



Annual Report

03



**INTEGRA LIFESCIENCES  
HOLDINGS CORPORATION**

**Corporate Officers**

Stuart M. Essig  
*President, Chief Executive Officer and  
Director*

Gerard S. Carlozzi  
*Executive Vice President, Chief Operating  
Officer*

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

David B. Holtz  
*Senior Vice President, Finance and  
Treasurer*

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*

Deborah A. Leonetti  
*Vice President, Global Marketing*

**Outside Directors**

Richard E. Caruso, PhD. <sup>(3)</sup>  
*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. <sup>(1) (2) (3)</sup>  
*Former Professor of International  
Management and Management Strategy  
at the Open University and City University,  
London Business Schools*

Neal Moszkowski <sup>(1) (2)</sup>  
*Managing Director of Soros Fund  
Management LLC and Co-Chief Executive  
of Soros Private Equity*

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

<sup>(1)</sup> 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:

In 2003, we achieved record revenues and operating income while continuing to develop our extensive product offerings and global infrastructure. We grew total revenues to \$185.6 million in 2003, a 58% increase over 2002. Operating income was \$39.6 million in 2003, a 107% increase over 2002. Net income totaled \$26.9 million in 2003, and cash flows generated from operations in 2003 totaled \$34.8 million — our best performance ever.

Many factors contributed to this record performance. 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 neurosurgery and neurotrauma), Integra Plastic and Reconstructive (calling on burn, plastic and reconstructive surgery) and JARIT® Surgical Instruments (calling on traditional and minimally invasive surgery). Our global selling organization now has over 200 sales, marketing, and clinical people who provide unparalleled product support, customer service and clinical education. Integra is also benefiting from the national contract relationships that JARIT has established with Group Purchasing Organizations (GPO's) such as Premier, HPG, Novation, Broadlane, MedAssets, and Consorta.

*New Products.* In 2003, we launched several new products, including our DuraGen Plus™, EnDura™ and INTEGRA™ Bilayer Matrix Wound Dressing products. DuraGen Plus, our next-generation dural graft product, is highly engineered to create a stronger, more conformable and more consistent dural graft. Our EnDura product is a suturable graft for the dura mater, which gives us access to that segment of the dural grafting market that requires suturing. Finally, the INTEGRA Bilayer Matrix Wound Dressing, which was approved last fall for use in the treatment of chronic and other wounds, significantly increases our opportunity in that market.

*Transactions.* Acquisitions also contributed to our growth in 2003. Integra completed four acquisitions during the year. In March, we acquired JARIT® Surgical Instruments. JARIT, based in Hawthorne, New York, markets a wide variety of high quality surgical instruments for use in both traditional and minimally invasive surgery. The JARIT organization has over 30 years of dedicated experience in meeting the general and specialty instrument needs of doctors and hospitals. Its unique distribution network and service management team is recognized for providing the industry's highest levels of customer service and fill rates. JARIT's instruments are used in virtually all surgical disciplines, including general, plastic, neuro, ENT, cardiovascular, ob-gyn, and ophthalmic surgery, at more than 5,200 hospitals and surgery centers worldwide. JARIT sells products in the United States through a twenty-person sales management force that works with over 100 distributor sales representatives. JARIT maintains the industry's most comprehensive inventory to insure complete and timely delivery. This acquisition broadens our existing customer base and allows us to expand into new market segments involving procedures that could benefit from innovative new products.

In August we acquired the assets of Tissue Technologies, Inc., the manufacturer and distributor of the UltraSoft™ line of facial implants for soft tissue augmentation of the facial area. These products, together with

the products acquired in the 2002 Padgett acquisition, are sold through Integra's Plastic and Reconstructive Surgery sales force.

In October, we acquired Spinal Specialties, Inc. from I-Flow Corporation. 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.

In December, we acquired the assets of Reconstructive Technologies, Inc., the developer of the Automated Cyclic Expansion or ACE System™, a tissue expansion device. The ACE System uses a compact pump that produces a cyclic force when attached to ballooning tissue expanders. The ACE System is designed to accelerate tissue expansion by stimulating the body's natural response to physical stress on the skin. We anticipate obtaining regulatory clearance and launching the product through our plastic and reconstructive sales force in 2005.

*2004 and Beyond.* With more than \$200 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 increase our efforts toward internal product development. We are actively seeking additional acquisitions in neurosurgery, related markets such as the ear, nose and throat (ENT), instruments, spine, and plastic and reconstructive surgery.

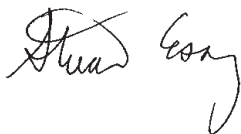
I am extremely pleased with our performance in 2003 and early 2004. In January 2004, after the termination of our distribution agreement with ETHICON, we resumed the marketing, sale and distribution of our INTEGRA® Dermal Regeneration Template. Timing was good for us to resume these activities, as we doubled our plastic and reconstructive surgery sales organization in 2003 in anticipation of our taking over the sales and marketing of this exciting product.

In January 2004, we acquired the R&B instrument business from R&B Surgical Solutions and the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. The R&B instrument line is a complete line of high-quality handheld surgical instruments used in neuro- and spinal surgery. We are marketing these products through our JARIT sales channel. The Sparta product line includes products used in plastic and reconstructive, ENT, neuro, ophthalmic and general surgery. We are marketing these product lines primarily to hospitals and physicians through a catalog and a network of distributors.

I am enthusiastic about Integra's future. I want to recognize again the efforts of our 880 dedicated employees located around the world. Our employees combine to help us realize our mission and make Integra the company that it is today. Looking forward to 2005, 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.

I would also like to thank you, our stockholders, for your continued support.

Sincerely,

A handwritten signature in black ink, appearing to read "Stuart Essig". The signature is written in a cursive, flowing style.

Stuart Essig  
President and Chief Executive Officer

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

## FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OF  
THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED  
DECEMBER 31, 2003

COMMISSION FILE NO. 0-26224

### INTEGRA LIFESCIENCES HOLDINGS CORPORATION

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE  
\_\_\_\_\_  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

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

311 ENTERPRISE DRIVE  
PLAINSBORO, NEW JERSEY  
\_\_\_\_\_  
(ADDRESS OF PRINCIPAL  
EXECUTIVE OFFICES)

08536  
\_\_\_\_\_  
(ZIP CODE)

**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**

(TITLE OF CLASS)

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, 2003, the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$703,166,000, 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 2, 2004 was 28,463,000.

#### DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement relating to its scheduled May 17, 2004 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, plastic and 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 \$185.6 million, an average annual growth rate of 44%, and we have broadened our product offerings to include more than 10,000 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™ Dural Graft Matrix, the NeuraGen™ Nerve Guide, the INTEGRA® Dermal Regeneration Template, and the INTEGRA™ Bi-Layer Matrix Wound Dressing, as well as more traditional medical devices, such as 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, plastic and 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 rapidly become a leading provider of products used in the diagnosis, monitoring and treatment of chronic diseases and acute injuries. We focus on injuries involving the brain, the cranium, the spine and the central nervous system, and the repair and reconstruction of soft tissue, such as dermis. We believe that additional growth potential exists through:

- 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), dental, maxillofacial and spine markets;
- continuing the development and promotion of innovative new products, such as the NeuraGen™ Nerve Guide, the Novus NeuroSensor® Cerebral Blood Flow Monitoring System and the LICOX® Brain Tissue Oxygen Monitoring System; and
- expanding our sales force and product offerings focused on plastic and reconstructive surgeons.

***Additional Strategic Acquisitions.*** Since 1999 we have completed more than fifteen acquisitions focused primarily on our neurosurgical product lines, plastic and reconstructive surgery and surgical instrumentation. 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 and INTEGRA™ Bi-Layer Matrix Wound Dressing, the DuraGen® Dural Graft Matrix, DuraGen Plus™ Dural Graft Matrix and NeuraGen™ Nerve Guide, Biomend® and Biomend® Extend Absorbable Collagen Membrane 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, Operating Room Products, Surgical Instrumentation, and Private Label Products. Our distribution channels include two direct sales organizations (Integra NeuroSciences and Integra Plastic and 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:

CHANNELS	PRODUCT GROUPS			
	Monitoring	Operating Room	Instruments	Private Label
Integra NeuroSciences	X	X	X	
Plastic and Reconstructive		X	X	
JARIT			X	
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
<b>MONITORING PRODUCTS</b>	
Camino® and Ventrix® Fiber Optic-Based Intracranial Monitoring Systems	Continuous monitoring of intracranial pressure and temperature 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
<b>OPERATING ROOM PRODUCTS</b>	
DuraGen® and DuraGen Plus™ Dural Graft Products	Onlay collagen matrix to repair dura mater
EnDura™ No-React®(1) Dural Substitute	Bovine pericardium suturable product for repair of dura mater
NeuraGen™ Nerve Guide	Repair of peripheral nerves

(1) No-React is a registered trademark of Shelhigh, Inc.

PRODUCT LINES	APPLICATIONS
<b><i>OPERATING ROOM PRODUCTS (continued)</i></b>	
Hydrocephalus shunts, including the Orbis-Sigma II® valves	Specifically designed for the management of hydrocephalus, a chronic condition involving excess cerebrospinal fluid in the brain
INTEGRA® Dermal Regeneration Template and INTEGRA™ Bi-Layer Matrix Wound Dressing	Regenerate dermis, repair skin defects, and wound dressings
Sundt™ and other carotid shunts	For shunting blood during surgical procedures involving blood vessels
<b><i>INSTRUMENTS</i></b>	
Selector® Integra Ultrasonic Aspirator; Dissectron® Ultrasonic Aspirator	Powered surgical systems that use ultrasonic energy to ablate tissue
JARIT Surgical Instruments	General and specialty instruments for open and endoscopic surgery
Ruggles™ Neurosurgical and Spinal Instruments	Specialized surgical instruments for use in brain or spinal surgery
Padgett Instruments	Instruments used in reconstructive and plastic surgery
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
<b><i>PRIVATE LABEL PRODUCTS</i></b>	
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 Membrane, 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®(2) Antimicrobial Wound Dressing	Provide protection against infection arising from long-term catheters and in wounds (manufactured for various medical device companies)

(2) 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 Novus NeuroSensor® Cerebral Blood Flow Monitoring System in the second half of 2004. The Novus 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 auto-regulation 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.* 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 EEG 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 have recently begun to market these products in the United States through our Integra NeuroSciences sales force.

*Neurological Supplies.* 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™ 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.

## **Operating Room Products**

*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 worldwide market for dural repair, including cranial and spinal applications, is estimated to be \$110 million.

The DuraGen® and DuraGen Plus™ Dural Graft Matrices are absorbable collagen products indicated for the repair of the dura mater surrounding the brain and spine. We believe that the DuraGen® and DuraGen Plus™ Dural Graft products address the shortcomings of other methods for repairing the dura mater. Clinical trials have shown our DuraGen® 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® product and replaces it with new natural tissues, the patient avoids some of the risks associated with a permanent implant inside the cranium or spinal cavity.

EnDura™ 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, 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 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 510(k) clearance for the sale of a related product, INTEGRA™ Bi-Layer 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 INTEGRA™ Bi-Layer 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 INTEGRA™ Bi-Layer Matrix Wound Dressing through our plastic and reconstructive surgery sales organization in the United States and parts of Western Europe and through a network of distributors elsewhere.

*Repair 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 market for the repair of severed peripheral nerves to be \$40 million.

The NeuraGen™ Nerve Guide is an absorbable implant for the repair of severed peripheral nerves. The NeuraGen™ product is a collagen tube designed to provide a protective environment for the regenerating nerve and to provide a conduit through which regenerating nerves can bridge the gap caused by the injury. The NeuraGen™ Nerve Guide offers a rapid method for rejoining severed peripheral nerves.

*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 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 approximately 80% of total cerebrospinal fluid shunt sales address birth-related hydrocephalus, and the remaining 20% 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 \$140 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, and may continue to, negatively affect the sales of our shunt products.

Later this year, we plan to introduce a low-flow hydrocephalus shunt that will regulate the flow of cerebrospinal fluid out of the brain, rather than the pressure created by cerebrospinal fluid inside the head. This shunt regulates the flow of cerebrospinal fluid to a range of 8-15 milliliters per hour, which, according to studies, is the preferred range of flow for patients with normal pressure hydrocephalus. 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. Certain reports estimate that approximately 20% of total cerebrospinal fluid shunt sales address normal pressure hydrocephalus.

*Hemodynamic Shunts.* Our Sundt™ 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. Our Selector® Integra Ultrasonic Aspirator and Dissectron® Ultrasonic Surgical Aspirator systems address the market for the surgical fragmentation and removal of malignant and non-malignant tumors and other tissue.

The Selector® Integra Ultrasonic Aspirator and Dissectron® Ultrasonic Surgical Aspirator use very high frequency sound waves to pulverize 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. In September 2002, we received FDA 510(k) clearance to market the Selector® product for use in general, gynecological, urological, plastic and reconstructive, orthopedic, thoracic and thoroscopic surgery procedures. We offer the Dissectron® product only outside the United States. Later this year, we plan to introduce a next generation Selector® Integra Ultrasonic Aspirator, which will be more efficient and offer a broader selection of handpieces and tips than is currently available in ultrasonic technology.

*JARIT® 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.

*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 Redmond/R&B name primarily for spinal procedures (including neuro-spine), and instruments under the Ruggles™ brand name primarily for cranial surgery.

