2004



ANNUAL REPORT





### **Corporate Officers**

Stuart M. Essig
President, Chief Executive Officer and
Director

Gerard S. Carlozzi Executive Vice President and Chief Operating Officer

John B. Henneman, III Executive Vice President, Chief Administrative Officer and Secretary

David B. Holtz Senior Vice President, Finance and Treasurer

Deborah A. Leonetti Senior Vice President, Global Marketing

Donald R. Nociolo Senior Vice President, Operations

Judith E. O'Grady, R.N., M.S.N., R.A.C. Senior Vice President, Regulatory, Quality Assurance and Clinical Affairs

Robert D. Paltridge Senior Vice President, Global Sales

### **Outside Directors**

Richard E. Caruso, PhD. (3)

Chairman of the Board of Directors

David C. Auth <sup>(1)</sup>
Former Chief Executive Officer and Founder of Heart Technology, Inc.

Keith Bradley, Ph.D. (1) (2) (3) Former Professor of International Management and Management Strategy at the Open University and Cass London Business Schools

Neal Moszkowski <sup>(1) (2)</sup> Co-Head, Soros Private Equity

James M. Sullivan <sup>(2) (3)</sup>
Executive Vice President – Lodging,
Marriott International, Inc.

Anne M. VanLent <sup>(2)</sup>
Executive Vice President and Chief
Financial Officer, Barrier Therapeutics

Compensation Committee member

<sup>(2)</sup> Audit Committee member

<sup>(3)</sup> Nominating Committee member

#### **OUR VISION:**

Integra is a market leading, innovative medical device company focused on helping the medical professional enhance the standard of care.

#### **OUR MISSION:**

Integra seeks to provide customers with clinically relevant, innovative and cost-effective products that improve the quality of life.

### President's Message

To Our Stockholders:

Your company had a great year.

In 2004, we achieved record revenues while continuing to develop our extensive product offerings and global infrastructure. Our total revenues grew to \$229.8 million, a 24% increase over 2003. Operating income was \$24.8 million in 2004. Net income totaled \$17.2 million in 2004, and cash flows generated from operations in 2004 totaled \$39.0 million.

Many factors contributed to our performance this year, and establish the basis for future growth. Several of the most important include:

Sales and Distribution. We have continued to expand our sales and distribution channels. We market most of our products directly through three separate sales forces: Integra NeuroSciences™ (calling on neurosurgeons, intensivists and neuro nurses), Integra Reconstructive Surgery (calling on orthopedic foot and ankle surgeons, surgical podiatrists, burn units, and reconstructive surgeons) and JARIT® Surgical Instruments. Our global selling organization now has over 250 sales, marketing, and clinical people who provide unparalleled product support, customer service and clinical education. Integra LifeSciences is also benefiting from the national contract relationships that JARIT® Surgical Instruments has established with Group Purchasing Organizations (GPO's) such as Broadlane, Consorta, HPG, MedAssets, Novation, and Premier.

*New Products.* In 2004, we launched almost twenty new products, including our INTEGRA Matrix Wound Dressings, NeuraWrap<sup>TM</sup> Nerve Protector, DuraGen Plus<sup>TM</sup> Adhesion Barrier Matrix (CE Only) and the Integra NPH<sup>TM</sup> Valve for normal pressure hydrocephalus. These and other new products bring important benefits to the patient and the surgeon. We expect them to power our organic growth in the coming years.

*Transactions*. Acquisitions also contributed to our growth in 2004. Integra completed four acquisitions during the year. These include the Sparta Surgical disposable critical care devices and surgical instruments business which was integrated into Integra NeuroSupplies, R&B Instruments which became a part of JARIT, the Mayfield headrest business which is now sold by our Integra Neurosciences sales organization and Berchtold ME GmbH, a German manufacturer of electrosurgery devices.

The Mayfield headrest business includes the MAYFIELD® Cranial Stabilization and Positioning Systems and the BUDDE® Halo Retractor System business. We acquired these product lines, which include skull clamps, headrests, reusable and disposable skull pins, blades, retractor systems and spinal implants, from Schaerer Mayfield USA, Inc. (formerly Ohio Medical Instrument Company) in May 2004. MAYFIELD® systems are the market leader in the United States and have been used by neurosurgeons for over thirty years.

In May 2004, we also acquired all of the capital stock of Berchtold Medizin-Elektronik GmbH, now named Integra ME GmbH, from Berchtold Holding GmbH. Integra ME manufactures and markets the ELEKTROTOM® line of electrosurgery generators and the SONOTOM® ultrasonic surgical aspirator, as well as a broad line of related handpieces, instruments and disposables used in many surgical procedures,

including neurosurgery. Integra ME markets and sells its products to hospitals and physicians primarily through a network of distributors in markets outside the United States.

In late 2004, we agreed to acquire the Newdeal group of companies, and we closed the acquisition on January 3, 2005. Newdeal, based in Lyon, France, is a leading developer and manufacturer of specialty implants and instruments specifically designed for foot and ankle surgery. Newdeal's products include a wide range of products for the forefoot, the mid-foot and the hind foot, including the Bold® Screw, Hallu-Fix® plate system and the HINTEGRA® total ankle prosthesis. Newdeal's target physicians include orthopedic surgeons specializing in injuries of the foot, ankle and extremities, as well as surgical podiatrists, of which there are 3,200 and 2,400, respectively, in the United States. The current products address an approximately \$500 million worldwide market. We are selling the Newdeal foot and ankle products through the Integra Reconstructive sales force in the United States, and are very excited about its prospects for the new year.

2005 and Beyond. With more than \$150 million in cash and marketable securities and a diversified and experienced management team, Integra now has more resources than ever to execute on our strategy. We will continue to develop exciting new products, and we are actively seeking additional acquisitions in neurosurgery, related markets such as the ear, nose and throat (ENT), instruments, spine, extremities, and reconstructive surgery.

We are enthusiastic about Integra's future. I want to recognize again the accomplishments of our 1,200 dedicated employees located around the world. Our employees realize our mission and make Integra LifeSciences the company that it is today. I expect that additional acquisitions and internal product development will enable us to continue our successful track record of profitably bringing critical life-saving and innovative products that enhance the standard of care to the medical community and to patients around the globe.

Finally, thank you, our stockholders, for your continued support.

Sincerely,

Stuart Essig

President and Chief Executive Officer

### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

### **FORM 10-K**

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

M	ar	k C	ne)

(Mai	rk One)
[X]	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT
	OF 1934
	For the fiscal year ended December 31, 2004
[]	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
	ACT OF 1934
	For the transition period from to
	COMMISSION FILE NO. 0-26224
$\mathbf{I}$	NTEGRA LIFESCIENCES HOLDINGS CORPORATION

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

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

### REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (609) 275-0500 SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: COMMON STOCK, PAR VALUE \$.01 PER SHARE

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ⊠ No □

As of June 30, 2004, the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$632,254,000, based upon the closing sales price of the registrant's common stock on NASDAQ on such date. For purposes of this calculation only, all directors, executive officers and holders of more than 10% of the registrant's outstanding common stock as of such date were deemed to be "affiliates" of the registrant.

The number of shares of the registrant's Common Stock outstanding as of March 11, 2005 was 29,311,367.

#### DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement relating to its scheduled May 17, 2005 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

#### PART I

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

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

Integra develops, manufactures and markets medical devices for use in neuro-trauma, neurosurgery, reconstructive surgery and general surgery. Integra was founded in 1989 and over the next decade developed technologies and products directed toward tissue regeneration. In 1999, we entered the neurosurgery market through an acquisition and the launch of our DuraGen® Dural Graft Matrix product for the repair of the dura mater. Since 1999, we have increased our revenues from \$42.9 million to \$229.8 million, a compound annual growth rate of 40%, and we have broadened our product offerings to include more than 15,000 products. We have achieved this growth in our overall business through the development and introduction of new products, the development of our distribution channels and acquisitions.

Our product lines include innovative tissue repair products that incorporate our proprietary absorbable implant technology, such as the DuraGen® Dural Graft Matrix, the DuraGen Plus<sup>TM</sup> Dural Regeneration Matrix, the DuraGen Plus<sup>TM</sup> Adhesion Barrier Matrix, the NeuraGen<sup>TM</sup> Nerve Guide, the NeuraWrap<sup>TM</sup> Nerve Protector, the INTEGRA® Dermal Regeneration Template, and the INTEGRA<sup>TM</sup> Bilayer Matrix and INTEGRA<sup>TM</sup> Matrix Wound Dressings. In addition, we offer a full range of medical devices that include monitoring and drainage systems, surgical instruments and fixation systems.

Financial information about our geographical areas is set forth in our financial statements under Notes to Consolidated Financial Statements, Note 14—Segment and Geographic Information.

### **STRATEGY**

Our goal is to become a global leader in the development, manufacturing and marketing of medical devices, implants and biomaterials in the neurosurgery, reconstructive surgery and general surgery markets. Key elements of our strategy include the following:

**Expand our presence in hospitals and other health care facilities.** Through acquisitions and internal growth, we have become a leading provider of products used in the diagnosis, monitoring and treatment of chronic diseases and acute injuries and have become a leading provider of surgical instruments. We focus on cranial, spinal, peripheral nervous system and small bone and joint injuries, as well as the repair and reconstruction of soft tissue, such as dermis. We believe that additional growth potential exists through the following:

- expanding our product portfolio and market reach through additional acquisitions;
- increasing the penetration of our existing products into closely related markets, such as the ear, nose, throat (ENT), maxillofacial, extremities and spine markets;
- continuing the development and promotion of innovative new products, such as our Dura Gen dural repair and antiadhesion products, the NeuraGen<sup>TM</sup> Nerve Guide, the NeuraWrap<sup>TM</sup> Nerve Protector, the NeuroSensor® Cerebral Blood Flow Monitoring System and the LICOX® Brain Tissue Oxygen Monitoring System; and
- expanding our sales force and product offerings focused on orthopedic foot and ankle, podiatric and reconstructive surgeons.

Additional Strategic Acquisitions. Since 1999 we have completed more than twenty acquisitions focused primarily on our neurosurgical product lines, reconstructive surgery, surgical instrumentation and orthopedic surgery. We regularly evaluate potential acquisition candidates in this market and in other specialty medical technology markets characterized by high margins, fragmented competition and focused target customers.

Continue To Develop New And Innovative Medical Products. We have built a leading proprietary absorbable implant franchise through our development of the INTEGRA® Dermal Regeneration Template, the INTEGRA™ Bilayer Matrix and INTEGRA™ Matrix Wound Dressings, the DuraGen® Dural Graft Matrix, the DuraGen Plus™ Dural Regeneration Matrix, the DuraGen Plus™ Adhesion Barrier Matrix, the NeuraGen™ Nerve Guide, the NeuraWrap™ Nerve Protector, Biomend® and Biomend® Extend Absorbable Collagen Membranes and biomaterials for the orthopedic implant market. We currently are developing a variety of innovative neurosurgical and other medical products and are seeking expanded applications for our existing products.

### PRODUCT GROUPS, MARKETING AND SALES

Our business is organized into product groups and distribution channels. Our product groups include Monitoring Products, Implants, Instruments and Private Label Products. Our distribution channels include two direct sales organizations (Integra NeuroSciences and Integra Reconstructive Surgery), one distributor network managed by a direct sales organization (JARIT) and strategic alliances. We sell the products from our four product groups through our various distribution channels, as follows:

		PRODUCT GROUPS				
		Monitoring	Implants	Instruments	Private Label	
D I S	Integra NeuroSciences	X	X	X		
T R I B	Integra Reconstructive		X	X		
U	JARIT			X		
O N	Alliances				X	

The following table summarizes the most important products in each of our product groups, which we discuss in more detail in the text following the table:

PRODUCT LINES	APPLICATIONS		
MONITORING PRODUCTS			
Camino® and Ventrix® Intracranial Pressure (ICP) Monitoring Systems and NeuroSensor® Cerebral Blood Flow and ICP System	Continuous monitoring of intracranial pressure, temperature and cerebral blood flow following injury or neurosurgical procedures		
LICOX® Oxygen Monitoring Systems	Continuous monitoring of intracranial oxygen following injury or neurosurgical procedures		
Integra Systems of Cranial Access and CSF Drainage	Access to the cranial cavity and drainage of excess cerebrospinal fluid from the brain		
Integra Epilepsy Monitoring Electrodes	Specialty electrodes for the intraoperative monitoring of epileptic seizures		
EEG, EP and EMG electrodes, disposables and other supplies	The diagnosis and monitoring of neurological, ENT and pulmonary disorders		

PRODUCT LINES	APPLICATIONS
IMPLANTS	
DuraGen® Dural Graft and DuraGen Plus <sup>TM</sup> Dural Regeneration Matrices	Onlay collagen matrix to repair dura mater
DuraGen Plus <sup>TM</sup> Adhesion Barrier Matrix <sup>(1)</sup>	Onlay collagen matrix to provide an adhesion barrier following spinal and cranial surgery and for restoration of the dura mater
EnDura <sup>TM</sup> No-React <sup>®(2)</sup> Dural Substitute	Bovine pericardium suturable product for repair of dura mater
NeuraGen <sup>™</sup> Nerve Guide and NeuraWrap <sup>™</sup> Nerve Protector	Repair and protection of peripheral nerves
Hydrocephalus shunts, including the new Integra NPH™ Valve	Specifically designed for the management of hydrocephalus, a chronic condition involving excess cerebrospinal fluid in the brain
INTEGRA® Dermal Regeneration Template, INTEGRA™ Bilayer Matrix Wound Dressing, INTEGRA™ Matrix Wound Dressing	Regenerate dermis, repair skin defects and wound dressings
Newdeal products, including the Bold® Screw, Uniclip® Compression Staple, Hallu-Fix® plate system and the HINTEGRA® total ankle prosthesis(1)	Full line of specialty implants and instruments specifically designed for foot and ankle surgery
Sundt <sup>TM</sup> and other carotid shunts	For shunting blood during carotid endarterectomy
INSTRUMENTS	
Selector® Integra Ultrasonic Aspirator; Dissectron® Ultrasonic Aspirator <sup>(1)</sup>	Electronic surgical systems that use ultrasonic energy to selectively dissect and ablate tissue
JARIT Surgical Instruments	General and specialty instruments for open and endoscopic surgery
MAYFIELD®(3) Cranial Stabilization and Positioning Systems and the BUDDE® Halo Retractor System	Intraoperative cranial stabilization and retraction instruments for use during neurosurgical procedures
Elektrotom® electrosurgery generators(1)	Electrosurgery system used to cut and coagulate selected tissue
Ruggles <sup>™</sup> Neurosurgical and Spinal Instruments and R&B Redmond <sup>™</sup> Spinal Instruments	Specialized surgical instruments for use in cranial and/or spinal surgery
Padgett Instruments	Instruments used in reconstructive and plastic surgery

PRODUCT LINES	APPLICATIONS			
INSTRUMENTS (continued)				
Padgett Dermatomes and Meshers	Devices for harvesting and conditioning skin grafts			
Spinal Specialties	Custom spinal, epidural, discogram and nerve block kits and products for chronic pain management			
PRIVATE LABEL PRODUCTS				
Absorbable Collagen Sponge and other matrices for use with bone morphogenetic protein (rhBMP-2)	Fracture management/enabling spinal fusion (manufactured for Wyeth BioPharma; Medtronic Sofamor Danek)			
BioMend® and BioMend® Extend Absorbable Collagen Membranes, CollaCote®, CollaTape® and CollaPlug® Absorbable Wound Dressings	Used in guided tissue regeneration in periodontal surgery and to control bleeding in dental surgery (manufactured for Zimmer)			
VitaCuff® Percutaneous Infection Control Device and BioPatch®(4) Antimicrobial Wound Dressing	Provide protection against infection arising from long- term catheters and in wounds (manufactured for various medical device companies)			

- (1) Not available for sale in the United States
- (2) No-React is a registered trademark of Shelhigh, Inc.
- (3) Mayfield is a registered trademark of SM USA, Inc., a wholly owned subsidiary of Schaerer Mayfield USA, Inc.
- (4) BioPatch is a registered trademark of Johnson & Johnson

#### **Monitoring Products**

The Monitoring Of Brain Parameters. Neurosurgeons use intracranial monitors to diagnose and treat cases of severe head trauma and other diseases. There are approximately 500,000 cases of head trauma each year in the United States, and the market for monitoring and intervention is estimated to approximate \$110 million.

We sell the Camino® and Ventrix® lines of intracranial pressure and temperature monitoring systems and the LICOX® Brain Tissue Oxygen Monitoring System. Currently more than 3,000 of our intracranial monitors are installed and in use worldwide. The Camino® and Ventrix® systems measure the intracranial pressure and temperature in the brain and ventricles, and the LICOX® system allows for continuous qualitative regional monitoring of dissolved oxygen in cerebral tissues.

We expect to introduce the NeuroSensor® Cerebral Blood Flow Monitoring System in the first half of 2005. This monitoring system measures both intracranial pressure and cerebral blood flow using a single combined probe and an electronic monitor for data display. Cerebral blood flow is considered to be an important parameter for monitoring cerebral autoregulation and, when combined with the measurement of intracranial pressure, is expected to facilitate improved patient care and clinical management with applications in neuro-trauma, cerebrovascular disease and post-operative neurosurgical treatment.

Core technologies underlying the brain parameter monitoring product line include the design and manufacture of the disposable catheters used in the monitoring systems, pressure transducer technology, optical detection/fiber optic transmission technology, sensor characterization and calibration technology and monitor design.

Cranial Access And External Drainage. Neurosurgeons use cranial access kits and external drainage systems to gain access to the cranial cavity and to drain excess cerebrospinal fluid from the ventricles of the brain into an external container. We manufacture and market a broad line of cranial access kits and ventricular and lumbar external drainage systems under the Integra CSF Drainage and Cranial Access Systems brand names.

Epilepsy Electrodes and Neurological Supplies. Neurosurgeons use electrodes for the intraoperative monitoring of epileptic seizures to determine if surgical options can be used in the treatment of epilepsy. Seizures vary from a momentary disruption of the senses to short periods of unconsciousness or convulsions. Seizures are caused by the sudden change in how the cells of the brain send electrical signals to each other. The neurosurgeon uses the electrodes in conjunction with an electroencephalography video monitor to determine if a patient is a viable candidate for surgery, which involves the removal of the damaged portion of brain tissue. The worldwide market for intraoperative epilepsy electrodes is estimated to be \$10 million. We sell these products in the United States through our Integra NeuroSciences sales force.

We distribute a wide variety of disposables and supplies, including surface electrodes, needle electrodes, recording transducers and stimulators, and respiratory sensors, that are used in the diagnosis and monitoring of neurological disorders. These products are designed to monitor and perform tests of the nervous system and brain, including electromyography (EMG), evoked potential (EP) and electroencephalography (EEG) tests, and to evaluate sleep disorders.

We sell these products under the Integra Supplies<sup>TM</sup> name primarily through catalogs and telemarketing to more than 6,000 neurologists, hospitals, sleep clinics and other physicians. Neurologists are the referring physicians for Integra's existing neurosurgeon customers and participate in the decision to use our line of epilepsy monitoring electrodes.

### **Implants**

Repair Of The Dura Mater. The dura mater is the thick membrane that contains the cerebrospinal fluid within the brain and the spine. The dura mater often must be penetrated during brain surgery and is often damaged during spinal surgery. In either case, surgeons may close or repair the dura mater with a graft. The graft may consist of tissue taken from elsewhere in the patient's body, or it may be one of the dural substitute products currently on the market, which are made of collagen, synthetic materials, processed human cadaver or bovine pericardium. The DuraGen® Dural Graft and DuraGen Plus<sup>TM</sup> Dural Regeneration Matrices are absorbable collagen products indicated for the repair of the dura mater surrounding the brain and spine. The worldwide market for dural repair, including cranial and spinal applications, is estimated to be \$120 million.

The DuraGen Plus<sup>™</sup> Adhesion Barrier Matrix is an absorbable collagen product, which is CE marked in the European Union as a barrier against adhesions following spinal and cranial surgery and for restoration of the dura mater. We estimate that the total worldwide market for treatment of spinal adhesions exceeds \$300 million. The DuraGen Plus<sup>™</sup> Adhesion Barrier Matrix is not approved for sale in the United States.

We believe that the DuraGen® Dural Graft and DuraGen Plus<sup>TM</sup> Dural Regeneration Matrices, as well as the DuraGen Plus<sup>TM</sup> Adhesion Barrier Matrix, address the shortcomings of other methods for repairing the dura mater. Clinical trials have shown our DuraGen® and DuraGen Plus<sup>TM</sup> products to be an effective means for closing the dura mater without the need for suturing, which allows the neurosurgeon to conclude the operation more efficiently. In addition, because the human body ultimately absorbs the DuraGen® and DuraGen Plus<sup>TM</sup> Matrices and replaces them with new natural tissues, the patient avoids some of the risks associated with a permanent implant inside the cranium or spinal cavity.

EnDura<sup>TM</sup> No-React® Dural Substitute is a bovine pericardium suturable product for the repair of the dura mater. It is treated with the proprietary No-React® process, which reduces the body's inflammatory response to the implant, prolongs the product's durability and eliminates the need for rinsing prior to implantation. Through the EnDura product, we address the approximately 15% of dural repair procedures that, due to pressure existing at the dural breach location, require a suturable graft.

Skin Replacement and Engineered Wound Dressings. Our skin replacement products address the market need created by severe burns, reconstructive surgery, trauma and chronic wounds.

The INTEGRA® Dermal Regeneration Template is designed to enable the human body to regenerate functional dermal tissue. The Food and Drug Administration (FDA) initially approved the product under a Premarket Approval application (PMA) for the post-excisional treatment of life-threatening deep or full-thickness dermal injury where sufficient autograft is not available at the time of excision or is not desirable due to the physiological condition of the patient.

In 2002, we received FDA approval to market our skin replacement products for use in certain procedures in which cadaver skin or an autograft would typically be used. The FDA approved a PMA supplement to permit the marketing of the INTEGRA® Dermal Regeneration Template for the repair of scar contractures in patients who have already recovered from their initial wound. The FDA also granted a Section 510(k) clearance for the sale of a related product, INTEGRATM Bilayer Matrix Wound Dressing, for the dressing of wounds, including chronic wounds. We estimate that the worldwide market now addressable by our skin replacement products exceeds \$1.0 billion.

Between 1999 and 2003, the ETHICON division of Johnson & Johnson was the exclusive seller of the INTEGRA® Dermal Regeneration Template and the INTEGRATM Bilayer Matrix Wound Dressing worldwide, except in Japan where Century Medical, Inc. has rights to distribute the INTEGRA® Dermal Regeneration Template. Effective December 31, 2003, we terminated our agreement with ETHICON and again assumed the sales and marketing responsibility for both products. We now distribute the INTEGRA® Dermal Regeneration Template and the INTEGRATM Bilayer Matrix Wound Dressing through our Reconstructive surgery sales organization in the United States and parts of Western Europe and through a network of distributors elsewhere.

In 2004, we received FDA approval and introduced the INTEGRA® Dermal Regeneration Template – Terminally Sterilized (IDRT-TS). We also introduced the INTEGRATM Matrix Wound Dressing. IDRT-TS is a terminally sterilized version of the INTEGRA® Dermal Regeneration Template. Although functionally the same as the INTEGRA® Dermal Regeneration Template, IDRT-TS does not require refrigeration and is not stored in alcohol, which simplifies considerably the preparation and handling of the INTEGRA product in the operating room. The INTEGRATM Matrix Wound Dressing is a single layer version of our advanced wound care product line, which is indicated for the management of partial and full-thickness soft tissue wounds.

Repair And Protection Of Peripheral Nerves. Peripheral nerves may become severed or damaged through traumatic accidents or surgical injuries, often resulting in the permanent loss of motor and sensory function. Although severed peripheral nerves regenerate spontaneously, they do not establish functional connections unless the nerve stumps are surgically reconnected. We estimate the worldwide market for the repair of severed and damaged peripheral nerves to be \$110 million.

The NeuraGen<sup>TM</sup> Nerve Guide and the NeuraWrap<sup>TM</sup> Nerve Protector are absorbable collagen implants for the repair and protection of severed and injured peripheral nerves. The NeuraGen<sup>TM</sup> product, used in the repair of severed peripheral nerves, is a collagen tube designed to provide an environment for the regenerating nerve and to provide a conduit through which regenerating nerves can bridge the gap caused by the injury. The NeuraGen<sup>TM</sup> Nerve Guide offers a rapid method for rejoining severed peripheral nerves. The NeuraWrap<sup>TM</sup> product, designed for the treatment of injured, compressed or scarred nerves, provides a protective environment for nerve healing, serving as an interface between damaged nerves and surrounding tissue.

Hydrocephalus Management. Hydrocephalus is an incurable condition resulting from an imbalance between the amount of cerebrospinal fluid produced by the brain and the rate at which the body absorbs cerebrospinal fluid. This condition causes the ventricles of the brain to enlarge and the pressure inside the head to increase. Hydrocephalus often is present at birth, but may also result from other causes, including head trauma, spina bifida, intraventricular hemorrhage, intracranial tumors and cysts. Hydrocephalus is most commonly treated by inserting a shunt into the ventricular system of the brain to divert the flow of cerebrospinal fluid out of the brain and using a pressure valve to maintain a normal level of cerebrospinal fluid within the ventricles.

According to the Hydrocephalus Association, hydrocephalus affects approximately one in 500 children born in the United States. We estimate that greater than 50% of total cerebrospinal fluid shunt sales address birth-related hydrocephalus, while the remainder address surgical procedures involving excess cerebrospinal fluid due to head trauma and adult onset normal pressure hydrocephalus. Based on industry sources, we believe that the total United States market for hydrocephalus management, including monitoring, shunting and drainage, is approximately \$150 million. Of that amount, it is estimated that a little more than half consists of sales of monitoring products, and the balance consists of sales of shunts and drains for the management of hydrocephalus.

In recent years, neurosurgeons have increased their use of programmable valves, which allow the neurosurgeon to adjust the pressure settings of the shunt while it is implanted in the patient. Shunts that do not incorporate programmable valve technology must be removed from the patient for subsequent pressure adjustments, a process that requires an additional surgical procedure. We do not market hydrocephalus management shunts with programmable valves and believe that the increasing use of programmable valves has negatively affected, and may continue to negatively affect, the sales of our shunt products.

