INTEGRA LIFESCIENCES HOLDINGS CORP
Form 8-K
June 27, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): June 27, 2003

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

(Exact name of Registrant as specified in its charter)

| Delaware | 0-26224 | 51-0317849 |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (I.R.S. Employer Identification No.) |

311 Enterprise Drive
Plainsboro, NJ 08536
(Address of principal executive offices) (Zip Code)

(609)-275-0500
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

ITEM 5. OTHER EVENTS

As previously reported in our report on Form 10-Q for the quarter ended March 31, 2003, Integra changed its reportable segments in March 2003. This Current Report on Form 8-K updates the following information contained in our Annual Report on Form 10-K for the year ended December 31, 2002 to reflect this new basis of segment reporting and to remove certain non-GAAP disclosures:

- Part I, Item 1. Business
- Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Part IV, Item 15. Financial Statements

Update to 2002 Annual Report on Form 10-K, 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 neurosurgery, plastic and reconstructive surgery, general surgery and soft tissue repair. Integra was founded in 1989 and over the next decade developed technologies and a product portfolio directed toward tissue regeneration. In 1999, we entered the neurosurgery market through an acquisition and the launch of our DuraGen(R) Dural Graft Matrix product for the repair of the dura mater. Since 1999, we have increased our revenues from $42.9 million to $117.8 million, an average annual growth rate of 40%, and we have broadened our product offerings to include more than 10,000 products. We have achieved this growth in our overall business through 12 acquisitions, the development and introduction of new products, and the expansion of our direct sales force.

We have historically managed our business and reviewed our financial results under two separate operating segments: Integra NeuroSciences(TM) and Integra LifeSciences(TM). In 2003, following the integration of several recently acquired, diverse businesses, we began to manage the business and review financial results on an aggregate basis, instead of through these two operating segments. Accordingly, we will report our 2003 financial results and now present our 2002 financial results for a single operating segment - the development, manufacturing and distribution of medical devices.

The Company's product lines include traditional medical devices, such as monitoring and drainage systems, surgical instruments and fixation systems, as well as innovative tissue repair products, such as the DuraGen(R) Dural Graft Matrix, the NeuraGen(TM) Nerve Guide, and the INTEGRA(R) Dermal Regeneration Template, that incorporate the Company's proprietary absorbable implant technology.

Financial information about our geographical areas is set forth in our financial statements under Notes to Consolidated Financial Statements, Note 13 - 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 markets in which we compete. Key elements of our strategy include the following:

Expand our presence in the hospital 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 involving the brain, spine and nervous system. 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 ENT, neurology, and spine markets;
- continuing the development and promotion of innovative new products, such as the NeuraGen(TM)Nerve Guide and the LICOX(R)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 twelve acquisitions focused primarily on our neurosurgical product lines. 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 Form Strategic Alliances For Our Private Label Products. We have collaborated with well-known medical device companies to develop and market the majority of our non-neurosurgical product lines. Significant ongoing strategic alliances include those with the Ethicon division of Johnson & Johnson to market our INTEGRA(R) Dermal Regeneration Template and Wyeth BioPharma and Medtronic Sofamor Danek to develop products for use in orthopedics. We intend to pursue additional strategic alliances selectively.

Continue To Develop New And Innovative Medical Products. As evidenced by our development of the INTEGRA(R) Dermal Regeneration Template, biomaterials for the orthopedic implant market, Biomend(R) and Biomend(R) Extend Absorbable Collagen Membrane, DuraGen(R) Dural Graft Matrix and the NeuraGen(TM) Nerve Guide, we have a leading proprietary absorbable implant franchise. We currently are developing a variety of innovative neurosurgical and other medical products and are seeking expanded applications for our existing products.

MARKETING AND PRODUCTS

We offer one of the most comprehensive product lines serving the neuro intensive care unit and operating room. We have established market positions in intracranial monitoring, dural repair, tumor ablation, neurosurgical shunting, surgical instrumentation, carotid shunting, peripheral nerve repair and central nervous system diagnostic and monitoring supplies.

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(TM): Our Integra NeuroSciences(TM)sales force provides implants, devices, instruments, and systems used in neurosurgery, neuromonitoring, neurotrauma, and related critical care to neurosurgeons and critical care units. These products are used primarily by neurosurgeons and nurses in the intensive care unit and the operating room and by neurologists in hospital and outpatient settings. We believe that we can access this focused group of hospital-based practitioners cost effectively through our direct sales and marketing infrastructure in the United States and Europe and our distribution network elsewhere. Integra NeuroSciences' direct marketing effort in the United States and Europe currently involves more than 100 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. A national sales manager and seven regional managers lead the United States sales force. We increased the number of our domestic sales territories from 44 to 63 in 2002. We believe our expanded sales force allows for smaller, more focused territories, better coverage of our customers, greater participation in trade shows and more extensive marketing efforts.



- Our Integra Padgett Instruments sales force markets a wide variety of high quality, reusable surgical instruments and implants to plastic and reconstructive surgeons, burn surgeons, ENT surgeons, hospitals, surgery centers, and other physicians. Padgett markets these products primarily through an eight-person sales force in the United States. Outside the United States, Padgett sells these products through a

network of distributors.

- Integra NeuroSupplies(TM) distributes disposables and supplies used in the diagnosis and monitoring of neurological disorders. These products are marketed primarily through a catalog, which is mailed once a year, and are used by neurologists, hospitals, sleep clinics, and other physicians in the United States.

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 Centerpulse, 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.