*Plastic and Reconstructive Instruments.* We market a wide variety of high quality, reusable surgical instruments 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 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™ Bone Cement Delivery System and the ACCU-DISC™ 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™ Bone Graft used with the LT-CAGE™ 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 Lumbar Tapered Fusion Device, and the INTER FIX and INTER FIX Threaded Fusion Devices, the InFUSE Bone Graft is indicated to treat certain types of spinal degenerative disc disease, a common cause of low back pain.

*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.

*Other Private Label Products.* Our current private label products also include the VitaCuff® catheter access infection control device, the BioPatch® anti-microbial wound dressing, a wide range of absorbable collagen products for hemostasis for use in dental surgery sold under the names CollaCote®, CollaTape® and CollaPlug®, the Instat® Absorbable Collagen Hemostat, and cranial fixation devices for use in craniomaxillofacial surgery.

### **Distribution Channels**

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

*Integra NeuroSciences™.* 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™ sales force sells our monitoring products (including Camino, LICOX and Ventrix monitoring lines, cranial access kits, external ventricular and lumbar monitoring and drainage products and epilepsy electrodes), our neurosurgical operating room products (including the DuraGen, EnDura and NeuraGen products and the Selector 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 sales and marketing infrastructure in the United States and Europe and our distribution network elsewhere.

*Plastic and Reconstructive Surgery.* Our plastic and reconstructive surgery sales and marketing organization consists of 18 professionals, including direct salespeople, sales management, clinical educators, marketing management and product managers, as well as distributors outside of the United States. This sales and marketing organization sells INTEGRA Dermal Regeneration Template, INTEGRA Bi-Layer Matrix Wound Dressing, the NeuraGen Nerve Guide, Padgett dermatomes and meshers, and a wide variety of high quality surgical instruments and implants to plastic 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 an 18-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 \$12.8 million, \$11.5 million and \$8.9 million in 2003, 2002, and 2001, respectively, on research and development activities. The 2003 and 2002 amounts include \$400,000 and \$2.3 million of acquired in-process research and development charges, respectively, 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, \$3.5 million and \$3.9 million in 2003, 2002, and 2001, 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™ Nerve Guide and DuraGen® Dural Graft Matrix.

We regularly review our research and development programs to ensure that they remain consistent with and supportive of our growth strategies. To that end, in 2003 we expanded our product development staff to increase the focus on our neurosurgical product development efforts and consolidated our San Diego research facility with our other facilities.

## **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 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, and certain supplemental PMA applications. 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 200 Premarket Notification 510(k) clearances, five approved PMA applications and 56 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, ISO 13485 and EN46001 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 each of our facilities annually to verify our compliance with these standards. In 2002, 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 do not currently export medical devices manufactured in the United States that have not been approved by the FDA, although we have in the past.

#### **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-DISC<sup>TM</sup>, BioMend<sup>®</sup>, Camino<sup>®</sup>, CollaCote<sup>®</sup>, CollaPlug<sup>®</sup>, CollaStat<sup>TM</sup>, CollaTape<sup>®</sup>, Dissectron<sup>®</sup>, DuraGen<sup>®</sup>, DuraGen Plus<sup>TM</sup>, EquiFlow<sup>®</sup>, Helistat<sup>®</sup>, Helitene<sup>®</sup>, Heyer-Schulte<sup>®</sup>, INTEGRA<sup>®</sup> Dermal Regeneration Template, INTEGRA<sup>TM</sup> Bi-Layer Matrix Wound Dressing, Integra NeuroSciences<sup>TM</sup>, Integra NeuroSupplies<sup>TM</sup>, Integra Supplies<sup>TM</sup>, JARIT<sup>®</sup>, LICOX<sup>®</sup>, NeuraGen<sup>TM</sup>, Novus<sup>®</sup>, LPV<sup>®</sup>, Orbis-Sigma<sup>®</sup>, Osteoject<sup>®</sup>, NeuroSensor<sup>®</sup>, Padgett Instruments, Inc<sup>®</sup>, Pudenz<sup>TM</sup>, Redmond<sup>TM</sup>, Ruggles<sup>TM</sup>, Selector<sup>®</sup>, Spetzler<sup>®</sup>, Spinal Specialties<sup>®</sup>, Sundt<sup>TM</sup>, Ventrix<sup>®</sup>, VitaCuff<sup>®</sup> 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 plastic and reconstructive surgery are LifeCell Corporation, Inamed Corporation, Mentor Corporation, Zimmer Holdings, Inc. and Brennen Medical, Inc.

We believe that we are the third largest surgical instrument company in the United States. The two larger companies are the Codman division of Johnson & Johnson, and the V. Mueller division of Cardinal Healthcare. In addition, there are many smaller instrument companies that compete with many of our 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<sup>®</sup> Dermal Regeneration Template, our duraplasty products, and the NeuraGen<sup>TM</sup> Nerve Guide). 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, 2003, we had approximately 880 regular 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 Biot, France facility, 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**

Integra is 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 [www.Integra-LS.com](http://www.Integra-LS.com). You may also obtain a copy of any of these reports, without charge, from our investor relations department, 311 Enterprise Drive, Plainsboro, NJ 08536. Alternatively, you may view or obtain reports filed with the Securities and Exchange Commission at the SEC Public Reference Room at 450 Fifth Street, N.W. in Washington, D.C. 20549, or at the SEC’s Internet site at [www.sec.gov](http://www.sec.gov). Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

## **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 Integra, 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;
- our ability to complete acquisitions and integrate operations post-acquisition; 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.

**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. Further, 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, the introduction of a competitively priced onlay dural graft matrix could reduce the sales, or growth in sales, of our DuraGen® Dural Graft products. We expect that one or more other companies will introduce such a product within the next two years.

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 plastic and reconstructive surgery business is small compared to its principal competitors, which include major medical device and wound care companies such as the ETHICON division of Johnson & Johnson, Smith and Nephew, Inamed, Mentor, and Zimmer. 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™ 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 17 businesses or product lines at a total cost of approximately \$118 million.

We may be unable to continue to implement our growth strategy, and our strategy may be ultimately 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 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 a third-party manufacturer or we 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. See “Business—Government Regulation”.

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

Certain of our products, including the DuraGen<sup>®</sup> Dural Graft products, the NeuraGen<sup>™</sup> Nerve Guide, and the INTEGRA<sup>®</sup> Dermal Regeneration Template, 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 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). Additionally, we use processes in the manufacturing of our products that are believed to inactivate prions. 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 effect on our current business or our ability to expand our business.

The European Union has recently announced that new medical devices containing tissues of animal origin will have to conform to new requirements, and existing medical devices containing animal tissue must be re-assessed between April 1, 2004 and September 30, 2004. If the required documentation is not submitted, received and approved, by September 30, 2004, existing EC Certificates will become invalid. We plan to submit all documents required for a re-assessment of our products within the schedule required by the European Union.

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, all of our tendon is sourced from the United States. If we cannot secure and qualify a source of tendon from a country that has never had a case of BSE, we may not be permitted to sell our collagen hemostatic agents and products for oral surgery in Japan after September 2004. 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™ 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 significant aspects of many 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 may take several years.

**Our Competitive Position Depends, In Part, Upon Unpatented Trade Secrets Which We May Be Unable To Protect.**

Our competitive position is also dependent 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 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, 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. 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 our Camino® and Ventrix® lines of intracranial pressure monitors and catheters, which we assemble using many different electronic parts from numerous suppliers. While we are not dependent on sole-source suppliers, 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 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.

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

In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties, such as infringement suits or interference proceedings. 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, 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 2004. We currently do not hedge our exposure to 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.

Currently, we do not use derivative financial instruments to manage 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 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.

**Changes In The Health Care Industry May Require Us To Decrease The Selling Price For Our Products Or Could Result In A Reduction In The Size Of The Market For Our Products, Each 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, 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 October 2003 ADVAMED, the principal U.S. trade association for the medical device industry, promulgated a model “code of conduct” that sets forth standards by which its members should abide in the promotion of their products. The ADVAMED Code became effective as of January 1, 2004. In addition, we have in place policies and procedures for compliance that we believe are as stringent as, or more stringent than, 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 affected and could adversely affect our expectations for the growth of private label products.

Our ability to enter into agreements with collaborators depends in part on convincing them that our technology can help them achieve their goals and execute their strategies. This may require substantial time, effort and expense on our part with no guarantee that a relationship will result. We may not be able to establish or maintain these relationships on commercially acceptable terms. Our future agreements may not ultimately be successful. Even if we enter into collaborative or alliance agreements, our collaborators could terminate these agreements, or these agreements could expire before meaningful developmental milestones are reached. The termination or expiration of any of these relationships could have a material adverse effect on our business.

Much of the revenue that we may receive under these collaborations will depend upon our collaborators’ ability to successfully introduce, market and sell new products derived from our products. Our success depends in part upon the performance by these collaborators of their responsibilities under these agreements. Some collaborators may not perform their obligations when and as we expect. Thus revenues to be derived from collaborations may vary significantly over time and be difficult to forecast. Some of the companies we currently have alliances with or are targeting as potential



allies offer products competitive with our products or may develop competitive production technologies or competitive products outside of their collaborations with us that could have a material adverse effect on our competitive position.

In addition, our role in the collaborations is mostly limited to the production aspects. As a result, we may also be dependent on collaborators for other aspects of the development, preclinical and clinical testing, regulatory approval, sales, marketing and distribution of our products. If our current or future collaborators fail to market our products effectively or to develop additional products based on our technology, our sales and other revenues could significantly be reduced.

Finally, we have received and may continue to receive payments from collaborators that may not be immediately recognized as revenue and therefore may not contribute to reported profits until further conditions are satisfied.

**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, Biot, France, Pembroke, Massachusetts, San Diego, California, Anasco, Puerto Rico, Andover, England and Mielkendorf, Germany. Our primary distribution centers are located in Cranbury, New Jersey, Hawthorne, New York, San Antonio, Texas, Andover, England and Biot, 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 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. Cheresch, 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. Cheresch 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 \$15,000,000 in damages, finding that Merck KGaA had willfully infringed and induced the infringement of our patents. The Trial Court dismissed Scripps and Dr. Cheresch 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 \$1,350,000, bringing the total award to approximately \$16,350,000, 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”). 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. We expect the Trial Court to begin new hearings on damages in the summer of 2004. We have not recorded any gain in connection with this matter.

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 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. NMT Medical, Inc., the former owner of these entities, has agreed to specifically indemnify Integra against any liability 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

The executive officers of Integra are elected annually and serve at the discretion of the Board of Directors. The only family relationship between any of the executive officers and our Board of 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 . . . . .	42	President, Chief Executive Officer and Director
Gerard S. Carlozzi . . . . .	47	Executive Vice President, Chief Operating Officer
John B. Henneman, III . . . . .	42	Executive Vice President, Chief Administrative Officer and Secretary
David B. Holtz . . . . .	37	Senior Vice President, Finance and Treasurer
Donald R. Nociolo . . . . .	41	Senior Vice President, Operations
Judith E. O'Grady . . . . .	53	Senior Vice President, Regulatory, Quality Assurance and Clinical Affairs
Robert D. Paltridge . . . . .	45	Senior Vice President, Global Sales
Deborah A. Leonetti . . . . .	48	Vice President, Global Marketing

*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.

*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 20 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. He received a BS degree in engineering and an MBA from Northeastern University. Mr. Carlozzi also serves on the Board of Directors of Cascade Medical Corporation.

*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. From 1994 until June 1997, Mr. Henneman was Vice President of Corporate Development, General Counsel and Secretary. From June 1997 through November 1997, he served in the additional capacity of interim Co-

Chief Executive Officer and from December 1997 to August 1998 Mr. Henneman was Executive Vice President, US Operations, and Chief Legal Officer. 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.

*Donald R. Nociolo* joined Integra as Director of Manufacturing in 1994, served as Vice President, Operations since March 1997, and was promoted 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.

*Deborah A. Leonetti* joined Integra in May of 1997 as Director of Marketing and was promoted to Vice President, Global Marketing in April 1999. 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.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Integra's 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
2003		
Fourth Quarter	\$34.99	\$27.23
Third Quarter	\$30.65	\$23.39
Second Quarter	\$29.94	\$22.49
First Quarter	\$23.72	\$15.66
2002		
Fourth Quarter	\$18.99	\$12.06
Third Quarter	\$21.80	\$14.30
Second Quarter	\$29.00	\$17.35
First Quarter	\$33.50	\$24.61

For purposes of calculating the aggregate market value of the shares of voting stock of Integra 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 Integra. Further information concerning ownership of the Integra's voting stock by executive officers, directors and principal stockholders will be included in our definitive proxy statement 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 2, 2004 was approximately 600, which includes stockholders whose shares were held in nominee name. The number of beneficial stockholders at that date was over 5,000.