In 2004, we introduced the NPH<sup>TM</sup> Low Flow Hydrocephalus Valve that regulates the flow of cerebrospinal fluid out of the brain, rather than the pressure created by cerebrospinal fluid inside the head. Designed specifically to meet the needs of patients with normal pressure hydrocephalus (NPH), the NPH<sup>TM</sup> Valve controls cerebrospinal fluid flow at a lower rate than Integra's other flow-control valves. Normal pressure hydrocephalus is a syndrome that occurs in both adults who have previously experienced birth-related hydrocephalus and those who have not. It is characterized by dementia, gait disturbance and urinary incontinence in patients that are typically over 65 years of age. As many as 10% of all patients with symptoms of dementia have NPH. While the symptoms associated with NPH can intensify over time if the condition is left untreated, the dementia associated with NPH can be reversed if treated properly. While shunting is the preferred treatment method for patients diagnosed with NPH, only approximately 5% of those with NPH are currently treated with a surgically implanted shunt. Based on these current treatment statistics, we estimate that the market opportunity for shunt systems designed to treat NPH is approximately \$35 million. Certain reports estimate that approximately 20% of total cerebrospinal fluid shunt sales address normal pressure hydrocephalus. Based on the NPH population as a whole, the potential market opportunity exceeds \$500 million.

Small Bone And Joint Fixation Devices and Instruments. Our line of Newdeal foot and ankle surgery devices address the reconstructive and fracture repair portion of the orthopedic market. The Newdeal line of implants include a wide range of products for the forefoot, the mid-foot and the hind foot, including the Bold® Screw, the Uniclip® Compression Staple, the Hallu-Fix® plate system and the HINTEGRA® total ankle prosthesis. These implants and the instruments used to implant them are specifically designed for foot and ankle surgery. We estimate that the current Newdeal products address an approximately \$500 million worldwide market.

 $Hemodynamic\ Shunts$ . Our Sundt<sup>TM</sup> and other carotid shunts are used to divert blood to vital organs, such as the brain, during surgical procedures involving blood vessels.

### **Instruments**

Neurosurgical Systems For Tissue Ablation. More than 145,000 primary and metastatic brain tumors are diagnosed annually in the United States alone. Our Selector® Integra Ultrasonic Aspirator, Dissectron® Ultrasonic Surgical Aspirator and Sonotom® Ultrasonic Surgical Aspirator systems address surgeons' needs for the surgical fragmentation and removal of malignant and non-malignant tumors and other tissue on a worldwide basis.

The Selector® Integra Ultrasonic Aspirator, Dissectron® Ultrasonic Surgical Aspirator and Sonotom® Ultrasonic Surgical Aspirator systems use very high frequency sound waves to ablate cancer tumors and allow the surgeon to remove the damaged tumor tissue by aspiration. Unlike other surgical techniques, ultrasonic surgery selectively dissects and fragments soft tissue leaving fibrous tissues such as nerves and blood vessels intact. Ultrasonic aspiration facilitates the removal of unwanted tissue adjacent or attached to vital structures. The Selector® product is indicated for use in

general, gynecological, urological, plastic and reconstructive, orthopedic, thoracic and thorascopic surgery procedures. We offer the Dissectron® and Sonotom® products only outside the United States.

The Elektrotom®, offered only outside the United States, is an electrosurgery system used to cut and coagulate selected tissue, automatically regulating and adapting the power required for the target tissue. The system is available with both monopolar and bipolar handpieces and accessories.

Cranial Stabilization And Brain Retraction Systems. The MAYFIELD® Headrest System is a market leader in cranial stabilization equipment. We work closely with surgeons and other health care providers throughout the world to develop unique cranial stabilization products.

*JARIT*<sup>®</sup> *Surgical Instruments*. For more than 30 years, JARIT has marketed a wide variety of high quality, reusable surgical instruments to virtually all surgical disciplines. With more than 5,000 instrument patterns and a 98% order fill rate, the JARIT brand has a strong reputation for high-quality surgical instruments and customer service.

Neurosurgical And Spinal Instrumentation. We provide neurosurgeons and spine surgeons with a full line of specialty hand-held spinal and neurosurgical instruments. We sell instruments under the R&B Redmond<sup>TM</sup> name primarily for spinal procedures (including neuro-spine) and instruments under the Ruggles<sup>TM</sup> brand name primarily for cranial surgery.

Plastic and Reconstructive Instruments. We market a wide variety of high quality, reusable surgical instruments under the Padgett Instruments<sup>TM</sup> brand to plastic and reconstructive surgeons, burn surgeons, ENT surgeons, hospitals, surgery centers and other physicians.

Dermatomes and Meshers. We sell a range of manual, air- and electric-powered dermatomes and related disposables for harvesting skin grafts. In 2003, we launched our new Padgett Dermatome-S, which is lighter, more ergonomic and more powerful than the other dermatomes in our line. Our variable skin mesher is designed to expand skin grafts prior to implantation to provide for greater coverage.

Spinal Specialties. Spinal Specialties' products include the OsteoJect<sup>TM</sup> Bone Cement Delivery System and the ACCU-DISC<sup>TM</sup> Pressure Monitoring System. Physicians use these products in a variety of spinal, orthopedic and pain management procedures. The OsteoJect product allows precise delivery of bone cement to a surgical site under active fluoroscopy by a surgeon whose hands remain outside the fluoroscopy field. The ACCU-DISC, which is used to interpret discography results, offers the accurate delivery of fluids to the body and the ability to monitor the fluids in discography interpretation.

### **Private Label Products**

Orthopedic Biomaterials. Since 1994, we have supplied Wyeth BioPharma with Absorbable Collagen Sponges for use in developing bone regeneration implants, including use with Wyeth BioPharma's recombinant human bone morphogenetic protein-2 (rhBMP-2), which Wyeth BioPharma is developing for clinical evaluation in several areas of bone repair and augmentation, including orthopedic, oral and maxillofacial surgery applications. We sell Absorbable Collagen Sponges for spinal applications through a related collaboration with Medtronic Sofamor Danek in North America. The FDA has approved Medtronic Sofamor Danek's InFUSE<sup>TM</sup> Bone Graft used with the LT-CAGE<sup>TM</sup> Lumbar Tapered Fusion Device and the INTER FIX and INTER FIX Threaded Fusion Devices for use in spinal fusion procedures. The InFUSE Bone Graft uses rhBMP-2 applied to our Absorbable Collagen Sponge in place of a painful secondary procedure to harvest small pieces of bone from the patient's own hip (autograft). When used with the LT-CAGE<sup>TM</sup> Lumbar Tapered Fusion Device and the INTER FIX and INTER FIX Threaded Fusion Devices, the InFUSE<sup>TM</sup> Bone Graft is indicated to treat certain types of spinal degenerative disc disease, a common cause of low back pain. InFUSE received a new PMA Approval from the FDA in 2004 for the treatment of open, acute tibial shaft fractures.

Guided Tissue Regeneration In Periodontal Surgery. Our BioMend® Absorbable Collagen Membrane is used for guided tissue regeneration in periodontal surgery. The BioMend® membrane is inserted between the gum and the tooth after surgical treatment of periodontal disease, preventing the gum tissue from interfering with the regeneration of the periodontal ligament that holds the tooth in place. The body absorbs the BioMend® product after approximately four to seven weeks, avoiding the requirement for additional surgical procedures to remove a non-absorbable membrane. The BioMend® Extend product has the same indication for use as the BioMend® product, except that it absorbs in approximately 16 weeks. The BioMend® and BioMend® Extend Absorbable Collagen Membranes are sold through Zimmer Holdings, Inc.

Other Private Label Products. Our current private label products also include the VitaCuff® catheter access infection control device, the BioPatch® anti-microbial wound dressing and a wide range of absorbable collagen products for hemostasis.

### **Distribution Channels**

We sell our products through various direct sales forces and a variety of other distribution channels. Our direct sales forces include the following:

Integra NeuroSciences<sup>TM</sup>. Integra NeuroSciences' direct marketing effort in the United States and Europe currently involves more than 130 professionals, including direct salespeople (called neurospecialists in the United States), sales management, and clinical educators who educate and train both our salespeople and customers in the use of our products. Our Integra NeuroSciences<sup>TM</sup> sales force sells our monitoring products (including Camino, LICOX, Ventrix and Neurosensor monitoring lines, cranial access kits, external ventricular and lumbar monitoring and drainage products and epilepsy electrodes), our neurosurgical operating room products (including the DuraGen<sup>®</sup>, DuraGen Plus<sup>TM</sup>, EnDura<sup>TM</sup> and NeuraGen<sup>TM</sup> products, the NPH<sup>TM</sup> Low Flow Hydrocephalus Valve and the Selector Integra Ultrasonic Aspirator) and the Ruggles line of neurosurgical instruments. These salespeople call primarily on neurosurgeons and intensive care units that are capable of managing neuro-trauma cases. We believe that we effectively address this focused group of hospital-based practitioners through our direct Integra NeuroSciences<sup>TM</sup> sales and marketing infrastructure in the United States and in parts of Europe and our distribution network elsewhere.

Reconstructive Surgery. Our reconstructive surgery sales and marketing organization in the United States and Europe consists of approximately 50 professionals, including direct salespeople, sales management, clinical educators and marketing managers. This sales and marketing organization sells the Newdeal line of orthopedic implants, devices and instruments, the INTEGRA® Dermal Regeneration Template, the INTEGRA™ Bilayer Matrix Wound Dressing, the NeuraGen™ Nerve Guide, the NeuraWrap™ Nerve Protector, Padgett dermatomes and meshers, and a wide variety of high quality surgical instruments and implants to orthopedic surgeons, podiatric surgeons, trauma and reconstructive surgeons, burn surgeons, hospitals, surgery centers and other physicians.

JARIT Surgical Instruments Our JARIT organization sells its products to more than 5,200 hospitals and surgery centers worldwide. In the United States, JARIT employs a 20-person sales management force that works with over 100 distributor sales representatives. The JARIT organization sells the JARIT line of general and specialty instruments for open and endoscopic surgery and a line of specialty instruments for spinal and neurosurgery.

*Private Label.* We market our private label products through strategic partners or original equipment manufacturer customers. Our private label products address large, diverse markets, and we believe that we can develop and promote these products more cost-effectively through leveraging the product development and distribution systems of our strategic partners than through developing the products ourselves or selling them through our own direct sales infrastructure. We have partnered with market leaders, such as Johnson & Johnson, Medtronic, Wyeth and Zimmer, for the development and marketing efforts related to many of these products.

We have established a reputation as a value-added and dependable development and manufacturing partner. Many of our current private label products are built on our expertise in absorbable collagen products. In addition, we have expertise

in the development, manufacture and supply of a variety of absorbable materials and can provide experienced personnel to support product quality and regulatory review efforts.

### RESEARCH AND DEVELOPMENT STRATEGY

Our research and development programs focus on developing new products based on our materials and collagen engineering technologies and our expertise in fiber optics, ultrasonic technology and surgical fixation. We spent \$14.1 million, \$12.8 million and \$11.5 million in 2004, 2003 and 2002, respectively, on research and development activities. The 2004 amount includes a \$1.4 million milestone payment relating to the completion of certain development activities for an advanced neuromonitoring system and a \$0.5 licensing fee paid for the development of a data acquisition system to support the integration of our advanced monitoring products. The 2003 and 2002 amounts include \$400,000 and \$2.3 million, respectively, of acquired in-process research and development charges recorded in connection with acquisitions. In addition to internal research and development activities, we may continue to use our capital resources to acquire businesses that include research and development programs, which could result in additional in-process research and development charges in the future. We also receive contract development revenues and government grant funding which support a portion of our research and development activities. Research and development activities funded by contract development and government grant revenues amounted to \$4.5 million and \$3.5 million in 2003 and 2002, respectively.

We have either acquired or secured the proprietary rights to several important technological and scientific platforms, including collagen matrix, intracranial monitoring, ultrasonic tissue ablation and implantable fixation technologies. These technologies provide support for our critical applications in neurosurgery and tissue regeneration with additional opportunities for generating near-term and long-term revenues from medical applications. We have been able to identify and bring together critical platform technology components from which we work to develop products for both tissue regeneration and neurosurgical applications. These efforts have led to the successful development of new products, such as the NeuraGen<sup>TM</sup> Nerve Guide, the NeuraWrap<sup>TM</sup> Nerve Protector, the DuraGen Plus<sup>TM</sup> Dural Regeneration Matrix, the DuraGen Plus<sup>TM</sup> Adhesion Barrier Matrix (CE Approved), the INTEGRA® Dermal Regeneration Template – TS and the INTEGRA<sup>TM</sup> Matrix Wound Dressing.

We regularly review our research and development programs to ensure that they remain consistent with and supportive of our growth strategies.

#### **GOVERNMENT REGULATION**

As a manufacturer of medical devices, we are subject to extensive regulation by the FDA 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 and promotion of the devices, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the export of devices and other matters. We believe that we are in substantial compliance with these governmental regulations.

From time to time, we have recalled certain of our products. We have recalled defective components or devices supplied by other vendors, kits assembled by us that included incorrect combinations of products and defective devices manufactured by us. None of these recalls resulted in a material direct expense to us or a long-term disruption of an important customer or supplier relationship. However, a future voluntary or involuntary recall of one of our major products, particularly if it involved a potential or actual risk to patients, could have an adverse financial impact on us as a result both of direct expenses and disrupted customer relationships.

The FDA requires, as a condition of marketing a medical device in the United States, that we secure a Premarket Notification clearance pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, an approved PMA application or a supplemental PMA application. Alternatively, we may seek United States market clearance through a Product Development Protocol approved by the FDA. Establishing and completing a Product Development Protocol, or obtaining a PMA application or supplemental PMA application, can take up to several years and can involve preclinical

studies and clinical testing. To perform clinical testing in the United States on an unapproved product, we are also required to obtain an Investigational Device Exemption from the FDA. In addition to requiring clearance for new products, FDA rules may require a filing and FDA approval, usually through a PMA application supplement or a 510(k) Premarket Notification clearance, prior to marketing products that are modifications of existing products or new indications for existing products. The FDA Medical Device User Fee and Modernization Act of 2002 (MDUFMA) imposes user fees payable to FDA for submission of Premarket Notifications, PMA applications, Product Development Protocols, certain supplemental PMA applications and other types of FDA submissions. The regulatory process of obtaining product approvals/clearances can be onerous and costly.

We may not receive the necessary regulatory approvals, including approval for product improvements and new products, on a timely basis, if at all. Delays in receipt of, or failure to receive, regulatory approvals could have a material adverse effect on our business. Moreover, after clearance 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. In addition, federal, state and foreign regulations regarding the manufacture and sale of medical devices are subject to future changes. We cannot predict what impact, if any, these changes might have. These changes, however, could have a material impact on our business.

We have received or acquired more than 245 Premarket Notification 510(k) clearances, five approved PMA applications and 57 supplemental PMA applications. We expect to file new applications during the next year to cover new products and variations on existing products.

We are also required to register with the FDA as a device manufacturer. As such, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality Systems 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 for labeling and promotion. The Medical Device Reporting regulations require that we provide information to the FDA whenever there is evidence to reasonably suggest that one of our devices may have caused or contributed to a death or serious injury or, if a malfunction were to recur, could cause or contribute to a death or serious injury. In addition, the FDA prohibits us from promoting a medical device before marketing clearance has been received or promoting an approved device for unapproved indications. Under FDA regulations, we are required to submit reports of certain voluntary recalls and corrections to FDA. If the FDA believes that a company is not in compliance with applicable regulations, it can institute proceedings to detain or seize products, issue a warning letter, issue a recall order, impose operating restrictions, enjoin future violations and assess civil penalties against that company, its officers or its employees and can recommend criminal prosecution to the Department of Justice. These actions could have a material impact on our business. Other regulatory agencies may have similar powers.

Medical Device Regulations also are in effect in many of the countries outside the United States in which we do business. These laws range from comprehensive 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. In June 1998, the European Union Medical Device Directive became effective, and all medical devices must meet the Medical Device Directive standards and receive CE Mark certification. CE Mark certification requires a comprehensive Quality System program and submission of data on a product to the Notified Body in Europe. 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 (an organization designated by the national governments of the European Union member states to make independent judgments about whether or not a product complies with the protection requirements established by each CE marking directive) audits our facilities annually to verify our compliance with these standards. In 2004, each of our certified facilities was audited, and we have maintained our certification to these standards.

In addition, we are required to notify the FDA if we export specified medical devices manufactured in the United States that have not been approved by the FDA for distribution in the United States. We are also required to maintain certain

records relating to exports and make the records available to the FDA for inspection, if required. We currently export medical devices manufactured in the United States that have not been approved by the FDA.

### OTHER UNITED STATES REGULATORY REQUIREMENTS

In addition to the regulatory framework for product approvals, we are and may be subject to regulation under federal and state laws, including requirements regarding occupational health and safety; laboratory practices; the maintenance of personal health information; sales and marketing practices, including product discounting practices; and the use, handling and disposal of toxic or hazardous substances. We may also be subject to other present and possible future local, state, federal and foreign regulations.

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 an accident, we could be held liable for any damages that 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.

### PATENTS AND INTELLECTUAL PROPERTY

We seek patent protection of our key technology, products and product improvements both in the United States and in selected foreign countries. When determined appropriate, we have enforced and plan to continue to enforce and defend our patent 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 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.

ACCU-DISCTM, BioMend®, Bold®, BUDDE®, CALCANEA®, Camino®, CollaCote®, CollaPlug®, CollaStatTM, CollaTape®, Dissectron®, DuraGen®, DuraGen PlusTM, Elektrotom®, EquiFlow®, Hallu-Fix®, Helistat®, Helitene®, Heyer-Schulte®, HINTEGRA®, INTEGRATM, INTEGRATM Bilayer Matrix Wound Dressing, INTEGRA® Dermal Regeneration Template, Integra NeuroSciencesTM, Integra NeuroSuppliesTM, Integra SuppliesTM, JARIT®, LICOX®, LPV®, Moni-Torr®, NeuraGenTM, NeuraWrapTM, Neurosensor®, Orbis-Sigma®, Osteoject®, Padgett Instruments, Inc®, PudenzTM, RedmondTM, RugglesTM, Selector®, Sonotom®, Spetzler®, Spin®, Spinal Specialties®, SundtTM, Uniclip®, Ventrix®, VitaCuff® are some of the trademarks of Integra and its subsidiaries. All other brand names, trademarks and service marks appearing in this report are the property of their respective holders.

#### **COMPETITION**

Our largest competitors in the neurosurgery markets are the Medtronic Neurotechnologies division of Medtronic, Inc., the Codman division of Johnson & Johnson, the Aesculap division of B. Braun and the Valleylab division of Tyco International Ltd. In addition, many of our neurosurgery product lines compete with smaller specialized companies or larger companies that do not otherwise focus on neurosurgery.

Our largest competitors in reconstructive surgery are Smith and Nephew plc, LifeCell Corporation, Organogenesis Inc., Wright Medical Group, Inc., the DePuy division of Johnson & Johnson and Synthes, Inc.

We believe that we are the second largest re-usable surgical instrument company in the United States. The largest re-usable instrument company is V. Mueller, a division of Cardinal Healthcare. In addition, the Codman division of Johnson & Johnson and many smaller instrument companies compete with both re-usable and disposable specialty instruments. We rely on the depth and breadth of our sales and marketing organization 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, rather than any particular product (such as autograft tissue as a substitute for the INTEGRA® Dermal Regeneration Template, our duraplasty products, the NeuraGen<sup>TM</sup> Nerve Guide and NeuraWrap<sup>TM</sup> Nerve Protector). 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.

#### **EMPLOYEES**

At December 31, 2004, we had approximately 922 full-time employees and 214 temporary 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 Belgium, France and Germany, none of our current employees are subject to a collective bargaining agreement.

Many of our employees, including those holding senior positions in our regulatory, operations, research and development, and sales and marketing departments, were recruited from large pharmaceutical or medical technology companies. Our sales representatives and regional sales managers attend in-depth product training meetings throughout the year, and our clinical development team consists of medical professionals who specialize in specific therapeutic areas that our products serve. We believe that our clinical development team differentiates us from our competition, as their knowledge and experience as medical professionals allows them to more effectively educate and train both our sales force and the customers who use our products. This team is especially valuable in communicating the clinical benefits of new products.

### AVAILABLE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, which we refer to as 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 <a href="https://www.Integra-LS.com">www.Integra-LS.com</a>. 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 450 Fifth Street, N.W. in Washington, D.C. 20549, or at the SEC's Internet site at <a href="https://www.sec.gov">www.sec.gov</a>. Please call the Securities and Exchange Commission at 1-800-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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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;
- 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 and our ability to secure regulatory approval for products in development;
- 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 "Factors That May Affect Our Future Performance" in this report.

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

We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

#### FACTORS THAT MAY AFFECT OUR FUTURE PERFORMANCE

### **Our Operating Results May Fluctuate.**

Our operating results, including components of operating results, such as gross margin on product sales, may fluctuate from time to time, which 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:

- the impact of acquisitions;
- the timing of significant customer orders;
- market acceptance of our existing products, as well as products in development;
- the timing of regulatory approvals;
- the timing of payments received and the recognition of those payments as revenue under collaborative arrangements and other alliances;
- changes in the rate of exchange between the U.S. dollar, the euro and the British pound;
- expenses incurred and business lost in connection with product field corrections or recalls;
- · our ability to manufacture our products efficiently; and
- the timing of our research and development expenditures.

### Non-Cash Compensation Charges May Affect Our Future Earnings.

In December 2004, the Financial Accounting Standards Board issued Statement No. 123 (revised 2004), "Share-Based Payment," which is a revision of Statement No. 123, "Accounting for Stock-Based Compensation." Statement 123(R) replaces APB Opinion No. 25, "Accounting for Stock Issued to Employees". Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value.

Statement 123(R) must be adopted no later than July 1, 2005, and we expect to adopt Statement 123(R) on July 1, 2005. For purposes of disclosing pro forma financial results in our financial statements as if compensation cost for our stock

option plans had been determined based on the fair value at the grant consistent with the provisions of Statement No. 123, we historically estimated the fair value of stock options granted prior to October 1, 2004 using the Black-Scholes valuation model. However, we estimated the pro forma additional compensation expense related to all options granted on or after October 1, 2004 using a binomial distribution model. Management believes that the binomial distribution model is preferable to the Black-Scholes model because the binomial distribution model is a more flexible model that considers the impact of non-transferability, vesting and forfeiture provisions in the valuation of employee stock options. Because Statement 123(R) prohibits pro forma footnote disclosure as an alternative to financial statement recognition, management is currently evaluating the potential impact that Statement 123(R) will have on our future results of operations. Previous estimates of option values using the Black-Scholes method may not be indicative of results from applying the binomial distribution model for valuing future option grants.

### 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, the medical technology industry is characterized by intense competition. We compete with established medical technology and pharmaceutical companies. 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 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 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 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 have recently introduced an onlay dural graft matrix, and other companies may be preparing to introduce similar products. The introduction of such products could reduce the sales, growth in sales and profitability of our duraplasty products, including our DuraGen®, DuraGen Plus<sup>TM</sup> and EnDura<sup>TM</sup> product lines, which are among our largest and fastest growing products.

Our largest competitors in the neurosurgery markets are the Medtronic Neurotechnologies division of Medtronic, Inc., the Codman division of Johnson & Johnson, the Aesculap division of B. Braun and the Valleylab division of Tyco International Ltd. In addition, many of our product lines compete with smaller specialized companies or larger companies that do not otherwise focus on neurosurgery. Our reconstructive surgery business is small compared to its principal competitors, which include major medical device and wound care companies such as Smith and Nephew plc, LifeCell Corporation and Organogenesis Inc., as well as companies focused on foot and ankle surgeons including Wright Medical Group, Inc., the DePuy division of Johnson & Johnson and Synthes, Inc. 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, rather than any particular product, such as autograft tissue as an alternative for the INTEGRA® Dermal Regeneration Template, our duraplasty products and the NeuraGen<sup>TM</sup> Nerve Guide.

### 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 internal growth, our current strategy involves growth through acquisitions. Since 1999, we have acquired 20 businesses or product lines at a total cost of approximately \$213 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 potential acquisitions may 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. As we grow by acquisitions, we must integrate and manage the new businesses to 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 new markets with 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 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. Future acquisitions may also result in potentially dilutive issuances of securities.

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.

Our research and development activities and the manufacturing, labeling, distribution and marketing of our existing and future products are subject to regulation by numerous governmental agencies in the United States and in other countries. The Food and Drug Administration (FDA) and comparable agencies in other countries impose mandatory procedures and standards for the conduct of clinical trials and the production and marketing of products for diagnostic and human therapeutic use.

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 full of uncertainties. 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. 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. In addition, for products with an approved PMA, the FDA requires annual reports and may require post-approval surveillance programs to monitor the products' safety and effectiveness. Results of post-approval programs may limit or expand the further marketing of the product.

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 legal 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.

The FDA and foreign regulatory authorities require that our products be manufactured according to rigorous standards. These regulatory requirements may significantly increase our production or purchasing costs and may 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 may mean that even if we develop promising new products, we may 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, and civil and criminal penalties.

We are also subject to the regulatory requirements of countries outside of the United States where we do business. For example, Japan is in the process of reforming its medical device regulations. A recent amendment to Japan's Pharmaceutical Affairs Law goes into effect on April 1, 2005. New regulations and requirements will 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 also may be needed to comply with the extensive auditing of all manufacturing facilities of our company and our vendors by 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 as well as maintain the certain businesses in Japan. Sales in Japan accounted for approximately \$3.1 million of our revenues in 2004.

## Certain Of Our Products Contain Materials Derived From Animal Sources And May Become Subject To Additional Regulation.