Our products can be segregated into the following categories:

| PRODUCT LINES | APPLICATION |
|---|---|
| NEUROMONITORING PRODUCTS | |
| Camino(R) and Ventrix(R) fiber optic-based intracranial Access, drainage and continuous Monitoring systems, LICOX(R) oxygen monitoring monitoring of intracranial pressure, Systems, Integra Systems of CSF Drainage and oxygen and temperature following injury Cranial Access or neurosurgical procedures | |
| Integra NeuroSupplies(TM) | Disposables and supplies used in the diagnosis and monitoring of neurological, ENT and pulmonary disorders |
| Integra epilepsy monitoring electrodes | Electrodes for the intraoperative monitoring of epileptic seizu |
| OPERATING ROOM PRODUCTS | |

| | |
|---|---|
| DuraGen(R)Dural Graft Matrix | Graft to close brain and spi |
| NeuraGen(TM)Nerve Guide | Repair of peripheral nerves |
| Neurosurgical shunts, including the Specifically designed for the management of Orbis-Sigma II(R), and the H-V Lumbar, hydrocephalus, a chronic condition involving Novus and Equi-Flow(R) Valves excess cerebrospinal fluid in the brain | |
| Sundt(TM)and other carotid shunts | For shunting blood during s involving blood vessels |
| Helistat(R)and Helitene(R)Absorbable Collagen Hemostats | For control of bleeding |



| PRODUCT LINES | APPLICATION |
|---|---|
| INSTRUMENTS | |
| Selector(R)Integra Ultrasonic Aspirator; Dissectron(R)Ultrasonic Aspirator | Surgical systems that ablate tissue |
| Redmond(TM)-Ruggles(TM)neurosurgical and spinal instruments | Specialized surgic brain or spinal surgery |
| Padgett Instruments | Devices and instruments reconstructive and plas |
| PRIVATE LABEL PRODUCTS | |
| INTEGRA(R)Dermal Regeneration Template (manufactured for Ethicon, Inc., a division of Japan) | Regenerate dermis and repair Johnson & Johnson, and Centu |
| BioMend(R)and BioMend(R)Extend Absorbable periodontal Collagen Membrane | Used in guided tissue regene surgery (manufactured for Ce |
| CollaCote(R), CollaTape(R)and CollaPlug(R) Absorbable wound dressings | Used to control bleeding in (manufactured for Centerpuls |
| Absorbable Collagen Sponge and other Fracture management / enabling spinal fusion Matrices for use with bone morphogenetic (manufactured for Wyeth BioPharma; Medtronic Protein (rhBMP-2) Sofamor Danek) | |

| | |
|---|---|
| VitaCuff(R) catheter access infection control | Provides protection against arising from long-term cathe (manufactured for Arrow Inte Bard Access Systems, Inc., T |
| BioPatch(R)(1) Antimicrobial Wound Dressing | Antimicrobial wound dressing for Ethicon, Inc. |
| Spembly Medical cryosurgery products | Allows surgeon to use low te easily extract diseased tiss for various distributors) |
| Cranial fixation devices; customer cranial plates | Allows neurosurgeon to repai cranium (manufactured for Me |

(1) BioPatch is a registered trademark of Johnson & Johnson

Neuromonitoring 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 400,000 cases of head trauma each year in the United States, and the market for monitoring and intervention is estimated to be approximately $40 million.

We sell the Camino(R) and Ventrix(R) lines of intracranial pressure and temperature monitoring systems and the LICOX(R) Brain Tissue Oxygen Monitoring



System. Currently there are more than 3,000 of our intracranial monitors installed worldwide. The Camino(R) and Ventrix(R) systems measure the intracranial pressure and temperature in the brain and ventricles, and the LICOX(R) system allows for continuous qualitative regional monitoring of dissolved oxygen in cerebral tissues. 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.

External Drainage And Cranial Access. Neurosurgeons use external drainage systems and cranial access kits 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.

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 test sleep disorders.

We sell these products under the Integra NeuroSupplies(TM) name primarily through a catalog 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.

Epilepsy Electrodes. We sell a line of electrodes for the intraoperative monitoring of epileptic seizures. We acquired these products and other assets in December 2002 from Radionics, a division of the Tyco Healthcare Group, and are transferring the manufacture of these products to our facility in Biot, France.

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 synthetic materials, processed human cadaver, or bovine pericardium. The worldwide market for dural repair, including cranial and spinal applications, is estimated to be $80 million.

The DuraGen(R) Dural Graft Matrix is an absorbable collagen matrix indicated for the repair of the dura mater surrounding the brain and spine. We believe that the DuraGen(R) Dural Graft Matrix addresses the shortcomings of other methods for repairing the dura mater. Clinical trials have shown our DuraGen(R) product 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(R) 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.

Repair Of Peripheral Nerves. Peripheral nerves may become severed 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(TM) Nerve Guide is an absorbable implant for the repair of severed peripheral nerves. The NeuraGen(TM) 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(TM) Nerve Guide offers a rapid method for rejoining severed peripheral nerves. In addition to targeting the neurosurgical operating room, we are also marketing the NeuraGen(TM) product to the non-hospital and private practice-based neurologists that purchase our Integra NeuroSupplies' products and to the Integra Padgett Instruments' customer base of hand and reconstructive surgeons.

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. Based on industry sources, we believe that the total United States market for hydrocephalus management, including monitoring, shunting and drainage, is approximately $70 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 2002 we strengthened our offering of hydrocephalus management products through our acquisition of the neurosciences division of NMT Medical, Inc. and certain assets of the Radionics business, a division of Tyco Healthcare Group. Those acquisitions added a range of leading pressure valves, including the Orbis-Sigma(R), Integra Hakim(R) horizontal-vertical ("H-V"), Equiflow(R) and Contour Flex(R) valves to our existing line of hydrocephalus management shunting products. We have sold the Heyer-Schulte(R), Novus(R), LPV(R) and Pudenz(TM) shunts, ventricular, peritoneal and cardiac catheters, physician-specified hydrocephalus management shunt kits, and Spetzler(R) lumbar and syringo-peritoneal shunts since our acquisition of the NeuroCare group of companies in 1999.

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 may negatively affect the future sales of our shunt products.

Hemodynamic Shunts. Our Sundt(TM) and other carotid shunts are used to divert blood to vital organs, such as the brain, during surgical procedures involving blood vessels. The Integra NeuroSciences sales force sells these products directly in the United States for use by vascular surgeons and neurosurgeons.

Instruments

Neurosurgical Systems For Tissue Ablation. More than 145,000 primary and metastatic brain tumors are diagnosed annually in the United States. Our Selector(R) Integra Ultrasonic Aspirator and Dissectron(R) Ultrasonic Surgical Aspirator systems address the market for the surgical destruction and removal of malignant and non-malignant tumors and other tissue.