## 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,				
	2003	2002	2001	2000	1999
	<i>(in thousands, except per share data)</i>				
<b>Operating Results:</b>					
Total revenue (1) . . . . .	\$185,599	\$117,822	\$ 93,442	\$ 71,649	\$ 42,876
Total operating costs and expenses (2) . . . . .	145,952	98,635	79,156	83,370	55,256
Operating income (loss) . . . . .	39,647	19,187	14,286	(11,721)	(12,380)
Interest income (expense), net . . . . .	471	3,535	1,393	(473)	294
Gain on disposition of product line . . . . .	—	—	—	1,146	4,161
Other income (expense), net (1) . . . . .	3,071	3	(392)	201	141
Income (loss) before income taxes . . . . .	43,189	22,725	15,287	(10,847)	(7,784)
Income tax expense (benefit) (3) . . . . .	16,328	(12,552)	(10,876)	108	(1,818)
Net income (loss) before cumulative effect of accounting change . . . . .	26,861	35,277	26,163	(10,955)	(5,966)
Cumulative effect of accounting change(5) . . . . .	—	—	—	(470)	—
Net income (loss) . . . . .	<u>\$ 26,861</u>	<u>\$ 35,277</u>	<u>\$ 26,163</u>	<u>\$(11,425)</u>	<u>\$ (5,966)</u>
Diluted net income (loss) per share . . . . .	\$0.88	\$1.14	\$0.94	\$(0.97)	\$(0.40)
Weighted average shares outstanding . . . . .	30,468	30,895	27,796	17,553	16,802
<b>Pro Forma Data (5):</b>					
Total revenue . . . . .					\$ 42,974
Net loss . . . . .					(5,868)
Basic and diluted net loss per share . . . . .					\$(0.40)
	December 31,				
	2003	2002	2001	2000	1999
	<i>(in thousands)</i>				
<b>Financial Position:</b>					
Cash, cash equivalents, and marketable securities(4,6) . .	\$206,743	\$132,311	\$131,036	\$ 15,138	\$ 23,612
Total assets . . . . .	412,526	274,668	227,588	86,514	66,253
Long-term debt (6) . . . . .	119,257	—	—	4,758	7,625
Accumulated deficit . . . . .	(17,462)	(44,323)	(79,600)	(105,729)	(94,304)
Stockholders’ equity . . . . .	268,530	247,597	204,056	53,781	37,989

- (1) 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 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 special items in operating expenses: \$1.1 million of expenses related to the closure of our San Diego research center, \$0.4 million of acquired in-process research and development and a \$2.0 million donation to the Integra Foundation in 2003; \$2.3 million of acquired in-process research and development charges recorded in connection with acquisitions in 2002; a \$13.5 million stock-based compensation charge incurred in connection with the extension of the employment of our President and Chief Executive Officer in 2000; and \$2.5 million in fair value inventory charges and \$1.0 million in severance costs related to acquisitions in 1999.

- (3) In 2002 and 2001, respectively, Integra 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 its deferred tax assets. In 1999, Integra recognized a \$1.8 million deferred income tax benefit from the reduction of the deferred tax liability recorded in the NeuroCare acquisition to the extent that consolidated deferred tax assets were generated subsequent to the acquisition.
- (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. Pro forma data reflects the amounts that would have been reported if SAB 101 had been retroactively applied.
- (6) 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 CONDITION AND RESULTS OF OPERATIONS**

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

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)**

Our distribution channels include a sales organization that we employ to call on neurosurgeons, another employed sales force to call on plastic and reconstructive surgeons, and networks of third-party distributors that we manage. 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 manufacture most of the operating room, 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 that we sell, but we 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 27%, 32% and 32% of product revenues in the years ended December 31, 2003, 2002 and 2001, 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 from products developed internally or acquired more than a year before the reporting period in question, gross margins on products revenues, which we hope to increase to more than 65% over a period of several years, operating margins for the entire company, which we hope to increase substantially from the level we reported in 2003, 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, 2003 not directly comparable to those of the corresponding prior year periods. Since the beginning of 2001, we have acquired the following businesses, assets and product lines:

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™), 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 plastic and reconstructive sales force.

In November 2003, we acquired all of the outstanding capital stock of Spinal Specialties, Inc. from I-Flow Corporation for approximately \$6.0 million in cash, subject to 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.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

In August 2003, we acquired the assets of Tissue Technologies, Inc., the manufacturer and distributor of the UltraSoft™ line of facial implants for soft tissue augmentation of the facial area. We market the UltraSoft products directly to cosmetic and reconstructive surgeons through our plastic and reconstructive surgery sales force.

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 Integra's customer base and surgical instrument product offering and facilitated the procurement of Integra's Ruggles™ 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 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 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 ("Novus") and entered into a related development agreement pursuant to which Novus will, at its own cost, conduct certain clinical studies, continue development of an additional monitoring product, and design and transfer to us a validated manufacturing process for these products. We paid Novus \$3.5 million in cash at closing and agreed to pay an additional \$1.5 million upon Novus' achievement of a development milestone and 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 Novus NeuroSensor® Cerebral Blood Flow Monitoring System in the second half of 2004. The Novus 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 auto-regulation 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.

In connection with the Novus acquisition, we recorded a \$1.1 million in-process research and development charge for the value associated with the development of a next generation monitoring system. Novus remains responsible for the costs to complete development and obtain regulatory clearance for this project, the value of which we recorded as prepaid research and development. We estimated the value of the in-process research and development 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.

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

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. Signature Technologies currently manufactures cranial fixation systems for sale primarily under a single contract manufacturing agreement that expires in June 2004.

In connection with the Signature Technologies acquisition, we recorded a \$1.2 million in-process research and development charge 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.

In December 2001, we acquired NeuroSupplies, Inc., a specialty distributor of disposables and supplies for neurologists, pulmonologists and other physicians, for \$4.1 million. The purchase price consisted of \$0.2 million in cash, a \$3.6 million note paid in January 2002, and 10,000 shares of Integra common stock. Integra NeuroSupplies markets a wide variety of supplies to neurologists, hospitals, sleep clinics, and other physicians in the United States as well as to original equipment manufacturers and distributors. In 2003, we relocated the NeuroSupplies operations to our facility in Pembroke, Massachusetts.

In April 2001, we acquired Satelec Medical, a manufacturer and marketer of the Dissectron<sup>®</sup> ultrasonic surgical aspirator console and a line of related handpieces, for \$3.9 million in cash. We completed the consolidation of the Satelec operations into our Andover, England and Biot, France facilities in 2002.

In April 2001, we acquired GMSmbH, the German manufacturer of the LICOX<sup>®</sup> product, for \$3.2 million. The purchase price consisted of \$2.6 million in cash, the forgiveness of \$0.2 million in notes receivable from GMSmbH, and \$0.4 million of future minimum royalty payments to the seller. Prior to the acquisition, we had exclusive marketing rights to the LICOX<sup>®</sup> products in the United States and certain other markets.

### RESULTS OF OPERATIONS

Net income in 2003 was \$26.9 million, or \$0.88 per diluted share, as compared to net income of \$35.3 million or \$1.14 per diluted share in 2002, and net income of \$26.2 million or \$0.94 per diluted share in 2001. 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:

#### *Recorded 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.

#### *Recorded 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.

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)**

*Recorded in 2001*

- We recorded an \$11.5 million deferred income tax benefit from the reduction of a portion of the valuation allowance recorded against our deferred tax assets associated with net operating loss carryforwards.
- We recorded a \$256,000 loss from the early retirement of debt.

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

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	<i>(in thousands, except per share data)</i>		
Monitoring products . . . . .	\$ 44,229	\$ 37,184	\$ 28,158
Operating room products . . . . .	53,301	38,326	27,240
Instruments . . . . .	47,168	16,802	14,972
Private label products . . . . .	<u>21,997</u>	<u>20,313</u>	<u>17,538</u>
Total product revenues . . . . .	166,695	112,625	87,908
Other revenue . . . . .	<u>18,904</u>	<u>5,197</u>	<u>5,534</u>
Total revenues . . . . .	185,599	117,822	93,442
Cost of product revenues . . . . .	70,597	45,772	36,014
Gross margin on product revenues . . . . .	96,098	66,853	51,894
Gross margin as a percentage of product revenues . . . . .	58%	59%	59%

In 2003, total revenues increased 58% over 2002 to \$185.6 million, led by a \$54.1 million or 48% increase in product revenues to \$166.7 million. Domestic product revenues increased \$42.4 million in 2003 to \$132.8 million, or 80% of total product revenues, as compared to 80% of product revenues in 2002 and 78% of product revenues in 2001. Sales of instruments and operating room products, which reported a 181% and 39% increase, respectively, in sales over 2002, led our growth in product revenues in 2003.

In 2002, total revenues increased 26% over 2001 to \$117.8 million, led by a 28% increase in product revenues to \$112.6 million. Domestic product revenues increased \$21.8 million in 2002 to \$90.4 million, or 80% of total product revenues. Sales of monitoring and operating room products, which reported a 32% and 41% increase, respectively, in sales over 2001, led our growth in product revenues in 2002.

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)**

Reported product revenues for 2003 and 2002 included the following amounts in revenues from acquired product lines:

	<u>2003</u>	<u>2002</u>	<u>% change</u>
	<u>Revenues</u>	<u>Revenues</u>	
	<i>(in thousands)</i>		
<b>Monitoring</b>			
Products acquired during 2002 . . . . .	\$ 3,832	\$ 1,626	136%
All other product revenues . . . . .	<u>40,397</u>	<u>35,558</u>	14%
Total Monitoring product revenues . . . . .	44,229	37,184	19%
<b>Operating Room</b>			
Products acquired during 2002 . . . . .	\$ 9,360	\$ 3,325	182%
All other product revenues . . . . .	<u>43,941</u>	<u>35,001</u>	26%
Total Operating Room product revenues . . . . .	53,301	38,326	39%
<b>Instruments</b>			
Products acquired during 2003 . . . . .	\$ 24,476	\$ —	N/A
Products acquired during 2002 . . . . .	4,775	1,238	286%
All other product revenues . . . . .	<u>17,917</u>	<u>15,564</u>	15%
Total Instruments product revenues . . . . .	47,168	16,802	181%
<b>Private Label</b>			
Products acquired during 2002 . . . . .	\$ 2,772	\$ 1,418	95%
All other product revenues . . . . .	<u>19,225</u>	<u>18,895</u>	2%
Total Private Label product revenues . . . . .	21,997	20,313	8%
<b>Consolidated</b>			
Products acquired during 2003 . . . . .	\$ 24,476	\$ —	N/A
Products acquired during 2002 . . . . .	20,739	7,607	173%
All other product revenues . . . . .	<u>121,480</u>	<u>105,018</u>	16%
Total product revenues . . . . .	166,695	112,625	48%

Product line revenues excluding 2003 and 2002 acquisitions grew at 16% for the year ended December 31, 2003 as compared to 2002. Increased sales of our DuraGen® Dural Graft Matrix, NeuraGen™ Nerve Guide, intracranial monitoring and drainage systems, and neurosurgical systems accounted for most of this growth in 2003.

Revenue from sales of drainage product lines acquired in 2002 and the Integra NeuroSupplies™ products acquired in December 2001 and increased sales of our intracranial monitoring systems and existing drainage systems all contributed significantly to the growth in our monitoring product revenues in 2002. Revenue from sales of the Padgett Instruments product line acquired in 2002 and a full year of sales of the Dissectron® Ultrasonic Aspirator product line acquired in April 2001 contributed to the growth in instruments product revenues in 2002. Growth in private label product revenues in 2002 was generated primarily by increased revenues from the Absorbable Collagen Sponge component of Medtronic's recently approved InFUSE™ Bone Graft product and \$1.4 million in sales of product lines acquired in 2002.

In 2003, we expanded our dural repair product offering with the introduction through our Integra NeuroSciences sales force of the DuraGen Plus™ Dural Graft Matrix and EnDura™ No-React® Dural Substitute in the United States. The DuraGen Plus product represents the second generation in Integra's line of absorbable and sutureless onlay collagen matrix grafts for cranial and spinal dural repair. The EnDura™ product is a new suturable product for the repair of the dura mater.

In addition, through our plastic and reconstructive sales force we launched the Dermatome Model S. Designed specifically for burn surgeons, it is lighter, more ergonomic and more powerful than the other dermatomes in Integra's Padgett instrument line.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

Through ETHICON, we also launched the INTEGRA™ Bi-Layer Matrix Wound Dressing. This product is used for the management of wounds, including partial and full-thickness wounds, as well as chronic wounds and trauma wounds. Following the termination of the ETHICON agreement in December 2003, we now market these products through our plastic and reconstructive sales force.

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 58% in 2003 and 59% in 2002 and 2001. Cost of product revenues included \$1,261,000, \$447,000 and \$203,000 in fair value inventory purchase accounting adjustments recorded in connection with acquisitions in 2003, 2002 and 2001, respectively. During 2003, the gross margin was negatively affected by acquisitions of lower margin products and the impact of foreign exchange rates on the cost of products that we manufacture or purchase in Europe. We expect our future gross margins to benefit as we resume the direct sales of the INTEGRA® Dermal Regeneration Template and related products and as sales of the higher margin products continue to grow faster than other products.

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

Other revenue consists 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. Other revenue increased in 2003 by \$13.7 million primarily due to the accelerated recognition of \$11.0 million of license and distribution fee revenue due to the termination of the ETHICON agreement. The \$337,000 decline in 2002 resulted from a decline in government grant funding and the expiration of a technology royalty agreement, although the receipt in 2002 of \$1.0 million in event-related payments partially offset those negative factors. Since our agreement with ETHICON was the main source of our other revenue, we expect it to significantly decrease in 2004.