Certain of our products, including the DuraGen® Dural Graft Matrix, DuraGen Plus<sup>TM</sup> Dural Regeneration Matrix and DuraGen Plus<sup>TM</sup> Adhesion Barrier Matrix products, the NeuraGen<sup>TM</sup> Nerve Guide, the NeuraWrap<sup>TM</sup> Nerve Protector, the INTEGRA® Dermal Regeneration Template, the INTEGRA<sup>TM</sup> Bilayer Matrix and INTEGRA<sup>TM</sup> Matrix Wound Dressing, the Helistat®/Helitene® Absorbable Collagen Hemostatic Agents, our Absorbable Collagen Sponges, the CollaCote®, CollaTape® and CollaPlug® Absorbable Wound Dressings and the BioMend® and BioMend® Extend Absorbable Collagen Membranes, contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food as well as pharmaceuticals and medical devices, are increasingly subject to scrutiny in the press 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 cattle, 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. Recent cases of BSE in cattle discovered in Canada and the United States 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, the collagen used in the manufacture of our products is derived only from the deep flexor tendon of cattle from the United States that are less than 24 months old. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon, the sole source of our collagen, 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 (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.

In addition, we have been notified that Japan has issued new regulations regarding medical devices that contain tissue of animal origin. Among other regulations, Japan may require 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 United States and have qualified a source of tendon from New Zealand, a country which has never had a case of BSE. If we cannot continue to 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 hemostatic agents and products for oral surgery in Japan. We do not currently sell our dural or skin repair products in Japan.

### 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® 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, we cannot be certain that the medical community will accept the NeuraGen<sup>TM</sup> Nerve Guide over conventional microsurgical techniques for connecting severed peripheral nerves.

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 may be too high to justify development. Competitors may develop products that are more effective, cost less or are ready for commercial introduction before our products. For example, our sales of shunt products could decline if neurosurgeons increase their use of programmable valves and we fail to introduce a competitive product, or our sales of certain catheters may be adversely affected by the recent introduction by other companies of catheters that contain anti-microbial agents intended to reduce the incidence of infection after implantation. 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, limited funding available for product and technology acquisitions by our customers, as well as internal obstacles to customer approvals of purchases of our products, could harm acceptance of our products. The industry is subject to rapid and continuous change arising from, among other things, consolidation and technological improvements. One or more of these factors may vary unpredictably, which could materially adversely affect 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, Which Could Enable Third Parties To Use Our Technology Or Very Similar Technology And Could Reduce Our Ability To Compete In The Market.

Our ability to compete effectively depends 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 certain of our product lines. However, you should not rely on our patents to provide us with any significant competitive advantage. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. Competitors may develop products similar to ours that our patents do not cover. In addition, our current and future patent applications may not result in the issuance of patents in the United States or foreign countries. Further, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications usually takes from 18 to 24 months.

### 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. Trade secrets 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, or 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, which could have a material adverse effect on our revenues and profitability.

### 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 supply interruption in a limited or sole source component or raw material could harm our ability to manufacture our products until a new 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 INTEGRA® Dermal Regeneration Template, DuraGen® Dural Graft Matrix and DuraGen Plus<sup>TM</sup> Dural Regeneration products, and our Absorbable Collagen Sponges;
- our products made from silicone, such as our neurosurgical shunts and drainage systems and hemodynamic shunts;
- products which use many different electronic parts from numerous suppliers, such as our Camino<sup>®</sup>, Ventrix<sup>®</sup> and NeuroSensor<sup>TM</sup> lines of intracranial monitors and catheters.

If we were suddenly unable to purchase products from one or more of these companies, we could 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 due to 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, California facility that manufactures our Camino® and Ventrix® product line is as susceptible to earthquake damage, wildfire damage and power losses from electrical shortages as are other businesses in the Southern California area. Our silicone manufacturing plant in Anasco, Puerto Rico is vulnerable to hurricane damage. Although we maintain property damage and business interruption insurance coverage on these facilities, 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, we are implementing in several stages over several years an enterprise business system for use in all of our facilities. This system will replace several systems on which we now rely. We have outsourced our product distribution function in the United States and are also planning to outsource our European product distribution function. A delay or other problem with the system or in our implementation schedule for either of these initiatives could have a material adverse effect on our operations.

### We May Be Involved In Lawsuits To Protect Or Enforce Our Intellectual Property Rights, Which May Be Expensive.

To protect or enforce our intellectual property rights, we may have to initiate legal proceedings, such as infringement suits or interference proceedings, against third parties. Intellectual property 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. We may also provoke these third parties to assert claims against us.

### We Are Exposed To A Variety Of Risks Relating To Our International Sales And Operations, Including Fluctuations In Exchange Rates, Local Economic Conditions And Delays In Collection Of Accounts Receivable.

We generate significant revenues outside the United States in euros, British pounds 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 an impact on the demand for our products in foreign countries where the U.S. dollar has increased in value compared to the local currency.

Because we have operations based in Europe and we generate revenues and incur operating expenses in euros and British pounds, we experience currency exchange risk with respect to those foreign currency-denominated revenues and expenses. In 2003 and 2004, the cost of products we manufactured in our European facilities or purchased in foreign currencies exceeded our foreign currency-denominated revenues. We expect this imbalance to continue. Accordingly, a further weakening of the dollar against the euro and British pound could negatively affect future gross margins and operating margins.

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

Changes In The Health Care Industry May Require Us To Decrease The Selling Price For Our Products Or May Reduce The Size Of The Market For Our Products, Either Of Which Could Have A Negative Impact On Our Financial Performance.

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

- major third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and
  private health care insurers, have substantially revised their payment methodologies, which has resulted in stricter
  standards for reimbursement of hospital charges for certain medical procedures;
- Medicare, Medicaid and private health care insurer cutbacks could create downward price pressure on our products;
- numerous legislative proposals have been considered that would result in major reforms in the U.S. health care system that could have an adverse effect on our business;
- there has been a consolidation among health care facilities and purchasers of medical devices in the United States
  who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may
  decide to stop purchasing our products or demand discounts on our prices;
- we are party to contracts with group purchasing organizations 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 health care costs in 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 health care industry; 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.

### Regulatory Oversight Of The Medical Device Industry Might Affect The Manner In Which We May Sell Medical Devices

There are laws and regulations that regulate the means by which companies in the health care industry may market their products to health care professionals and may compete by discounting the prices of their products. 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, we believe that the sales and marketing practices of our industry will be subject to increased scrutiny from government agencies.

### Our Private Label Business Depends Significantly On Key Relationships With Third Parties, Which We May 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. 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 Other Regulatory Requirements Relating To Occupational Health And Safety And The Use Of Hazardous Substances Which May Impose Significant Compliance Costs On Us.

We are subject to regulation under federal and state laws regarding occupational health and safety, laboratory practices and the use, handling and disposal of toxic or hazardous substances. Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. Although we believe that our safety procedures for handling and disposing of those materials comply with the standards prescribed by the applicable laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any related liability could exceed the limits or fall outside the coverage of our insurance and could exceed our resources. We may not be able to maintain insurance on acceptable terms or at all. We may incur significant costs to comply with environmental laws and regulations in the future. We may also be subject to other present and possible future local, state, federal and foreign regulations.

### 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.

### **ITEM 2. PROPERTIES**

Our principal executive offices are located in Plainsboro, New Jersey. Principal manufacturing and research facilities are located in Plainsboro, New Jersey, Cincinnati, Ohio, San Diego, California, Anasco, Puerto Rico, Andover, England, Biot, France, Lyon, France, Mielkendorf, Germany and Tuttlingen, Germany. Our primary distribution centers are located in Sparkes, Nevada, Hawthorne, New York, Andover, England, Biot, France, Vilvoorde, Belgium and Lyon, France. In addition, we lease several smaller facilities to support additional administrative, assembly, and distribution operations. We lease all of our facilities other than our facilities in Andover, England, Biot, France and Tuttlingen, Germany, which we own.

All of our manufacturing and distribution 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

In July 1996, we filed a patent infringement lawsuit in the United States District Court for the Southern District of California (the "Trial Court") against Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps, seeking damages and injunctive relief. The complaint charged, among other things, that the defendant Merck KGaA willfully and deliberately induced, and continues willfully and deliberately to induce, defendants Scripps Research Institute and Dr. Cheresh to infringe certain of our patents. These patents are part of a group of patents granted to The Burnham Institute and licensed by us that are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid ("RGD") peptide sequence found in many extracellular matrix proteins. The defendants filed a countersuit asking for an award of defendants' reasonable attorney fees.

In March 2000, a jury returned a unanimous verdict in our favor and awarded us \$15.0 million in damages, finding that Merck KGaA had willfully infringed and induced the infringement of our patents. The Trial Court dismissed Scripps and Dr. Cheresh from the case.

In October 2000, the Trial Court entered judgment in our favor and against Merck KGaA in the case. In entering the judgment, the Trial Court also granted to us pre-judgment interest of approximately \$1.4 million, bringing the total award to approximately \$16.4 million, plus post-judgment interest. Merck KGaA filed various post-trial motions requesting a judgment as a matter of law notwithstanding the verdict or a new trial, in each case regarding infringement, invalidity and damages. In September 2001, the Trial Court entered orders in favor of us and against Merck KGaA on the final post-judgment motions in the case, and denied Merck KGaA's motions for judgment as a matter of law and for a new trial.

Merck KGaA and we each appealed various decisions of the Trial Court to the United States Court of Appeals for the Federal Circuit (the "Circuit Court"). In June 2003, the Circuit Court affirmed the Trial Court's finding that Merck KGaA had infringed our patents. The Circuit Court also held that the basis of the jury's calculation of damages was not clear from the trial record, and remanded the case to the Trial Court for further factual development and a new calculation of damages consistent with the Circuit Court's decision. Merck KgaA filed a writ for certiorari with the United States Supreme Court seeking review of the Circuit Court's decision, and the Supreme Court granted the writ in January 2005. Oral arguments are scheduled for April 2005, and we expect the Supreme Court to render a decision before the end of the current term.

In September 2004, the Trial Court ordered Merck KgaA to pay us \$6.4 million in damages following the Circuit Court's order. Further enforcement of the Trial Court's order has been stayed pending the decision of the Supreme Court.

We have not recorded any gain in connection with this matter, pending final resolution and completion of the appeals process.

In addition to the Merck KGaA matter, we are subject to various claims, lawsuits and proceedings in the ordinary course of our business, including claims by current or former employees and distributors 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.

Three of our French subsidiaries that were acquired from the neurosciences division of NMT Medical, Inc. received a tax reassessment notice from the French tax authorities seeking in excess of 1.7 million euros in back taxes, interest and penalties. Following objection from NMT Medical, the amount claimed by the authorities was reduced to 930,367 euros, and negotiations and other procedures are under way, which may lead to a further reduction of the amount owed. NMT Medical, the former owner of these entities, has agreed to indemnify us against direct damages and liability arising

from misrepresentations in connection with these tax claims. In addition, NMT Medical, Inc. has agreed to provide the French tax authorities with payment of the tax liabilities on behalf of each of these subsidiaries.

### 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.

### ADDITIONAL INFORMATION:

The following information is furnished in this Part I pursuant to Instruction 3 to Item 401(b) of Regulation S-K.

### **Executive Officers of the Company**

Our executive officers are elected annually and serve at the discretion of the Board of Directors. The only family relationship between any of our executive officers and directors is that Mr. Holtz is the nephew of Richard E. Caruso, Ph.D., the Chairman of the Board of Directors. The following information indicates the position and age of our executive officers as of the date of this report and their previous business experience.

NAME	AGE	POSITION
Stuart M. Essig	43	President, Chief Executive Officer and Director
Gerard S. Carlozzi	49	Executive Vice President, Chief Operating Officer
John B. Henneman, III	43	Executive Vice President, Chief Administrative Officer and Secretary
David B. Holtz	38	Senior Vice President, Finance and Treasurer
Deborah A. Leonetti	49	Senior Vice President, Marketing
Donald R. Nociolo	42	Senior Vice President, Operations
Judith E. O'Grady	54	Senior Vice President, Regulatory, Quality Assurance and Clinical Affairs
Robert D. Paltridge	47	Senior Vice President, Global Sales

Stuart M. Essig has served as President and Chief Executive Officer and a director of Integra since December 1997. Before joining Integra, Mr. Essig supervised the medical technology practice at Goldman, Sachs & Co. as a managing director. Mr. Essig had ten years of broad health care experience at Goldman Sachs serving as a senior merger and acquisitions advisor to a broad range of domestic and international medical technology, pharmaceutical and biotechnology clients. Mr. Essig received an A.B. degree from the Woodrow Wilson School of Public and International Affairs at Princeton University and an MBA and a Ph.D. degree in Financial Economics from the University of Chicago, Graduate School of Business. Mr. Essig also serves on the Board of Directors of St. Jude Medical Corporation and ADVAMED, the Advanced Medical Technology Association.

Gerard S. Carlozzi is Integra's Executive Vice President and Chief Operating Officer, and is responsible for the company's marketing, sales, manufacturing, distribution and research and development functions. Mr. Carlozzi joined Integra in September 2003, after serving as a consultant to the Company from March 2003 to September 2003. Prior to joining Integra, Mr. Carlozzi had spent over 25 years in the medical device industry. From 1999 to 2003, he was President, Chief Executive Officer and a director of Bionx Implants, a company focused on the development of novel biomaterial devices for various surgical specialties. Prior to 1999, he held various management positions with Synthes USA, Acufex microsurgical and Infusaid Corporation. Mr. Carlozzi also serves on the Board of Directors of Cascade Medical Corporation, a privately held company. He received a BS degree in engineering and an MBA from Northeastern University.

John B. Henneman, III is Integra's Executive Vice President, Chief Administrative Officer and Secretary, and is responsible for the law department, regulatory affairs, corporate quality systems, clinical affairs, business development, human resources, information management and investor relations. Mr. Henneman was our General Counsel from September 1998 until September 2000 and our Senior Vice President, Chief Administrative Officer and Secretary from September 2000 until February 2003. Prior to joining Integra in August 1998, Mr. Henneman served Neuromedical Systems, Inc., a public company developer and manufacturer of in vitro diagnostic equipment, in various capacities for more than four years. Mr. Henneman received his A.B. from Princeton University and his J.D. from the University of Michigan Law School.

David B. Holtz joined Integra as Controller in 1993, served as Vice President, Finance and Treasurer from March 1997 to January 2001, and was promoted to Senior Vice President, Finance and Treasurer in February 2001. From August 2002 through October 2003, Mr. Holtz was given responsibility for managing Integra's European operations to support the transition of our acquisitions in Europe. His current responsibilities include managing all financial reporting and accounting functions. Before joining Integra, Mr. Holtz was an associate with Coopers & Lybrand, L.L.P. in Philadelphia and Cono Leasing Corporation, a private leasing company. He received a BS degree in Business Administration from Susquehanna University and has been certified as a public accountant.

Deborah A. Leonetti joined Integra in May of 1997 as Director of Marketing, was promoted to Vice President, Global Marketing in April 1999 and to Senior Vice President, Marketing in May 2004. Her responsibilities include worldwide strategic marketing for all Integra products. From September 1989 through May 1997, Ms. Leonetti worked for Cabot Medical, which was later acquired by Circon Corporation, and held positions in sales, sales training, and marketing. Prior to her experience at Cabot-Circon, Ms. Leonetti completed fifteen years of clinical practice as a registered nurse at St. Christopher's Hospital for Children in Philadelphia. She received her nursing degree from St. Joseph's Hospital School of Nursing and La Salle University.

Donald R. Nociolo joined Integra as Director of Manufacturing in 1994, and was promoted to Vice President, Operations in March 1997 and to Senior Vice President of Operations in May 2000. He is responsible for managing Integra's worldwide manufacturing and distribution operations. Mr. Nociolo has over sixteen years experience working in engineering and manufacturing management in the medical device industry. Six of those years were spent working at ETHICON, Inc., a division of Johnson & Johnson. Mr. Nociolo received a BS degree in Industrial Engineering from Rutgers University and an MBA in Industrial Management from Fairleigh Dickinson University.

Judith E. O'Grady has served as Senior Vice President of Regulatory Affairs, Quality Assurance and Clinical Affairs, since 1985. Ms. O'Grady has worked in the areas of medical devices and collagen technology for over 20 years. Prior to joining Integra, Ms. O'Grady worked for Colla-Tec, Inc., a Marion Merrell Dow Company. During her career she has held positions with Surgikos, a Johnson & Johnson Company, and was on the faculty of Boston University College of Nursing and Medical School. Ms. O'Grady led the team that obtained the FDA approval for INTEGRA® Dermal Regeneration Template, the first regenerative product approved by the FDA, and has led teams responsible for more than 500 FDA and international submissions. She received her BS degree from Marquette University and MSN in Nursing from Boston University.

Robert D. Paltridge joined Integra as National Sales Director in February 1995 and was appointed Vice President, North American Sales in September 1997. He was promoted to Vice President, Global Sales in October 2002 and Senior Vice President, Global Sales in January 2003. His responsibilities include managing the worldwide sales activities of Integra's three sales organizations and third-party distributors. Mr. Paltridge has 21 years of sales and sales management experience in the medical device industry. Before joining Integra, he was National Sales Manager at Strato Medical, a division of Pfizer, Inc. He received a BS degree in Business Administration from Rutgers University.

#### **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 National 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:

	HIGH	LOW
2004		
Fourth Quarter	\$37.36	\$29.41
Third Quarter	\$35.79	\$27.14
Second Quarter	\$36.00	\$29.76
First Quarter	\$33.86	\$28.74
2003		
Fourth Quarter	\$34.99	\$27.23
Third Quarter	\$30.65	\$23.39
Second Quarter	\$29.94	\$21.75
First Quarter	\$23.72	\$15.66

For purposes of calculating the aggregate market value of the shares of our voting stock held by non-affiliates, as shown on the cover page of this report, we have assumed that all outstanding shares not held by our directors and executive officers and stockholders owning 10% or more of outstanding shares were held by non-affiliates. However, this should not be deemed to constitute an admission that any such persons are, in fact, affiliates of ours. Further information concerning ownership of our voting stock by executive officers, directors and principal stockholders will be included in our definitive proxy statement for our upcoming Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

We have not paid any cash dividends on our common stock since our formation. 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 and financial condition and other factors deemed relevant by the Board of Directors.

The number of stockholders of record as of March 11, 2005 was approximately 480, which includes stockholders whose shares were held in nominee name.

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

We did not purchase any shares of our common stock during the quarter ended December 31, 2004.

In March 2004, our Board of Directors authorized us to repurchase up to 1.5 million shares of our common stock for an aggregate purchase price not to exceed \$40 million. We were authorized to repurchase shares under this program through December 31, 2004 either in the open market or in privately negotiated transactions. We purchased 500,000 shares for \$14.2 million under this program

### ITEM 6. SELECTED FINANCIAL DATA

The information set forth below should be read in conjunction with "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,			
	2004	2003	2002	2001	2000
		(in thousands, except per share data)		a)	
Operating Results:					
Total revenues (1)	\$229,825	\$185,599	\$117,822	\$ 93,442	\$ 71,649
Total operating costs and expenses (2)	205,046	145,952	98,635	79,156	83,370
Operating income (loss)	24,779	39,647	19,187	14,286	(11,721)
Interest income (expense), net	555	471	3,535	1,393	(473)
Gain on disposition of product line	_	_	_	_	1,146
Other income (expense), net (1)	2,674	3,071	3	(392)	201
Income (loss) before income taxes	28,008	43,189	22,725	(15,287)	(10,847)
Income tax expense (benefit) (3)	10,811	16,328	(12,552)	(10,876)	108
Net income (loss) before cumulative					
effect of accounting change	17,197	26,861	35,277	26,163	(10,955)
Cumulative effect of accounting change (5)	_	_	_	_	(470)
Net income (loss)	\$ 17,197	\$ 26,861	\$ 35,277	\$ 26,163	\$ (11,425)
Diluted net income (loss) per share (6)	\$ 0.55	\$ 0.86	\$ 1.14	\$ 0.92	\$ (0.97)
Weighted average shares outstanding	31,102	33,104	30,720	27,196	17,553
			December 3	R1	
	2004	2003	2002	2001	2000
			(in thousand		
Financial Position:			(	/	
Cash, cash equivalents, and marketable securities (4,7).	\$195,982	\$206,743	\$132,311	\$131,036	\$ 15,138
Total assets	456,713	412,526	274,668	227,588	86,514
Long-term debt (7)	118,900	119,257	_	_	4,758
Accumulated deficit	(265)	(17,462)	(44,323)	(79,600)	(105,729)
Stockholders' equity	307,823	268,530	247,597	204,056	53,781

- (1) In 2003, we recorded \$11.0 million of other revenue related to the acceleration of the recognition of unused minimum purchase payments and deferred license fee revenue from ETHICON following the termination of the supply distribution and collaboration agreement in December 2003. We also recorded a \$2.0 million gain in other income associated with a related termination payment received from ETHICON.
- (2) We recorded the following significant items in operating expenses: \$23.9 million and \$13.5 million in stock-based compensation charges incurred in connection with the extensions of the employment agreement of our President and Chief Executive Officer in 2004 and 2000, respectively; \$0.4 million and \$2.3 million of acquired in-process research and development charges recorded in connection with acquisitions in 2003 and 2002, respectively; \$1.1 million of expenses related to the closing of our San Diego research center and a \$2.0 million donation to the Integra Foundation in 2003.
- (3) In 2002 and 2001, respectively, we recognized a \$20.4 million and \$11.5 million deferred income tax benefit primarily related to the reduction of a portion of the valuation allowance recorded against our deferred tax assets.
- (4) In August 2001, we issued 4,747,500 shares of common stock at \$25.50 per share in a follow-on public offering. The net proceeds generated by the offering, after expenses, were \$113.4 million. We subsequently used a portion

- of these proceeds to repay outstanding indebtedness totaling \$9.3 million, for which we recorded a \$256,000 loss on the early retirement of debt.
- (5) As the result of the adoption of SEC Staff Accounting Bulletin No. 101 "Revenue Recognition" (SAB 101), we recorded a \$470,000 cumulative effect of an accounting change to defer a portion of a nonrefundable, up-front fee received and recorded in other revenue in 1998. The cumulative effect of this accounting change was measured as of January 1, 2000. As a result of this accounting change, other revenue in 2003, 2002, 2001 and 2000 includes \$112,000 of amortization of the amount deferred as of January 1, 2000.
- (6) Diluted net income per share for 2003 was restated for the adoption of EITF Issue 04-08 "The Effect of Contingently Convertible Instruments on Diluted Earnings per Share". Issue 04-08 requires issuers of contingent convertible securities to account for these securities on an "if-converted" basis pursuant to Statement of Financial Accounting Standards No. 128 "Earnings Per Share" in computing diluted earnings per share whether or not the issuer's stock is above the contingent conversion price. The provisions of Issue 04-08 are effective for all periods ending after December 15, 2004 and have been applied on a retroactive basis. Previously disclosed 2003 diluted net income per share was reduced by \$0.02 to \$0.86.
- (7) 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. The notes are convertible into approximately 3.5 million shares.

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS 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 "Factors That May Affect Our Future Performance."

Regulation G, "Conditions for Use of Non-GAAP Financial Measures," and other provisions of the Securities Exchange Act of 1934, as amended, define and prescribe the conditions for the use of certain non-GAAP financial information. In Management's Discussion and Analysis of Financial Condition and Results of Operations, we provide information regarding growth in product revenues excluding recently acquired product lines, which is a non-GAAP financial measure. A reconciliation of this non-GAAP financial measure to the most comparable GAAP measure is provided in this annual report.

This non-GAAP financial measure should not be relied upon to the exclusion of GAAP financial measures. Management believes that this non-GAAP financial measure constitutes important supplemental information to investors which reflects an additional way of viewing aspects of our operations that, when viewed with our GAAP results and the accompanying reconciliations, provides a more complete understanding of factors and trends affecting our ongoing business and operations. Management strongly encourages investors to review our financial statements and publicly-filed reports in their entirely and to not rely on any single financial measure. Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names.

#### **GENERAL**

Integra develops, manufactures and markets medical devices for use in neuro-trauma, neurosurgery, reconstructive surgery and general surgery. Our business is organized into product groups and distribution channels. Our product groups include implants and other devices for use in surgical procedures, monitoring systems for the measurement of various parameters in tissue (such as pressure, temperature and oxygen), hand-held and ultrasonic surgical instruments, and private label products that we manufacture for other medical device companies.

Our distribution channels include three sales organizations in the United States: one that we employ to call on neurosurgeons known as our Integra NeuroSciences<sup>TM</sup> sales organization, another employed to call on reconstructive

surgeons and a third group that utilizes a network of third-party distributors. Internationally, we combine resources across different sales channels in some cases with direct sales organizations in France, Germany, the United Kingdom and the Benelux region. Outside of these areas, we operate through a number of distributors that sell our products in over 90 countries. We invest substantial resources and management effort to develop our sales organizations, and we believe that we compete very effectively in this aspect of our business. We distribute private label products through strategic alliances.

We manufacture most of the implant, monitoring and private label products that we sell in various plants located in the United States, Puerto Rico, France, the United Kingdom and Germany. We also manufacture the ultrasonic surgical instruments and source most of our hand-held surgical instruments through specialized third-party vendors.

We believe that we have a particular advantage in the development, manufacture and sale of specialty tissue repair products derived from bovine collagen. We develop and build these products in our manufacturing facility in Plainsboro, New Jersey. Taken together, these products accounted for approximately 31%, 27% and 32% of product revenues in the years ended December 31, 2004, 2003 and 2002, respectively.

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

Our objective is 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 product revenues both through 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 tend to support the view that our profitability can grow for a period of years. These measurements include revenue growth, derived through acquisitions and products developed internally, gross margins on products revenues, which we hope to increase to more than 65% over a period of several years, operating margins, which we hope to continually expand on as we leverage our existing infrastructure, and earnings per fully diluted share of common stock.

### **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, 2004 not directly comparable to those of the corresponding prior year periods. Since the beginning of 2002, we have acquired the following businesses, assets and product lines:

In May 2004, we acquired the MAYFIELD® Cranial Stabilization and Positioning Systems and the BUDDE® Halo Retractor System business from Schaerer Mayfield USA, Inc. (formerly Ohio Medical Instrument Company) for \$20.0 million in cash paid at closing, a \$0.3 million working capital adjustment and \$0.3 million of acquisition related expenses. The MAYFIELD and BUDDE lines include skull clamps, headrests, reusable and disposable skull pins, blades, retractor systems and spinal implants. MAYFIELD systems are the market leader in the United States and have been used by neurosurgeons for over thirty years. The products are sold in the United States through our Integra NeuroSciences<sup>TM</sup> direct sales organization and in international markets through distributors.