The Selector(R) Integra Ultrasonic Aspirator and Dissectron(R) 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(R) product for use in general, gynecological, urological, plastic and reconstructive, orthopedic, thoracic and thorascopic surgery procedures. We offer the Dissectron(R) product only outside the United States.

Neurosurgical And Spinal Instrumentation. We provide neurosurgeons and spine

surgeons with a full line of specialty hand-held spinal and neurosurgical instruments sold under the Redmond(TM) and Ruggles(TM) brand names and a line of disposable neuroendoscopy products sold under the Neuro Navigational(R) brand name.

The Redmond(TM)-Ruggles(TM) products include retractors, kerrisons, dissectors, and curettes. Major product lines include spinal instruments, microsurgical neuro instruments, and customized products sold through other companies and distributors. Specialty surgical steel fabricators in Germany manufacture most of the Redmond(TM) and Ruggles(TM) products to our specifications. The Neuro Navigational(R) product line consists of fiber optic instruments used to facilitate minimally invasive neurosurgery, including third ventriculostomies, which are increasingly substituted for shunt placement for patients who meet the criteria.

Padgett 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. We sell these products in the United States through our Integra Padgett Instruments eight-person direct sales force and through certain distributors and original equipment manufacturer accounts. We sell these products internationally through distributors.

Private Label Products

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

INTEGRA(R) Dermal Regeneration Template is designed to enable the human body to regenerate functional dermal tissue. The 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, the FDA approved a PMA supplement to permit the marketing of the INTEGRA(R) Dermal Regeneration Template for the repair of scar contractures in patients who have already recovered from their initial wound. In 2002, we also received FDA 510(k) clearance to sell a related product, Integra(TM) Bilayer Matrix Wound Dressing and Integra(TM) Matrix Wound Dressing, for the dressing of wounds, including chronic wounds.

The Ethicon division of Johnson & Johnson is the exclusive seller of the INTEGRA(R) Dermal Regeneration Template and the Integra(TM) BiLayer Wound Matrix worldwide, except in Japan where Century Medical, Inc. has rights to distribute the INTEGRA(R) Dermal Regeneration Template.

In 2002, we sold $4.2 million of INTEGRA(R) Dermal Regeneration Template to Ethicon and received $2.0 million in research payments and $1.0 million in clinical and regulatory event payments that were recorded in other revenue.

Ethicon has not been successful in selling the minimum amounts of INTEGRA(R)



Dermal Regeneration Template specified in its agreement with us. In addition, we have notified Ethicon that certain clinical and regulatory events have been achieved under the agreement and that payments for the achievement of those events are due to us. Ethicon has informed us that it disagrees that the clinical and regulatory events in question have been achieved, and that it does not intend to make the payments we have demanded. In addition, Ethicon has

informed us that if we do not agree to substantial amendments to its agreement with us, it will consider alternatives that may include exercising its right to terminate the agreement.

The agreement requires Ethicon to give us notice one year in advance of a termination of the agreement, during which time Ethicon is required to continue to comply with the terms of the contract. At the end of that period, Ethicon may be required to pay additional amounts based on the termination provisions of the agreement and is required to cooperate in the transfer of the business back to Integra. Additionally, Ethicon may apply the value of any minimum payments in excess of actual product purchases against future purchases of products for sale on a non-exclusive basis for a specified period of time.

If Ethicon does terminate the agreement or if we determine that Ethicon is in breach of the agreement and we terminate the agreement, there is no assurance that we will be able to recover the money that we believe Ethicon is obligated to pay us under the agreement. If Ethicon does give us notice that it will terminate the agreement, it is possible that Ethicon will diminish its sales and marketing efforts for the product during the one-year notice period and that its sales will decline as a result. In addition, we may not be successful in sustaining or restoring the sales of the INTEGRA(R) Dermal Regeneration Template at current levels after the termination date. Finally, if Ethicon terminates the agreement it is possible that we may become involved in litigation with Ethicon, which could also impair our ability to sell products under our other agreements with Ethicon, including the BioPatch(R) and Instat(R) products.

Guided Tissue Regeneration In Periodontal Surgery. Our BioMend(R) Absorbable Collagen Membrane is used for guided tissue regeneration in periodontal surgery. The BioMend(R) 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(R) product after approximately four to seven weeks, avoiding the requirement for additional surgical procedures to remove a non-absorbable membrane. The BioMend(R) Extend product has the same indication for use as the BioMend(R) product, except that it absorbs in approximately 16 weeks. The BioMend(R) and BioMend(R) Extend Absorbable Collagen Membranes are sold through Centerpulse.

Orthopedic Biomaterials. We supply Wyeth BioPharma with Absorbable Collagen Sponges for use in developing bone regeneration implants. Since 1994, we have supplied Absorbable Collagen Sponges for use with Wyeth BioPharma's recombinant human bone morphogenetic protein-2 (rhBMP-2), a manufactured version of human protein naturally present in very small quantities in the body. Wyeth BioPharma is developing rhBMP-2 for clinical evaluation in several areas of bone repair and augmentation, including orthopedic, oral and maxillofacial surgery applications.

We are selling Absorbable Collagen Sponges for spinal applications through a related collaboration with Medtronic Sofamor Danek in North America. In July 2002, the FDA approved Medtronic Sofamor Danek's InFUSE(TM) Bone Graft used with the LT-CAGE(TM) Lumbar Tapered Fusion Device 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, the InFUSE Bone Graft is indicated to treat certain types of spinal degenerative disc disease, a common cause of low back pain.

Wyeth BioPharma has filed a PMA application with the FDA seeking approval for the use of InductOs(TM), rhBMP-2 used in conjunction with our Absorbable Collagen Sponge, for use in the treatment of acute long-bone fractures requiring open surgical management. In November 2002, the Orthopedic and Rehabilitation

Panel of the FDA Medical Devices Advisory Committee recommended that the FDA approve, with conditions, Wyeth BioPharma's PMA application.

We receive development funding and other payments from Medtronic Sofamor Danek and Wyeth BioPharma related to the development of additional matrices for various applications. Although the agreement provides for no milestone or other contingent payments, Wyeth BioPharma pays us to assist with regulatory affairs and research.

