	\$ 818,012
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Borrowings under senior credit facility	\$ 100,000	\$
Convertible securities		119,962
Accounts payable, trade	22,964	23,232
Deferred revenue	3,053	2,901
Accrued compensation	16,030	16,877
Accrued expenses and other current liabilities	32,704	28,699
Total current liabilities	174,751	191,671
Long-term borrowings under senior credit facility	160,000	1,0,1
Long-term convertible securities	330,000	330,000
Deferred tax liabilities	220,000	16,052
Other liabilities	19,474	19,860
	-, -	- )
Total liabilities	684,225	557,583
Commitments and contingencies		
Stockholders Equity:		
Preferred Stock; no par value; 15,000 authorized shares; none outstanding		
Common stock; \$.01 par value; 60,000 authorized shares; 34,352 and 32,252		
issued	344	323
Additional paid-in capital	464,668	395,266
Treasury stock, at cost; 6,354 shares	(252,380)	(252,380)
Accumulated other comprehensive income (loss):	( ))	× ,)
Foreign currency translation adjustment	6,314	19,768
Pension liability adjustment, net of tax	(959)	(723)
······································	(101)	(,==)

Retained earnings	132,219	98,175
Total stockholders equity	350,206	260,429
Total liabilities and stockholders equity	\$ 1,034,431	\$ 818,012

The accompanying notes are an integral part of these consolidated financial statements

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS

	Yea 2008	r Ended Decembe 2007 In thousands	er 31, 2006
OPERATING ACTIVITIES:			
Net income	\$ 34,933	\$ 33,471	\$ 29,407
Adjustments to reconcile net income to net cash provided by			
operating activities:			
Depreciation and amortization	30,717	25,627	19,018
In-process research and development	25,240	4,600	5,875
(Gain) loss on sale of assets/investments		(111)	755
Amortization of bond issuance costs	2,431	1,412	2,096
Excess tax benefits from stock-based compensation arrangements	(1,590)	(1,224)	(1,335)
Deferred income tax (benefit) provision	(28,277)	(12,720)	3,235
Amortization of discount/premium on investments			364
Share-based compensation	32,635	15,394	14,115
Other, net	18	791	336
Changes in assets and liabilities, net of business acquisitions:			
Accounts receivable	(4,710)	(2,841)	(26,131)
Inventories	10,823	(18,591)	3,461
Prepaid expenses and other current assets	3,974	616	(2,465)
Refundable income taxes	(18,821)		
Other non-current assets	(102)	364	(799)
Accounts payable, accrued expenses and other current liabilities	(17,258)	118	14,011
Income taxes payable		1,235	7,496
Deferred revenue	(372)	(3,071)	2,409
Other liabilities	2,949	1,956	(146)
Net cash provided by operating activities	72,590	47,026	71,702
INVESTING ACTIVITIES:			
Proceeds from the sales of investments			109,872
Proceeds from sales of property and equipment		411	689
Purchases of available for sale investments	(12, 101)		(13,074)
Purchases of property and equipment	(13,401)	(22,572)	(11,520)
Cash used in acquisitions, net of cash acquired	(86,874)	(100,810)	(228,662)
Net cash used in investing activities	(100,275)	(122,971)	(142,695)
FINANCING ACTIVITIES:			
Borrowings under senior credit facility	260,000	75,000	162,000
Repayment of convertible notes and credit facility	(119,558)	(175,045)	(63,530)
Proceeds from issuance of convertible notes		330,000	
Proceeds from sale of stock purchase warrants		21,662	
Purchase option hedge on convertible notes		(46,771)	
Convertible note issuance and other financing costs		(9,832)	
Proceeds from exercised stock options and warrants	11,504	18,781	15,867

0 0						
Purchases of treasury stock				(106,534)		(70,031)
Excess tax benefits from stock-based compensation arrangements		1,590		1,224		1,335
		1,0 > 0		-,		1,000
Net cash provided by financing activities		153,536		108,485		45,641
Net cush provided by manening ded vides		100,000		100,100		10,011
Effect of exchange rate changes on cash and cash equivalents		356		2,102		1,160
Enfort of exchange rate changes on each and each equivalents		550		2,102		1,100
Net increase (decrease) in cash and cash equivalents		126,207		34,642		(24,192)
		,		,		,
Cash and cash equivalents at beginning of period		57,339		22,697		46,889
Cash and cash equivalents at end of period	\$	183,546	\$	57,339	\$	22,697
Cash and cash equivalents at end of period	ψ	165,540	φ	57,559	φ	22,097
Cash paid during the year for interest	\$	17,259	\$	10,870	\$	8,060
	Ψ	,	Ψ	,	Ψ	-
Cash paid during the year for income taxes		41,246		38,664		16,395
Supplemental non-cash disclosure:						
Acquisition fees included in liabilities	\$		\$	1,478	\$	
Property and equipment purchases included in liabilities		571		294		765
The accompanying notes are an integral part of the	se cons	olidated fina	ancial	statements		
1, 2, 8, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1,						

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Preferree Stock	nmon tock	Т	`reasury Stock	Pa	litional aid-In apital In tho	Con	cumulated Other prehensive Income (Loss) ds	e I	Retained Earnings / ccumulated Deficit)	Total Equity
Balance, December 31, 2005 Net income	\$	\$ 298	\$	(75,815)	\$ 3	33,179	\$	(4,773)	\$	36,929 29,407	\$ 289,818 29,407
Realized gains on investments Reversal of unrealized losses on investments, net								254			254
of tax Foreign currency								547			547
translation Minimum pension liabilit	x7							12,345			12,345
adjustment, net of tax	y							(293)			(293)
Total comprehensive income											\$ 42,260
Issuance of 1,649 shares of common stock through employee benefit plans Tax benefit related to stock option exercises and		17				15,888					15,905
issuance of restricted stock						3,237					3,237
Share-based compensation Repurchase 1,779 shares of common stock	n			(70.021)		14,973					14,973
				(70,031)							(70,031)
Balance, December 31, 2006	\$	\$ 315	\$	(145,846)	\$ 3	67,277	\$	8,080	\$	66,336	\$ 296,162
Net income Foreign currency										33,471	33,471
translation Minimum pension liabilit	x7							9,723			9,723
adjustment, net of tax	y							1,242			1,242
Total comprehensive income											\$ 44,436
		8				18,528					18,536