In May 2004, we acquired all of the capital stock of Berchtold Medizin-Elektronik GmbH, now named Integra ME GmbH, from Berchtold Holding GmbH for \$5.0 million in cash. Integra ME manufactures and markets the ELEKTROTOM® line of electrosurgery generators and the SONOTOM® ultrasonic surgical aspirator, as well as a broad line of related handpieces, instruments and disposables used in many surgical procedures, including neurosurgery. Integra ME markets and sells its products to hospitals and physicians primarily through a network of distributors in markets outside the United States.

In January 2004, we acquired two small instruments businesses: the R&B instrument business from R&B Surgical Solutions, LLC for approximately \$2.0 million in cash and the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. for approximately \$1.6 million in cash. The R&B instrument line is a complete line of high-quality handheld surgical instruments used in neuro- and spinal surgery. We market these products through our JARIT sales organization. The Sparta product line includes products used in plastic and reconstructive, ear, nose and throat (ENT), neuro, ophthalmic and general surgery. We sell the Sparta products through a direct marketing organization and an existing distributor network.

In December 2003, we acquired the assets of Reconstructive Technologies, Inc. for \$400,000 in cash and an agreement to make future payments based on product sales. Reconstructive Technologies is the developer of the Automated Cyclic Expansion System (ACE System<sup>TM</sup>), a tissue expansion device. As the ACE system is not yet approved, we recorded an in-process research and development charge in connection with this acquisition. Once approved, we plan to market the system through our reconstructive sales organization.

In November 2003, we acquired all of the outstanding capital stock of Spinal Specialties, Inc. from I-Flow Corporation for \$6.4 million in cash, including expenditures associated with the acquisition and a working capital adjustment. Spinal Specialties assembles and sells custom kits and products for chronic pain management, including the OsteoJect™ Bone Cement Delivery System and the ACCU-DISC™ Pressure Monitoring System. Spinal Specialties markets its products to anesthesiologists and interventional radiologists through an in-house telemarketing team and a network of distributors. We report sales of Spinal Specialties products as instrument revenues.

In August 2003, we acquired the assets of Tissue Technologies, Inc., the manufacturer and distributor of the UltraSoft<sup>TM</sup> line of facial implants for soft tissue augmentation of the facial area, for \$0.6 million in cash and up to an additional \$1.5 million based on future sales of the acquired products. We market the UltraSoft<sup>TM</sup> products directly to cosmetic and reconstructive surgeons through our reconstructive surgery sales organization

In March 2003, we acquired all of the outstanding capital stock of J. Jamner Surgical Instruments, Inc. (doing business as JARIT® Surgical Instruments) for \$45.6 million in cash. JARIT sells its products to more than 5,200 hospitals and surgery centers worldwide. JARIT generates its domestic product sales primarily through sales to hospitals that are members of group purchasing organizations. Group purchasing organizations use the combined leverage of their member hospitals to obtain better prices for medical products for the participating hospitals and other health care providers than might otherwise be available to these institutions individually. The acquisition of JARIT broadened our customer base and surgical instrument product offering and facilitated the procurement of our Ruggles<sup>TM</sup> and Padgett instrument products directly from the instrument manufacturers.

In December 2002, we acquired the epilepsy monitoring and neurosurgical shunt business of the Radionics division of Tyco Healthcare Group for \$3.7 million in cash. We moved the manufacturing of the acquired lines to our facility in Biot, France and are selling the acquired products through our Integra NeuroSciences<sup>TM</sup> sales force.

In October 2002, we acquired Padgett Instruments, Inc., a marketer of instruments used in reconstructive and plastic surgery, for \$9.6 million in cash. Our acquisition of Padgett Instruments broadened our existing surgical customer base and allowed us to expand into new market segments. We consolidated Padgett's operations into our then existing distribution center located in Cranbury, New Jersey in March 2003.

In August 2002, we acquired certain assets, including the NeuroSensor® monitor and rights to certain intellectual property, from Novus Monitoring Limited of the United Kingdom and entered into a related development agreement pursuant to which Novus agreed to provide, at its own cost, certain development activities related to the acquired products and technology. We paid Novus \$3.5 million in cash at closing and a \$1.4 million milestone payment related to the development of a next-generation, advanced neuromonitoring system in September 2004. We are required to pay up to an additional \$2.5 million based upon revenues from Novus' products. We expect the Novus products to complement our existing line of brain parameter monitoring products. We expect to introduce the NeuroSensor® Cerebral Blood Flow

Monitoring System in the first half of 2005. The NeuroSensor® Cerebral Blood Flow Monitoring System measures both intracranial pressure and cerebral blood flow using a single combined probe and an electronic monitor for data display.

In August 2002, we acquired the neurosciences division of NMT Medical, Inc. for \$5.7 million in cash. Through this acquisition, we added a range of leading differential pressure valves, including the Orbis-Sigma®, Integra Hakim® and horizontal-vertical lumbar valves, and external ventricular drainage products to our neurosurgical product line. The acquired operations included a facility located in Biot, France that manufactures, packages and distributes shunting, catheter and drainage products.

In July 2002, we acquired the assets of Signature Technologies, Inc., a specialty manufacturer of titanium and stainless steel implants for the neurosurgical and spinal markets, and certain other intellectual property assets. The purchase price consisted of \$2.9 million in cash, \$0.5 million of deferred consideration and royalties on future sales of products to be developed. Our acquisition of Signature Technologies gave us the capability of developing and manufacturing metal implants for our strategic partners and for our direct sale organizations. Through June 2004, Signature Technologies manufactured cranial fixation systems for sale primarily under a single contract manufacturing agreement. In December 2004, we consolidated the Signature manufacturing operation into our Cincinnati, Ohio facility.

In November 2004, we agreed to acquire all of the outstanding capital stock of Newdeal Technologies for 38.5 million euros in cash, subject to certain adjustments. The acquisition closed on January 3, 2005. Based in Lyon, France, Newdeal is a leading developer and marketer of specialty implants and instruments specifically designed for foot and ankle surgery. The company sells its products through a direct sales force in France, Belgium and the Netherlands and through distributors in more than 30 countries, including the United States and Canada.

# RESULTS OF OPERATIONS

Net income in 2004 was \$17.2 million, or \$0.55 per diluted share, as compared to net income of \$26.9 million, or \$0.86 per diluted share, in 2003 and net income of \$35.3 million, or \$1.14 per diluted share, in 2002. Included in these amounts are certain revenues, charges or gains resulting from facts and circumstances that, based on our recent history and future expectations, may not recur with similar materiality or impact on continuing operations. We believe that the identification of all revenues, charges and gains that meet these criteria promotes comparability of reported financial results. The following revenues, charges and gains were included in net income and net income per diluted share:

# In 2004

- We recorded a \$1.4 million charge in connection with the milestone payment related to the completion of certain development activities related to the NeuroSenor® Cerebral Blood Flow Monitoring System and a \$0.5 million licensing fee paid for the development of a data acquisition system to support the integration of our advanced monitoring products.
- We recorded a \$23.9 million share-based compensation charge associated with the renewal of our President and Chief Executive Officer's employment agreement.
- We recorded a \$1.3 million tax charge incurred in connection with the reorganization of certain European operations.
- We recognized \$1.4 million of 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 US dollar as a result of
  our commitment to acquire Newdeal Technologies for 38.5 million euros. The Newdeal Technologies acquisition
  was completed in January 2005.

# In 2003

 We recorded \$11.0 million of other revenue related to the acceleration of the recognition of unused minimum purchase payments and unamortized license fee revenue from ETHICON following the termination of the Supply, Distribution and Collaboration agreement in December 2003.

- We incurred \$1.1 million of expenses related to the closing of our San Diego research center, consolidation of the research activities into our other facilities and the discontinuation of certain research programs.
- We recorded an acquired in-process research and development charge of \$400,000 in connection with an acquisition.
- We made a \$2.0 million donation to the Integra Foundation, which is included in general and administrative expenses.
- We received a \$2.0 million payment from ETHICON from the termination of our agreement with them, which is
  included in other income.

# In 2002

- We recorded a \$20.4 million deferred income tax benefit primarily from the reduction of the valuation allowance recorded against our deferred tax assets associated with net operating loss carryforwards.
- We recorded acquired in-process research and development charges of \$2.3 million in connection with acquisitions.

# **Total Revenues and Gross Margin on Product Revenues**

	2004	2003	2002
	(in thousar	ıds, except per	share data)
Monitoring products	\$ 48,217	\$ 44,229	\$ 37,184
Implant products	78,418	53,301	38,326
Instruments	77,667	47,168	16,802
Private label products	24,188	21,997	20,313
Total product revenues	228,490	166,695	112,625
Other revenue	1,335	18,904	5,197
Total revenues	229,825	185,599	117,822
Cost of product revenues	87,299	70,597	45,772
Gross margin on product revenues	141,191	96,098	66,853
Gross margin as a percentage of product revenues	62%	58%	59%

In 2004, total revenues increased 24% over 2003 to \$229.8 million, led by a \$61.8 million, or 37%, increase in product revenues to \$228.5 million. Domestic product revenues increased \$48.1 million in 2004 to \$180.9 million, or 79% of total product revenues, as compared to 80% of product revenues in 2003 and 2002. Sales of instruments and implant products, which reported a 65% and 47% increase, respectively, in sales over 2003, led our growth in product revenues in 2004.

In 2003, total revenues increased 58% over 2002 to \$185.6 million, led by a 48% increase in product revenues to \$166.7 million. Domestic product revenues increased \$42.4 million in 2003 to \$132.8 million. Sales of instruments and implant products, which reported a 181% and 39% increase, respectively, in sales over 2002, led our growth in product revenues in 2003.

Reported product revenues for 2004 and 2003 included the following amounts in revenues from acquired product lines:

	2004	2003	
	Revenues	Revenues	% change
		(in thousands)	
Total Product Revenues			
Products acquired during 2004	\$ 13,632	\$ —	N/A
Products acquired during 2003	39,898	24,476	63%
All other product revenues	174,960	\$142,219	23%
Total product revenues	228,490	166,695	37%

Product revenues excluding 2004 and 2003 acquisitions grew at 23% for the year ended December 31, 2004 as compared to 2003. Increased sales of our DuraGen® Dural Graft Matrix and INTEGRA® Dermal Regeneration Template product families as well as an increase in our Absorbable Collagen Sponge product sold to Wyeth BioPharma accounted for a significant portion of this growth. Our revenue growth in 2003 over 2002, excluding acquisitions, was driven by our DuraGen® Dural Graft Matrix, NeuraGen<sup>TM</sup> Nerve Guide, intracranial monitoring and drainage systems, and neurosurgical systems products. All of the products acquired in 2004 and 2003 were added to the instrument product group.

In 2004, we launched several new products under the DuraGen® Dural Graft Matrix and INTEGRA® Dermal Regeneration Template product families. However, we expect growing competition in the area of absorbable implant technology products, which could affect growth in our product lines. We continue to broaden our product offerings using our proprietary absorbable implant technology by developing products that meet the additional needs of surgeons within the markets we serve. Our acquisition in January 2005 of the Newdeal foot and angle implant product lines gives us additional opportunities to expand the use of our absorbable implant products into additional areas within the surgical reconstructive market.

We have generated our product revenue growth through acquisitions, new product launches and increased direct sales and marketing efforts both domestically and in Europe. We expect that our future growth will derive from our expanded domestic sales force, the continued implementation of our direct sales strategy in Europe and from internally developed and acquired products. We also intend to continue to acquire businesses that complement our existing businesses and products.

Gross margin as a percentage of product revenues was 62% in 2004, 58% in 2003 and 59% in 2002. Cost of product revenues included \$270,000, \$1,261,000 and \$447,000 in fair value inventory purchase accounting adjustments recorded in connection with acquisitions in 2004, 2003 and 2002, respectively. Product gross margins improved in 2004 as a result of increased sales of higher margin products, including the effect of selling our INTEGRA® Dermal Regeneration products directly, as well as the contribution of the MAYFIELD product line we acquired in 2004. During 2003, the gross margin was negatively affected by fair value inventory purchase accounting adjustments and from the acquisition of lower margin products. The impact of foreign exchange rates on the cost of products that we manufacture or purchase in Europe negatively affected gross margins in 2004 and 2003. We expect our future gross margins to continue to benefit as our higher margin products continue to grow faster than other products and as we continue to increase sales of our products in foreign currencies.

We currently do not hedge our exposure to operating foreign currency risk. In 2004 and 2003, the cost of products we manufacture or purchase in Europe exceeded our foreign currency-denominated revenues. We expect this imbalance to continue into 2005. A further weakening of the dollar against the euro and British pound could negatively affect future gross margins.

Other revenue has historically consisted of research and development funding from strategic partners and government grants, and license, distribution, and other event-related revenues from strategic partners and other third parties. In 2003, our other revenue included \$16.3 million of revenues derived from an agreement with ETHICON that was terminated in December 2003. We do not expect to generate significant revenues in the future from these types of arrangements.

# **Other Operating Expenses**

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

	2004	2003	2002
Research and development	6%	7%	10%
Selling, general and administrative	43%	32%	34%

Research and development costs have continued to decline as percentage of total revenue as we continue to restructure our research and development activities. The percentage declines are also the result of significant increases in handheld instrument sales, which by their nature require less research and development expenditures compared to our other

product lines. Our 2004 research and development expenses increased \$1.3 million to \$14.1 million and included a \$1.4 million milestone payment related to the completion of certain development activities for an advanced neuromonitoring system and a \$0.5 million licensing fee paid for the development of a data acquisition system to support the integration of our advanced monitoring products. In 2003 we incurred \$950,000 of expenses related to the consolidation of our San Diego research center with our other facilities. We also reported in-process research and development charges of \$400,000 and \$2.3 million in 2003 and 2002, respectively. In 2005, we expect our research and development expenses as a percentage of total revenues to remain consistent with 2004 as we increase expenditures on research and clinical activities directed towards expanding the indications for use of our absorbable implant technology products, including a multi-center clinical trial suitable to support an application to the FDA for approval of the DuraGen Plus<sup>TM</sup> Adhesion Barrier Matrix product in the United States.

Selling, general and administrative expenses increased significantly in 2004 and included a stock-based compensation charge of \$23.9 million related to the renewal of our President and Chief Executive Officer's employment agreement. This stock-based compensation charge represented 10% of total revenues. We reported significant increases in sales and marketing expenditures as we continue to build our direct sales and marketing organizations around all three direct selling platforms. Sales and marketing increases included additional personnel costs, additional trade show activities as well as costs related to acquired product lines. We made significant investments in our infrastructure with the implementation of a new enterprise business system and the relocation and expansion of our distribution capabilities through a third-party service provider. We also incurred a significant increase in professional fees associated with compliance with new internal controls compliance and reporting. In 2003, increases in spending included sales support for JARIT instrument sales and the expansion of the reconstructive sales force in anticipation of the termination of the ETHICON agreement. We also hired more experienced marketing professionals and spent more on advertising. In addition, in 2003 we donated \$2.0 million to the Integra Foundation and incurred additional costs to consolidate several facilities. In 2005, we expect our selling, general and administrative costs as a percentage of revenue will return to the 2003 and 2002 range.

Amortization expense increased to \$4.3 million in 2004 because of amortization on intangible assets acquired through our business acquisitions. Including the expected impact of intangible assets acquired in the acquisition of Newdeal in January 2005, we expect annual amortization expense to be approximately \$6.1 million in 2005, \$6.0 million in 2006, \$5.7 million in 2007, \$5.4 million in 2008 and \$4.7 million in 2009.

# **Non-Operating Income and Expenses**

In March and April 2003, we received approximately \$115.9 million of net proceeds from the sale of \$120.0 million of our 2½% contingent convertible subordinated notes due in March 2008. In 2004 and 2003, we recorded interest expense of \$3.5 million and \$2.7 million, respectively, in connection with these notes, which was offset by \$4.0 million and \$3.2 million, respectively of interest income on our invested cash and marketable debt securities.

We will pay additional interest ("Contingent Interest") on our convertible notes if, at thirty days prior to maturity, our common stock price is greater than \$37.56 per share. We recorded a \$365,000 liability related to the estimated fair value of the Contingent Interest obligation at the time the notes were issued. The fair value of this Contingent Interest obligation is marked to its fair value at each balance sheet date, with changes in the fair value recorded to interest expense. At December 31, 2004 and 2003, the estimated fair value of the Contingent Interest obligation was \$710,000 and \$460,000, respectively.

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. We receive a 2½% fixed rate from the counterparty, payable on a semi-annual basis, and pay to the counterparty a floating rate based on 3-month LIBOR minus 35 basis points, payable on a quarterly basis. The interest rate swap agreement terminates in March 2008, subject to early termination upon the occurrence of certain events, including redemption or conversion of the convertible notes.

The interest rate swap agreement qualifies 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 is recorded as a component of interest expense. Interest expense for the years ended December 31, 2004 and 2003, respectively, reflects a \$686,000 and \$330,000 reduction associated with the interest rate swap.

The net fair value of the interest rate swap at inception was \$767,000. In 2004 and 2003, the net fair value of the interest rate swap increased \$287,000 to \$1.4 million and \$305,000 to \$1.1 million, respectively. In connection with this fair value hedge, we recorded in 2004 and 2003 a \$430,000 and \$433,000, respectively, net decrease in the carrying value of our contingent convertible notes. The \$143,000 and \$128,000 net difference between changes in the fair value of the interest rate swap and the contingent convertible notes represents the ineffective portion of the hedging relationship, and these amounts are recorded in other income (expense), net.

Our net other income/expense declined in 2004 by \$400,000 to \$2.7 million as a result of an increase in foreign currency transaction gains, including a \$1.4 million unrealized gain associated with the foreign currency collar in 2004, offset by the decline of \$2.0 million from the termination payment received from ETHICON in 2003.

## **Income Taxes**

Since 1999, we have generated positive taxable income on a cumulative basis. In light of this trend, our projections for future taxable earnings and the expected timing of the reversal of deductible temporary differences, in 2002, we reduced the remaining valuation allowance recorded against our net operating loss carryforwards by \$23.4 million, which reflected our estimate of additional tax benefits that we expected to realize in the future. A valuation allowance of \$5.4 million is recorded against the remaining \$31.5 million of net deferred tax assets recorded at December 31, 2004. 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.

In 2004, our effective income tax rate was 38.6% of income before income taxes compared to 37.8% in 2003. Our 2004 rate includes a \$1.3 million tax charge related to the transfer of certain intangible assets. We recorded a net income tax benefit in 2002 related to the reduction of deferred tax asset valuation allowances previously recorded.

The net decrease in our tax asset valuation allowance was \$2.3 million and \$26.7 million in 2003 and 2002, respectively.

At December 31, 2004, we had net operating loss carryforwards of approximately \$46.8 million and \$0.6 million for federal and state income tax purposes, respectively, to offset future taxable income. The federal and state net operating loss carryforwards expire through 2018 and 2005, respectively.

At December 31, 2004, several of our subsidiaries had unused net operating loss carryforwards and tax credit carryforwards arising from periods prior to our ownership which expire through 2005. The Internal Revenue Code limits the timing and manner in which we may use any acquired net operating losses or tax credits.

The American Jobs Creation Act of 2004 (the "Act") was signed into law in October 2004 and has several provisions that may impact our income taxes in the future, including the repeal of the extraterritorial income exclusion and a deduction related to qualified production activities taxable income. The Financial Accounting Standards Board ("FASB") proposed that the qualified production activities deduction is a special deduction and will have no impact on deferred taxes existing at the enactment date. Rather, the impact of this deduction will be reported in the period in which the deduction is claimed on our tax return. We are currently evaluating the impact of the FASB guidance related to qualified production activities on our effective tax rate in future periods.

# INTERNATIONAL PRODUCT REVENUES AND OPERATIONS

Product revenues by major geographic area are summarized below:

	United		Asia	Other	
	States	Europe	Pacific	Foreign	Consolidated
			(in thousands)		
2004	\$180,887	\$30,941	\$8,535	\$8,127	\$228,490
2003	132,805	21,433	5,828	6,629	166,695
2002	90,422	14,737	4,062	3,404	112,625

In 2004, revenues from customers outside the United States totaled \$47.6 million, or 21% of consolidated product revenues, of which approximately 65% were to European customers. Revenues from customers outside the United States included \$33.6 million of revenues generated in foreign currencies.

In 2003, product revenues from customers outside the United States totaled \$33.9 million, or 20% of consolidated product revenues, of which approximately 63% were to European customers. Revenues from customers outside the United States included \$21.3 million of revenues generated in foreign currencies.

In 2002, product revenues from customers outside the United States totaled \$22.2 million, or 20% of consolidated product revenues, of which approximately 66% were to European customers. Revenues from customers outside the United States included \$13.4 million of revenues generated in foreign currencies.

Because we have operations based in Europe and we generate revenues and incur operating expenses in euros and British pounds, we will experience currency exchange risk with respect to those foreign currency denominated revenues or expenses.

In 2004, the cost of products we manufactured in our European facilities or purchased in foreign currencies exceeded our foreign currency-denominated revenues. We expect this imbalance to continue into 2005. We currently do not hedge our exposure to operating foreign currency risk. Accordingly, a further weakening of the dollar against the euro and British pound could negatively affect 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 United States, a portion of which are U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. As a result, currency fluctuations between the U.S. dollar and the currencies in which those customers do business may have an impact on the demand for our products in foreign countries.

Our sales to foreign markets may be affected by local economic conditions, regulatory or political considerations, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice.

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

# LIQUIDITY AND CAPITAL RESOURCES

# **Cash and Marketable Securities**

At December 31, 2004, we had cash, cash equivalents and marketable securities totaling \$196 million. Investments consist almost entirely of highly liquid, interest bearing debt securities.

# **Cash Flows**

We generated positive operating cash flows of \$39.0 million, \$34.8 million and \$32.0 million in 2004, 2003 and 2002, respectively. Operating cash flows continued to improve primarily as a result of higher pre-tax income adjusted for the add back of non-cash items and the benefits from the continued utilization of our net operating loss carryforwards and tax deductions generated by employee stock option exercises. Included in the 2004 operating cash flow was a \$20.2 million use of cash related to changes in working capital items. A significant increase in accounts receivable and inventory was primarily due to the overall growth in the business and delays in customer collections related to business systems transitions. We expect our days on hand in accounts receivable and inventory to return to historic trend levels during 2005. Based on our current unused net operating loss carryforward position and various other future potential tax deductions, we expect our operating cash flows to continue to benefit from actual cash tax payments being lower than our effective book income tax rate for at least the next two years.

In 2004, we used \$14.2 million to repurchase 500,000 shares of our common stock, which was partially offset by \$6.1 million in cash flows generated from the issuance of common stock under employee benefit plans. Other principal uses of funds in 2004 were \$29.3 million for acquisitions and \$8.5 million in purchases in property and equipment. The \$4.7 million increase in purchases of property and equipment in 2004 was primarily related to our procurement and implementation of our new enterprise business software. We had positive cash flows of \$50.6 million from the net sales and maturities of marketable debt securities.

In 2003, we generated \$14.2 million from the issuance of common stock under employee benefit plans and \$115.9 million of net proceeds from the sale of \$120.0 million of our contingent convertible subordinated notes. We had uses of funds of \$50.4 million for acquisitions, \$72.9 million for the net purchases of marketable debt securities, \$35.4 million for the repurchase of approximately 1.5 million shares our common stock and \$3.8 million for capital expenditures. The significant repurchase of our common stock in 2003 was made simultaneously with the issuance of our convertible notes.

In 2002, our principal sources of funds were \$32.0 million of operating cash flow and \$3.3 million from the issuance of common stock under employee benefit plans. In 2002, our principal uses of funds were \$25.0 million for acquisitions, the repayment of a \$3.6 million note and \$2.3 million for capital expenditures.

# **Working Capital**

At December 31, 2004 and 2003, working capital was \$192.0 million and \$171.0 million, respectively. The increase in working capital in 2004 was primarily due to increases in inventory to support our growth in product revenues, higher accounts receivable balances related to increased sales and delays in customer collections. Both items were also affected by our transition to our new enterprise business system in the second half of the year. We expect our days on hand in accounts receivable and inventory to return to historic trend levels during 2005. The December 31, 2004 amount includes the funds subsequently used on January 3, 2005 to purchase Newdeal Technologies, as discussed below.

# Convertible Debt and Related Hedging Activities

In 2003, we generated \$115.9 million of net proceeds from the sale of \$120.0 million of our contingent convertible subordinated notes due in March 2008. We pay interest on the convertible notes at an annual rate of  $2\frac{1}{2}$ % each September 15th and March 15th. We will also pay contingent interest on the notes if, at thirty days prior to maturity, our common stock price is greater than \$37.56. The contingent interest will be payable for each of the last three years the notes remain outstanding in an amount equal to the greater of (1) 0.50% of the face amount of the 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 note is convertible. Holders of the notes may convert the notes into shares of our common stock under certain circumstances, including when the market price of our common stock on the previous trading day is more than \$37.56 per share, based on an initial conversion price of \$34.15 per share.

The notes are general, unsecured obligations of Integra and will be subordinate to any future senior indebtedness. We cannot redeem the notes prior to their maturity, and the notes' holders may compel us to repurchase the notes upon a change of control. There are no financial covenants associated with the convertible notes.

In August 2003, we entered into an 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 notes. We receive a  $2\frac{1}{2}$ % fixed rate from the counterparty, payable on a semi-annual basis, and pay to the counterparty a floating rate based on 3-month LIBOR minus 35 basis points, payable on a quarterly basis. The interest rate swap agreement terminates in March 2008, subject to early termination upon the occurrence of certain events, including redemption or conversion of the contingent convertible notes. Our effective interest rate on the hedged portion of the notes was 1.6% as of December 31, 2004.

# **Share Repurchase Plans**

During 2004, 2003 and 2002, we repurchased approximately 500,000, 1.5 million and 100,000 shares, respectively, of our common stock under authorized share repurchase programs.

# **Dividend Policy**

We have not paid any cash dividends on our common stock since our formation. 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 deemed relevant by the Board of Directors.

# **Requirements and Capital Resources**

We believe that our cash and marketable securities are sufficient to finance our operations and capital expenditures in the near term. In January 2005, we used \$50.9 million in cash to complete the acquisition of Newdeal Technologies. We also expect to invest approximately \$3.5 million in 2005 associated with the continued worldwide implementation of our new enterprise business software.