In addition, we are continuing to develop additional biomaterial technologies, such as a new class of absorbable polycarbonates created through the polymerization of tyrosine, that enhance the rate and quality of healing and tissue regeneration with synthetic biodegradable scaffolds that support cell attachment and growth. No medical device containing these materials has yet been approved for sale.

Other Private Label Products. Our current private label products also include the VitaCuff(R) catheter access infection control device, the BioPatch(R) anti-microbial wound dressing, a wide range of absorbable collagen products for hemostasis for use in dental surgery sold under the names CollaCote(R), CollaTape(R) and CollaPlug(R), the Instat(R) Absorbable Collagen Hemostat, and cranial fixation devices for use in craniomaxillofacial surgery. Our Spembly Medical cryosurgery products allow surgeons to use low temperatures to more easily extract diseased tissue in ophthalmic, general, gynecological, urological and cardiac applications.

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. Contract development revenues from strategic alliance partners and government grants fund a portion of our research and development activities. We spent approximately $10.6 million, $8.0 million, and $7.5 million in 2002, 2001, and 2000, respectively, on research and development activities. The 2002 amount includes $2.3 million of acquired in-process research and development charges recorded in connection with acquisitions. Research and development activities funded by contract development and government grant revenues amounted to $3.5 million, $3.9 million, and $2.8 million in 2002, 2001, and 2000, respectively.

We have either acquired or secured the proprietary rights to several important technological and scientific platforms, including collagen matrix, peptide, biomaterials, and intracranial monitoring technologies. These technologies provide support for our critical applications in neurosciences and tissue regeneration and 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 neuroscience applications. These efforts have led to the successful development of new products, such as the NeuraGen(TM) Nerve Guide and DuraGen(R) 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 2002 we expanded our product development staff to increase the focus on our neurosurgical product development efforts and to seek additional strategic alliances and applications for our other products and technologies.

GOVERNMENT REGULATION

As a manufacturer of medical devices, we are subject to extensive regulation by the Food and Drug Administration (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. However, the changes could have a material impact on our business.

We have received or acquired more than 190 Premarket Notification 510(k) clearances, five approved PMA applications and 54 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, 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 pursue a policy of seeking patent protection of our 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.

BioMend(R), Camino(R), CollaCote(R), CollaPlug(R), CollaStat(TM), CollaTape(R), Dissectron(R), DuraGen(R), EquiFlow(R), Helistat(R), Helitene(R), Heyer-Schulte(R), INTEGRA(R) Dermal Regeneration Template, Integra NeuroSciences(TM), Integra NeuroSupplies(TM), JARIT(R), LICOX(R), NeuraGen(TM), NeuroNavigational(R), Novus(R), LPV(R), Ommaya(R), Orbis-Sigma(R), Padgett Instruments, Inc(R), Pudenz(TM), Redmond(TM), Ruggles(TM), Selector(R), Spetzler(R), Sundt(TM), Ventrix(R), VitaCuff(R) 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, various of our neurosurgery product lines compete with smaller specialized companies or larger companies that do not otherwise focus on neurosurgery. 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 INTEGRA(R) Dermal Regeneration Template). 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, 2002, we had approximately 760 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 in the "SEC Filings" page of the Investor Relations section of our website at www.Integra-LS.com. You may also obtain a copy of any of these reports, without charge, from our investor relations department, 311 Enterprise Drive, Plainsboro, NJ 08536. Alternatively, you may view or obtain reports filed with the Securities and Exchange Commission at the SEC Public Reference Room at 450 Fifth Street, N.W. in Washington, D.C. 20549, or at the SEC's Internet site at www.sec.gov. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

RECENT DEVELOPMENT

On March 17, 2003, we acquired JARIT(R) Surgical Instruments, Inc. ("JARIT") for $44.5 million in cash, subject to a working capital adjustment and other adjustments with respect to certain income tax elections. For more than 30 years, JARIT has marketed 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. In the United States, JARIT sells through a 20 person sales management force that works with over 100 distributor sales representatives.

With more than 5,000 instrument patterns and a 98% order fill rate, JARIT has developed a strong reputation as a leading provider of high-quality surgical instruments. JARIT manages its vendor relationships and purchases, packages and labels its products directly from instrument manufacturers through its facility

in Tuttlingen, Germany.

The acquisition of JARIT broadens Integra's existing customer base and surgical instrument product offering and provides an opportunity to achieve operating costs savings, including the procurement of Integra's Redmond(TM)-Ruggles(TM) and Padgett Instruments Inc.(R) products directly from the instrument manufacturers.

The acquired business generated approximately $30.9 million in revenues and $7.8 million in income before income taxes for the year ended December 31, 2002.

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", which 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 o other risk factors described in the section entitled "Risk Factors" in this report.

You can identify these forward-looking statements by forward-looking words such as believe, may, could, 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.



Update to 2002 Annual Report on Form 10-K, Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with the selected consolidated financial data and our financial statements and the related notes appearing elsewhere in this

report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those under the heading "Risk Factors".

General

Integra develops, manufactures, and markets medical devices for use in neurosurgery, plastic and reconstructive surgery, general surgery and soft tissue repair.

We have historically managed our business and reviewed our financial results under two separate operating segments: Integra NeuroSciences(TM) and Integra LifeSciences(TM). In 2003, following the integration of several recently acquired, diverse businesses, we began to manage the business and review financial results on an aggregate basis, instead of through these two operating segments. Accordingly, we will report our 2003 financial results and now present our 2002 financial results for a single operating segment - the development, manufacturing and distribution of medical devices.

We offer one of the most comprehensive product lines serving the needs of the neuro intensive care unit and operating room. We have established market positions in intracranial monitoring, dural repair, tumor ablation, neurosurgical shunting, surgical instrumentation, carotid shunting, peripheral nerve repair and central nervous system diagnostic and monitoring supplies. We sell our products directly through various sales forces and through a variety of other distribution channels.

Acquisitions

Our recent growth in product revenues reflect increased sales of existing products, sales of newly launched products and sales of acquired businesses and product lines. We have acquired ten businesses and product lines since January 1, 2000, and those acquisitions have contributed significantly to our growth.