### Other Operating Expenses

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

	2003	2002	2001
Research and development . . . . .	7.7%	10.2%	10.1%
Selling and marketing . . . . .	22.9%	22.3%	23.1%
General and administrative . . . . .	12.8%	12.9%	12.7%

We recorded \$400,000 and \$2.3 million of in-process research and development charges in connection with acquisitions in 2003 and 2002, respectively. Other research and development expenses increased in both 2003 and 2002 as a result of increased headcount and spending on product development focused on our neuro products. We incurred additional expenses of \$950,000 in 2003 related to the consolidation of our San Diego research center with our other facilities. During 2003, we also increased spending on clinical research relationships with research institutions related to markets in which we compete.

We expect our research and development expenses as a percentage of product revenues to decline further in 2004 because of the significant increase in hand-held instrument product revenues as a proportion of our total revenues. By their nature, our hand-held instrument product lines require less research and development and depend on sales and marketing efforts to support continued growth.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

Sales and marketing expenses increased significantly in both 2003 and 2002 with the expansion of our domestic and international sales and marketing organization and increased trade show activities. In 2003, the increase included sales support for JARIT Instruments and the expansion of the plastic and 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 2004, we expect to continue to expand our neuro and plastic and reconstructive sales forces.

General and administrative expenses increased \$6.8 million in 2003, \$2.5 million of which is related to operating costs associated with recently acquired businesses that were not reflected in our results for the full year in 2002. In addition, in 2003 we donated \$2.0 million to the Integra Foundation and incurred additional costs to consolidate several facilities.

General and administrative expenses increased \$3.4 million in 2002, \$1.9 million of which was related to operating costs associated with acquired businesses that were not reflected in our results for the full year in 2001. The remaining increase in general and administrative expenses in 2002 consisted primarily of increased rent at our expanded corporate headquarters and higher insurance and legal costs.

We initiated and completed a number of activities in the fourth quarter of 2003, including the expansion of our marketing capability, the doubling of our plastic and reconstructive surgery sales organization, the consolidation of our San Diego research and manufacturing facilities, and making a significant contribution to the Integra Foundation. These activities resulted in higher operating costs compared to our recent trend. We anticipate our 2004 operating costs as a percentage of product revenues to decrease compared to the levels incurred in the fourth quarter of 2003.

Amortization expense increased in 2003 primarily because of amortization on additional intangible assets acquired through our business acquisitions. Annual amortization expense is expected to be approximately \$3.3 million in 2004, \$3.1 million in 2005, \$3.0 million in 2006, \$2.8 million in 2007, and \$2.5 million in 2008.

### Non-Operating Income and Expenses

In 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. We have recorded \$2.7 million for the interest expense associated with the notes, which was offset by \$3.2 million 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, Integra's common stock price is greater than \$37.56 per share. 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. We recorded a \$365,000 liability related to the estimated fair value of the Contingent Interest obligation at the time the notes were issued. At December 31, 2003, the estimated fair value of the Contingent Interest obligation was \$458,000.

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 year ended December 31, 2003 reflects a \$330,000 reduction associated with the interest rate swap.

The net fair value of the interest rate swap at inception was \$767,000. At December 31, 2003, the net fair value of the interest rate swap increased \$305,000 to \$1.1 million, and this amount is included in other liabilities. In connection with

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)**

this fair value hedge transaction, we recorded a \$433,000 net decrease in the carrying value of our convertible notes. The net \$128,000 difference between changes in the fair value of the interest rate swap and the convertible notes represents the ineffective portion of the hedging relationship, and this amount is recorded in other income.

Our net other income/expense increased by \$3.1 million in 2003. This increase consisted primarily of the \$2.0 million termination payment received from ETHICON and foreign currency transaction gains.

In August 2001, we raised \$113.4 million from a follow-on public offering of 4.7 million shares of common stock. Accordingly, net interest income in 2002 increased to \$3.5 million, as compared to net interest income of \$1.4 million in 2001.

### **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, we concluded in the fourth quarter of 2001 that we no longer needed to maintain a portion of the valuation allowance recorded against federal and state net operating loss carryforwards and certain other temporary differences. We reduced the valuation allowance by \$12.0 million in 2001 because we believed that it was more likely than not that we would realize the benefit of that portion of the deferred tax assets recorded at December 31, 2001.

In the fourth quarter of 2002, we reduced the remaining valuation allowance recorded against 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 \$33.5 million of net deferred tax assets recorded at December 31, 2003. 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 2003, our effective income tax rate was 37.8% of income before income taxes. The increase as compared to 2002 and 2001 resulted from the income tax benefits related to the reduction of deferred tax asset valuation allowances recorded in 2002 and 2001 and a larger proportion of our taxable income being generated in higher tax jurisdictions in 2003.

The net change in the Company's valuation allowance was \$(2.3) million, \$(26.7) million, and \$(10.4) million, in 2003, 2002 and 2001, respectively.

At December 31, 2003, we had net operating loss carryforwards of approximately \$72.8 million and \$10.5 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 2009, respectively. New Jersey has imposed a moratorium on the ability of corporations to use their net operating loss carryforwards to reduce their New Jersey state tax obligations.

At December 31, 2003, several of our subsidiaries had unused net operating loss carryforwards and tax credit carryforwards arising from periods prior to our ownership which expire through 2010. The Internal Revenue Code limits the timing and manner in which we may use any acquired net operating losses or tax credits.

### **INTERNATIONAL PRODUCT REVENUES AND OPERATIONS**

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.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

In 2003, 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 2004. We currently do not hedge our exposure to 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.

Product revenues by major geographic area are summarized below:

	<u>United States</u>	<u>Europe</u>	<u>Asia Pacific</u>	<u>Other Foreign</u>	<u>Consolidated</u>
			<i>(in thousands)</i>		
2003 .....	\$132,805	\$21,433	\$5,828	\$6,629	\$166,695
2002 .....	90,422	14,737	4,062	3,404	112,625
2001 .....	68,612	10,577	4,838	3,881	87,908

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. Of this amount, \$21.3 million of these revenues were 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. Of this amount, \$13.4 million of these revenues were generated in foreign currencies.

In 2001, revenues from customers outside the United States totaled \$19.3 million, or 22% of consolidated product revenues, of which approximately 55% were to European customers. Of this amount, \$7.2 million of these revenues were generated in foreign currencies.

## LIQUIDITY AND CAPITAL RESOURCES

### Cash and Marketable Securities

At December 31, 2003, we had cash, cash equivalents and marketable securities totaling \$206.7 million. Investments consist almost entirely of highly liquid, interest bearing debt securities.

### Cash Flows

We generated positive operating cash flows of \$34.8 million, \$32.0 million and \$15.7 million in 2003, 2002 and 2001, respectively. Operating cash flows improved in 2003 and 2002 primarily as a result of higher pre-tax income and the benefits from the continued utilization of our net operating loss carryforwards and tax deductions generated by employee



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

stock option exercises. 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 2003, we also 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.

Our principal uses of funds in 2003 were \$50.4 million for acquisitions, \$38.6 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. 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.

In August 2001, we issued 4.7 million shares of common stock in a public offering at \$25.50 per share. The net proceeds generated by the offering, after expenses, were \$113.4 million. With the proceeds from the public offering of common stock, we repaid all outstanding debt, including \$7.9 million of bank loans and \$1.4 million payable under the terms of a promissory note, in 2001. Additionally, a related term loan and revolving credit facility was terminated in 2001.

### Working Capital

At December 31, 2003 and 2002, working capital was \$167.3 million and \$130.3 million, respectively. The increase in working capital in 2003 was primarily due to a decrease in the overall maturity of our marketable securities portfolio, additional investments in inventory to support our growth in product revenues, higher accounts receivable balances related to increased sales, and the recognition of significant amounts of deferred revenue and customer advances as revenue in 2003.

### 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 2½% each September 15<sup>th</sup> and March 15<sup>th</sup>. We will also pay contingent interest on the notes if, at thirty days prior to maturity, Integra's 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 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. 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 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 contingent convertible notes.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)

### Share Repurchase Plans

In March 2004, our Board of Directors authorized us to repurchase up to an additional 1.5 million shares of our common stock for an aggregate purchase price not to exceed \$40.0 million. We may repurchase shares under this program through March 2005 either in the open market or in privately negotiated transactions.

During 2003 and 2002, respectively, we repurchased approximately 1.5 million and 100,000 shares of our common stock under previously 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 2004, we expect to increase cash outlays for capital expenditures as compared to 2003, primarily because of an estimated \$4.3 million of expenditures associated with information system upgrades.

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

We are obligated to pay the following amounts under various agreements:

	Total	Less than 1 year	More than 1–3 Years	3–5 Years	5 years
			<i>(in millions)</i>		
Long Term Debt . . . . .	\$120.0	\$ —	\$ —	\$120.0	\$ —
Interest on Long Term Debt . . . . .	13.5	3.0	9.0	1.5	—
Operating Leases . . . . .	9.1	2.2	2.9	1.9	2.1
Purchase Obligations . . . . .	10.2	6.3	3.2	0.7	—
Pension Contribution(1) . . . . .	0.2	0.2	—	—	—
Other Long Term Liabilities . . . . .	0.4	—	0.2	0.1	0.1
Total . . . . .	<u>\$153.4</u>	<u>\$ 11.7</u>	<u>\$ 15.3</u>	<u>\$124.2</u>	<u>\$ 2.2</u>

(1) Pension contributions after 2004 cannot be reasonably estimated.

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.

In January 2004, the Company acquired the R&B instrument business from R&B Surgical Solutions, LLC for approximately \$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 acquired business generated approximately \$1.2 million in revenues for the twelve months ended December 31, 2003. The Company plans to market these products through its JARIT sales force.

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)**

In January 2004, the Company acquired the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. for approximately \$1.5 million in cash. The Sparta product line includes products used in plastic and reconstructive, ear, nose and throat (ENT), neuro, ophthalmic and general surgery. Prior to the acquisition, Fleetwood Medical marketed these product lines primarily to hospitals and physicians through a catalogue and a network of distributors. The acquired business generated approximately \$1.0 million in revenues for the twelve months ended December 31, 2003.

### **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, derivatives, 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

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (CONTINUED)**

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 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. 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, and 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.

## **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 2003, 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 2004. 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 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 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, 2003 would increase or decrease interest income by approximately \$2.1 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, 2003, 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 2½% contingent convertible subordinated notes due March 2008.

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, 2003, the net fair value of the interest rate swap approximated \$1.1 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**

Our management, including our Chief Executive Officer and Senior Vice President, Finance, conducted an evaluation of the effectiveness of the Company’s disclosure controls and procedures as of December 31, 2003. Based on that evaluation, our management, including our Chief Executive Officer and Senior Vice President, Finance, has concluded that our disclosure controls and procedures are effective. During the period covered by this report, there was no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### 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 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, 2004, 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, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(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 Auditors .....	F-1
Consolidated Statements of Operations for the years ended December 31, 2003, 2002, and 2001 .....	F-2
Consolidated Balance Sheets as of December 31, 2003 and 2002 .....	F-3
Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002, and 2001 .....	F-4
Consolidated Statements of Changes in Stockholders' Equity For the years ended December 31, 2003, 2002, and 2001 .....	F-5
Notes to Consolidated Financial Statements .....	F-8

2. Financial Statement Schedules.

Report of Independent Auditors on Financial Statement Schedule .....	F-34
Financial Statement Schedule .....	F-35

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.

<u>Number</u>	<u>Description</u>	<u>Exhibit in Incorporated Filing</u>
2.1	Stock Purchase Agreement, dated as of March 17, 2003, Integra LifeSciences Corporation and Howard Jamner and other individual stockholders of J. Jamner Surgical Instruments, Inc. (17)	(Exh. 2.1)
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 23, 1998 (3)	(Exh. 3.1(b))
3.2	Amended and Restated By-laws of the Company (7)	(Exh. 3)
4.1	Indenture, dated as of March 31, 2003, between Integra LifeSciences Holdings Corporation and Wells Fargo Bank Minnesota, National Association (19)	(Exh. 4.1)
4.2	Registration Rights Agreement, dated as of March 31, 2003, between Integra LifeSciences Holdings Corporation and Credit Suisse First Boston, LLC, Banc of America Securities LLC and U.S. Bancorp Piper Jaffray Inc. (20)	(Exh. 4.3)
4.3	Stock Option Grant and Agreement dated December 27, 1997 between the Company and Stuart M. Essig* (7)	(Exh. 10.2)
4.4	Restricted Units Agreement dated December 27, 1997 between the Company and Stuart M. Essig* (7)	(Exh. 10.3)
4.5	Stock Option Grant and Agreement dated December 22, 2000 between Integra LifeSciences Holdings Corporation and Stuart M. Essig* (12)	(Exh. 4.1)
4.6	Stock Option Grant and Agreement dated December 22, 2000 between Integra LifeSciences Holdings Corporation and Stuart M. Essig* (12)	(Exh. 4.2)
4.7	Restricted Units Agreement dated December 22, 2000 between Integra LifeSciences Holdings Corporation and Stuart M. Essig* (12)	(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 (11)	(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)