Given the significant level of liquid assets and our objective to grow by acquisition and alliances, our financial position could change significantly if we were to complete a business acquisition by utilizing a significant portion of our liquid assets.

Currently, we do not have any existing borrowing capacity or other credit facilities in place to raise significant amounts of capital if such a need arises.

# **Contractual Obligations and Commitments**

As of December 31, 2004, we were obligated to pay the following amounts under various agreements:

		Less than			More than
	Total	1 year	1-3 Years	3-5 Years	5 years
			(in millions)		
Long Term Debt	\$120.0	\$ —	\$ —	\$120.0	\$ —
Interest on Long Term Debt	10.5	3.0	6.0	1.5	_
Operating Leases	8.6	2.6	3.3	0.9	1.8
Purchase Obligations	6.3	6.3	_	_	_
Pension Contributions	0.2	0.2	_	_	_
Other Long Term Liabilities	0.4		0.1	0.1	0.2
Total	\$146.0	\$12.1	\$9.4	\$122.5	\$2.0

In addition, under other agreements we are required to make payments based on sales levels of certain products or if specific development milestones are achieved.

The above table does not include contingent interest that we may be obligated to pay on our contingent convertible subordinated notes due in March 2008. See "—Non-Operating Income and Expenses."

In November 2004, we agreed to acquire all of the outstanding capital stock of Newdeal Technologies for 38.5 million euros in cash, subject to certain adjustments. The acquisition closed on January 3, 2005. The above table does not include the amount we paid at the closing of this transaction on January 3, 2005 and does not include the obligation to pay up to 1.25 million euros plus a working capital adjustment that we may be obligated to pay under the Newdeal acquisition agreement on January 3, 2006 as a post-closing payment.

# USE OF ESTIMATES AND CRITICAL ACCOUNTING POLICIES

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, net realizable value of inventories, estimates of future cash flows associated with acquired in-process research and development charges, fair market value of derivative instruments, amortization periods for acquired intangible 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 And Sales Returns

We evaluate 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 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. We record a provision for estimated sales returns and allowances on product revenues in the same period as the related revenues are recorded. We base these estimates on historical sales returns and other known factors. Actual returns could be different from our estimates and the related provisions for sales returns and allowances, resulting in future changes to the sales returns and allowances provision.

# **Inventories**

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost, the value 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 and projections of future demand. To the extent that we determine there are excess, obsolete or expired inventory quantities, we record valuation reserves against all or a portion of the value of the related products. If future demand or market conditions are different than our projections, a change in recorded inventory valuation reserves may be required and would be reflected in cost of revenues in the period the revision is made.

# **Derivatives**

We report all derivatives at their estimated fair value and record changes in fair value in current earnings or defer these changes until a related hedged item is recognized in earnings, depending on the nature and effectiveness of the hedging relationship. The designation of a derivative as a hedge is made on the date the derivative contract is executed. On an ongoing basis, we assess whether each derivative continues to be highly effective in offsetting changes in the fair value or cash flows of hedged items. If and when a derivative is no longer expected to be highly effective, we discontinue hedge accounting. All hedge ineffectiveness is included in current period earnings in other income (expense), net.

We document all relationships between hedged items and derivatives. Our overall risk management strategy describes the circumstances under which we may undertake hedge transactions and enter into derivatives. The objective of our current risk management strategy is to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of our fixed rate debt.

The determination of fair value of derivatives is based on valuation models that use observable market quotes or projected cash flows and our view of the creditworthiness of the derivative counterparty. If a derivative is no longer deemed to qualify as an effective hedge, changes in the fair value of that derivative could significantly affect our non-operating income or expense.

# **Acquired In-Process Research and Development Charges**

In-process research and development charges are recorded in connection with acquisitions and represent the value assigned to acquired assets which have not yet reached technological feasibility and for which there is no alternative use. Fair value is generally assigned to these assets based on the net present value of the projected cash flows expected to be generated by those assets. Significant assumptions underlying these cash flows include our assessment of the timing and our ability to successfully complete the in-process research and development project, projected cash flows associated with the successful completion of the project, and interest rates used to discount these cash flows to their present value.

# **Amortization Periods**

We provide for amortization using the straight-line method over the estimated useful lives of acquired intangible assets. We base the determination of these useful lives on the period over which we expect the related assets to contribute to our cash flows or a shorter period such that recognition of the amortization better corresponds with the distribution of expected revenues. If our assessment of the useful lives of intangible assets changes, we may change future amortization expense.

# **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. 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 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 if we change our assessment of the likely outcome of these matters.

# **OTHER MATTERS**

# **Recently Issued Accounting Standards**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 123 (revised 2004), "Share-Based Payment," which is a revision of Statement No. 123, "Accounting for Stock-Based Compensation." Statement

123(R) replaces APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends Statement No. 95, "Statement of Cash Flows." Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value. Pro forma footnote disclosure will no longer be an alternative to financial statement recognition.

Statement 123(R) must be adopted no later than July 1, 2005. We expect to adopt Statement 123(R) on July 1, 2005. Statement 123(R) permits companies to adopt its requirements using either the "modified prospective" method or the "modified retrospective" method. Management is currently evaluating the potential impact of Statement 123(R) on our consolidated financial position and results of operations and the alternative adoption methods.

In November 2004, the FASB issued Statement No. 151, "Inventory Costs—an amendment of ARB No. 43, Chapter 4" (Statement 151), which is effective beginning January 1, 2006. Statement 151 requires that abnormal amounts of idle facility expense, freight, handling costs and wasted material be recognized as current period charges. Statement 151 also requires that the allocation of fixed production overhead be based on the normal capacity of the production facilities. We are currently assessing the potential effect that Statement 151 could have on the our financial position or results of operations.

In October 2004, the FASB Emerging Issue Task Force (EITF) reached a consensus on Issue 04-08 "The Effect of Contingently Convertible Instruments on Diluted Earnings per Share" that requires issuers of contingent convertible securities to account for these securities on an "if-converted" basis pursuant to Statement of Financial Accounting Standards No. 128 "Earnings Per Share", in computing their diluted earnings per share whether or not the issuer's stock is above the contingent conversion price. The provisions of Issue 04-08 are effective for all periods ending after December 15, 2004 and we have applied them on a retroactive basis. We have restated all earnings per share amounts to reflect the impact of Issue 04-08. We reduced previously disclosed 2003 diluted net income per share by \$0.02 to \$0.86. We present restated quarterly diluted net income per share for 2004 and 2003 in Note 15 to our consolidated financial statements.

In March 2004, the EITF reached a consensus on Issue 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments". Issue 03-01 provides guidance regarding recognition and measurement of unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, "Accounting for Certain Investments in Debt and Equity Securities". The application of certain paragraphs covering the measurement provisions of Issue 03-01 have been deferred pending the issuance of a final FASB Staff Position providing implementation guidance on Issue 03-01. The disclosures are effective in annual financial statements for fiscal years ending after December 15, 2003. Management is currently assessing the impact that the recognition and measurement provisions of Issue 03-01 could have on our financial statements.

# 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 impact 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

Because we have operations based in Europe and we generate revenues and incur operating expenses in euros and British pounds, we will experience currency exchange risk with respect to those foreign currency denominated revenues or expenses. In 2004, the total cost of products we manufacture in or purchase in foreign currencies and other operating expenses that we incur in foreign currencies exceeded our total foreign currency-denominated revenues. We expect this imbalance to continue into 2005. A further weakening of the dollar against the euro and British pound could negatively affect future gross margins and operating margins.

In November 2004, we entered into a collar contract for 38.5 million euros expiring in January 2005 to reduce our exposure to fluctuations in the exchange rate between the euro and the US dollar as a result of our commitment to acquire Newdeal in January 2005 for 38.5 million euros (see Note 16 to the financial statements). The collar contract did not qualify as a hedge under SFAS No. 133. Accordingly, the collar contract is recorded at fair value and changes in fair value are recorded in other income (expense), net. In 2004, we recorded a \$1.4 million gain related to the change in the fair value of the collar contract.

Other than this foreign currency collar, 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 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 additional 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 and investments in available-for-sale marketable debt securities. A hypothetical 100 basis point movement in interest rates applicable to our cash and cash equivalents and investments in marketable debt securities outstanding at December 31, 2004 would increase or decrease interest income by approximately \$2.0 million on an annual basis. We are not subject to material foreign currency exchange risk with respect to these investments.

# Interest Rate Risk—Long Term Debt and Related Hedging Instruments

We are exposed to the risk of interest rate fluctuations on the net interest received or paid under the terms of an interest rate swap. At December 31, 2004, we had outstanding a \$50.0 million notional amount interest rate swap used to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of our \$120.0 million principal amount fixed rate  $2\frac{1}{2}$ % contingent convertible subordinated notes due March 2008. We receive a  $2\frac{1}{2}$ % fixed rate from the counterparty, payable on a semi-annual basis, and pay to the counterparty a floating rate based on 3-month LIBOR minus 35 basis points, payable on a quarterly basis. The floating rate resets each quarter. The interest rate swap agreement terminates on March 15, 2008, subject to early termination upon the occurrence of certain events, including redemption or conversion of our contingent convertible notes. Our effective interest rate payable on the floating rate portion of the swap was 1.6% as of December 31, 2004.

Our interest rate swap agreement qualifies as a fair value hedge under SFAS No. 133, as amended, "Accounting for Derivative Instruments and Hedging Activities." At December 31, 2004, the net fair value of the interest rate swap approximated \$1.4 million and is included in other liabilities. The net fair value of the interest rate swap represents the estimated receipts or payments that would be made to terminate the agreement. A hypothetical 100 basis point movement in interest rates applicable to the interest rate swap would increase or decrease interest expense by approximately \$500,000 on an annual basis.

# 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 Notes to Consolidated Financial Statements, Note 15—Selected Quarterly Information—unaudited.

# 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 ensure 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 the end of the quarter covered by this report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

# Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2004. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

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

In August 2004, we implemented in our main business units a new enterprise business system, which included the following modules: order management, procurement and payables, general ledger (including receivables, inventory and fixed assets), manufacturing and human resources. As of August 15, 2004, all of our business units subject to this implementation began using the new system. The implementation has involved changes in systems that included internal control over financial reporting, and accordingly, these changes have required changes to our system of internal control over financial reporting. We have reviewed each system as it is being implemented and the internal control over financial reporting affected by the implementation of the new systems and made appropriate changes to affected internal control over financial reporting as we implemented the new systems.

# ITEM 9B. OTHER INFORMATION

Not applicable.

# **PART III**

# INCORPORATED BY REFERENCE

The information called for by Item 10. Directors and Executive Officers of the Registrant (other than the information concerning executive officers set forth after Item 4 of Part I herein), 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 Item 14 Principal Accountant Fees and Services is incorporated herein by reference to the Company's definitive proxy statement for its Annual Meeting of Stockholders scheduled to be held on May 17, 2005, 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, 2004, 2003 and 2002	F-3
Consolidated Balance Sheets as of December 31, 2004 and 2003	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002	F-5
Consolidated Statements of Changes in Stockholders' Equity For the years ended December 31, 2004, 2003 and 2002	F-6
Notes to Consolidated Financial Statements	F-9
2. Financial Statement Schedules.	
Financial Statement Schedule	F-37

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.

		Exhibit in Incorporated Filing
3.1(a)	Amended and Restated Certificate of Incorporation of the Company (2)	(Exh. 3.1)
3.1(b)	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated May 22, 1998 (3)	(Exh. 3.1(b))
3.1(c)	Certificate of Amendment to Amended and Restated Certificate of Incorporation dated May 17, 1999 (1)	
3.2	Amended and Restated By-laws of the Company (23)	(Exh. 3.1)
4.1	Indenture, dated as of March 31, 2003, between the Company and Wells Fargo Bank Minnesota, National Association (17)	(Exh. 4.1)
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. (18)	(Exh. 4.3)
10.1	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 (2)	(Exh. 10.30)
10.2	Equipment Lease Agreement between Medicus Corporation and the Company, dated as of June 1, 2000 (9)	(Exh. 10.1)
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 (4)	(Exh. 10.37)
10.4	1993 Incentive Stock Option and Non-Qualified Stock Option Plan* (2)	(Exh. 10.32)
10.5(a)	1996 Incentive Stock Option and Non-Qualified Stock Option Plan* (5)	(Exh. 4.3)
10.5(b)	Amendment to 1996 Incentive Stock Option and Non-Qualified Stock Option Plan* (7)	(Exh. 10.4)
10.6	1998 Stock Option Plan* (6)	(Exh. 4.1)

		Exhibit in Incorporated Filing
10.7	1999 Stock Option Plan* (8)	(Exh. 10.13)
10.8	Employee Stock Purchase Plan* (21)	(App. B)
10.9	Deferred Compensation Plan* (8)	(Exh. 10.15)
10.10	2000 Equity Incentive Plan* (11)	(Exh. 10.17)
10.11	2001 Equity Incentive Plan* (12)	(Exh. 4)
10.12	2003 Equity Incentive Plan* (16)	(App. A)
10.13	Second Amended and Restated Employment Agreement dated July 27, 2004 between the Company and Stuart M. Essig* (22)	(Exh. 10.1)
10.14	Indemnity letter agreement dated December 27, 1997 from the Company to Stuart M. Essig* (7)	(Exh. 10.5)
10.15(a)	Registration Rights Provisions for Stuart Essig* (7)	(Exh. 10.1, Exh. B)
10.15(b)	Registration Rights Provisions for Stuart Essig* (10)	(Exh. 10.2)
10.15(c)	Registration Rights Provisions for Stuart Essig* (22)	(Exh. 10.1, Exh. B)
10.16	Amended and Restated Employment Agreement between John B. Henneman, III and the Company dated October 31, 2003* (19)	(Exh. 10.2)
10.17	Employment Agreement between Gerard Carlozzi and the Company dated September 25, 2003* (19)	(Exh. 10.1)
10.18	Employment Agreement between Judith O'Grady and the Company dated February 20, 2003* (14)	(Exh. 10.17)
10.19	Employment Agreement between David B. Holtz and the Company dated September 10, 2002* (13)	(Exh. 10.38)
10.20	Employment Agreement between Donald R. Nociolo and the Company dated February 20, 2003* (20)	(Exh. 10.20)
10.21	Retention Agreement between Robert Paltridge and the Company dated February 20, 2003* (17)	(Exh. 10.1)
10.22	Severance Agreement between Deborah Leonetti and the Company dated February 20, 2003* (1)	

		Exhibit in Incorporated Filing
10.23(a)	Lease Contract dated June 30, 1994 between the Puerto Rico Industrial Development Company and Heyer-Schulte NeuroCare, Inc. (8)	(Exh. 10.32)
10.23(b)	Construction and Lease Contract dated June 30, 1994 between the Puerto Rico Industrial Development Company and Integra NeuroSciences P.R., Inc. (1)	
10.24(a)	Industrial Real Estate Triple Net Sublease dated July 1, 2001 between Sorrento Montana, L.P. and Camino NeuroCare, Inc. (1)	
10.24(b)	First Amendment to Sublease dated as of July 1, 2003 by and between Sorrento Montana, L.P. and Camino NeuroCare, Inc. (1)	
10.24(c)	Second Amendment to Sublease dated as of June 1, 2004 by and between Sorrento Montana, L.P. and Camino NeuroCare, Inc. (1)	
10.24(d)	Third Amendment to Sublease dated as of June 15, 2004 by and between Sorrento Montana, L.P. and Integra LifeSciences Corporation (1)	
10.25	Stock Purchase Agreement, dated as of March 17,2003, among Integra LifeSciences Corporation and Howard Jamner and other individual stockholders of J. Jamner Surgical Instruments, Inc. (15)	(Exh. 2.1)
10.26	Restricted Units Agreement dated December 27, 1997 between the Company and Stuart M. Essig* (7)	(Exh. 10.3)
10.27	Stock Option Grant and Agreement dated December 22, 2000 between the Company and Stuart M. Essig* (10)	(Exh. 4.1)
10.28	Stock Option Grant and Agreement dated December 22, 2000 between the Company and Stuart M. Essig* (10)	(Exh. 4.2)
10.29	Restricted Units Agreement dated December 22, 2000 Between the Company and Stuart M. Essig* (10)	(Exh. 4.3)
10.30	Stock Option Grant and Agreement dated July 27, 2004 between the Company and Stuart M. Essig* (1)	
10.31	Contract Stock/Restricted Units Agreement dated July 27, 2004 between the Company and Stuart M. Essig* (1)	
10.32	Form of Stock Option Grant and Agreement between the Company and Stuart M. Essig* (1)	

# Exhibit in Incorporated Filing

10.33	Share Purchase Agreement dated November 10, 2004 between Integra LifeSciences Corporation and Eric Fourcault, Theo Knevels, Jean-Christophe Giet and Bertrand Gauneau (1)
10.34	Form of Notice of Grant of Stock Option and Stock Option Agreement* (1)
10.35	Form of Non-Qualified Stock Option Agreement (Non-Directors)* (1)
10.36	Form of Incentive Stock Option Agreement* (1)
10.37	Form of Non-Qualified Stock Option Agreement (Directors)* (1)
10.38	Compensation of Directors of the Company* (1)
21	Subsidiaries of the Company (1)
23	Consent of PricewaterhouseCoopers LLP (1)
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (1)
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (1)
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (1)
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (1)

- \* Indicates a management contract or compensatory plan or arrangement.
- (1) Filed herewith.
- (2) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form 10/A (File No. 0-26224) which became effective on August 8, 1995.
- (3) Incorporated by reference to the indicated exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1998.
- (4) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-1 (File No. 33-98698) which became effective on January 24, 1996.
- (5) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-8 (File No. 333-06577) filed on June 21, 1996.
- (6) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-8 (File No. 333-58235) filed on June 30, 1998.

- (7) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on February 3, 1998.
- (8) Incorporated by reference to the indicated exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999.
- (9) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended June 30, 2000.
- (10) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on January 8, 2001.
- (11) Incorporated by reference to the indicated exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 as filed on April 2, 2001.
- (12) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-8 (File No. 333-73512) filed on November 16, 2001.
- (13) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended September 30, 2002.
- (14) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-K for the year ended December 31, 2002.
- (15) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on March 25, 2003.
- (16) Incorporated by reference to the indicated exhibit to the Company's Definitive Proxy Statement on Form 14A filed on April 17, 2003.
- (17) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended March 31, 2003.
- (18) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-3 filed on June 30, 2003 (File No. 333-106625).
- (19) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended September 30, 2003.
- (20) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-K for the year ended December 31, 2003.
- (21) Incorporated by reference to the indicated exhibit to the Company's Definitive Proxy Statement on Form 14A filed on April 12, 2004.
- (22) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended September 30, 2004.
- (23) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on February 24, 2005.

# **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

Date: March 16, 2005 By: /s/ Stuart M. Essig

Stuart M. Essig

President and Chief Executive Officer

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	<u>Title</u>	Date
/s/ Stuart M. Essig	President, Chief Executive Officer and	March 16, 2005
Stuart M. Essig	Director (Principal Executive Officer)	
/s/ David B. Holtz	Senior Vice President, Finance and Treasurer	March 16, 2005
David B. Holtz	(Principal Financial and Accounting Officer)	
/s/ Richard E. Caruso	Chairman of the Board	March 16, 2005
Richard E. Caruso, Ph.D.		
/s/ Keith Bradley	Director	March 16, 2005
Keith Bradley, Ph.D.		
/s/ David Auth	Director	March 16, 2005
David Auth		
/s/ Neal Moszkowski	Director	March 16, 2005
Neal Moszkowski		
/s/ James M. Sullivan	Director	March 16, 2005
James M. Sullivan	<del>_</del>	
/s/ Anne M. VanLent	Director	March 16, 2005
Anne M. VanLent		

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Integra LifeSciences Holdings Corporation and Subsidiaries

We have completed an integrated audit of Integra LifeSciences Holdings Corporation's 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

# Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) "Exhibits and Financial Statement Schedules" present fairly, in all material respects, the financial position of Integra LifeSciences Holdings Corporation and its Subsidiaries (the Company) at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing 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. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes 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. We believe that our audits provide a reasonable basis for our opinion.

# Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing in Item 9A "Controls and Procedures", that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal* Control—Integrated Framework issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey March 15, 2005

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS

In thousands, except per share amounts

	Years Ended December 31,		
	2004	2003	2002
Total revenues	\$229,825	\$185,599	\$117,822
COSTS AND EXPENSES			
Cost of product revenue	87,299	70,597	45,772
Research and development	14,121	12,814	11,517
Selling, general and administrative	99,360	59,461	39,702
Amortization	4,266	3,080	1,644
Total costs and expenses	205,046	145,952	98,635
Operating income	24,779	39,647	19,187
Interest income	4,030	3,195	3,575
Interest expense	(3,475)	(2,724)	(40)
Other income (expense), net	2,674	3,071	3
Income before income taxes	28,008	43,189	22,725
Income tax expense (benefit)	10,811	16,328	(12,552)
Net income	\$ 17,197	\$ 26,861	\$ 35,277
Basic net income per share	\$ 0.57	\$ 0.92	\$ 1.21
Diluted net income per share	\$ 0.55	\$ 0.86	\$ 1.14
Weighted average common shares outstanding:			
Basic	30,064	29,071	29,021
Diluted	31,102	33,104	30,720

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

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED BALANCE SHEETS

In thousands, except per share amounts

	Decem	iber 31,
	2004	2003
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 69,855	\$ 26,054
Short-term investments	30,955	82,492
Trade accounts receivable, net of allowances of \$2,749 and \$2,025	46,765	28,936
Inventories	55,947	41,046
Prepaid expenses and other current assets	12,716	13,093
Total current assets	216,238	191,621
Noncurrent investments	95,172	98,197
Property, plant, and equipment, net	25,461	20,072
Deferred income taxes, net	15,787	17,641
Goodwill	39,237	26,683
Intangible assets, net	59,817	52,435
Other assets	5,001	5,877
Total assets	\$456,713	\$412,526
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable, trade	\$ 10,160	\$ 7,947
Income taxes payable	1,022	774
Accrued compensation	4,212	3,726
Accrued expenses and other current liabilities	8,840	8,171
Total current liabilities	24,234	20,618
Long term debt	118,900	119,257
Deferred revenue	310	418
Other liabilities	5,446	3,703
Total liabilities	148,890	143,996
Commitments and contingencies		
Stockholders' Equity: Common stock; \$.01 par value; 60,000 authorized shares; 29,202		
and 28,611 issued	292	286
Additional paid-in capital	320,602	286,716
Treasury stock, at cost; 718 and 218 shares	(19,474)	(5,236)
Other	(1), (1)	(5,236)
Accumulated other comprehensive income (loss):		(3)
Unrealized gain (loss) on available-for-sale securities, net of tax	(818)	63
Foreign currency translation adjustment	9,266	5,400
Minimum pension liability adjustment, net of tax	(1,780)	(1,232)
Accumulated deficit	(265)	(17,462)
Total stockholders' equity	307,823	268,530
Total liabilities and stockholders' equity	\$456,713	\$412,526
Total Intelliges and Stockholders equity	Ψ130,713	Ψ112,320

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

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands

	Years Ended December 31,				
	2004	2003	2002		
OPERATING ACTIVITIES:					
Net income	\$ 17,197	\$ 26,861	\$ 35,277		
Adjustments to reconcile net income to net cash					
provided by operating activities:					
Depreciation and amortization	9,087	7,030	5,020		
In process research and development charge	_	400	2,328		
Deferred tax provision (benefit)	6,101	12,357	(13,401)		
Amortization of discount and premium on investments	2,505	2,013	2,142		
Stock-based compensation	23,572	26	31		
Other, net	696	776	157		
Changes in assets and liabilities, net of business acquisitions:					
Accounts receivable	(13,287)	(4,819)	(2,109)		
Inventories	(9,738)	(1,829)	1,153		
Prepaid expenses and other current assets	(1,949)	(505)	(1,131)		
Non-current assets	(169)	480	185		
Accounts payable, accrued expenses and other liabilities .	6,029	2,537	(90)		
Customer advances and deposits	(959)	(6,431)	2,565		
Deferred revenue	(110)	(4,070)	(142)		
Net cash provided by operating activities	\$ 38,975	\$ 34,826	\$ 31,985		
recount provided by operating activities the control of the contro	<del>+ 23,272</del>	<del>* 5 .,525</del>	<del>\$ 51,555</del>		
INVESTING ACTIVITIES:					
Proceeds from the sales/maturities of investments	241,440	287,558	35,402		
Purchases of available for sale investments	(190,888)	(360,470)	(57,713)		
Purchases of property and equipment	(8,508)	(3,843)	(2,254)		
Payment of product license fee	_	(1,500)	_		
Cash used in business acquisitions, net of cash acquired	(29,302)	(50,405)	(25,015)		
Net cash provided by (used in) investing activities	\$ 12,742	\$(128,660)	\$(49,580)		
	·	1( -,,	1( - ) /		
FINANCING ACTIVITIES:					
Repayment of note payable and bank loans	_	_	(3,600)		
Proceeds from exercised stock options and warrants	6,123	14,152	3,323		
Purchases of treasury stock	(14,238)	(35,402)	(1,761)		
Proceeds from issuance of convertible notes, net		115,923			
Net cash provided by (used in) financing activities	\$ (8,115)	\$ 94,673	\$ (2,038)		
Effect of exchange rate changes on cash and cash equivalents	199	232	98		
Net increase (decrease) in cash and cash equivalents	\$ 43,801	1,071	(19,535)		
Cash and cash equivalents at beginning of period	26,054	24,983	44,518		
Cash and cash equivalents at end of period	\$ 69,855	\$ 26,054	\$ 24,983		
Cash paid during the year for interest	\$ 2,331	\$ 1,476	\$ 20		
Cash paid during the year for income taxes	1,789	1,309	1,435		
	1,709	1,509	1,433		
Supplemental non-cash disclosure:					
Property and equipment purchases included in liabilities	\$ 969	\$ 2,000	_		

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

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

In thousands

Total Equity	\$204,056	624 2,394	(1,011)			3,293 31	4,694	(1,761)
Accumulated Deficit	35,277							\$(44,323)
Accumulated Other Comprehensive Income (Loss)	(539)	624 2,394	(1,011)					\$1,468
Other	(37)					22		\$(15)
Additional Paid-In Capital	284,021				(5)	3,288	4,694	\$292,007
Treasury Stock	(51)							(1,761)
Common Stock	261				9	S		\$272
Preferred Stock	-				(1)			
	Balance, December 31, 2001  Net income	of tax  Foreign currency translation  Minimum nension liability adjustment	net of tax	Conversion of 54 shares of Series C Preferred Stock into 600 shares of	common stock	through employee benefit plans Stock-based compensation	Tax benefit related to stock option exercises	stock

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

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

In thousands

	Total	Equity	26,861	(210)	(588)	3,673	Ć	(112)	\$ 29,624			14,102	50		 26		12,533		(35,402)	\$268,530
	∢	Deficit	26,861																	\$ (17,462)
Accumulated Other		Income (Loss)		(210)	(588)	3,673	(	(1112)												\$4,231
		Other													10					\$ (2)
Additional	Paid-In	Capital										(17,880)	50	Ó	(10)		12,533			\$286,716
	Treasury	Stock										31,978							(35,402)	\$ (5,236)
	Common	Stock										4		9	IO					\$286
	Preferred	Stock																		
			Net income	Realized gains on investments	Unrealized losses on investments, net of tax	Foreign currency translation	Minimum pension liability adjustment,	net of tax	Total comprehensive income	Issuance of 1,788 shares of common	stock through employee benefit	plans	Warrants exercised for cash	Conversion of 1,000 Restricted Units	Into 1,000 snares of common stock Stock-based compensation	Tax benefit related to stock option	exercises	Repurchase 1,503 shares of common	stock	Balance, December 31, 2003

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

# INTEGRA LIFESCIENCES HOLDINGS CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

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thousands	٠.
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	Total Equity	17,197	88	(696)	3,833		(548)	\$ 19,601		6,498		23.535	35		3,829		(14,238)	\$307,790
	Acc	17,197																\$ (265)
Accumulated Other	Comprehensive Income (Loss)		88	(696)	3,833		(548)											\$6,635
	Other												S					
Additional	Paid-In Capital									6,492		23,535	30		3,829			\$320,602
	Treasury Stock																(14,238)	\$(19,474)
	Common Stock									9								\$292
	Preferred Stock																	
		Net income	Realized gains on investments	of tax	Foreign currency translation	Minimum pension liability adjustment,	net of tax	Total comprehensive income	Issuance of 592 shares of common	stock through employee benefit plans	Issuance of contract stock unit award	for 750 shares of common stock	Other stock-based compensation	Tax benefit related to stock option	exercises	Repurchase 500 shares of common	stock	Balance, December 31, 2004

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

# 1. BUSINESS

Integra LifeSciences Holdings Corporation (the "Company") develops, manufactures, and markets medical devices for use in neuro-trauma, neurosurgery, reconstructive surgery, and general surgery. The Company's product lines include innovative tissue repair products that incorporate the Company's proprietary absorbable implant technology, such as the DuraGen® Dural Graft Matrix, the DuraGen Plus<sup>TM</sup> Dural Regeneration Matrix, the NeuraGen<sup>TM</sup> Nerve Guide and NeuraWrap<sup>TM</sup> Nerve Protector, the INTEGRA® Dermal Regeneration Template, and the INTEGRA<sup>TM</sup> Bilayer Matrix and INTEGRA<sup>TM</sup> Matrix Wound Dressing. In addition, we offer a full range of medical devices to include monitoring and drainage systems, surgical instruments and fixation systems.