Reported product revenues for 2002 and 2001 included the following amounts in sales of acquired product lines:

| | 2002 Revenues | 2001 Revenues |
|---|---|---|
| | (in thousands) | |
| Neuromonitoring | | |
| Products acquired during 2002 | $ 1,626 | $ -- |
| Products acquired during 2001 | 6,460 | 990 |
| All other product revenues | 29,098 | 27,168 |
| Total Neuromonitoring product revenues | 37,184 | 28,158 |
| Operating Room | | |
| Products acquired during 2002 | $ 3,460 | $ -- |
| Products acquired during 2001 | 1,921 | 1,054 |
| All other product revenues | 32,945 | 26,186 |

| | | |
|---|---|---|
| Total Operating Room product revenues ..... | 38,326 | 27,240 |
| Instruments | | |
| Products acquired during 2002 ..... | $ 1,110 | $ -- |
| Products acquired during 2001 ..... | -- | -- |
| All other product revenues ..... | 15,692 | 14,972 |
| Total Instruments product revenues ..... | 16,802 | 14,972 |
| Private Label | | |
| Products acquired during 2002 ..... | $ 1,419 | $ -- |
| Products acquired during 2001 ..... | -- | -- |
| All other product revenues ..... | 18,894 | 17,538 |
| Total Private Label product revenues ..... | 20,313 | 17,538 |
| Consolidated | | |
| Products acquired during 2002 ..... | $ 7,615 | $ -- |
| Products acquired during 2001 ..... | 8,381 | 2,044 |
| All other product revenues ..... | 96,629 | 85,864 |
| Total product revenues ..... | $112,625 | $ 87,908 |

(1) Excludes sales of the LICOX(R) product in those territories where Integra had exclusive distribution rights to the product prior to our acquisition of GMSmbH.

Since the beginning of 2000, we have acquired the following businesses and product lines:

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 are moving 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.(R), 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 expect to complete the consolidation of Padgett's operations into our distribution center located in Cranbury, New Jersey in March 2003.

In September 2002, we acquired certain assets, including the NeuroSensor(TM) 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 neuromonitoring 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. The NeuroSensor(TM) monitor received 510(k) clearance from the FDA in February 2002 but has not been launched, pending the results of clinical trials and other factors. We expect the Novus products to complement our existing line of brain parameter monitoring products.

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 neuromonitoring system. The design and functionality of this next generation neuromonitoring system is based, in part, on certain technology employed in the NeuroSensor(TM) system that has been modified specifically for this project and which has no alternative use in the modified state. Early prototypes of this next generation neuromonitoring system have been designed and manufactured based on this modified core technology. Novus remains responsible for the costs to complete development and obtain regulatory clearance for this project, the value of which we have 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(R), Integra Hakim(R) and horizontal-vertical lumbar valves, and external ventricular drainage products to our neurosurgical product line. The acquired operations include a facility located in Biot, France that manufactures, packages and distributes shunting, catheter and drainage products, and a distribution facility located in Atlanta, Georgia. We completed the consolidation of the Atlanta operations into our Cranbury, New Jersey distribution center as of September 30, 2002.

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

In connection with this 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. 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. We estimated the value of the in-process research and development charge 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, 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 April 2001, we acquired Satelec Medical, a subsidiary of the Satelec-Pierre Rolland group, for $3.9 million in cash. Satelec Medical, based in France, manufactures and markets the Dissectron(R) ultrasonic surgical aspirator console

and a line of related handpieces. We completed the consolidation of the Satelec manufacturing operations into our Andover, England and Biot, France facilities in 2002.

In April 2001, we acquired GMSmbH, the German manufacturer of the LICOX(R) 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(R) products in the United States and certain other markets.

In April 2000, we purchased the Selector(R) Ultrasonic Aspirator, Ruggles(TM) hand-held neurosurgical instruments and Spembly Medical cryosurgery product lines from NMT Medical, Inc. for $11.6 million in cash.

In January 2000, we purchased the business of Clinical Neuro Systems, Inc. for $6.8 million. The purchase price consisted of $4.0 million in cash and a $2.8 million promissory note issued to the seller, which we repaid in full in 2001. The acquired business designed and manufactured neurosurgical external ventricular drainage systems, catheters, drainage bags, and cranial access kits.

We have accounted for these acquisitions using the purchase method of accounting and have included the results of operations of each of the acquired businesses in our consolidated financial statements since its date of acquisition. The following table provides a comparison of pro forma product revenues for the years 2002 and 2001 as if all acquisitions completed after January 1, 2001 had occurred as of the beginning of that year. This pro forma product revenues data is based upon estimates of product revenues generated by the acquired businesses during the period prior to which Integra acquired them and does not necessarily represent results that would have occurred if the acquisitions had taken place on the basis assumed above.

| | 2002 | | 2001 | | Growth Ove |
|---|---|---|---|---|---|
| | Reported | Pro Forma | Reported | Pro Forma | Reported |
| | ($ in thousands) | | | | |
| Total product revenues | 112,625 | 128,909 | 87,908 | 118,498 | 28.1% |
| Other revenue | 5,197 | 5,197 | 5,534 | 5,534 | (0.6%) |
| Total revenue | $117,822 | $ 134,106 | $ 93,442 | $ 124,032 | 26.1% |

On March 17, 2003, we acquired JARIT Surgical Instruments, Inc. ("JARIT") for $44.5 million in cash, subject to a working capital adjustment and other adjustments with respect to certain income tax elections. For more than 30 years, JARIT has marketed 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. In the United States, JARIT sells through a 20 person sales management force that works with over 100



distributor sales representatives.

With more than 5,000 instrument patterns and a 98% order fill rate, JARIT has developed a strong reputation as a leading provider of high-quality surgical instruments. JARIT manages its vendor relationships and purchases, packages and labels its products directly from instrument manufacturers through its facility

in Tuttlingen, Germany.

The acquisition of JARIT broadens Integra's existing customer base and surgical instrument product offering and provides an opportunity to achieve operating costs savings, including the procurement of Integra's Redmond(TM)-Ruggles(TM) and Padgett Instruments Inc.(R) products directly from the instrument manufacturers.