Issuance of 788 shares of common stock through employee benefit plans Tax benefit related to call options on convertible notes Tax benefit related to stock option exercises and				17,542			17,542
issuance of restricted stock Share-based compensation				3,087 15,478			3,087 15,478
Repurchase 2,207 shares of common stock			(106,534)	13,170			(106,534)
Purchase option hedge on convertible notes				(46,771)			(46,771)
Sale of stock purchase warrants				21,662			21,662
Equity portion of debt issuance costs				(1,573)			(1,573)
Cumulative effect of the adoption of FIN 48						(1,632)	(1,632)
Convertible note share conversion				36			36
Balance, December 31, 2007	\$\$	323	\$ (252,380)	\$ 395,266	\$ 19,045	\$ 98,175	\$ 260,429
Non-employee stock compensation expense				1,095		(889)	206
Net income						34,933	34,933
Foreign currency translation					(13,454)		(13,454)
Minimum pension liability adjustment, net of tax					(236)		(236)
Total comprehensive income							\$ 21,243
Issuance of 1,132 shares of common stock through employee benefit plans Issuance of 768 shares of common stock for		11		11,442			11,453
convertible note settlement		8		396			404
Recapture of deferred tax for convertible debt Tax benefit related to stock option exercises and				11,453 1,813			11,453 1,813

issuance of restricted											
stock											
Share-based compensation						32,496					32,496
Issuance and commitment											
of 310 shares of common											
stock for acquisition			2			10,707					10,709
Balance, December 31,											
2008	\$	\$	344	\$ (252,380)	\$	464,668	\$	5,355	\$	132,219	\$ 350,206
The accompanying notes are an integral part of these consolidated financial statements											

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 1. BUSINESS

Integra LifeSciences Holdings Corporation (the Company ) incorporated in Delaware in 1989. The Company, a world leader in regenerative medicine, is dedicated to improving the quality of life for patients through the development, manufacturing, and marketing of cost-effective surgical implants and medical instruments. Its products are used primarily in neurosurgery, extremity reconstruction, orthopedics and general surgery.

The Company sells its products directly through various sales forces and through a variety of other distribution channels.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES BASIS OF PRESENTATION

These financial statements and the accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America and conform to Regulation S-X under the Securities Exchange Act of 1934, as amended. The Company has made all necessary adjustments so that the financial statements are presented fairly and all such adjustments are of a normal recurring nature except as described in *Adjustments* below.

#### **PRINCIPLES OF CONSOLIDATION**

The consolidated financial statements include the accounts of the Company and its subsidiaries, all of which are wholly owned. All significant intercompany accounts and transactions are eliminated in consolidation. See Note 3, Acquisitions, for details of new subsidiaries included in the consolidation.

# **USE OF ESTIMATES**

The preparation of consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount 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, amortization periods for acquired intangible assets and goodwill, discount rates and estimated projected cash flows used to value and test impairments of long-lived assets and goodwill, computation of taxes, valuation allowances recorded against deferred tax assets, the valuation of stock-based compensation, estimates of projected cash flows and depreciation and amortization periods for long-lived assets, valuation of intangible assets and in-process research and development, 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.

# **ADJUSTMENTS**

During 2007, the Company noted certain adjustments which related to prior periods. Because these changes are not material to the current or previous periods, we have recorded them in 2007.

The impact of recording these adjustments during 2007 resulted in net increases to operating income and income before income taxes of \$1.3 million and \$1.7 million, respectively. In addition, income tax expense includes approximately \$1.5 million of expense associated with prior years. After considering the after-tax impact of the pre-tax adjustments combined with the specific tax adjustments noted above, there was a decrease to 2007 net income of \$0.5 million as a result of recording these out of period adjustments. See Note 16, Selected Quarterly Information Unaudited, for a discussion of the impact of out of period corrections in the fourth quarter of 2007 related to prior annual and quarterly periods.

#### CASH AND CASH EQUIVALENTS

The Company considers all short term, highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

#### **INVESTMENTS**

In 2006, the Company liquidated its portfolio of marketable securities. Proceeds from the sales totaled \$109.9 million. As the amounts were previously classified as available for sale securities based on the guidance of SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*, the unrealized losses of \$0.8 million were reclassified from accumulated other comprehensive income into other income upon sale.

Prior to their liquidation in 2006, securities were carried at fair value, which was based on quoted market prices. Increases and decreases in fair value were recorded as unrealized gains and losses in other comprehensive income. Realized gains and losses were determined on the specific identification cost basis and reported in other income (expense), net. Management evaluated its available-for-sale investments for other-than-temporary impairment when the fair value of the investment was lower than its book value. Factors that were considered when evaluating for other-than-temporary impairment included the length of time and the extent to which market value has been less than cost, the financial condition and near-term prospects of the issuer, interest rates, credit risk, the value of any underlying portfolios or investments, and the Company s intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in the market.

#### TRADE ACCOUNTS RECEIVABLE AND ALLOWANCES FOR DOUBTFUL ACCOUNTS RECEIVABLE

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables.

The Company evaluates the collectibility of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to the Company, a provision to the allowances for doubtful accounts is recorded against amounts due to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a prov