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

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

# PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of the Company and its subsidiaries, all of which are wholly owned. All intercompany accounts and transactions are eliminated in consolidation.

# **REVISION**

In 2004, we determined that our investments in auction rate securities should be classified as short term investments. Auction rate securities are reset to current interest rates periodically, but no later than every 90 days. These securities were previously recorded in cash and cash equivalents due to the liquidity provided by their short-term pricing reset features and the Company's ability to liquidate them in monthly auctions. Prior period balance sheet and cash flow information has been revised to conform to the current year presentation. Short term investments at December 31, 2004 and 2003, include \$0 and \$52.9 million, respectively, of auction rate securities. Cash flows from investing activities decreased by \$34.3 million and \$18.6 million in 2003 and 2002, respectively, and in 2004 included \$52.9 million in cash provided by the sale of these securities. There was no impact on the Company's net income or cash flows from operations or financing activities as a result of this revision. The Company does not have any debt covenants that are affected by reported cash balances.

Certain other prior year amounts have been reclassified to conform to the current year presentation.

# CASH AND CASH EQUIVALENTS

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

# FINANCIAL INSTRUMENTS

Investments in marketable debt and equity securities are classified and accounted for as available-for-sale securities and are carried at fair value, which is based on quoted market prices. Unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). Realized gains and losses are determined on the specific identification cost basis and reported in other income (expense), net. Investment balances as of December 31, 2004 and 2003 were as follows:

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

		Unrealized						
	Cost	Gains	Losses	Value				
<u>2004</u>		(in thousands)						
Marketable Securities, current								
Corporate Debt Securities with continuous								
unrealized losses less than 1 year	\$ 16,273	\$ 0	\$ (122)	\$ 16,151				
Corporate Debt Securities with continuous								
unrealized losses greater than 1 year	7,919	0	(66)	7,853				
U.S. Government Debt Securities with continuous								
unrealized losses less than 1 year	6,999	0	(48)	6,951				
Total marketable securities, current	\$ 31,191	\$ 0	\$ (236)	\$ 30,955				
Marketable Securities, non-current								
Corporate Debt Securities with continuous								
unrealized losses less than 1 year	\$ 29,510	\$ 0	\$ (374)	\$ 29,136				
Corporate Debt Securities with continuous								
unrealized losses greater than 1 year	15,198	0	(167)	15,031				
Corporate Debt Securities with unrealized gains	4,069	30	0	4,099				
U.S. Government Debt Securities with continuous								
unrealized losses less than 1 year	45,456	0	(557)	44,899				
Other Securities with continuous								
unrealized losses less than 1 year	2,045	0	(38)	2,007				
Total marketable securities, non-current	\$ 96,278	\$ 30	\$(1,136)	\$ 95,172				
2003:								
Marketable securities, current	\$ 82,471	\$ 22	\$ (1)	\$ 82,492				
Marketable securities, non-current	98,152	156	(111)	98,197				
	\$180,623	\$178	\$ (112)	\$180,689				

The primary reason for the unrealized losses on the Company's marketable debt securities is the recent increase in interest rates since the Company acquired these investments. Management does not believe that the unrealized losses on these marketable securities are other than temporary because of its intent and ability to hold these investments for a sufficiently long period of time such that recovery of these unrealized losses is expected as the investments get closer to their maturity. The maturity dates or interest rate reset periods for marketable debt securities classified as current are less than one year. The maturity dates for marketable debt securities classified as non-current are less than 45 months and less than 60 months as of December 31, 2004 and 2003, respectively.

The fair value of the Company's \$120.0 million principal amount 2½% contingent convertible subordinated notes outstanding at December 31, 2004 and 2003 was \$115.5 million and \$116.7 million, respectively.

The carrying values of all other financial instruments were not materially different from their estimated fair values.

# TRADE ACCOUNTS RECEIVABLE, ALLOWANCES FOR DOUBTFUL ACCOUNTS RECEIVABLE AND SALES RETURNS

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.

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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 us, 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 provision to the allowances for doubtful accounts is recorded based on the length of time the receivables are past due, the current business environment and our historical experience. Provisions to the allowances for doubtful accounts are recorded to selling, general and administrative expenses. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered.

The Company records a provision for estimated returns and allowances on product sales in the same period as the related revenues are recorded. These estimates are based on historical sales returns and other known factors. The provisions are recorded as a reduction to revenues.

# **INVENTORIES**

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost, the value determined by the first-in, first-out method, or market. Inventories consisted of the following:

	Decem	ber 31,
	2004	2003
	(in thou	usands)
Finished goods	\$36,490	\$26,239
Work in process	7,496	5,069
Raw materials	11,961	9,738
	\$55,947	\$41,046

At each balance sheet date, the Company evaluates ending inventories for excess quantities, obsolescence or shelf-life expiration. This evaluation includes analyses of historical sales levels by product and projections of future demand. To the extent that management determines there are excess, obsolete or expired inventory quantities, valuation reserves are recorded against all or a portion of the value of the related products.

# PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at cost. The Company provides for depreciation using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the lease term or the useful life. The cost of major additions and improvements is capitalized, while maintenance and repair costs that do not improve or extend the lives of the respective assets are charged to operations as incurred.

Property, plant and equipment balances and corresponding lives were as follows:

	Decen		
	2004	2003	Lives
	(in tho		
Land	\$ 941	\$ 892	
Buildings and leasehold improvements	12,886	12,082	2 - 40 years
Machinery and equipment	19,369	19,498	3 - 15 years
Furniture, fixtures and information systems	11,569	3,277	5 - 7 years
Construction in progress	3,252	2,316	
	48,017	38,065	
Less: Accumulated depreciation	(22,556)	(17,993)	
	\$ 25,461	\$ 20,072	

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Depreciation expense associated with property, plant and equipment was \$4.8 million, \$3.9 million, and \$3.4 million, in 2004, 2003, and 2002 respectively.

### GOODWILL AND OTHER INTANGIBLE ASSETS

The excess of the cost over the fair value of net assets of acquired businesses is recorded as goodwill. Goodwill is not subject to amortization, but is reviewed for impairment at the reporting unit level annually, or more frequently if impairment indicators arise. The Company's assessment of the recoverability of goodwill is based upon a comparison of the carrying value of goodwill with its estimated fair value. The Company conducted its annual impairment review for goodwill as of June 30, 2004 and determined that its goodwill was not impaired.

Changes in the carrying amount of goodwill in 2004 and 2003 were as follows:

	2004	2003
	(in thou	usands)
Goodwill, net of accumulated amortization beginning of year	\$26,683	\$22,073
Acquisitions	11,596	3,321
Foreign currency translation	958	1,318
Goodwill, end of year	\$39,237	\$26,683

The components of the Company's identifiable intangible assets were as follows:

	Weighted	Decemb	per 31, 2004	December 31, 2003			
	Average		Accumulated		Accumulated		
	Life	Cost	Amortization	Cost	Amortization		
			(in thou	sands)			
Completed technology	14 years	\$17,108	\$ (4,505)	\$15,062	\$(3,337)		
Customer relationships	20 years	17,417	(3,214)	16,755	(2,053)		
Trademarks / brand names	36 years	28,689	(1,862)	25,235	(1,017)		
Noncompetetion agreements	5 years	6,352	(1,198)	765	(265)		
All other	11 years	2,233	(1,203)	2,144	(854)		
		\$71,799	\$(11,982)	\$59,961	\$(7,526)		
Accumulated amortization		(11,982)		(7,526)			
		\$59,817		\$52,435			

The Company does not have any indefinite life intangible assets.

Including the expected impact of intangible assets acquired in the acquisition of Newdeal Technologies SA in January 2005 (see Note 16), annual amortization expense is expected to approximate \$6.1 million in 2005, \$6.0 million in 2006, \$5.7 million in 2007, \$5.4 million in 2008, and \$4.7 million in 2009. Identifiable intangible assets are initially recorded at fair market value at the time of acquisition generally using an income or cost approach.

# LONG-LIVED ASSETS

Long-lived assets held and used by the Company, including property, plant and equipment and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. For purposes of evaluating the recoverability of long-lived assets to be held and used, a recoverability test is performed using projected undiscounted net cash flows applicable to the long-lived assets. If an impairment exists,

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

the amount of such impairment is calculated based on the estimated fair value of the asset. Impairments to long-lived assets to be disposed of are recorded based upon the fair value of the applicable assets.

## INTEGRA FOUNDATION

The Company may periodically, at the discretion of its Board of Directors, make a contribution to the Integra Foundation, Inc. The Integra Foundation was incorporated in 2002 exclusively for charitable, educational, and scientific purposes and qualifies under IRC 501(c)(3) as an exempt private foundation. Under its charter, the Integra Foundation engages in activities that promote health, the diagnosis and treatment of disease, and the development of medical science through grants, contributions and other appropriate means. The Integra Foundation is a separate legal entity and is not a subsidiary of the Company. Therefore, its results are not included in these consolidated financial statements. The Company contributed \$2.0 million to the Integra Foundation in 2003, which was recorded in selling, general, and administrative expense.

# **DERIVATIVES**

The Company reports all derivatives at their estimated fair value and records changes in fair value in current earnings or defers these changes until a related hedged item is recognized in earnings, depending on the nature and effectiveness of the hedging relationship. The designation of a derivative as a hedge is made on the date the derivative contract is executed. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes in the fair value or cash flows of hedged items. If and when a derivative is no longer expected to be highly effective, the Company discontinues hedge accounting. All hedge ineffectiveness is included in current period earnings in other income (expense), net.

The Company documents all relationships between hedged items and derivatives. The Company's overall risk management strategy describes the circumstances under which it may undertake hedge transactions and enter into derivatives. The objective of the Company's current risk management strategy is to hedge the risk of changes in fair value attributable to interest rate risk with respect to a portion of fixed rate debt.

The determination of fair value of derivatives is based on valuation models that use observable market quotes or projected cash flows and the Company's view of the creditworthiness of the derivative counterparty.

# FOREIGN CURRENCY

All assets and liabilities of foreign subsidiaries are translated at the rate of exchange at year-end, while elements of the income statement are translated at the average exchange rates in effect during the year. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss). These currency translation adjustments are not currently adjusted for income taxes as they relate to permanent investments in non-U.S. subsidiaries. Foreign currency transaction gains and losses are reported in other income (expense), net.

# **INCOME TAXES**

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period when the change is enacted.

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### REVENUE RECOGNITION

Total revenues include product sales and product royalties and other operating revenues, such as fees received under research, licensing, and distribution arrangements, research grants, and technology-related royalties. Total revenues for 2004, 2003 and 2002 consisted of the following:

	2004	2003	2002
Product sales and product royalties	\$228,490	\$166,695	\$112,625
Other operating revenues	1,335	18,904	5,197
Total revenues	\$229,825	\$185,599	\$117,822

Product sales are recognized when delivery has occurred and title has passed to the customer, there is a fixed or determinable sales price, and collectability of that sales price is reasonably assured. Product royalties are recognized as the royalty products are sold by our customers and the amount earned by Integra is fixed and determinable.

Other operating revenues include fees received under research, licensing, and distribution arrangements, technology-related royalties, and research grants. Non-refundable fees received under research, licensing and distribution arrangements or for the licensing of technology are recognized as revenue when received if the Company has no continuing obligations to the other party. For those arrangements where the Company has continuing performance obligations, revenue is recognized using the lesser of the amount of non-refundable cash received or the result achieved using the proportional performance method of accounting based upon the estimated cost to complete these obligations. Research grant revenue is recognized when the related expenses are incurred.

# SHIPPING AND HANDLING FEES AND COSTS

Amounts billed to customers for shipping and handling are included in product revenues. The related shipping and freight charges incurred by the Company are included in cost of product revenues. Distribution and handling costs of \$3.8 million, \$2.6 million, and \$1.5 million are recorded in selling, general and administrative expense during 2004, 2003, and 2002, respectively.

# PRODUCT WARRANTIES

Certain of the Company's medical devices, including monitoring systems and neurosurgical systems, are reusable and are designed to operate over long periods of time. These products are sold with warranties generally extending for up to two years from date of purchase. The Company accrues estimated product warranty costs at the time of sale based on historical experience. Any additional amounts are recorded when such costs are probable and can be reasonably estimated.

Accrued warranty expense consisted of the following:

	December 31,	
	2004	2003
	(in thousands)	
Beginning balance	\$ 403	\$ 216
Liability acquired through acquisition	255	95
Charged to expense	258	243
Deductions	(168)	(151)
Ending balance	\$ 748	\$ 403

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# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

# RESEARCH AND DEVELOPMENT

Research and development costs, including salaries, depreciation, consultant and other external fees, and facility costs directly attributable to research and development activities, are expensed in the period in which they are incurred.

In-process research and development charges recorded in connection with acquisitions represent the value assigned to acquired assets to be used in research and development activities and for which there is no alternative use. Value is generally assigned to these assets based on the net present value of the projected cash flows expected to be generated by those assets.

In 2004, the Company recorded to research and development expense a \$1.4 million charge for a milestone payment related to the completion of certain development activities for an advanced neuromonitoring system and a \$500,000 charge for a licensing fee paid for the development of a data acquisition system to support the integration of our advanced monitoring products. The Company recorded \$400,000 and \$2.3 million of in-process research and development in connection with acquisitions during 2003 and 2002, respectively.

### STOCK BASED COMPENSATION

Employee stock based compensation is recognized using the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" and Financial Accounting Standards Board Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation—an interpretation of APB Opinion No. 25".

Had the compensation cost for the Company's stock option plans been determined based on the fair value at the grant consistent with the provisions of Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation", the Company's net income and basic and diluted net income per share would have been as follows:

	2004	2003	2002
	(in thousands, except per share amounts)		
Net income:			
As reported	\$ 17,197	\$26,861	\$35,277
Add back: Total stock-based employee compensation expense			
determined under the intrinsic value-based method			
for all awards, net of related tax effects	15,372	_	_
Less: Total stock-based employee compensation expense			
determined under the fair value-based method for all			
awards, net of related tax effects	(21,799)	(5,537)	(4,774)
Pro forma	\$ 10,770	\$21,324	\$30,503
Net income per share:			
Basic			
As reported	\$ 0.57	\$ 0.92	\$ 1.21
Pro forma	\$ 0.36	\$ 0.73	\$ 1.04
Diluted			
As reported	\$ 0.55	\$ 0.86	\$ 1.14
Pro forma	\$ 0.35	\$ 0.70	\$ 1.02

As options vest over a varying number of years and awards are generally made each year, the pro forma impacts shown above may not be representative of future pro forma expense amounts. The pro forma additional compensation expense related to all options granted prior to October 1, 2004 was calculated based on the fair value of each option grant using the Black-Scholes model, while the pro forma additional compensation expense related to all options granted on or after October 1, 2004 was calculated based on the fair value of each option grant using the binomial distribution model. The following weighted-average assumptions:

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

	2004	2003	2002
Dividend yield	0%	0%	0%
Expected volatility	48%	61%	65%
Risk free interest rate	3.2%	2.9%	3.0%
Expected life of option from grant date	4.7 years	4.5 years	4.5 years

The effect of the change in estimate related to the use of the bionomial distribution model has been accounted for on a prospective basis. The Company will value all future stock option grants using the binomial distribution model. Management believes that the binomial distribution model is better than the Black-Scholes model because the binomial distribution model is a more flexible model that considers the impact of non-transferability, vesting and forfeiture provisions in the valuation of employee stock options.

In December 2004, the Financial Accounting Standards Board issued Statement No. 123 (revised 2004), "Share-Based Payment," which is a revision of Statement No. 123, "Accounting for Stock-Based Compensation." Statement 123(R) replaces APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends Statement No. 95, "Statement of Cash Flows." Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value. Pro forma footnote disclosure will no longer be an alternative to financial statement recognition.

Statement 123(R) must be adopted no later than July 1, 2005. The Company expects to adopt Statement 123(R) on July 1, 2005. Statement 123(R) permits companies to adopt its requirements using either the "modified prospective" method or the "modified retrospective" method. Management is currently evaluating the potential impact of Statement 123(R) on the Company's consolidated financial position and results of operations and the alternative adoption methods.

# CONCENTRATION OF CREDIT RISK

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents, which are held at major financial institutions, investment-grade marketable debt securities and trade receivables. The Company's products are sold on an uncollateralized basis and on credit terms based upon a credit risk assessment of each customer.

# **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, net realizable value of inventories, estimates of projected cash flows and discount rates used to value and test impairments of long-lived assets, depreciation and amortization periods for long-lived assets, valuation allowances recorded against deferred tax assets, loss contingencies, and in-process research and development charges. 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.

# RECENTLY ISSUED AND ADOPTED ACCOUNTING STANDARDS

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 151, "Inventory Costs—an amendment of ARB No. 43, Chapter 4" (Statement 151), which is effective beginning January 1, 2006. Statement 151 requires that abnormal amounts of idle facility expense, freight, handling costs and wasted material be recognized as current period charges. Statement 151 also requires that the allocation of fixed production overhead be based on the normal capacity of the production facilities. The effect of Statement 151 on the Company's financial position or results of operations has not yet been determined.

### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

In October 2004, the FASB Emerging Issue Task Force (EITF) reached a consensus on Issue 04-08 "The Effect of Contingently Convertible Instruments on Diluted Earnings per Share" that requires issuers of contingent convertible securities to account for these securities on an "if-converted" basis pursuant to Statement of Financial Accounting Standards No. 128 "Earnings Per Share", in computing their diluted earnings per share whether or not the issuer's stock is above the contingent conversion price. The provisions of Issue 04-08 are effective for all periods ending after December 15, 2004 and have been applied on a retroactive basis. All earnings per share amounts have been restated to reflect the impact of Issue 04-08. Previously disclosed 2003 diluted net income per share was reduced by \$0.02 to \$0.86. Restated quarterly diluted net income per share for 2004 and 2003 is presented in Note 15.

In March 2004, the EITF reached a consensus on Issue 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments". Issue 03-01 provides guidance regarding recognition and measurement of unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, "Accounting for Certain Investments in Debt and Equity Securities". The application of certain paragraphs covering the measurement provisions of Issue 03-01 have been deferred pending the issuance of a final FASB Staff Position providing implementation guidance on Issue 03-01. The disclosures are effective in annual financial statements for fiscal years ending after December 15, 2003. Management is currently assessing the impact that the recognition and measurement provisions of Issue 03-01 could have on the Company's financial statements.

In March 2004, the EITF reached a consensus on Issue 03-6, "Participating Securities and the Two-Class Method Under FASB Statement No. 128". Issue 03-6 expanded the notion of participation rights in calculating earnings per share from previous practice. Issue 03-6 defines participation rights based solely on whether the holder would be entitled to receive any dividends declared during the period, even if the company would not declare any dividends during the period due to economic or practical concerns or legal or contractual limitations on the company's ability to pay dividends. The adoption of Issue 03-06 in 2004 did not change the previously reported basic or diluted earnings per share for any period during the three years ended December 31, 2004. Previously disclosed pro forma basic and diluted net income per share for 2002, adjusted to reflect compensation cost for the Company's stock option plans as if it had been determined based on the fair value at the grant consistent with the provisions of Statement 123, was reduced as follows:

- 2002 pro forma basic net income per share was reduced by \$0.01 to \$1.04
- 2002 pro forma diluted net income per share was reduced by \$0.01 to \$1.02

### 3. ACQUISITIONS

#### **BUSINESS COMBINATIONS**

In May 2004, the Company acquired the MAYFIELD® Cranial Stabilization and Positioning Systems and the BUDDE® Halo Retractor System business from Schaerer Mayfield USA, Inc. (formerly Ohio Medical Instrument Company) for \$20.0 million in cash paid at closing, a \$0.3 million working capital adjustment, and \$0.3 million of acquisition related expenses. The MAYFIELD and BUDDE lines include skull clamps, headrests, reusable and disposable skull pins, blades, retractor systems, and spinal implants. MAYFIELD systems are the market leader in the United States and have been used by neurosurgeons for over thirty years. The products are sold in the United States through the Integra NeuroSciences direct sales organization and in international markets through distributors.

The acquired business includes a facility located in Cincinnati, Ohio that manufactures, packages and distributes MAYFIELD and BUDDE stabilization products, as well as a broad line of related instruments and disposables used in many neurosurgical and spinal procedures. In addition, as part of the acquisition, Integra entered into a long-term license with SM USA, Inc., a wholly owned subsidiary of Schaerer Mayfield USA, Inc., for the use of the MAYFIELD name in connection with the acquired business.

### 3. ACQUISITIONS (CONTINUED)

In connection with this acquisition, the Company recorded \$8.4 million of goodwill and \$8.1 million of intangible assets, consisting of a non-compete agreement, trade name, and technology, which are being amortized on a straight-line basis over lives ranging from 5 to 30 years.

In May 2004, the Company acquired all of the capital stock of Berchtold Medizin-Elektronik GmbH, now named Integra ME, from Berchtold Holding GmbH for \$5.0 million in cash. Integra ME manufactures and markets the ELEKTROTOM® line of electrosurgery generators and the SONOTOM® ultrasonic surgical aspirator, as well as a broad line of related handpieces, instruments and disposables used in many surgical procedures, including neurosurgery. Integra ME markets and sells its products to hospitals and physicians primarily through a network of distributors.

The acquired business includes a facility located in Tuttlingen, Germany that manufactures, packages and distributes the ELEKTROTOM and SONOTOM products. This acquisition provided Integra with additional devices for the European and international markets and an existing infrastructure through which it can sell certain of its other products directly into Germany.

In connection with this acquisition, the Company recorded \$1.7 million of goodwill and \$1.3 million of intangible assets, consisting primarily of trade name, technology, and customer relationships, which are being amortized on a straight-line basis over lives ranging from 3 to 10 years.

In January 2004, the Company acquired the R&B instrument business from R&B Surgical Solutions, LLC for \$2.0 million in cash. The R&B instrument line is a complete line of high-quality handheld surgical instruments used in neuro- and spinal surgery. The Company markets these products through its JARIT sales organization. In connection with this acquisition, the Company recorded \$1.5 million of intangible assets and goodwill. The acquired intangible assets are being amortized on a straight-line basis over lives ranging from 5 to 20 years. If the Company had consummated this acquisition as of the beginning of 2003, its operating results would not have been materially different from those presented herein.

In January 2004, the Company acquired the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. for \$1.6 million in cash. The Sparta product line includes products used in plastic and reconstructive, ear, nose and throat (ENT), neuro, ophthalmic and general surgery. The Company sells the Sparta products through a direct marketing organization and an existing distributor network. In connection with this acquisition, the Company recorded \$1.6 million of intangible assets and goodwill. The acquired intangible assets are being amortized on a straight-line basis over 5 years. If the Company had consummated this acquisition as of the beginning of 2003, its operating results would not have been materially different from those presented herein.