The acquired business generated approximately $30.9 million in revenues and $7.8 million in income before income taxes for the year ended December 31, 2002.

Results of Operations

As a result of our recent acquisitions, the following financial results may not be directly comparable.

| (in thousands, except per share data) | 2002 | 2001 | 2000 |
|---|---|---|---|
| Neuromonitoring products | $ 37,184 | $ 28,158 | $ 23,532 |
| Operating room products | 38,326 | 27,240 | 18,988 |
| Instruments | 16,802 | 14,972 | 8,647 |
| Private label products | 20,313 | 17,538 | 14,193 |
| Total product revenues | 112,625 | 87,908 | 65,360 |
| Other revenue | 5,197 | 5,534 | 6,289 |
| Total revenue | 117,822 | 93,442 | 71,649 |
| Cost of product revenues | 45,772 | 36,014 | 29,511 |
| Gross margin on product revenues | 66,853 | 51,894 | 35,849 |
| Gross margin as a percentage of product revenues | 59% | 59% | 55% |
| Research and development expenses | 8,304 | 7,992 | 7,524 |
| Acquired in-process research and development | 2,328 | -- | -- |
| Sales and marketing expenses | 25,118 | 20,322 | 15,371 |
| General and administrative expenses | 15,469 | 12,044 | 28,483 |
| Amortization | 1,644 | 2,784 | 2,481 |
| Total other operating costs and expenses | 52,863 | 43,142 | 53,859 |
| Operating income (loss) | 19,187 | 14,286 | (11,721) |
| Interest income (expense), net | 3,535 | 1,393 | (473) |
| Gain on disposition of product line | -- | -- | 1,146 |
| Other income (expense), net | 3 | (136) | 201 |
| Income (loss) before income taxes | 22,725 | 15,543 | (10,847) |
| Income tax expense (benefit) | (12,552) | (10,863) | 108 |
| Net income (loss) before extraordinary item and accounting change | 35,277 | 26,406 | (10,955) |
| Extraordinary loss / accounting change | -- | (243) | (470) |
| Net income (loss) | $ 35,277 | $ 26,163 | $(11,425) |
| Diluted net income (loss) per share | $ 1.14 | $ 0.94 | $ (0.97) |
| Weighted average shares outstanding | 30,895 | 27,796 | 17,553 |

Net income in 2002 was $35.3 million, or $1.14 per diluted share, as compared to net income of $26.2 million in 2001, or $0.94 per diluted share, and a net loss of $11.4 million in 2000, or $(0.97) per diluted share. Included in these amounts are certain 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 charges and gains that meet this criteria promotes comparability of reported financial results. The following charges and gains were included in net income (loss) and net income (loss) per share:

Recorded in 2002

- 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; and
- acquired in-process research and development charges of $2.3 million recorded in connection with acquisitions.

Recorded in 2001

- A $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; and
- An extraordinary loss of $243,000, net of tax, from the early retirement of debt;

Recorded in 2000

- A $13.5 million non-cash, stock-based compensation charge related to the extension of the Chief Executive Officer's employment agreement recorded in operating expenses;
- A $1.1 million gain on the sale of product lines;
- A $470,000 charge recorded as the cumulative effect of an accounting change associated with the adoption of a new accounting policy for revenue recognition; and
- A $4.2 million non-recurring, non-cash dividend related to the beneficial conversion feature of our Series C Convertible Preferred Stock when it was issued in March 2000 that did not affect the reported net loss for 2000 but was reflected in the calculation of net loss per share for 2000;

PRODUCT AND OTHER REVENUES and GROSS MARGINS ON PRODUCT REVENUES

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, as compared to 78% of product revenues in 2001 and 79% of product revenues in 2000. Growth in product revenues in 2002 was led primarily by sales of neuromonitoring and operating room products, which reported a 32% and 41% increase, respectively, in sales over 2001.

In 2001, total revenues increased 30% over 2000 to $93.4 million, led by a 35% increase in product revenues to $87.9 million. Domestic product revenues increased $16.9 million in 2001 to $68.6 million, or 78% of total product revenues, as compared to 79% of product revenues in 2000. Growth in product revenues in 2001 was led primarily by sales of operating room products and instruments, which reported a 43% and 73% increase, respectively, in sales over 2000.

Increased sales of our DuraGen(R) Dural Graft Matrix and sales of recently acquired product lines accounted for most of our growth in 2002 and 2001.

Revenue from sales of neurosurgical shunt product lines acquired in 2002, offset in part by a decline in sales from our existing shunt lines, and increased sales of the DuraGen(R) product and the NeuraGen(TM) Nerve Guide contributed to the growth in our 2002 operating room product revenue. In 2001, increased sales of the DuraGen(R) product led the growth in operating room products revenues.

Revenue from sales of drainage product lines acquired in 2002 and the Integra NeuroSupplies(TM) 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 neuromonitoring product revenues in 2002. In 2001, the launch of the LICOX(R) product in the United States and increased sales of our existing neuromonitoring and drainage and cranial access systems led growth in neuromonitoring product revenues.

Revenue from sales of the Padgett Instruments product line acquired in 2002 and a full year of sales of the Dissectron(R) Ultrasonic Aspirator product line acquired in April 2001 contributed to the growth in instruments product revenues in 2002. In 2001, sales of the Dissectron product and a full year of sales of the Selector(R) Ultrasonic Aspirator product line acquired in April 2000 contributed to the growth in instrument product revenues.

Effective January 2003, our Integra NeuroSciences sales force began to sell our neurosurgical products to certain hospitals through a group purchasing organization. Group purchasing organizations use the leverage of large, organized buying groups 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. We expect that our participation in group purchasing organizations will improve our ability to sell our products to those participating hospitals that have not historically purchased from us.

Growth in sales of private label products in 2002 was generated primarily by increased revenues from the Absorbable Collagen Sponge component of Medtronic's recently approved InFUSE(TM) Bone Graft product and $1.4 million in sales of product lines acquired in 2002. The increase in private label product revenues in 2001 was generated primarily by increased sales of our INTEGRA(R) Dermal Regeneration Template product and the Absorbable Collagen Sponge and a $600,000 increase in revenues from the cryosurgery product line acquired in the second quarter of 2000.