<u>Number</u>	<u>Description</u>	<u>Exhibit in Incorporated Filing</u>
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. 10.2)
10.7	1999 Stock Option Plan* (9)	(Exh. 10.13)
10.8	Employee Stock Purchase Plan* (6)	(Exh. 10.1)
10.9	Deferred Compensation Plan* (9)	(Exh. 10.15)
10.10	2000 Equity Incentive Plan* (13)	(Exh. 10.17)
10.11	2001 Equity Incentive Plan* (14)	(Exh. 4)
10.12	2003 Equity Incentive Plan* (18)	(App. A)
10.13	Amended and Restated Employment Agreement dated December 22, 2000 between Integra LifeSciences Holdings Corporation and Stuart M. Essig* (12)	(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	Registration Rights Provisions* (12)	(Exh. 10.2)
10.16	Amended and Restated Employment Agreement between John B. Henneman, III and the Company dated October 31, 2003* (22)	(Exh. 10.2)
10.17	Employment Agreement between Gerard Carlozzi and the Company dated September 25, 2003* (22)	(Exh. 10.1)
10.18	Employment Agreement between Judith O'Grady and the Company dated February 20, 2003* (16)	(Exh. 10.17)
10.19	Employment Agreement between David B. Holtz and the Company dated September 10, 2002* (15)	(Exh. 10.38)
10.20	Employment Agreement between Donald R. Nociolo and the Company dated February 20, 2003* (1)	
10.21	Retention Agreement between Robert Paltridge and the Company dated February 20, 2003* (19)	(Exh. 10.1)
10.22(a)	Supply, Distribution and Collaboration Agreement between Integra LifeSciences Corporation and Johnson & Johnson Medical, a Division of Ethicon, Inc. dated as of June 3, 1999, certain portions of which are subject to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934. (8)	(Exh. 10.1)



<u>Number</u>	<u>Description</u>	<u>Exhibit in Incorporated Filing</u>
10.22(b)	Amendment to Supply, Distribution and Collaboration Agreement by and between Integra LifeSciences Corporation and Ethicon, Inc., dated as of September 30, 2003) (21)	(Exh. 10.1)
10.23	Lease Contract dated June 30, 1994 between the Puerto Rico Industrial Development Company and Heyer-Schulte NeuroCare, Inc. (9)	(Exh. 10.32)
10.24	Industrial Real Estate Triple Net Sublease dated April 1, 1993 between GAP Portfolio Partners and Camino Laboratories. (9)	(Exh. 10.33)
10.25	Industrial Real Estate Triple Net Sublease dated January 15, 1997 between Sorrento Montana, L.P. and Camino NeuroCare, Inc. (9)	(Exh. 10.34)
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.

\*\* Schedules and other attachments to the indicated exhibit were omitted. The Company agrees to furnish supplementally to the Commission upon request a copy of any omitted schedules or attachments.

(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) which became effective on June 22, 1996.

(6) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-8 (File No. 333-58235) which became effective 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 Report on Form 10-Q for the quarter ended June 30, 1999.
  - (9) Incorporated by reference to the indicated exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999.
  - (10) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended March 31, 2000.
  - (11) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended June 30, 2000.
  - (12) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on January 8, 2001.
  - (13) 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.
  - (14) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-8 (File No. 333-73512) which became effective on November 16, 2001.
  - (15) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended September 20, 2002.
  - (16) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-K for the year ended December 31, 2002.
  - (17) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on March 25, 2003.
  - (18) Incorporated by reference to the indicated exhibit to the Company's Definitive Proxy Statement on Form 14A filed on April 17, 2003.
  - (19) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended March 31, 2003.
  - (20) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-3 (File No. 333-106625).
  - (21) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K filed on October 23, 2003.
  - (22) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended September 30, 2003.
- (b) Reports on Form 8-K.

On October 6, 2003, we filed with the Securities and Exchange Commission a Report on Form 8-K under items 5 and 7 reporting the amendment of the 1999 Supply, Distribution and Collaboration Agreement between Integra LifeSciences Corporation and ETHICON, Inc.

On October 31, 2003, we furnished with the Securities and Exchange Commission a Report on Form 8-K under items 7 and 12 regarding our earnings for the quarter ended September 30, 2003.

On November 12, 2003, we filed with the Securities and Exchange Commission a Report on Form 8-K under item 9 regarding the conversion of restricted units held by an executive officer of the company into shares of common stock of the company and the executive officer's subsequent sale of some of those shares.

## 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 12, 2004

By: /s/ Stuart M. Essig

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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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Stuart M. Essig</u> Stuart M. Essig	President, Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2004
<u>/s/ David B. Holtz</u> David B. Holtz	Senior Vice President, Finance and Treasurer (Principal Financial and Accounting Officer)	March 12, 2004
<u>/s/ Richard E. Caruso</u> Richard E. Caruso, Ph.D.	Chairman of the Board	March 12, 2004
<u>/s/ Keith Bradley</u> Keith Bradley, Ph.D.	Director	March 12, 2004
<u>/s/ David Auth</u> David Auth	Director	March 12, 2004
<u>/s/ Neal Moszkowski</u> Neal Moszkowski	Director	March 12, 2004
<u>/s/ James M. Sullivan</u> James M. Sullivan	Director	March 12, 2004



## REPORT OF INDEPENDENT AUDITORS

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, cash flows and stockholders' equity present fairly, in all material respects, the financial position of Integra LifeSciences Holdings Corporation and Subsidiaries (the Company) at December 31, 2003 and 2002 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit 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.

As discussed in Note 2 to the consolidated financial statements, the Company has adopted Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", effective January 1, 2002.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey  
February 25, 2004

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

*In thousands, except per share amounts*

	Years Ended December 31,		
	2003	2002	2001
<b>REVENUES</b>			
Product revenue .....	\$166,695	\$112,625	\$ 87,908
Other revenue .....	18,904	5,197	5,534
Total revenue .....	185,599	117,822	93,442
<b>COSTS AND EXPENSES</b>			
Cost of product revenue .....	70,597	45,772	36,014
Research and development .....	12,814	11,517	8,884
Selling and marketing .....	38,097	25,118	20,322
General and administrative .....	21,364	14,584	11,152
Amortization .....	3,080	1,644	2,784
Total costs and expenses .....	145,952	98,635	79,156
Operating income .....	39,647	19,187	14,286
Interest income .....	3,195	3,575	2,039
Interest expense .....	(2,724)	(40)	(646)
Other income (expense), net .....	3,071	3	(392)
Income before income taxes .....	43,189	22,725	15,287
Income tax expense (benefit) .....	16,328	(12,552)	(10,876)
Net income .....	\$ 26,861	\$ 35,277	\$ 26,163
Basic net income per share .....	\$ 0.92	\$ 1.21	\$ 1.08
Diluted net income per share .....	\$ 0.88	\$ 1.14	\$ 0.94
Weighted average common shares outstanding:			
Basic .....	29,071	29,021	23,353
Diluted .....	30,468	30,895	27,796

*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*

	December 31,	
	2003	2002
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents .....	\$ 78,979	\$ 43,583
Short-term investments .....	29,567	55,278
Trade accounts receivable, net of allowances of \$2,025 and \$1,387 .....	28,936	19,412
Inventories .....	41,046	28,502
Prepaid expenses and other current assets .....	9,365	5,498
Total current assets .....	187,893	152,273
Noncurrent investments .....	98,197	33,450
Property, plant, and equipment, net .....	20,072	16,556
Deferred income taxes, net .....	21,369	25,218
Goodwill .....	26,683	22,073
Intangible assets, net .....	52,435	23,091
Other assets .....	5,877	2,007
Total assets .....	\$412,526	\$274,668
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable, trade .....	\$ 7,947	\$ 3,764
Customer advances and deposits .....	977	7,908
Accrued expenses and other current liabilities .....	11,694	10,249
Total current liabilities .....	20,618	21,921
Long term debt .....	119,257	—
Deferred revenue .....	418	3,263
Other liabilities .....	3,703	1,887
Total liabilities .....	143,996	27,071
Commitments and contingencies		
Stockholders' Equity:		
Common stock; \$.01 par value; 60,000 authorized shares; 28,611 and 27,204 issued .....	286	272
Additional paid-in capital .....	286,716	292,007
Treasury stock, at cost; 219 and 106 shares .....	(5,236)	(1,812)
Other .....	(5)	(15)
Accumulated other comprehensive income (loss):		
Unrealized gain on available-for-sale securities .....	63	861
Foreign currency translation adjustment .....	5,400	1,618
Minimum pension liability adjustment .....	(1,232)	(1,011)
Accumulated deficit .....	(17,462)	(44,323)
Total stockholders' equity .....	268,530	247,597
Total liabilities and stockholders' equity .....	\$412,526	\$274,668

*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,		
	2003	2002	2001
<b>OPERATING ACTIVITIES:</b>			
Net income	\$ 26,861	\$ 35,277	\$ 26,163
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	7,030	5,020	5,959
In process research and development charge	400	2,328	—
Deferred tax provision (benefit)	12,357	(13,401)	(12,085)
Amortization of discount and premium on investments	2,013	2,142	298
Other, net	802	188	443
Changes in assets and liabilities, net of business acquisitions:			
Accounts receivable	(4,819)	(2,109)	98
Inventories	(1,829)	1,153	(6,987)
Prepaid expenses and other current assets	(505)	(1,131)	(1,443)
Non-current assets	480	185	1,858
Accounts payable, accrued expenses and other liabilities	2,537	(90)	(941)
Customer advances and deposits	(6,431)	2,565	4,020
Deferred revenue	(4,070)	(142)	(1,682)
Net cash provided by operating activities	<u>\$ 34,826</u>	<u>\$ 31,985</u>	<u>\$ 15,701</u>
<b>INVESTING ACTIVITIES:</b>			
Proceeds from the sales/maturities of investments	178,483	35,402	3,000
Purchases of available for sale investments	(217,070)	(39,113)	(88,533)
Purchases of property and equipment	(3,843)	(2,254)	(2,860)
Payment of product license fee	(1,500)	—	—
Cash used in business acquisitions, net of cash acquired	<u>(50,405)</u>	<u>(25,015)</u>	<u>(6,348)</u>
Net cash used in investing activities	<u>\$ (94,335)</u>	<u>\$ (30,980)</u>	<u>\$ (94,741)</u>
<b>FINANCING ACTIVITIES:</b>			
Repayment of note payable and bank loans	—	(3,600)	(13,652)
Proceeds from the issuance of common stock, net	—	—	113,433
Proceeds from exercised stock options and warrants	14,152	3,323	9,676
Purchases of treasury stock	(35,402)	(1,761)	—
Proceeds from issuance of convertible notes, net	<u>115,923</u>	<u>—</u>	<u>—</u>
Net cash provided by (used in) financing activities	<u>\$ 94,673</u>	<u>\$ (2,038)</u>	<u>\$ 109,457</u>
Effect of exchange rate changes on cash and cash equivalents	<u>232</u>	<u>98</u>	<u>15</u>
Net increase (decrease) in cash and cash equivalents	35,396	(935)	30,432
Cash and cash equivalents at beginning of period	<u>43,583</u>	<u>44,518</u>	<u>14,086</u>
Cash and cash equivalents at end of period	<u>\$ 78,979</u>	<u>\$ 43,583</u>	<u>\$ 44,518</u>
Cash paid during the year for interest	\$ 1,476	\$ 20	\$ 778
Cash paid during the year for income taxes	1,309	1,435	928
Supplemental non-cash disclosure:			
Property and equipment purchases included in liabilities	\$ 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*

	Preferred Stock	Common Stock	Treasury Stock	Additional Paid-In Capital	Other	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity
Balance, December 31, 2000	2	173	(180)	160,134	(66)	(553)	(105,729)	53,781
Net income								26,163
Unrealized gains on investments						333		333
Foreign currency translation						(319)		(319)
Total comprehensive income								\$ 26,177
Conversion of 100 shares of Series B Preferred Stock into 2,618 shares of common stock	(1)	26		(25)				—
Public offering of 4,748 shares of common stock		48		113,385				113,433
Issuance of 879 shares of common stock through employee benefit plans		9	129	5,998				6,102
Warrants exercised for cash		5		3,611			(34)	3,616
Issuance of 10 shares of common stock in acquisition				276				276
Amortization of unearned compensation					29			29
Tax benefit related to stock option exercises				642				642
Balance, December 31, 2001	1	261	(51)	284,021	(37)	(539)	(79,600)	\$204,056

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

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

*In thousands*

	Preferred Stock	Common Stock	Treasury Stock	Additional Paid-In Capital	Other	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity
Net income							35,277	35,277
Unrealized losses on investments						624		624
Foreign currency translation						2,394		2,394
Minimum pension liability adjustment						(1,011)		(1,011)
Total comprehensive income								<u>\$ 37,284</u>
Conversion of 54 shares of Series C Preferred Stock into 600 shares of common stock	(1)	6		(5)				—
Issuance of 475 shares of common stock through employee benefit plans		5		3,288				3,293
Amortization of unearned compensation				9	22			31
Tax benefit related to stock option exercises				4,694				4,694
Repurchase 100 shares of common stock			(1,761)					(1,761)
Balance, December 31, 2002	<u>\$ —</u>	<u>\$272</u>	<u>\$ (1,812)</u>	<u>\$292,007</u>	<u>\$ (15)</u>	<u>\$1,468</u>	<u>\$(44,323)</u>	<u>\$247,597</u>

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

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

*In thousands*

	Preferred Stock	Common Stock	Treasury Stock	Accumulated Additional Paid-In Capital	Other	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Equity
Net income	\$ —						26,861	26,861
Realized gains on investments						(210)		(210)
Unrealized losses on investments						(588)		(588)
Foreign currency translation						3,673		3,673
Minimum pension liability adjustment						(112)		(112)
Total comprehensive income							<u>26,861</u>	<u>26,861</u>
Issuance of 1,788 shares of common stock through employee benefit plans		4	31,978	(17,880)				14,102
Warrants exercised for cash				50				50
Conversion of 1,000 Restricted Units into 1,000 shares of common stock		10		(10)				—
Amortization of unearned compensation				16	10			26
Tax benefit related to stock option exercises				12,533				12,533
Repurchase 1,503 shares of common stock			(35,402)					(35,402)
Balance, December 31, 2003	<u>\$ —</u>	<u>\$286</u>	<u>\$ (5,236)</u>	<u>\$286,716</u>	<u>\$ (5)</u>	<u>\$4,231</u>	<u>\$(17,462)</u>	<u>\$268,530</u>

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

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. BUSINESS**

Integra LifeSciences Holdings Corporation (the “Company”) develops, manufactures, and markets medical devices for use in neuro-trauma, neurosurgery, plastic and 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 NeuraGen™ Nerve Guide, and the INTEGRA® Dermal Regeneration Template, as well as, more traditional medical devices, such as 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.