In November 2003, the Company acquired all of the outstanding capital stock of Spinal Specialties, Inc. for \$6.4 million in cash, including expenditures associated with the acquisition and a working capital adjustment. In connection with this acquisition, the Company recorded \$5.4 million of goodwill and intangible assets. The acquired intangible assets consisted primarily of trade name, technology and customer relationships and are being amortized on a straight-line basis over lives ranging from 3 to 15 years. Spinal Specialties markets its products primarily to anesthesiologists and interventional radiologists through an in-house telemarketing team and a network of distributors. Spinal Specialties' products include the OsteoJect<sup>TM</sup> Bone Cement Delivery System and the ACCU-DISC<sup>TM</sup> Pressure Monitoring System.

In August 2003, the Company acquired substantially all of the assets of Tissue Technologies, Inc., the manufacturer and distributor of the UltraSoft<sup>TM</sup> line of implants for soft tissue augmentation of the facial area. The Company paid \$0.6 million in cash and is obligated to pay the seller up to an additional \$1.5 million in contingent consideration based upon a multiple of the Company's sales of the UltraSoft product in the third year following the acquisition. Any future contingent consideration paid to the seller is expected be recorded as additional goodwill.

### 3. ACQUISITIONS (CONTINUED)

In March 2003, the Company acquired all of the outstanding capital stock of J. Jamner Surgical Instruments, Inc. (doing business as JARIT® Surgical Instruments) ("JARIT") for \$43.5 million in cash, including expenditures associated with the acquisition and net of \$2.1 million of cash acquired. JARIT markets a wide variety of high quality, reusable surgical instruments to virtually all surgical disciplines. The acquisition of JARIT has broadened Integra's existing customer base and surgical instrument product offering and has provided Integra with operating costs savings from the procurement of Integra's Ruggles<sup>TM</sup> and Padgett<sup>TM</sup> instruments products directly from the instrument manufacturers.

In connection with this acquisition, the Company recorded \$29.1 million of intangible assets, consisting primarily of trade name and customer relationships, which are being amortized on a straight-line basis over lives ranging from 5 to 40 years.

In December 2002, the Company acquired the neurosurgical shunt and epilepsy monitoring business of the Radionics division of Tyco Healthcare Group for \$3.7 million in cash, including expenditures associated with the acquisition. This acquisition broadened Integra's neurosurgical product line offering and customer base and increased capacity utilization at the Company's Biot facility.

In October 2002, the Company acquired all of the outstanding capital stock of Padgett Instruments, Inc., an established marketer of instruments used in reconstructive and plastic surgery, for \$9.6 million in cash, including expenditures associated with the acquisition. For more than 40 years, Padgett has been providing high quality instruments to meet the needs of the plastic and reconstructive surgeon and, as a result, has become one of the most recognized names in the plastic and reconstructive surgery market. Approximately \$5.4 million of the purchase price was allocated to the trademarks and trade name of the acquired business, which are being amortized on a straight-line basis over 40 years.

In August 2002, the Company acquired all of the capital stock of the neurosciences division of NMT Medical, Inc. for \$5.7 million in cash, including expenditures associated with the acquisition. Through this acquisition, the Company added a range of leading differential pressure valves and external ventricular drainage products to its neurosurgical product line. The acquired operations included a manufacturing facility located in Biot, France. The \$4.2 million fair value assigned to the land, building and equipment in Biot was determined based on a third party appraisal.

In July 2002, the Company acquired the assets of Signature Technologies, Inc., a specialty manufacturer of titanium and stainless steel implants for the neurosurgical and spinal markets, and certain other intellectual property assets. The Company acquired Signature Technologies to gain the capability of developing and manufacturing metal implants for strategic partners and for direct sale by Integra. The purchase price consisted of \$2.9 million in cash (including expenditures associated with the acquisition), \$0.5 million of deferred consideration that was paid in 2003, and royalties on future sales of products to be developed.

In connection with this acquisition, the Company recorded a \$1.2 million in-process research and development charge of for the value associated with a project for the development of an enhanced cranial fixation system using patented technology for improved identification and delivery of certain components of the system. The value of the in-process research and development charge was estimated with the assistance of a third party appraiser using probability weighted cash flow projections with factors for successful development ranging from 10% to 35% and a 15% discount rate.

The results of operations of the acquired businesses have been included in the consolidated financial statements since their respective dates of acquisition.

### 3. ACQUISITIONS (CONTINUED)

The following table summarizes the fair value of the assets acquired and liabilities assumed as a result of 2004 and 2003 acquisitions:

(All amounts in thousands)

,	MAYFIELD/		
2004 Acquisitions	BUDDE	Integra ME	R&B/Sparta
Current assets	\$ 3,489	\$3,151	\$ 817
Property, plant and equipment	1,400	78	10
Intangible assets	8,030	1,320	1,639
Goodwill	8,397	1,775	1,478
Total assets acquired	21,316	6,324	3,944
Current liabilities	768	837	340
Deferred tax liabilities	_	240	_
Other non-current liabilities		265	
Total liabilities assumed	768	1,342	340
Net assets acquired	\$20,548	\$4,982	\$3,604
	Spinal	Jarit	Tissue
2003 Acquisitions	Spinal Specialties	Jarit Instruments	Tissue Technologies
2003 Acquisitions Current assets	*		
<del></del>	Specialties	Instruments	Technologies
Current assets Property, plant and equipment Intangible assets	Specialties \$1,944	Instruments \$17,498	Technologies \$ 81
Current assets	Specialties \$1,944 307	Instruments \$17,498 1,285	Technologies \$ 81 88
Current assets Property, plant and equipment Intangible assets	Specialties \$1,944 307 2,300	Instruments \$17,498 1,285	Technologies
Current assets Property, plant and equipment Intangible assets Goodwill	Specialties \$1,944 307 2,300	Instruments \$17,498 1,285 29,091	Technologies
Current assets Property, plant and equipment Intangible assets Goodwill Other non-current assets	\$1,944 307 2,300 3,070	Instruments \$17,498 1,285 29,091 — 104	Technologies \$ 81 88 281 251
Current assets Property, plant and equipment Intangible assets Goodwill Other non-current assets Total assets acquired	\$1,944 307 2,300 3,070 — 7,621	Instruments \$17,498 1,285 29,091 — 104 47,978	Technologies \$ 81 88 281 251 701
Current assets Property, plant and equipment Intangible assets Goodwill Other non-current assets Total assets acquired Current liabilities	\$1,944 307 2,300 3,070 ———————————————————————————————————	Instruments \$17,498 1,285 29,091 — 104 47,978	Technologies \$ 81 88 281 251 701

The goodwill acquired in the MAYFIELD/BUDDE, R&B, Sparta, Tissue Technologies and Radionics acquisitions is expected to be deductible for tax purposes. The acquired intangible assets are being amortized on a straight-line basis over lives ranging from 2 to 40 years.

The following unaudited pro forma financial information summarizes the results of operations for the periods indicated as if the acquisitions consummated in 2004 and 2003 had been completed as of the beginning of each period. The pro forma results are based upon certain assumptions and estimates and they give effect to actual operating results prior to the acquisitions and adjustments to reflect increased depreciation expense, increased intangible asset amortization, and increased income taxes at a rate consistent with Integra's effective rate in each year. No effect has been given to cost reductions or operating synergies. As a result, these pro forma results do not necessarily represent results that would have occurred if the acquisition had taken place on the basis assumed above, nor are they indicative of the results of future combined operations.

		2004		2003
		(in tho	usand	(s)
Total revenue	\$23	36,031	\$21	12,372
Net income	1	17,872	2	27,937
Basic net income per share	\$	0.59	\$	0.96
Diluted net income per share	\$	0.57	\$	0.89

### 3. ACQUISITIONS (CONTINUED)

### ASSET ACQUISITIONS

In December 2003, the Company acquired the assets of Reconstructive Technologies, Inc.("RTI") for \$400,000 in cash and agreed to make certain future performance-based payments for the RTI assets. Any future contingent consideration paid to the seller is expected to be recorded as a technology-based intangible asset. RTI is the developer of the Automated Cyclic Expansion System (ACE System<sup>TM</sup>), a tissue expansion device. Because the ACE System was not approved by the FDA for sale and the Company did not acquire any assets other than technology and intellectual property underlying the ACE System, the Company recorded the entire acquisition price as an in-process research and development charge in the fourth quarter of 2003. This transaction was accounted for as an asset purchase because the acquired assets did not constitute a business under Statement 141.

In September 2002, the Company acquired certain assets, including the NeuroSensor<sup>TM</sup> monitoring system and rights to certain intellectual property, from Novus Monitoring Limited of the United Kingdom for \$3.7 million in cash (including expenditures associated with the acquisition), a \$1.4 million milestone payment related to the development of a next-generation, advanced neuromonitoring system that was paid in September 2004, and up to an additional \$2.5 million payable based upon revenues from Novus' products. As part of the consideration paid, Novus agreed to perform certain product development efforts on Integra's and those efforts were completed in 2004.

The assets acquired from Novus were accounted for as an asset purchase because the acquired assets did not constitute a business under Statement 141. The initial \$3.7 million purchase price was allocated as follows (in thousands):

Prepaid research and development expense	\$	771
Other assets		151
Intangible assets	1	,663
In-process research and development	1	,151

The acquired intangibles assets consisted primarily of technology-related intangible assets, which are being amortized on a straight-line basis over lives ranging from 3 to 15 years. The prepaid research and development expense represents the estimated fair value of future services to be provided by Novus under the development agreement. The \$1.2 million in-process research and development charge represents the value associated with the development of a next generation neuromonitoring system. The value of the in-process research and development was estimated with the assistance of a third party appraiser using probability weighted cash flow projections with factors for successful development ranging from 15% to 20% and a 15% discount rate.

The \$1.4 million product development milestone was recorded as research and development expense in 2004, as the underlying product technology was not approved by the FDA for sale.

### 4. DEBT

In March and April 2003, the Company completed a \$120.0 million private placement of contingent convertible subordinated notes due 2008.

The notes bear interest at 2.5 percent per annum, payable semiannually. The Company will pay additional interest ("Contingent Interest") if, at thirty days prior to maturity, Integra's common stock price is greater than \$37.56 per share. The Contingent Interest will be payable for each of the last three years the notes remain outstanding in an amount equal to the greater of i) 0.50% of the face amount of the notes and ii) the amount of regular cash dividends paid during each such year on the number of shares of common stock into which each note is convertible. The Company recorded a \$365,000 liability related to the estimated fair value of the Contingent Interest obligation at the time the notes were issued. The fair value of the Contingent Interest obligation is marked to its fair value at each balance sheet date, with changes in the fair value recorded to interest expense. At December 31, 2004 and 2003, the estimated fair value of the Contingent Interest obligation was \$710,000 and \$460,000, respectively.

### 4. DEBT (CONTINUED)

Debt issuance costs totaled \$4.1 million and are being amortized using the straight-line method over the five-year term of the notes.

Holders may convert their notes into shares of Integra common stock at an initial conversion price of \$34.15 per share, upon the occurrence of certain conditions, including when the market price of Integra's common stock on the previous trading day is more than 110% of the conversion price.

The notes are general, unsecured obligations of the Company and will be subordinate to any future senior indebtedness of the Company. The Company cannot redeem the notes prior to their maturity. Holders of the notes may require the Company to repurchase the notes upon a change in control.

Concurrent with the issuance of the notes, the Company used \$35.3 million of the proceeds to purchase 1.5 million shares of its common stock.

#### 5. DERIVATIVE INSTRUMENTS

In August 2003, the Company entered into an 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 its fixed rate contingent convertible subordinated notes. The Company receives a  $2\frac{1}{2}$ % fixed rate from the counterparty, payable on a semi-annual basis, and pays to the counterparty a floating rate based on 3-month LIBOR minus 35 basis points, payable on a quarterly basis. The floating rate resets each quarter. The interest rate swap agreement terminates on March 15, 2008, subject to early termination upon the occurrence of certain events, including redemption or conversion of the contingent convertible notes.

The interest rate swap agreement qualifies as a fair value hedge under SFAS No. 133, as amended, "Accounting for Derivative Instruments and Hedging Activities".

Accordingly, the interest rate swap is recorded at fair value and changes in fair value are recorded in other income (expense), net. The net amount to be paid or received under the interest rate swap agreement is recorded as a component of interest expense. Interest expense for the years ended December 31, 2004 and 2003, respectively, reflects a \$686,000 and a \$330,000 reduction associated with the interest rate swap. Our effective interest rate on the hedged portion of the notes was 1.6% as of December 31, 2004.

The net fair value of the interest rate swap at inception was \$767,000. In 2004 and 2003, respectively, the net fair value of the interest rate swap increased \$287,000 to \$1.4 million and \$305,000 to \$1.1 million. In connection with this fair value hedge, the Company recorded in 2004 and 2003, respectively, a \$430,000 and \$433,000 net decrease in the carrying value of its contingent convertible notes. The \$143,000 and \$128,000 net difference between changes in the fair value of the interest rate swap and the contingent convertible notes represents the ineffective portion of the hedging relationship, and these amounts are recorded in other income (expense), net.

At December 31, 2004 and 2003, the Company had \$2.9 million and \$2.2 million of cash pledged as collateral in connection with the interest rate swap agreement.

In November 2004, the Company entered into a collar contract for euro 38.5 million expiring in January 2005 to reduce its exposure to fluctuations in the exchange rate between the euro and the US dollar as a result of its commitment to acquire Newdeal in January 2005 for euro 38.5 million (see Note 16). The collar contract did not qualify as a hedge under SFAS No. 133. Accordingly, the collar contract is recorded at fair value and changes in fair value are recorded in other income (expense), net. In 2004, the Company recorded a \$1.4 million gain related to the change in the fair value of the collar contract.

### 6. COMMON AND PREFERRED STOCK

### PREFERRED STOCK TRANSACTIONS

The Company is authorized to issue up to 15,000,000 shares of preferred stock in one or more series, of which 2,000,000 shares have been designated as Series A, 120,000 shares have been designated as Series C.

On March 29, 2000, the Company issued 54,000 shares of Series C Convertible Preferred Stock (Series C Preferred) and warrants to purchase 300,000 shares of common stock at \$9.00 per share to affiliates of Soros Private Equity Partners LLC (SPEP) for \$5.4 million, net of issuance costs. The Series C Preferred ranked on a parity with the Company's then existing Series B Convertible Preferred Stock, was senior to the Company's common stock and all other preferred stock of the Company, and had a 10% cumulative annual dividend yield payable only upon liquidation. The Series C Preferred was converted into 600,000 shares of common stock in April 2002. The warrants issued with the Series C Preferred were exercised in December 2001 for proceeds of \$2.7 million.

SPEP is entitled to certain registration rights for shares of common stock obtained through conversion of its preferred stock or the exercise of the related warrants.

#### COMMON STOCK TRANSACTIONS

In 2004 and 2003, respectively, the Company repurchased 500,000 and 1.5 million shares of its common stock for \$14.2 million and \$35.4 million.

### 7. STOCK PURCHASE AND AWARD PLANS

### EMPLOYEE STOCK PURCHASE PLAN

The Company received stockholder approval for its Employee Stock Purchase Plan (ESPP) in May 1998. The purpose of the ESPP is to provide eligible employees of the Company with the opportunity to acquire shares of common stock at periodic intervals by means of accumulated payroll deductions. Under the ESPP, a total of 500,000 shares of common stock were originally reserved for issuance. In May 2004, stockholders of the Company approved an amendment to the ESPP that increased the number of shares available for issuance under the Plan by 1.0 million to 1.5 million shares. These shares will be made available either from the Company's authorized but unissued shares of common stock or from shares of common stock reacquired by the Company as treasury shares. At December 31, 2004, 1.1 million shares remain available for purchase under the amended ESPP.

### STOCK OPTION PLANS

As of December 31, 2004 the Company had stock options outstanding under seven plans, the 1993 Incentive Stock Option and Non-Qualified Stock Option Plan (the 1993 Plan), the 1996 Incentive Stock Option and Non-Qualified Stock Option Plan (the 1998 Plan), the 1998 Stock Option Plan (the 1998 Plan), the 1999 Stock Option Plan (the 1999 Plan), the 2000 Equity Incentive Plan (the 2000 Plan), the 2001 Equity Incentive Plan (the 2003 Plan, and collectively, the Plans). No new options may be granted under the 1993 Plan.

The Company has reserved 750,000 shares of common stock for issuance under both the 1993 Plan and 1996 Plan, 1,000,000 shares under the 1998 Plan, 2,000,000 shares under each of the 1999 Plan, the 2000 Plan and the 2001 Plan, and 2,500,000 shares under the 2003 Plan. The 1993 Plan, 1996 Plan, 1998 Plan, and the 1999 Plan permit the Company to grant both incentive and non-qualified stock options to designated directors, officers, employees and associates of the Company. The 2000 Plan, 2001 Plan, and 2003 Plan permit the Company to grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, performance stock, or dividend equivalent rights to designated directors, officers, employees and associates of the Company. Options issued under the Plans become exercisable over specified periods, generally within four years from the date of grant, and generally expire six years from the grant date.

### 7. STOCK PURCHASE AND AWARD PLANS (CONTINUED)

Option activity for all the Plans was as follows:

	20	004	20	003 200		2003 2002		002
		Wtd. Avg.		Wtd. Avg.		Wtd. Avg.		
	Options	Ex. Price	Options	Ex. Price	Options	Ex. Price		
			(shares in	thousands)				
Options outstanding at								
January 1,	2,884	\$16.19	4,295	\$12.15	4,261	\$10.79		
Granted	1,473	\$31.81	430	\$24.81	618	\$17.73		
Exercised	(547)	\$ 9.80	(1,726)	\$ 7.70	(425)	\$ 6.15		
Cancelled	(127)	\$21.97	(115)	\$17.40	(159)	\$13.39		
Options outstanding at								
December 31,	3,683	\$23.42	2,884	\$16.19	4,295	\$12.15		
Options exercisable at								
December 31,	1,641	\$17.61	1,495	\$13.65	2,380	\$ 8.75		

At December 31, 2004, there were 1,330,072 shares available for grant under the Plans.

The following table summarizes information about stock options outstanding as of December 31, 2004:

	Options Outstanding		Options E	Exercisable	
	As of	Wtd. Avg.	Wtd. Avg.	As of	Wtd. Avg.
Range Of	Dec. 31,	Exercise	Remaining	Dec. 31	Exercise
Exercise Prices	2004	Price	Contractual Life	2004	Price
	(shares in thousands)				
\$ 3.50 - \$13.63	838	\$10.05	2.9 years	712	\$ 9.87
\$13.75 - \$26.34	918	\$20.26	3.6 years	544	\$20.52
\$26.45 - \$28.78	897	\$27.95	4.3 years	306	\$27.10
\$28.80 - \$34.49	761	\$32.39	6.7 years	80	\$30.40
\$34.62 - \$35.52	269	\$35.43	5.9 years		\$ 0.00
	3,683	\$23.42	4.4 years	1,641	\$17.61

The weighted average fair market value of options granted in 2004, 2003 and 2002 was \$13.48, \$13.01, and \$9.57 per share, respectively.

### CONTRACT STOCK AND RESTRICTED UNITS AWARDS

In July 2004, the Company's President and Chief Executive Officer (Executive) renewed his employment agreement with the Company through December 31, 2009. In connection with the renewal of the agreement, the Executive received a grant of fair market value options to acquire up to 250,000 shares of Integra common stock and a fully vested contract stock unit award providing for the payment of 750,000 shares of Integra common stock which shall generally be delivered to the Executive following his termination of employment or retirement but not before December 31, 2009, or later under certain circumstances, or earlier if he is terminated without cause, if he leaves his position for good reason or upon a change of control or certain tax related events. The options and contract stock award were granted under the 2003 Plan. In connection with the fully vested contract stock award, the Company recorded a share-based compensation charge of \$23.9 million, including payroll taxes, in 2004 for the compensation expense related to the fully-vested contract stock unit grant. The Executive has demand registration rights under the Restricted Units issued.

### 7. STOCK PURCHASE AND AWARD PLANS (CONTINUED)

In December 2000, the Company issued 1,250,000 restricted units (Restricted Units) under the 2000 Plan as a fully vested equity based bonus to the Executive in connection with the extension of his employment agreement. Each Restricted Unit represents the right to receive one share of the Company's common stock. The Executive has demand registration rights under the Restricted Units issued.

The Executive received 1,000,000 Restricted Units in December 1997, each of which entitles him to receive one share of the Company's common stock. The Restricted Units issued in December 1997 were not issued under any of the Plans.In November 2003, the 1997 restricted units were converted into 1,000,000 shares of the Company's common stock.

No other stock-based awards are outstanding under any of the Plans.

#### 8. RETIREMENT BENEFIT PLANS

#### DEFINED BENEFIT PLAN

The Company maintains defined benefit pension plans that cover employees in its manufacturing plants located in Andover, United Kingdom (the "UK Plan") and Tuttlingen, Germany (the "Germany Plan"). The plans cover certain current and former employees. The UK Plan is no longer open to new participants. The Company uses a December 31 measurement date for both of its pension plans.

Net periodic benefit costs for these defined benefit pension plans included the following amounts:

	2004	2003	2002
	(	(in thousands)	
Service cost	\$ 179	\$ 88	\$ 122
Interest cost	522	397	355
Expected return on plan assets	(434)	(330)	(331)
Recognized net actuarial loss	203	116	85
Net periodic benefit cost	\$ 470	\$ 271	\$ 231

The following weighted average assumptions were used to develop net periodic benefit cost and the actuarial present value of projected benefit obligations:

	2004	2003	2002
Discount rate	5.2%	5.4%	5.5%
Expected return on plan assets	5.8%	6.2%	6.5%
Rate of compensation increase	3.3%	3.3%	3.8%

The expected return on plan assets represents the average rate of return expected to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data as well as actual returns on the plan assets and applies adjustments that reflect more recent capital market experience. Using this reference information, the long-term return expectations for each asset category is developed, according to the allocation among those investment categories.

### 8. RETIREMENT BENEFIT PLANS (CONTINUED)

The following sets forth the change in benefit obligations and change in plan assets at December 31, 2003 and 2002 and the accrued benefit cost:

	December 31,	
	2004	2003
	(in thou	sands)
CHANGE IN PROJECTED BENEFIT OBLIGATION		
Projected benefit obligation, beginning of year	\$ 8,832	\$ 6,803
Service cost	179	88
Interest cost	522	397
Participant contributions	42	36
Benefits paid	(183)	(151)
Actuarial (gain) loss	656	857
Acquisitions	474	_
Effect of foreign currency exchange rates	845	802
Projected benefit obligation, end of year	\$11,367	\$ 8,832
CHANGE IN PLAN ASSETS		
Plan assets at fair value, beginning of year	\$ 6,646	\$ 5,068
Actual return on plan assets	816	881
Employer contributions	238	211
Participant contributions	37	36
Benefits paid	(183)	(151)
Other	46	_
Acquisitions	162	
Effect of foreign currency exchange rates	617	601
Plan assets at fair value, end of year	\$ 8,379	\$ 6,646
RECONCILIATION OF FUNDED STATUS		
Funded status, projected benefit obligation in excess of plan assets	\$ (2,988)	\$(2,186)
Unrecognized net actuarial loss	2,759	2,416
Adjustment to recognize minimum liability	(2,543)	(1,804)
Accrued benefit cost	\$ (2,772)	\$(1,574)

The accrued benefit liability recorded at December 31, 2004 and 2003 is included in other liabilities.

The combined accumulated benefit obligation for the defined benefit plans was \$11.2 million and \$8.2 million as of December 31, 2004 and 2003, respectively. The accumulated benefit obligation for each plan exceeded that plan's assets for all periods presented.

The weighted-average allocation of plan assets by asset category is as follows:

	December 31,	
	2004	2003
Equity securities	52%	54%
Corporate bonds	19%	19%
Government bonds	22%	22%
Insurance contracts	2%	0%
Cash	5%	5%
	100%	100%

### 8. RETIREMENT BENEFIT PLANS (CONTINUED)

The investment strategy for the Company's defined benefit plans is both to meet the liabilities of the plans as they fall due and to maximize the return on invested assets within appropriate risk tolerances. In 2002, the UK Plan began shifting its portfolio from primarily equity securities to a portfolio more weighted towards corporate bonds. The assets of the Germany Plan consist entirely of insurance contracts.

The Company anticipates contributing approximately \$250,000 to its defined benefit plans in 2005. The Company expects to pay the following estimated future benefit payments in the years indicated:

2005	\$	218,000
2006		248,000
2007		264,000
2008		293,000
2009		337,000
2010-2014	2	2,384,000

#### DEFINED CONTRIBUTION PLAN

The Company also has various defined contribution savings plans that cover substantially all employees in the United States, the United Kingdom, and Puerto Rico. The Company matches a certain percentage of each employee's contributions as per the provisions of the plans. Total contributions by the Company to the plans were \$622,000, \$483,000 and \$575,000 in 2004, 2003 and 2002, respectively.

### 9. LEASES

The Company leases administrative, manufacturing, research and distribution facilities and various manufacturing, office and transportation equipment through operating lease agreements.

In November 1992, a corporation whose shareholders are trusts, whose beneficiaries include family members of the Company's Chairman, acquired from independent third parties a 50% interest in the general partnership from which the Company leases its manufacturing facility in Plainsboro, New Jersey. The lease provides for a rent escalation of 8.5% in 2007 and expires in October 2012.

In June 2000, the Company signed a ten-year agreement to lease certain production equipment from a corporation whose sole stockholder is a general partnership, for which the Company's Chairman is a partner and the President. Under the terms of the lease agreement, the Company paid \$90,000 to the related party lessor in 2004, 2003 and 2002.

Future minimum lease payments under operating leases at December 31, 2004 were as follows:

	Related Parties	Third Parties	Total
		(in thousands)	
2005	\$ 321	\$2,317	\$2,638
2006	321	1,719	2,040
2007	324	936	1,260
2008	341	119	460
2009	341	119	460
Thereafter	755	991	1,746
Total minimum lease payments	\$2,403	\$6,201	\$8,604

Total rental expense in 2004, 2003, and 2002 was \$2.3 million, \$2.9 million, and \$2.0 million, respectively, and included \$321,000, \$321,000, and \$321,000, in related party expense, respectively.