In 2002, the FDA approved a Premarket Approval ("PMA") supplement to permit the marketing of the INTEGRA(R) Dermal Regeneration Template for the repair of scar contractures in patients who have already recovered from their initial wound. In 2002 we also received FDA 510(k) clearance to sell related products, Integra(TM) Bilayer Matrix Wound Dressing and Integra(TM) Matrix Wound Dressing, for the dressing of wounds, including chronic wounds. We are continuing to work with Ethicon to obtain additional marketing indications for the INTEGRA(R) product.

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



acquire businesses that complement our existing businesses and products.

Gross margin as a percentage of product revenues was 59%, 59% and 55%, in 2002, 2001 and 2000, respectively. Cost of product revenues included $447,000, $203,000, and $429,000 in fair value inventory purchase accounting adjustments recorded in connection with acquisitions in 2002, 2001, and 2000, respectively. The positive effect on gross margins of an increasing percentage of overall product revenues generated from higher margin operating room products and of increased direct sales to hospitals in Europe in 2002 and 2001 offset the negative impact of certain unfavorable manufacturing overhead variances incurred in the production of our private label products in 2002 and of fair value inventory purchase accounting adjustments. We expect our future gross margins to benefit as sales of the higher margin operating room products continue to grow faster than other products. We also have developed or are developing plans to improve gross margins by consolidating our manufacturing facilities and increasing the efficiency of various manufacturing sites.

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 decreased by $337,000 in 2002 as a decline in government grant funding and the expiration of a technology royalty agreement were slightly offset by the receipt in 2002 of $1.0 million in event related payments. The $756,000 decline in other revenue in 2001 was primarily the result of $1.5 million of event-related revenues received in 2000, as compared to none in 2001, partially offset by higher research and development funding received in 2001. Other revenue includes $2.0 million per year in research and development funding related to our strategic alliance with Ethicon. The Ethicon Agreement provides us with research funding of $2.0 million per year through the year 2004. After 2004, funding amounts are based on a percentage of net revenues of the INTEGRA(R) Dermal Regeneration Template.

Although the research, development and distribution agreements with our strategic partners provide us with funding when certain events occur, such as advances in research programs, critical publications or product approvals, the timing of these event payments is uncertain and difficult to predict.

In 2002, we sold $4.2 million of INTEGRA(R) Dermal Regeneration Template to Ethicon and received $2.0 million in research payments and $1.0 million in clinical and regulatory event payments that were recorded in other revenue.

Ethicon has not been successful in selling the minimum amounts of INTEGRA(R) Dermal Regeneration Template specified in its agreement with us. In addition, we have notified Ethicon that certain clinical and regulatory events have been achieved under the agreement and that payments for the achievement of those events is due to us. Ethicon has informed us that it disagrees that the clinical and regulatory events in question have been achieved, and that it does not intend to make the payments we have demanded. In addition, Ethicon has informed us that if we do not agree to substantial amendments to its agreement with us, it will consider alternatives that may include exercising its right to terminate the agreement.

The agreement requires Ethicon to give us notice one year in advance of a termination of the agreement, during which time Ethicon is required to continue to comply with the terms of the contract. At the end of that period, Ethicon may be required to pay additional amounts based on the termination provisions of the



agreement and is required to cooperate in the transfer of the business back to Integra. Additionally, Ethicon may apply the value of any minimum payments in excess of actual product purchases against future purchases of products for sale

on a non-exclusive basis for a specified period of time.

If Ethicon does terminate the agreement or if we determine that Ethicon is in breach of the agreement and we terminate the agreement, there is no assurance that we will be able to recover the money that we believe Ethicon is obligated to pay us under the agreement. If Ethicon does give us notice that it will terminate the agreement, it is possible that Ethicon will diminish its sales and marketing efforts for the product during the one-year notice period and that its sales will decline as a result. In addition, we may not be successful in sustaining or restoring the sales of the INTEGRA(R) Dermal Regeneration Template at current levels after the termination date. Finally, if Ethicon terminates the agreement it is possible that we may become involved in litigation with Ethicon, which could also impair our ability to sell products under our other agreements with Ethicon, including the BioPatch(R) and Instat(R) products.

OTHER OPERATING EXPENSES

In 2002, we recorded $2.3 million of in-process research and development charges in connection with our acquisitions of Signature Technologies, Inc. and certain assets of Novus Monitoring Limited. Other research and development expenses increased in 2002 as a result of increased headcount and spending on product development focused on our neurosurgical product lines, offset by reduced development spending on INTEGRA(R) Dermal Regeneration Template and a $0.5 million decrease in government grants for research. Research and development expenses increased in 2001 primarily due to the development of a collagen hemostatic device for use in neurosurgical procedures and development costs for the NeuraGen(TM) Nerve Guide product, offset by decreased spending from the termination of a program with a partner to develop a product to regenerate articular cartilage.

We expect to continue to increase our efforts and focus on product development in the future.

Sales and marketing expenses have increased significantly since 2000, consistent with the expansion of our domestic and international sales and marketing infrastructure and increased trade show activities. Sales and marketing expenses represented 22%, 23%, and 24% of total product revenues in 2002, 2001 and 2000, respectively.

Since the end of 1999, we have more than doubled the size of our domestic Integra NeuroSciences(TM) sales force to more than 80 professionals, including neurospecialists, regional managers and clinical educators. With the acquisitions of GMSmbH and Satelec Medical in April 2001 and the neurosciences division of NMT Medical in July 2002, we have a direct neurosurgical sales and marketing presence in the key markets of western Europe. Through the acquisition of Padgett Instruments in 2002 we have an eight person direct sales force in the United States that sells to plastic and reconstructive surgeons, burn surgeons, hand surgeons, ENT surgeons and other physicians. Through the acquisition of JARIT Surgical Instruments in March 2003, we have a 20 person sales management force in the United States that works with over 100 distributor sales representatives selling to virtually all surgical disciplines.



General and administrative expenses increased $3.4 million in 2002, $1.9 million of which were operating costs associated with recently 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 facility rent at our expanded corporate headquarters and higher insurance and legal costs.