*RECLASSIFICATIONS*

Certain 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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*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, 2003 and 2002 were as follows:

	<u>Cost</u>	<u>Unrealized</u> <u>Gains</u> <u>Losses</u>		<u>Fair</u> <u>Value</u>
	(in thousands)			
<u>2003:</u>				
<u>Marketable Securities, current</u>				
Corporate Debt Securities . . . . .	\$23,761	\$ 21	\$ (1)	\$23,781
U.S. Government Debt Securities . . . . .	5,550	1	—	5,551
Other Securities . . . . .	235	—	—	235
Total marketable securities, current . . . . .	<u>\$29,546</u>	<u>\$ 22</u>	<u>\$ (1)</u>	<u>\$29,567</u>
<u>Marketable Securities, non-current</u>				
Corporate Debt Securities . . . . .	\$56,811	\$ 98	\$(105)	\$56,804
U.S. Government Debt Securities . . . . .	41,341	58	(6)	41,393
Total marketable securities, non-current . . . . .	<u>\$98,152</u>	<u>\$ 156</u>	<u>\$(111)</u>	<u>\$98,197</u>
<u>2002:</u>				
Marketable securities, current . . . . .	\$54,755	\$ 525	\$ (2)	\$55,278
Marketable securities, non-current. . . . .	33,112	347	(9)	33,450
	<u>\$87,867</u>	<u>\$ 872</u>	<u>\$ (11)</u>	<u>\$88,728</u>

The maturity dates 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 60 months and less than 40 months as of December 31, 2003 and 2002, respectively.

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

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

*ALLOWANCES FOR DOUBTFUL ACCOUNTS RECEIVABLE AND SALES RETURNS*

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, an allowance 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, allowances for doubtful accounts are recorded based on the length of time the receivables are past due, the current business environment and our historical experience.

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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*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:

	December 31,	
	2003	2002
	<i>(in thousands)</i>	
Finished goods . . . . .	\$26,239	\$17,497
Work in process . . . . .	5,069	3,019
Raw materials . . . . .	9,738	7,986
	\$41,046	\$28,502

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:

	December 31,		
	2003	2002	Lives
	<i>(in thousands)</i>		
Land . . . . .	\$ 892	\$ 511	
Buildings and leasehold improvements	12,082	11,877	2 – 40 years
Machinery and equipment . . . . .	19,498	16,492	3 – 15 years
Furniture and fixtures . . . . .	3,277	3,561	5 – 7 years
Construction in progress . . . . .	2,316	500	
	38,065	32,941	
Less: Accumulated depreciation . . . . .	(17,993)	(16,385)	
	\$ 20,072	\$ 16,556	

Depreciation expense associated with property, plant and equipment was \$3.9 million, \$3.4 million, and \$3.2 million, in 2003, 2002, and 2001 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 acquired prior to July 1, 2001 was amortized on a straight line basis over a period of 15 years through December 31, 2001. Goodwill acquired after July 1, 2001 was not subject to amortization.

Effective January 1, 2002, goodwill is no longer amortized, but is reviewed for impairment at the reporting unit level annually, or more frequently if impairment indicators arise.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

Upon adoption of Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", the Company reassessed the useful lives of its existing identifiable intangible assets and determined that they continue to be appropriate. The Company does not have any indefinite life intangible assets.

If the Company had applied the non-amortization provisions of Statement 142 for all of 2001, net income would have been as follows:

	<u>2001</u>
	<i>(in thousands)</i>
Net income, as reported . . . . .	\$ 26,163
Effect of goodwill and assembled workforce amortization . . . . .	<u>858</u>
Net income, as adjusted . . . . .	\$ 27,021
Basic net income per share, as reported . . . . .	\$1.08
Effect of goodwill and assembled workforce amortization . . . . .	<u>.03</u>
Basic net income per share, as adjusted . . . . .	\$ 1.11
Diluted net income per share, as reported . . . . .	\$ 0.94
Effect of goodwill and assembled workforce amortization . . . . .	<u>.03</u>
Diluted net income per share, as adjusted . . . . .	\$ 0.97

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 updated its impairment review for goodwill as of June 30, 2003 and determined that its goodwill was not impaired.

Changes in the carrying amount of goodwill in 2003 and 2002 were as follows:

	<u>2003</u>	<u>2002</u>
	<i>(in thousands)</i>	
Goodwill, net of accumulated amortization beginning of year . . . . .	\$22,073	\$14,627
Reclassification of net assembled workforce intangible . . . . .	—	1,275
Acquisitions . . . . .	3,321	5,775
Adjustments to previously recorded pre-acquisition income tax contingencies . . . . .	—	(484)
Other, net . . . . .	(29)	64
Foreign currency translation . . . . .	<u>1,318</u>	<u>816</u>
Goodwill, end of year . . . . .	<u>\$26,683</u>	<u>\$22,073</u>

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

	<u>Weighted Average Life</u>	<u>December 31, 2003</u>		<u>December 31, 2002</u>	
		<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Cost</u>	<u>Accumulated Amortization</u>
<i>(in thousands)</i>					
Completed technology . . . . .	15 years	\$15,062	\$ (3,337)	\$ 13,165	\$ (2,380)
Customer relationships . . . . .	20 years	16,755	(2,053)	4,661	(1,085)
Trademarks / brand names . . . . .	38 years	25,235	(1,017)	7,151	(445)
All other . . . . .	10 years	<u>2,909</u>	<u>(1,119)</u>	<u>2,601</u>	<u>(577)</u>
		\$59,961	\$ (7,526)	\$ 27,578	\$ (4,487)
Accumulated amortization . . . . .		<u>(7,526)</u>		<u>(4,487)</u>	
		<u>\$52,435</u>		<u>\$ 23,091</u>	

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

Annual amortization expense is expected to approximate \$3.3 million in 2004, \$3.1 million in 2005, \$3.0 million in 2006, \$2.8 million in 2007, and \$2.5 million in 2008. 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, 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. During 2003, the Company contributed \$2.0 million to the Integra Foundation. This contribution is included in general and administrative expenses.

*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.



**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*REVENUE RECOGNITION*

Product revenues include both product sales and royalties earned on sales by strategic alliance partners of the Company's products or of products incorporating one or more of the Company's products. 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 revenues include research grants, fees received under research, licensing, and distribution arrangements, and technology-related royalties. Research grant revenue is recognized when the related expenses are incurred. 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 percentage of completion accounting based upon the estimated cost to complete these obligations.

*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 approximately \$2.6 million, \$1.5 million, and \$1.5 million are recorded in selling and marketing expense during 2003, 2002, and 2001, 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,	
	2003	2002
	<i>(in thousands)</i>	
Beginning balance . . . . .	\$ 216	\$ 226
Liability acquired through acquisition . . . . .	95	—
Charged to expense . . . . .	209	257
Deductions . . . . .	(151)	(267)
Ending balance . . . . .	\$ 369	\$ 216

*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.

The Company recorded \$400,000 and \$2.3 million of in-process research and development in connection with acquisitions during 2003 and 2002, respectively.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*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:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	<i>(in thousands, except per share amounts)</i>		
Net income:			
As reported . . . . .	\$ 26,861	\$ 35,277	\$ 26,163
Less: Total stock-based employee compensation expense determined under the fair value-based method for all awards, net of related tax effects . . . .	(5,537)	(4,774)	(5,911)
Pro forma . . . . .	\$ 21,324	\$ 30,503	\$ 20,252
Net income per share:			
<i>Basic</i>			
As reported . . . . .	\$ 0.92	\$ 1.21	\$ 1.08
Pro forma . . . . .	\$ 0.73	\$ 1.05	\$ 0.82
<i>Diluted</i>			
As reported . . . . .	\$ 0.88	\$ 1.14	\$ 0.94
Pro forma . . . . .	\$ 0.70	\$ 1.03	\$ 0.75

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 was calculated based on the fair value of each option grant using the Black-Scholes model.

The Company used the following weighted-average assumptions for the valuation of stock option grants:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Dividend yield . . . . .	0%	0%	0%
Expected volatility . . . . .	61%	65%	80%
Risk free interest rate . . . . .	2.92%	3.00%	4.50%
Expected life of option from vesting date . . . .	4.5 years	4.5 years	4.5 years

*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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*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 ACCOUNTING STANDARDS*

In December 2003, the FASB issued SFAS No. 132 (revised 2003), Employers' Disclosures about Pensions and Other Postretirement Benefits—an amendment of FASB Statement No. 87, 88 and 106. This Statement revises employers' disclosures about pension plans and other postretirement benefit plans. The Company will adopt the disclosure requirements of SFAS 132 (revised 2003) in 2004, as the Company's only pension plan is a non-U.S. plan.

In May 2003, the Financial Accounting Standards Board ("FASB") issued SFAS No. 150, "Accounting for Certain Instruments with Characteristics of both Liabilities and Equity", which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company's adoption of the initial recognition and initial measurement provisions of SFAS 150 did not have a material impact on the Company's results of operations or financial position.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities", which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS 133. SFAS 149 is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. The adoption of SFAS 149 did not have a material impact on the Company's results of operations or financial position.

In November 2002, the Emerging Issues Task Force (EITF) issued EITF 00-21 "Accounting for Revenue Arrangements with Multiple Deliverables". EITF 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company will continue to evaluate the impact of EITF 00-21 on revenue arrangements it may enter into in the future.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". Among other things, SFAS 145 eliminates the requirement that gains and losses related to extinguishments of debt be classified as extraordinary items. Accordingly, the Company reclassified the \$256,000 loss on the early retirement of debt incurred in 2001 to other income/(expense), net.

**3. ACQUISITIONS**

In November 2003, the Company acquired all of the outstanding capital stock of Spinal Specialties, Inc. for \$6.0 million in cash including expenditures associated with the acquisition and subject to a working capital adjustment. At December 31, 2003, we have accrued \$380,000 for the estimated amount to be paid for the working capital adjustment. In connection with this acquisition, the Company recorded approximately \$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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**3. ACQUISITIONS (CONTINUED)**

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™ Bone Cement Delivery System and the ACCU-DISC™ Pressure Monitoring System. Physicians use these products in a variety of spinal, orthopedic and pain management procedures.

In August 2003, the Company acquired substantially all of the assets of Tissue Technologies, Inc., the manufacturer and distributor of the UltraSoft™ 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. The Company markets the UltraSoft products directly to cosmetic and reconstructive surgeons through its plastic and reconstructive surgery sales force and through a network of distributors. The acquired assets consist primarily of technology, which is being amortized on a straight-line basis over 10 years, and goodwill. Any future contingent consideration paid to the seller is expected to be recorded as additional goodwill.

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. JARIT sells its products to more than 5,200 hospitals and surgery centers worldwide. The acquisition of JARIT has broadened Integra's existing customer base and surgical instrument product offering and has provided an opportunity to achieve operating costs savings, including the procurement of Integra's Ruggles™ and Padgett™ instruments products directly from the instrument manufacturers.

In connection with this acquisition, the Company recorded approximately \$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. The manufacturing of the acquired product lines was transferred to Integra's manufacturing facility located in Biot, France. 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 connection with this acquisition, the Company terminated all of NMT's independent neurosciences sales agents based in the United States and exited the Atlanta, Georgia distribution facility. These termination and closure costs were accrued as part of the purchase price because they provided no future benefit to the Company's operations.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**3. ACQUISITIONS (CONTINUED)**

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. Signature Technologies currently manufactures cranial fixation systems primarily for sale under a single contract manufacturing agreement that expires in June 2004.

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. Signature Technologies has manufactured prototypes of this enhanced cranial fixation system and we do not expect to incur significant costs to complete development and obtain regulatory clearance to market the product. 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.

In December 2001, the Company acquired all of the capital stock of NeuroSupplies, Inc., a specialty distributor of disposables and supplies for neurologists, pulmonologists and other physicians, for \$4.1 million. The purchase price consisted of \$0.2 million in cash (including expenditures associated with the acquisition), a \$3.6 million note that was repaid in 2002, and 10,000 shares of Integra common stock. This acquisition extended Integra's reach to the neurologist and allied fields and further into products used for the diagnosis and monitoring of neurological disorders. In 2003, the Company relocated the NeuroSupplies operations to its facility in Pembroke, Massachusetts.