#### 10. INCOME TAXES

The income tax expense (benefit) consisted of the following:

	2004	2003	2002
		(in thousands)	
Current:			
Federal	\$ 1,899	\$ 972	\$ —
State	1,670	2,470	1,276
Foreign	1,141	529	(427)
Total current	4,710	3,971	849
Deferred:			
Federal	\$ 5,802	\$12,800	\$(13,671)
State	53	83	373
Foreign	246	(526)	(103)
Total deferred	6,101	12,357	(13,401)
Income tax expense (benefit)	\$10,811	\$16,328	\$(12,552)

The temporary differences that give rise to deferred tax assets are presented below:

	December 31,	
	2004	2003
	(in thou	isands)
Net operating loss and tax credit carryforwards	\$13,405	\$22,695
Inventory reserves and capitalization	2,145	2,294
Other	_	1,758
Deferred compensation	14,164	5,361
Deferred income	1,821	1,434
Total deferred tax assets before valuation allowance	31,535	33,542
Valuation allowance	(5,360)	(5,360)
Depreciation and amortization	(5,327)	(6,421)
Other	(1,095)	(392)
Net deferred tax assets	\$19,753	\$21,369

At December 31, 2004 and 2003, respectively, \$4.0 million and \$3.7 million of the net deferred tax asset is included in prepaid expenses and other current assets.

Since 1999, the Company has generated positive taxable income on a cumulative basis. In light of this trend, current projections for future taxable earnings, and the expected timing of the reversal of deductible temporary differences, in 2002, the Company reduced the remaining valuation allowance recorded against net operating loss carryforwards by \$23.4 million, which reflected the Company's estimate of additional tax benefits that it expected to realize in the future. A valuation allowance of \$5.4 million is recorded against the remaining \$31.5 million of deferred tax assets recorded at December 31, 2004. This valuation allowance relates to deferred tax assets for certain expenses that will be deductible for tax purposes in very limited circumstances and for which the Company believes it is unlikely that it will recognize the associated tax benefit. The Company does not anticipate additional income tax benefits through future reductions in the valuation allowance. However, in the event that the Company determines that it would be able to realize more or less than the recorded amount of net deferred tax assets, an adjustment to the deferred tax asset valuation allowance would be recorded in the period such a determination is made.

### 10. INCOME TAXES (CONTINUED)

In 2004, our effective income tax rate was 38.6% of income before income taxes compared to 37.8% in 2003. Our 2004 rate includes a \$1.3 million tax charge related to the transfer of certain intangible assets. We recorded a net income tax benefit in 2002 related to the reduction of the deferred tax asset valuation allowance.

The net change in the Company's valuation allowance was \$(2.3) million and \$(26.7) million, in 2003 and 2002, respectively.

A reconciliation of the United States Federal statutory rate to the Company's effective tax rate for the years ended December 31, 2004, 2003, and 2002 is as follows:

	2004	2003	2002
Federal statutory rate	35.0%	35.0%	35.0%
Increase (reduction) in income taxes resulting from:			
State income taxes, net of federal tax benefit	4.0%	3.9%	3.7%
Foreign taxes booked at different rates	(4.2%)	(1.0%)	(2.5%)
Tax on asset transfer	4.5%	_	_
Other	(0.7%)	(0.1%)	(1.5%)
Change in valuation allowance			(89.9%)
Effective tax rate	38.6%	37.8%	<u>(55.2%)</u>

At December 31, 2004, the Company had net operating loss carryforwards of \$46.8 million and \$0.6 million for federal and state income tax purposes, respectively, to offset future taxable income. The federal and state net operating loss carryforwards expire through 2018 and 2005, respectively.

At December 31, 2004, several of the Company's subsidiaries had unused net operating loss carryforwards and tax credit carryforwards arising from periods prior to the Company's ownership which expire through 2005. The Internal Revenue Code limits the timing and manner in which we may use any acquired net operating losses or tax credits.

Income taxes are not provided on undistributed earnings of non-U.S. subsidiaries because such earnings are expected to be permanently reinvested. Undistributed earnings of foreign subsidiaries totaled \$2.6 million at December 31, 2004.

The American Jobs Creation Act of 2004 (the "Act") was signed into law in October 2004 and has several provisions that may impact the Company's income taxes in the future, including the repeal of the extraterritorial income exclusion and a deduction related to qualified production activities taxable income. The Financial Accounting Standards Board ("FASB") proposed that the qualified production activities deduction is a special deduction and will have no impact on deferred taxes existing at the enactment date. Rather, the impact of this deduction will be reported in the period in which the deduction is claimed on the Company's tax return. Management is currently evaluating the impact of the FASB guidance related to qualified production activities on the Company's effective tax rate in future periods.

### 11. NET INCOME PER SHARE

Amounts used in the calculation of basic and diluted net income per share were as follows:

	2004	2003	2002
Basic:	(in thousand	s, except per sh	are amounts)
Net income	\$17,197	\$26,861	\$35,277
Less: Dividends on Series C Preferred Stock	_	_	(159)
Series C Preferred Stock			(96)
Net income applicable to common stock	\$17,197	\$26,861	\$35,022
Basic net income per share	\$0.57	\$0.92	\$1.21
Weighted average common shares outstanding—Basic	30,064	29,071	29,021
Diluted:			
Net income	\$17,197	\$26,861	\$35,277
Add back: Interest expense and other income/(expense) related			
to convertible notes payable, net of tax	_	1,608	_
Less: Dividends on Series C Preferred Stock	_	_	(159)
Series C Preferred Stock			(96)
Net income applicable to common stock	\$17,197	\$28,469	\$35,022
Diluted net income per share	\$0.55	\$0.86	\$1.14
Weighted average common shares outstanding—Basic Effect of dilutive securities:	30,064	29,071	29,021
Stock options and warrants	1,038	1,397	1,699
Shares issuable upon conversion of notes payable		2,636	
Weighted average common shares outstanding	31,102	33,104	30,720

Shares of common stock issuable through exercise or conversion of the following dilutive securities were not included in the computation of diluted net income per share for each period because their effect would have been antidilutive:

	2004	2003	2002
		(in thousands)	
Stock options	155	424	1,104
Shares issuable upon conversion of notes payable	3,514		
Total	3,669	424	1,104

A contract stock unit award that entitles the holder to 750,000 shares of common stock and Restricted Units that entitle the holder to 1,250,000 shares of common stock (see Note 7) are included in the weighted average shares outstanding calculation from their date of issuance because no further consideration is due related to the issuance of the underlying common shares.

### 12. DEVELOPMENT, DISTRIBUTION, AND LICENSE AGREEMENTS AND GOVERNMENT GRANTS

The Company has various development, distribution, and license agreements under which it receives payments. Significant agreements include the following:

From 1999 through 2003, ETHICON, Inc., a division of Johnson & Johnson, marketed and distributed the Company's INTEGRA® Dermal Regeneration Template under the terms of a ten year distribution agreement (the "ETHICON Agreement"). Upon signing the ETHICON Agreement, the Company received a nonrefundable payment from ETHICON of \$5.3 million for the exclusive use of the Company for trademarks and regulatory filings related to the INTEGRA® Dermal Regeneration Template and certain other rights. This amount was initially recorded as deferred revenue and was recognized as revenue in accordance with the Company's revenue recognition policy for nonrefundable, up-front fees received. Additionally, the ETHICON Agreement required ETHICON to make nonrefundable payments to the Company each year based upon minimum purchases of INTEGRA® Dermal Regeneration Template. Upon early termination of the ETHICON Agreement in December 2003, ETHICON paid Integra \$2.0 million, which the Company recorded as other income. The Company also recorded \$11.0 million of other revenue in the fourth quarter of 2003 related to the acceleration of the recognition of unused minimum purchase payments and unamortized license fee revenue.

In 2003, and 2002, the Company received \$2.8 million and \$1.0 million, respectively, of event-related payments from ETHICON and \$2.0 million of research funding. Both the event-related payments and the research funding were recorded in other operating revenue in accordance with the Company's revenue recognition policy.

The Company has an agreement with Wyeth for the development of collagen and other absorbable matrices to be used in conjunction with Wyeth's recombinant human bone morphogenetic protein-2 (rhBMP-2) in a variety of bone regeneration applications. The agreement with Wyeth requires Integra to supply Absorbable Collagen Sponges to Wyeth (including those that Wyeth sells to Medtronic Sofamor Danek with rhBMP-2 for use in Medtronic Sofamor Danek's InFUSE<sup>TM</sup> product) at specified prices. In addition, the Company receives a royalty equal to a percentage of Wyeth's sales of surgical kits combining rhBMP-2 and the Absorbable Collagen Sponges. The agreement terminates in 2007, but may be extended at the option of the parties. The agreement does not provide for milestones or other contingent payments, but Wyeth pays the Company to assist with regulatory affairs and research. The Company received \$2.2 million and \$1.2 million of research and development revenues under the agreement in 2003 and 2002, respectively.

### 13. COMMITMENTS AND CONTINGENCIES

As consideration for certain technology, manufacturing, distribution and selling rights and licenses granted to the Company, the Company has agreed to pay royalties on the sales of products that are commercialized relative to the granted rights and licenses. Royalty payments under these agreements by the Company were not significant for any of the periods presented.

Various lawsuits claims and proceedings are pending or have been settled by the Company. The most significant of those are described below.

In July 1996, the Company filed a patent infringement lawsuit in the United States District Court for the Southern District of California (the "Trial Court") against Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps, seeking damages and injunctive relief. The complaint charged, among other things, that the defendant Merck KGaA willfully and deliberately induced, and continues willfully and deliberately to induce, defendants Scripps Research Institute and Dr. Cheresh to infringe certain of the Company's patents. These patents are part of a group of patents granted to The Burnham Institute and licensed by Integra that are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid ("RGD") peptide sequence found in many extracellular matrix proteins. The defendants filed a countersuit asking for an award of defendants' reasonable attorney fees.

### 13. COMMITMENTS AND CONTINGENCIES (CONTINUED)

In March 2000, a jury returned a unanimous verdict in the Company's favor and awarded Integra \$15.0 million in damages, finding that Merck KGaA had willfully infringed and induced the infringement of our patents. The Trial Court dismissed Scripps and Dr. Cheresh from the case.

In October 2000, the Trial Court entered judgment in Integra's favor and against Merck KGaA in the case. In entering the judgment, the Trial Court also granted to the Company pre-judgment interest of \$1.4 million, bringing the total award to \$16.4 million, plus post-judgment interest. Merck KGaA filed various post-trial motions requesting a judgment as a matter of law notwithstanding the verdict or a new trial, in each case regarding infringement, invalidity and damages. In September 2001, the Trial Court entered orders in favor of Integra and against Merck KGaA on the final post-judgment motions in the case, and denied Merck KGaA's motions for judgment as a matter of law and for a new trial.

Merck KGaA and Integra each appealed various decisions of the Trial Court to the United States Court of Appeals for the Federal Circuit (the "Circuit Court"). In June 2003, the Circuit Court affirmed the Trial Court's finding that Merck KGaA had infringed our patents. The Circuit Court also held that the basis of the jury's calculation of damages was not clear from the trial record, and remanded the case to the Trial Court for further factual development and a new calculation of damages consistent with the Circuit Court's decision. Merck KGaA filed a petition for a writ of certiorari with the United States Supreme Court (the "Supreme Court") seeking review of the Circuit Court's decision, and the Supreme Court granted the writ in January 2005. Oral argument is scheduled for April 2005, and we expect the Supreme Court to render a decision before the end of its current term.

In September 2004, the Trial Court ordered Merck KgaA to pay Integra \$6.4 million in damages. following the Circuit Court's order. Further enforcement of the Trial Court's order has been stayed pending the decision of the Supreme Court.

The Company has not recorded any gain in connection with this matter, pending final resolution and completion of the appeals process.

In addition to the Merck KGaA matter, the Company is subject to various claims, lawsuits and proceedings in the ordinary course of its 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 the Company's 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.

Three of the Company's French subsidiaries that were acquired from the neurosciences division of NMT Medical, Inc. received a tax reassessment notice from the French tax authorities seeking in excess of 1.7 million euros in back taxes, interest and penalties. Following objection from NMT Medical, the amount claimed by the authorities was reduced to 930,367 euros, and negotiations and other procedures are under way, which may lead to a further reduction of the amount owed. NMT Medical, the former owner of these entities, has agreed to indemnify Integra against direct damages and liability arising from misrepresentations in connection with these tax claims. In addition, NMT Medical, Inc. has agreed to provide the French tax authorities with payment of the tax liabilities on behalf of each of these subsidiaries.

In December 2003, the Company recorded a \$1.1 million charge in connection with closing of its San Diego research center, the termination of certain research programs conducted there, and the consolidation of the remaining research activities into its other facilities. The charge consisted of the following (in thousands):

### 13. COMMITMENTS AND CONTINGENCIES (CONTINUED)

Facility lease termination fee	\$	379
Research program termination costs		216
Property and equipment impairment		183
Inventory write-off		157
Employee severance		120
Other		52
Total	\$1	,107

The inventory write-off was recorded to cost of product revenues. All other amounts were recorded to research and development expense. All amounts were paid in 2003, except for the employee severance amounts, which were included in accrued expenses and other current liabilities at December 31, 2003 and subsequently paid in 2004.

#### 14. SEGMENT AND GEOGRAPHIC INFORMATION

Integra management reviews financial results and manages the business on an aggregate basis. Therefore, financial results are reported in a single operating segment, the development, manufacture and marketing of medical devices for use in neuro-trauma, neurosurgery, reconstructive surgery and general surgery.

Product revenues consisted of the following:

	2004	2003	2002
		(in thousands)	
Monitoring products	\$ 48,217	\$ 44,229	\$ 37,184
Implant products	78,418	53,301	38,326
Instruments	77,667	47,168	16,802
Private label products	24,188	21,997	20,313
Consolidated product revenues	\$228,490	\$166,695	\$112,625

Certain of the Company's products, including the DuraGen® Dural Graft products, NeuraGen<sup>TM</sup> Nerve Guide, INTEGRA® Dermal Regeneration Template, INTEGRA™ Bi-Layer Matrix Wound Dressing, and BioMend® Absorbable Collagen Membrane, contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food as well as pharmaceuticals and medical devices, are increasingly subject to scrutiny from the press and regulatory authorities. These products comprised 31%, 27% and 32% of product revenues in 2004, 2003 and 2002, respectively. Accordingly, widespread public controversy concerning collagen products, new regulation, or a ban of the Company's products containing material derived from bovine tissue, could have a material adverse effect on the Company's current business or its ability to expand its business.

### 14. SEGMENT AND GEOGRAPHIC INFORMATION (CONTINUED)

Product revenue and long-lived assets (excluding financial instruments and deferred tax assets) by major geographic area are summarized below:

	United		Asia	Other	
	States	Europe	Pacific	Foreign	Consolidated
			(in thousands)		
Product revenue:					
2004	\$180,887	\$30,941	\$8,535	\$8,127	\$228,490
2003	132,805	21,433	5,828	6,629	166,695
2002	90,422	14,737	4,062	3,404	112,625
Long-lived assets:					
December 31, 2004	\$ 83,235	\$46,282	\$ —	\$ —	\$129,517
December 31, 2003	81,182	21,082	_	_	102,264
December 31, 2002	45,319	18,408	_		63,727

### 15. SELECTED QUARTERLY INFORMATION—UNAUDITED

	Fourth Ouarter	Third Ouarter	Second Ouarter	First Quarter
2004:		thousands, exce		
Total revenue	\$61,811 23,221 24,959	\$ 59,130 22,412 48,898	\$56,441 21,665 23,176	\$52,443 20,001 20,714
Operating income (loss)	13,631	(12,180)	11,600	11,728
Interest income (expense), net  Other income (expense), net	95 2,250	243 306	160 135	57 (17)
Income (loss) before income taxes	15,977 6,137	(11,631) (4,034)	11,895 4,377	11,768 4,331
Net income (loss)	\$ 9,839	\$ (7,597)	\$ 7,518	\$ 7,437
Basic net income per share	\$ 0.32	\$ (0.25)	\$ 0.25	\$ 0.25
Diluted net income per share	\$ 0.30	\$ (0.25)	\$ 0.23	\$ 0.23

The retroactive application of EITF Issue 04-08 reduced previously reported diluted earnings per share by \$0.01 in both the first and second quarters of 2004.

In the third quarter of 2004, the Company recorded the following:

- a \$1.4 million charge in connection with a milestone payment related to the completion of certain development activities related to an advanced neuromonitoring system;
- a \$23.9 million share-based compensation charge associated with the renewal of the Company's President and Chief Executive Officer's employment agreement; and
- a \$1.3 million tax charge incurred in connection with the reorganization of certain European operations.

In the fourth quarter of 2004, the Company recognized \$1.4 million of other income related to an unrealized gain on a foreign currency collar, which was used to reduce the exposure to fluctuations in the exchange rate between the euro and the US dollar as a result of the Company's commitment to acquire Newdeal Technologies for 38.5 million euros. The Newdeal Technologies acquisition was completed in January 2005.

### 15. SELECTED QUARTERLY INFORMATION—UNAUDITED (CONTINUED)

	Fourth	Third	Second	First
	Quarter	Quarter	Quarter	Quarter
<u>2003</u> :	(in	thousands, exce	pt per share da	ta)
Total revenue	\$59,025	\$47,058	\$42,736	\$36,780
Cost of product revenues	20,935	18,869	17,090	13,703
Total other operating expenses	25,095	17,266	17,357	15,637
Operating income	12,995	10,923	8,289	7,440
Interest income (expense), net	81	(188)	(198)	776
Other income (expense), net	1,962	309	451	349
Income before income taxes	15,038	11,044	8,542	8,565
Income tax expense	5,867	4,210	3,124	3,127
Net income	\$ 9,171	\$ 6,834	\$ 5,418	\$ 5,438
Basic net income per share	\$ 0.31	\$ 0.24	\$ 0.19	\$ 0.18
Diluted net income per share	\$ 0.28	\$ 0.22	\$ 0.18	\$ 0.18

In the fourth quarter of 2003, the Company recorded the following:

- \$11.0 million of other revenue related to the acceleration of the recognition of unused minimum purchase payments and unamortized license fee revenue from ETHICON following the termination of the Supply, Distribution and Collaboration agreement in December 2003;
- a \$2.0 million payment from ETHICON from the termination of the agreement with them, which is included in other income:
- \$1.1 million of expenses related to the closing of the Company's San Diego research center, consolidation of the research activities into other facilities and the discontinuation of certain research programs;
- a \$400,000 acquired in-process research and development charge in connection with an acquisition; and
- a \$2.0 million donation to the Integra Foundation, which is included in selling, general and administrative expenses.

The retroactive application of EITF Issue 04-08 reduced previously reported diluted earnings per share by \$0.01 and \$0.02, respectively, in the second and third quarters of 2003.

### 16. SUBSEQUENT EVENT

In November 2004, the Company agreed to acquire all of the outstanding capital stock of Newdeal Technologies SA ("Newdeal") for euro 38.5 million in cash, subject to certain adjustments. The acquisition closed on January 3, 2005.

Based in Lyon, France, Newdeal is a leading developer and marketer of specialty implants and instruments specifically designed for foot and ankle surgery. Newdeal's products include a wide range of products for the forefoot, the mid-foot and the hind foot, including the Bold® Screw, Hallu-Fix® plate system and the HINTEGRA® total ankle prosthesis. The company sells its products through a direct sales force in France, Belgium and the Netherlands, and through distributors in more than 30 countries, including the United States and Canada. Newdeal's target physicians include orthopedic surgeons specializing in injuries of the foot, ankle and extremities, as well as podiatric surgeons. The Company expects to benefit from the synergy between Newdeal's reconstructive foot and ankle fixation products and Integra's regenerative products that are used in the treatment of chronic and traumatic wounds of the foot and ankle.

### 16. SUBSEQUENT EVENT (CONTINUED)

The determination of the fair value of the assets acquired and liabilities assumed as a result of this acquisition is in progress. Based on a preliminary valuation, the following summarizes the fair value of the assets acquired and liabilities assumed:

(All amounts in thousands)

Current assets	\$12,616
Property, plant and equipment	1,078
Intangible assets	14,900
Goodwill	27,614
Total assets acquired	56,208
Liabilities assumed	4,341
Net assets acquired	\$51,867

The acquired intangible assets consist primarily of developed technology, trade name, and customer relationships and are expected to be amortized over lives ranging from 5 to 30 years.

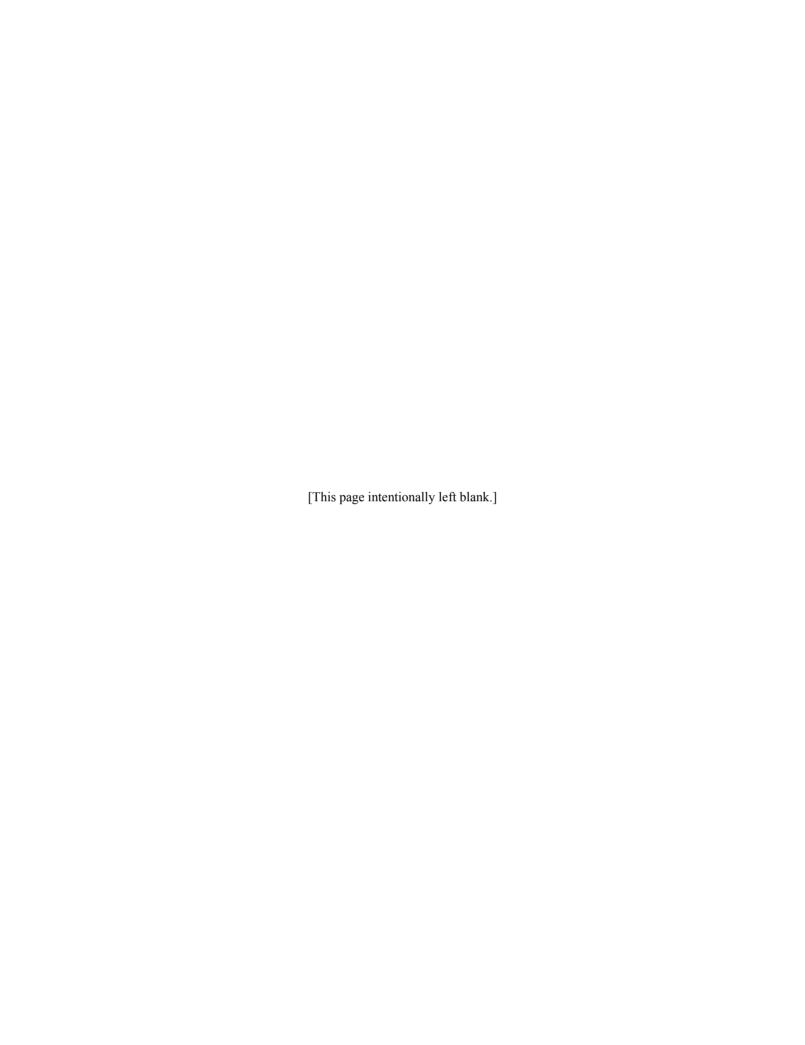
# INTEGRA LIFESCIENCES HOLDINGS CORPORATION VALUATION AND QUALIFYING ACCOUNTS

### **SCHEDULE II**

Description	Balance at Beginning Of Period	Charged to Costs and Expenses		Deductions(2)	Balance at End of Period
Year ended December 31, 2004			(in thousands)		
Allowance for doubtful accounts and Sales Returns	\$ 2,025	\$ 802	\$ 249	\$ (327)	\$2,749
Inventory reserves	6,204	1,210	1,056	(870)	7,600
Deferred tax asset valuation allowance	5,360	_	_	_	5,360
Year ended December 31, 2003					
Allowance for doubtful accounts and Sales Returns	\$ 1,387	\$ 541	\$ 497	\$ (400)	\$2,025
Inventory reserves	9,573	3,193	894	(7,456)	6,204
Deferred tax asset valuation allowance	7,692	_	(2,332)	_	5,360
Year ended December 31, 2002					
Allowance for doubtful accounts and Sales Returns	\$ 1,403	\$ 1,961	\$ 559	\$ (2,537)	\$1,387
Inventory reserves	5,812	4,152	787	(1,178)	9,573
Deferred tax asset valuation allowance	34,356	(20,389)	(3,260)	(3,015)	7,692

<sup>(1)</sup> All amounts shown were recorded to goodwill in connection with acquisitions except for the \$2.3 million and \$3.3 million reduction in the deferred tax asset valuation allowance in 2003 and 2002, respectively, which were written off against the gross deferred tax asset.

<sup>(2)</sup> The \$3.0 million reduction of the deferred tax asset valuation allowance in 2002 was recorded to additional paid-in capital.



### **Corporate Information**

### Annual Meeting

The 2005 Annual Meeting of Stockholders will be held at 9:00 a.m., Tuesday, May 17, 2005 at the Radisson Hotel Princeton, 4355 Route 1 at Ridge Road, Princeton, New Jersey 08540

### Stock Trading Information

Integra stock trades on the Nasdaq National Market under the symbol "IART"

#### Investor Relations

Contact the Integra Investor Relations department at (609) 936-2491 or <a href="IR@Integra-LS.com">IR@Integra-LS.com</a> for business-related inquiries

Stockholders may obtain, without charge, a copy of the following documents:

- Proxy statement for the 2005 Annual Meeting of Stockholders
- Quarterly reports on Form 10-Q
- Additional copies of the 2004 Annual Report on Form 10-K

Requests for these documents should be addressed to:

Investor Relations Department Integra LifeSciences Holdings Corporation 311 Enterprise Drive Plainsboro, New Jersey 08536 Email: IR@Integra-LS.com

### Internet Address

Additional information about the Company, including a copy of this Annual Report and quarterly reports on Form 10-Q, a description of our business and products, recent financial data and press releases, investor relations calendar and stock price information is available on our home page on the Internet at <a href="https://www.integra-LS.com">www.integra-LS.com</a>.

### Headquarters

Integra LifeSciences Holdings Corporation 311 Enterprise Drive Plainsboro, New Jersey 08536 (609) 275-0500 (609) 799-3297 fax

### Stockholder Account Maintenance

Our transfer agent, American Stock Transfer & Trust, Co., can help you with a variety of stockholder related services, including:

- change of address
- lost stock certificates
- transfer of stock to another person
- verification of your holdings

You can call our transfer agent toll-free at (800) 937-5449 or reach them on the Internet at <a href="https://www.amstock.com">www.amstock.com</a>.

### Independent Public Accountants

PricewaterhouseCoopers L.L.P. Florham Park, New Jersey