In April 2001, the Company acquired all of the outstanding capital stock of Satelec Medical, a subsidiary of the Satelec-Pierre Rolland group, for \$3.9 million in cash, including expenditures associated with the acquisition. Satelec Medical, based in France, manufactures and markets the Dissectron® ultrasonic surgical aspirator console and a line of related handpieces. The Company completed the consolidation of the Satelec manufacturing operations into its Andover, England and Biot, France facilities in 2002. This acquisition broadened Integra's neurosurgical product line offering and its direct sales and marketing presence in Europe.

In April 2001, the Company acquired all of the outstanding capital stock of GMSmbH, the German manufacturer of the LICOX® Brain Tissue Oxygen Monitoring System, for \$3.2 million. The purchase price consisted of \$2.6 million in cash (including expenditures associated with the acquisition), the forgiveness of \$0.2 million in notes receivable from GMSmbH, and \$0.4 million of future minimum royalty payments to the seller. Prior to the acquisition, the Company had exclusive marketing rights to the LICOX® products in the United States and certain other markets. This acquisition provided Integra with full rights to the LICOX® product technology.

All of these acquisitions have been accounted for using the purchase method of accounting, and the results of operations of the acquired businesses have been included in the consolidated financial statements since their respective dates of acquisition.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**3. ACQUISITIONS (CONTINUED)**

The following table summarizes the fair value of the assets acquired and liabilities assumed as a result of 2003 and 2002 acquisitions:

*(All amounts in thousands)*

<u>2003 Acquisitions</u>	<u>Spinal Specialties</u>	<u>Jarit Instruments</u>	<u>Tissue Technologies</u>	
Current assets . . . . .	\$ 1,944	\$17,498	\$ 81	
Property, plant and equipment . . .	307	1,285	88	
Intangible assets . . . . .	2,300	29,091	281	
Goodwill . . . . .	3,070	—	251	
Other non-current assets . . . . .	—	104	—	
Total assets acquired . . . . .	<u>7,621</u>	<u>47,978</u>	<u>701</u>	
Current liabilities . . . . .	358	2,357	76	
Deferred tax liabilities . . . . .	836	—	—	
Total liabilities assumed . . . . .	<u>1,194</u>	<u>2,357</u>	<u>76</u>	
Net assets acquired . . . . .	<u>\$ 6,427</u>	<u>\$45,621</u>	<u>\$ 625</u>	
 <u>2002 Acquisitions</u>	 <u>Radionics</u>	 <u>Padgett</u>	 <u>NMT Neuro</u>	 <u>Signature</u>
Current assets . . . . .	\$ 977	\$ 1,895	\$ 5,977	\$ 490
Property, plant and equipment . . .	75	65	4,138	1,165
Intangible assets . . . . .	391	6,437	—	626
Goodwill . . . . .	2,028	3,658	—	—
In-process research and development . . . . .	—	—	—	1,177
Other non-current assets . . . . .	18	281	—	—
Total assets acquired . . . . .	<u>3,489</u>	<u>12,336</u>	<u>\$10,115</u>	<u>3,458</u>
Current liabilities . . . . .	10	200	3,789	76
Deferred tax liabilities . . . . .	—	2,524	665	—
Total liabilities assumed . . . . .	<u>10</u>	<u>2,724</u>	<u>4,454</u>	<u>76</u>
Net assets acquired . . . . .	<u>\$ 3,479</u>	<u>\$ 9,612</u>	<u>\$ 5,661</u>	<u>\$ 3,382</u>

The 2003 purchase price allocations are preliminary.

The goodwill acquired in the 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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**3. ACQUISITIONS (CONTINUED)**

The following unaudited pro forma financial information summarizes the results of operations for the periods indicated as if the acquisitions consummated in 2003 and 2002 had been completed as of January 1, 2002. 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.

	2003	2002
	<i>(in thousands)</i>	
Total revenue .....	\$195,327	\$168,915
Net income .....	27,469	41,987
Basic net income per share .....	\$ 0.94	\$ 1.45
Diluted net income per share .....	\$ 0.90	\$ 1.36

In December 2003, the Company acquired the assets of Reconstructive Technologies, Inc. ("RTI") for approximately \$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™), a tissue expansion device. RTI's technology encompasses a sophisticated and compact pump that produces a cyclic force when attached to ballooning tissue expanders. RTI's ACE System technology rapidly expands tissue by stimulating the body's natural response to physical stress on the skin. Because the ACE System is 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™ 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), an additional \$1.5 million to be paid upon Novus' achievement of a product development milestone, and up to an additional \$2.5 million payable based upon revenues from Novus' products. As part of the consideration paid, Novus has also agreed to conduct certain clinical studies on the NeuroSensor™ system, continue development of a next generation, advanced neuromonitoring product, and design and transfer to Integra a validated manufacturing process for these products.

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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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, 2003, the estimated fair value of the Contingent Interest obligation was \$458,000.

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

Holder 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 approximately \$35.3 million of the proceeds to purchase 1.5 million shares of its common stock.

In connection with the prepayment of all outstanding bank loans and a \$2.8 million note payable issued in connection with an acquisition, the Company recorded in 2001 a loss on the early retirement of debt of \$256,000, which is included in other income/(expense), net.

**5. INTEREST RATE SWAP AGREEMENT**

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 2½% 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 year ended December 31, 2003 reflects a \$330,000 reduction in interest expense associated with the interest rate swap. Our effective interest rate on the hedged portion of the notes was 0.79% as of December 31, 2003.



**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**5. INTEREST RATE SWAP AGREEMENT (CONTINUED)**

The net fair value of the interest rate swap at inception was \$767,000. At December 31, 2003, the net fair value of the interest rate swap increased \$305,000 to \$1.1 million and is included in other liabilities. In connection with this fair value hedge transaction, the Company recorded a \$433,000 net decrease in the carrying value of its contingent convertible notes. The \$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 this amount is recorded in other income.

**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 B, and 54,000 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 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.

The Company issued 100,000 shares of Series B Convertible Preferred Stock (Series B Preferred) and warrants to purchase 240,000 shares of common stock at \$3.82 per share to SPEP for \$9.9 million, net of issuance costs. In June 2001, SPEP converted the Series B Preferred into 2,617,800 shares of common stock. The Series B Preferred had a 10% cumulative annual dividend yield payable only upon liquidation. The warrants issued with the Series B Preferred were exercised in March 2001 for proceeds of \$916,800.

SPEP is entitled to certain registration rights for shares of common stock obtained through conversion of the Series B Preferred or Series C Preferred or the exercise of the related warrants.

*COMMON STOCK TRANSACTIONS*

In August 2001, the Company 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.

In 2003 and 2002, respectively, the Company repurchased 1.5 million and 100,000 shares of its common stock for \$35.4 million and \$1.8 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 have been reserved for issuance. 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, 2003, approximately 196,000 shares remain available for purchase under the ESPP.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

*STOCK OPTION PLANS*

As of December 31, 2003 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 1996 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 2001 Plan), and the 2003 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.

Option activity for all the Plans was as follows:

	<u>2003</u>		<u>2002</u>		<u>2001</u>	
	<u>Options</u>	<u>Wtd. Avg. Ex. Price</u>	<u>Options</u>	<u>Wtd. Avg. Ex. Price</u>	<u>Options</u>	<u>Wtd. Avg. Ex. Price</u>
			<i>(shares in thousands)</i>			
Options outstanding at January 1, .	4,295	\$12.15	4,261	\$10.79	4,519	\$ 7.74
Granted . . . . .	430	\$24.81	618	\$17.73	748	\$24.61
Exercised . . . . .	(1,726)	\$ 7.70	(425)	\$ 6.15	(836)	\$ 6.49
Cancelled . . . . .	(115)	\$17.40	(159)	\$13.39	(170)	\$11.88
Options outstanding at						
December 31, . . . . .	2,884	\$16.49	4,295	\$12.15	4,261	\$10.79
Options exercisable at						
December 31, . . . . .	1,495	\$13.65	2,380	\$ 8.75	1,986	\$ 6.89

At December 31, 2003, there were 3,436,000 shares available for grant under the Plans.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

The following table summarizes information about stock options outstanding as of December 31, 2003:

Range Of Exercise Prices	Options Outstanding			Options Exercisable	
	As of Dec. 31, 2003	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contractual Life <i>(shares in thousands)</i>	As of Dec. 31 2003	Wtd. Avg. Exercise Price
\$ 3.38 - \$ 6.00	478	\$ 4.85	1.5 years	478	\$ 4.85
\$ 6.28 - \$12.00	496	\$10.00	4.9 years	226	\$ 8.85
\$12.19 - \$17.00	490	\$14.20	3.4 years	300	\$14.13
\$17.07 - \$23.00	630	\$18.91	4.9 years	156	\$18.31
\$23.58 - \$32.42	790	\$27.12	4.5 years	335	\$26.87
	<u>2,884</u>	<u>\$16.49</u>	<u>4.0 years</u>	<u>1,495</u>	<u>\$13.65</u>

The weighted average fair market value of options granted in 2003, 2002 and 2001 was \$13.01, \$9.57, and \$16.14 per share, respectively.

**RESTRICTED UNITS**

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 Company's President and Chief Executive Officer (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 a defined benefit pension plan in the United Kingdom covering certain current and former employees. This plan is no longer open to new participants. Net periodic benefit costs for this defined benefit pension plan included the following amounts:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	<i>(in thousands)</i>		
Service cost . . . . .	\$ 88	\$ 122	\$ 115
Interest cost . . . . .	397	355	332
Expected return on plan assets . . . . .	(330)	(331)	(356)
Recognized net actuarial loss . . . . .	<u>116</u>	<u>85</u>	<u>7</u>
Net periodic benefit cost . . . . .	\$ 271	\$ 231	\$ 98

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**8. RETIREMENT BENEFIT PLANS (CONTINUED)**

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

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Discount rate . . . . .	5.4%	5.5%	5.9%
Expected return on plan assets . . . . .	6.2%	6.5%	6.5%
Rate of compensation increase . . . . .	3.3%	3.8%	4.1%

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:

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
	<i>(in thousands)</i>	
<b>CHANGE IN BENEFIT OBLIGATION</b>		
Benefit obligation, beginning of year . . . . .	\$ 6,803	\$ 5,733
Service cost . . . . .	88	123
Interest cost . . . . .	397	356
Participant contributions . . . . .	36	33
Actuarial (gain) loss . . . . .	857	30
Benefits paid . . . . .	(151)	(105)
Effect of foreign currency exchange rates . . . . .	<u>802</u>	<u>633</u>
Benefit obligation, end of year . . . . .	\$ 8,832	\$ 6,803
<b>CHANGE IN PLAN ASSETS</b>		
Plan assets at fair value, beginning of year . . . . .	\$ 5,068	\$ 5,153
Actual return on plan assets . . . . .	881	(669)
Employer contributions . . . . .	211	153
Benefits paid . . . . .	(151)	(105)
Participant contributions . . . . .	36	33
Effect of foreign currency exchange rates . . . . .	<u>601</u>	<u>503</u>
Plan assets at fair value, end of year . . . . .	\$ 6,646	\$ 5,068
<b>RECONCILIATION OF FUNDED STATUS</b>		
Funded status, Benefit obligation in excess of plan assets . . . . .	\$(2,186)	\$(1,735)
Unrecognized net actuarial loss . . . . .	2,416	2,001
Adjustment to recognize minimum liability . . . . .	<u>(1,804)</u>	<u>(1,444)</u>
Accrued benefit cost . . . . .	\$(1,574)	\$(1,178)

The accrued benefit liability recorded at December 31, 2003 and 2002 is included in other liabilities.

**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 \$483,000, \$575,000 and \$411,000 in 2003, 2002 and 2001, respectively.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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 2003, 2002 and 2001.

Future minimum lease payments under operating leases at December 31, 2003 were as follows:

	<u>Related Parties</u>	<u>Third Parties</u>	<u>Total</u>
		<i>(in thousands)</i>	
2004 .....	\$ 321	\$1,860	\$2,181
2005 .....	321	1,378	1,699
2006 .....	321	894	1,215
2007 .....	324	854	1,178
2008 .....	341	364	705
Thereafter .....	<u>999</u>	<u>1,090</u>	<u>2,089</u>
Total minimum lease payments .....	<u>\$2,627</u>	<u>\$6,440</u>	<u>\$9,067</u>

Total rental expense in 2003, 2002, and 2001 was \$2.9 million, \$2.0 million, and \$1.9 million, respectively, and included \$321,000, \$321,000, and \$306,000, in related party expense, respectively.

**10. INCOME TAXES**

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

	<u>2003</u>	<u>2002</u>	<u>2001</u>
		<i>(in thousands)</i>	
Current:			
Federal .....	\$ 972	\$ —	\$ 208
State .....	2,470	1,276	446
Foreign .....	<u>529</u>	<u>(427)</u>	<u>555</u>
Total current .....	3,971	849	1,209
Deferred:			
Federal .....	\$ 12,800	\$ (13,671)	\$ (10,774)
State .....	83	373	(739)
Foreign .....	<u>(526)</u>	<u>(103)</u>	<u>(572)</u>
Total deferred .....	12,357	(13,401)	(12,085)
Income tax expense (benefit) .....	<u>\$ 16,328</u>	<u>\$ (12,552)</u>	<u>\$ (10,876)</u>

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**10. INCOME TAXES (CONTINUED)**

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

	December 31,	
	2003	2002
	<i>(in thousands)</i>	
Net operating loss and tax credit carryforwards . . . . .	\$ 22,695	\$ 23,749
Inventory reserves and capitalization . . . . .	2,294	2,722
Other . . . . .	1,758	2,102
Deferred compensation . . . . .	5,361	7,692
Deferred income . . . . .	1,434	2,167
Total deferred tax assets before valuation allowance . . . . .	33,542	38,432
Valuation allowance . . . . .	(5,360)	(7,692)
Depreciation and amortization . . . . .	(6,421)	(5,130)
Other . . . . .	(392)	(392)
Net deferred tax assets . . . . .	<u>\$ 21,369</u>	<u>\$ 25,218</u>

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, management concluded in the fourth quarter of 2001 that a portion of the valuation allowance recorded against federal and state net operating loss carryforwards and certain other temporary differences was no longer necessary. The valuation allowance was reduced by \$12.0 million in 2001 because management believed that it was more likely than not that the Company would realize the benefit of that portion of the deferred tax assets recorded at December 31, 2001. The \$12.0 million reduction in the valuation allowance consisted of an \$11.5 million deferred income tax benefit and a \$450,000 credit to additional paid-in capital related to net operating loss carryforwards generated through the exercise of stock options.

In the fourth quarter of 2002, the Company reduced the remaining valuation allowance recorded against net operating loss carryforwards by \$23.4 million, which reflects the Company's estimate of additional tax benefits that it expects to realize in the future. The \$23.4 million reduction in the valuation allowance consisted of a \$20.4 million deferred income tax benefit and a \$3.0 million credit to additional paid-in capital related to net operating loss carryforwards generated through the exercise of stock options. A valuation allowance of \$5.4 million is recorded against the remaining \$33.3 million of deferred tax assets recorded at December 31, 2003. 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.

The net change in the Company's valuation allowance was \$ (2.3) million, \$(26.7) million, and \$(10.4) million, in 2003, 2002, and 2001, respectively. Included in the 2002 reduction was the write off of the valuation allowance associated with \$3.3 million of deferred tax assets which the Company wrote off because they are no longer expected to be utilizable. Included in the 2003 reduction was the write off of the valuation allowance associated with \$2.3 million of deferred tax assets which the Company wrote off because they are not expected to be utilizable.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**10. INCOME TAXES (CONTINUED)**

A reconciliation of the United States Federal statutory rate to the Company's effective tax rate for the years ended December 31, 2003, 2002, and 2001 is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Federal statutory rate . . . . .	35.0%	35.0%	34.0%
Increase (reduction) in income taxes resulting from:			
State income taxes, net of federal tax benefit . . . . .	3.9%	3.7%	1.9%
Foreign taxes booked at different rates . . .	(1.0%)	(2.5%)	(1.3%)
Alternative minimum tax, net of state benefit . . . . .	—	—	1.4%
Nondeductible items . . . . .	(0.1%)	(0.5%)	1.1%
Other . . . . .	—	(1.0%)	0.7%
Change in valuation allowance . . . . .	—	<u>(89.9%)</u>	<u>(108.9%)</u>
Effective tax rate . . . . .	<u>37.8%</u>	<u>(55.2%)</u>	<u>(71.1%)</u>

At December 31, 2003, the Company had net operating loss carryforwards of approximately \$72.8 million and \$10.5 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 2009, respectively.

At December 31, 2003, 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 2010. The timing and manner in which any acquired net operating losses or tax credits may be utilized in any year by the Company are limited by the Internal Revenue Code of 1986, as amended, Section 382 and other provisions of the Internal Revenue Code and its applicable regulations.

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 \$11.8 million and \$9.0 million at December 31, 2003 and 2002, respectively.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**11. NET INCOME PER SHARE**

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

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	<i>(in thousands, except per share amounts)</i>		
<u>Basic:</u>			
Net income .....	\$ 26,861	\$ 35,277	\$ 26,163
Dividends on preferred stock .....	—	(159)	(1,026)
Net income applicable to common stock .....	<u>\$ 26,861</u>	<u>\$ 35,118</u>	<u>\$ 25,137</u>
Basic net income per share .....	<u>\$ 0.92</u>	<u>\$ 1.21</u>	<u>\$ 1.08</u>
Weighted average common shares outstanding—Basic .....	<u>29,071</u>	<u>29,021</u>	<u>23,353</u>
<u>Diluted:</u>			
Net income applicable to common stock .....	\$ 26,861	\$ 35,277	\$ 26,163
Diluted net income per share .....	<u>\$ 0.88</u>	<u>\$ 1.14</u>	<u>\$ 0.94</u>
Weighted average common shares outstanding—Basic .....	29,071	29,021	23,353
Effect of dilutive securities:			
Assumed conversion of Preferred Stock .....	—	175	1,873
Stock options and warrants .....	<u>1,397</u>	<u>1,699</u>	<u>2,570</u>
Weighted average common shares outstanding .....	<u>30,468</u>	<u>30,895</u>	<u>27,796</u>

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:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	<i>(in thousands)</i>		
Stock options and warrants .....	424	1,104	65

Notes payable outstanding at December 31, 2003 that are convertible into 3,514,166 shares of common stock were excluded from the computation of diluted net income per share in 2003 because the conditions required to convert the notes were not met.

Restricted Units issued by the Company (see Note 7) that entitle the holder to 1,250,000 shares of common stock 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.



**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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:

In 1999, the Company and ETHICON, Inc., a division of Johnson & Johnson, signed an agreement (the ETHICON Agreement) providing ETHICON with exclusive marketing and distribution rights to INTEGRA® Dermal Regeneration Template worldwide, excluding Japan. Under the ETHICON Agreement, the Company manufactured INTEGRA® Dermal Regeneration Template and collaborated with ETHICON to conduct research and development and clinical research aimed at expanding indications and developing future products in the field of skin repair and regeneration. 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.

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

In September 2003, the Company and ETHICON amended the ETHICON agreement. Under the amended ETHICON agreement, ETHICON continued to market and sell INTEGRA Dermal Regeneration Template through December 31, 2003 under the original terms, and ETHICON paid Integra \$2.0 million on December 31, 2003 in connection with the termination of the agreement. The Company has recorded this termination fee as other income.

Due to the termination of the ETHICON agreement, the Company 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.

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™ 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, \$1.2 million, and \$1.1 million of research and development revenues under the agreement in 2003, 2002, and 2001, respectively.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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, 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 \$15,000,000 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 \$1,350,000, bringing the total award to approximately \$16,350,000, 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"). 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. We expect the Trial Court to begin new hearings on damages in the summer of 2004. We have not recorded any gain in connection with this matter.

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. NMT Medical, Inc., the former owner of these entities, has agreed to specifically indemnify Integra against any liability 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.

The Company is also 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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**13. COMMITMENTS AND CONTINGENCIES (CONTINUED)**

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:

Facility lease termination fee . . . . .	\$ 379,000
Research program termination costs . . . . .	216,000
Property and equipment impairment . . . . .	183,000
Inventory write-off . . . . .	157,000
Employee severance . . . . .	120,000
Other . . . . .	52,000
Total . . . . .	<u>\$1,107,000</u>

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.

**14. SEGMENT AND GEOGRAPHIC INFORMATION**

In 2003, following the integration of several recently acquired, diverse businesses, Integra began to manage the business and review financial results on an aggregate basis, instead of through two operating segments. Accordingly, all prior period financial results provided below have been revised to reflect the retroactive application of this change to a single operating segment.

Product revenues consisted of the following:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
		<i>(in thousands)</i>	
Neuromonitoring products . . . . .	\$ 44,229	\$ 37,184	\$ 28,158
Operating room products . . . . .	53,301	38,326	27,240
Instruments . . . . .	47,168	16,802	14,972
Private label products . . . . .	<u>21,997</u>	<u>20,313</u>	<u>17,538</u>
Consolidated product revenues . . . . .	<u>\$166,695</u>	<u>\$112,625</u>	<u>\$ 87,908</u>

Certain of the Company's products, including the DuraGen® Dural Graft products, NeuraGen™ 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 approximately 27%, 32% and 32% of product revenues in 2003, 2002 and 2001, 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.

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**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:

	<u>United States</u>	<u>Europe</u>	<u>Asia Pacific</u>	<u>Other Foreign</u>	<u>Consolidated</u>
			<i>(in thousands)</i>		
Product revenue:					
2003 .....	\$132,805	\$21,433	\$5,828	\$6,629	\$166,695
2002 .....	90,422	14,737	4,062	3,404	112,625
2001 .....	68,612	10,577	4,838	3,881	87,908
Long-lived assets:					
December 31, 2003 .....	\$ 81,182	\$21,082	\$ —	\$ —	\$102,264
December 31, 2002 .....	45,319	18,408	—	—	63,727
December 31, 2001 .....	33,001	12,057	—	—	45,058

**15. SELECTED QUARTERLY INFORMATION—UNAUDITED**

	<u>Fourth Quarter</u>	<u>Third Quarter</u>	<u>Second Quarter</u>	<u>First Quarter</u>
	<i>(in thousands, except per share data)</i>			
<u>2003:</u>				
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 .....	\$ 0.30	\$ 0.23	\$ 0.18	\$ 0.18
<u>2002:</u>				
Total revenue .....	\$ 35,261	\$30,204	\$26,441	\$25,916
Cost of product revenues .....	14,168	12,611	9,465	9,528
Total other operating expenses .....	14,313	16,001	11,486	11,063
Operating income .....	6,780	1,592	5,490	5,325
Interest income, net .....	727	822	993	993
Other income (expense), net .....	(18)	(11)	55	(23)
Income before income taxes .....	7,489	2,403	6,538	6,295
Income tax expense (benefit) .....	(17,885)	840	2,289	2,204
Net income .....	\$ 25,374	\$ 1,563	\$ 4,249	\$ 4,091
Basic net income per share .....	\$ 0.87	\$ 0.05	\$ 0.15	\$ 0.14
Diluted net income per share .....	\$ 0.83	\$ 0.05	\$ 0.14	\$ 0.13

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**16. SUBSEQUENT EVENTS**

In January 2004, the Company acquired the R&B instrument business from R&B Surgical Solutions, LLC for approximately \$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 plans to market these products through its JARIT sales force.

In January 2004, the Company acquired the Sparta disposable critical care devices and surgical instruments business from Fleetwood Medical, Inc. for approximately \$1.5 million in cash. The Sparta product line includes products used in plastic and reconstructive, ear, nose and throat (ENT), neuro, ophthalmic and general surgery. Prior to the acquisition, Fleetwood Medical marketed these product lines primarily to hospitals and physicians through a catalogue and a network of distributors.

The determination of the fair value of the assets acquired and liabilities assumed as a result of these acquisitions is in progress.

## **REPORT OF INDEPENDENT AUDITORS ON FINANCIAL STATEMENT SCHEDULE**

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

Our audits of the consolidated financial statements referred to in our report dated February 25, 2004, appearing in the 2003 Annual Report on Form 10-K of Integra LifeSciences Holdings Corporation and Subsidiaries also included an audit of the financial statement schedule listed in the index in Item 15(a)(2) of this Form 10-K. In our opinion, this financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey

February 25, 2004

**INTEGRA LIFESCIENCES HOLDINGS CORPORATION**  
**VALUATION AND QUALIFYING ACCOUNTS**

**SCHEDULE II**

<u>Description</u>	<u>Balance at Beginning Of Period</u>	<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts(1)</u>	<u>Deductions(2)</u>	<u>Balance at End of Period</u>
<i>(in thousands)</i>					
<u>Year ended December 31, 2003</u>					
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	—	(2,331)	—	5,361
<u>Year ended December 31, 2002</u>					
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
<u>Year ended December 31, 2001</u>					
Allowance for doubtful accounts and Sales Returns .....	\$ 1,253	\$ 2,142	\$ 4	\$(1,996)	\$ 1,403
Inventory reserves .....	3,420	3,734	—	(1,342)	5,812
Deferred tax asset valuation allowance .....	44,776	(9,970)	—	(450)	34,356

- (1) 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.
- (2) The \$3.0 million and \$450,000 reductions of the deferred tax asset valuation allowance in 2002 and 2001, respectively, were recorded to additional paid-in capital.

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## Corporate Information

### *Annual Meeting*

The 2004 Annual Meeting of Stockholders will be held at 9:00 a.m., Monday, May 17, 2004 at the Radisson Hotel Princeton, 4355 Route 1 at Ridge Road, Princeton, New Jersey 08540

### *Headquarters*

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

### *Stock Trading Information*

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

### *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

### *Investor Relations*

Contact the Integra Investor Relations department at (609) 936-2491 or [IR@Integra-LS.com](mailto:IR@Integra-LS.com) for business-related inquiries

You can call our transfer agent toll-free at (800) 937-5449 or reach them on the Internet at [www.amstock.com](http://www.amstock.com).

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

- Proxy statement for the 2004 Annual Meeting of Stockholders
- Quarterly reports on Form 10-Q
- Additional copies of the 2003 Annual Report on Form 10-K

### *Independent Public Accountants*

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

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](mailto: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 [www.Integra-LS.com](http://www.Integra-LS.com).

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