General and administrative expenses decreased $16.4 million in 2001 as compared to 2000. General and administrative expenses in 2000 included a $13.5 million non-cash, stock-based compensation charge related to the extension of the Chief Executive Officer's employment agreement. The remaining decrease in general and administrative expenses in 2001 resulted primarily from a decrease in legal expenses related to the conclusion of the jury trial in the patent infringement lawsuit against Merck KGaA in the first quarter of 2000 as well as a reduction in other litigation matters outstanding in 2001 and because of the write-off in 2000 of a large distributor account receivable.

Amortization expense decreased in 2002 because of the adoption of Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets", which requires that goodwill no longer be amortized. Excluding the effect of the recently acquired Jarit Instruments business, annual amortization expense is expected to approximate $2.1 million in both 2003 and 2004, $1.8 million in both 2005 and 2006, and $1.6 million in 2007.

NON-OPERATING INCOME AND EXPENSES

In August 2001, we raised $113.4 million from a follow-on public offering of 4.7 million shares of common stock, of which $9.3 million was subsequently used to repay all outstanding indebtedness. Accordingly, net interest income in 2002 increased to $3.5 million, as compared to net interest income of $1.4 million in 2001 and net interest expense of $473,000 in 2000.

We recorded a $1.1 million pre-tax gain on the disposition of two product lines in 2000.

INCOME TAXES

Since 1999, we have generated positive taxable income on a cumulative basis. In light of this trend, our current 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. 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, 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 expect 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 $7.7 million is recorded against the remaining $32.9 million of net deferred tax assets recorded at December 31, 2002. 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, in the event that 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.

The net change in the Company's valuation allowance was $(26.7) million, $(10.4) million, and $3.3 million, in 2002, 2001, and 2000, 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.

At December 31, 2002, we had net operating loss carryforwards of approximately $74.4 million and $19.8 million for federal and state income tax purposes, respectively, to offset future taxable income. The federal and state net operating loss carryforwards expire through 2013 and 2010, 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. In 2000, we recognized a tax benefit of $467,000 from the sale of certain state net operating loss carryforwards through a special program offered by the State of New Jersey.

At December 31, 2002, 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 certain revenues and incur certain operating expenses in British Pounds and the Euro, we will experience currency exchange risk with respect to those foreign currency denominated revenues or expenses.

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 this potential impact is believed to present a significant risk to our business, we may enter into derivative financial instruments, including forward contracts to purchase or sell foreign currencies, 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 where the U.S. dollar has increased compared to the local currency.

Our sales to foreign markets may be affected by local economic conditions.



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:

| | United States | Europe | Asia Pacific | Other Foreign | Consolidated |
|---|---|---|---|---|---|

(in thousands)

| | | | | | |
|---|---|---|---|---|---|
| Product revenues: | | | | | |
| 2002 ..... | $ 90,422 | $ 14,737 | $ 4,062 | $ 3,404 | $ 112,625 |
| 2001 ..... | 68,612 | 10,577 | 4,838 | 3,881 | 87,908 |
| 2000 ..... | 51,752 | 6,759 | 4,628 | 2,221 | 65,360 |

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 from our foreign-based subsidiaries in the United Kingdom, Germany and France. We expect revenues from customers outside the United States and expenses and revenues denominated in foreign currencies to increase in absolute terms, but not as a proportion of our total revenues, in 2003 as our acquisition of a significant facility in France in July 2002 and our continued expansion of our European sales force offset the effect of our recent acquisitions of entities that sell solely in the United States.

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 from our foreign subsidiaries in the United Kingdom, Germany and France.

In 2000, revenues from customers outside the United States totaled $13.6 million, or 21% of consolidated product revenues, of which approximately 50% were to European customers. Of this amount, $3.2 million of these revenues were generated in foreign currencies from our subsidiary based in the United Kingdom, which was acquired in April 2000.

Liquidity And Capital Resources

Historically, we have funded our operations primarily through private and public offerings of equity securities, product revenues, research and collaboration funding, borrowings under a revolving credit line and cash acquired in connection with business acquisitions and dispositions. Since 1999, we have substantially reduced our net use of cash from operations and, in 2002 and 2001, we generated positive operating cash flows of $32.0 million and $15.7 million, respectively. Operating cash flows improved in 2002 as a result of higher net income and improved working capital management.

Our principal uses of funds in 2002 were $25.0 million for business acquisitions, the repayment of a $3.6 million note given to a seller as consideration for the acquisition of NeuroSupplies, Inc. and $2.3 million for purchases of property and equipment. Principal sources of funds were approximately $3.3 million from the issuance of common stock and $32.0 million of positive operating cash flow.

On August 13, 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 the third quarter of 2001. Additionally, a related term loan and revolving credit facility was terminated in August 2001. We had no debt outstanding at December 31, 2002.

At December 31, 2002, we had cash, cash equivalents and marketable securities totaling $132.3 million. Investments consist almost entirely of highly liquid, interest bearing debt securities. We believe that our cash and marketable securities are sufficient to finance our operations in the short term. However, given the significant level of liquid assets and our objective to grow by acquisition and alliances, our financial position and future financial results could change significantly if we were to complete a business acquisition by utilizing a significant portion of our liquid assets. On March 17, 2003, we used $44.5 million to acquire the business of Jarit Instruments.

Excluding the effect of the acquisition of JARIT Surgical Instruments in March 2003, we are obligated to pay approximately $2.5 million and $2.2 million in 2003 and 2004, respectively, under the terms of operating lease agreements for our facilities. Thereafter, through 2012, we are contractually obligated to pay an aggregate of $6.1 million in total lease costs. We may be obligated to pay Novus 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. Additionally, we are obligated to pay royalties based on sales of certain of our products, including $0.3 million in future guaranteed minimum royalty payments to the seller of the GMSmbH business. We have no other significant future contractual obligations.

In February 2003, our Board of Directors authorized us to repurchase up to one million shares of our common stock for an aggregate cost not to exceed $15.0 million. We may repurchase shares under this program through February 2004 either in the open market or in privately negotiated transactions. During 2002, we repurchased 100,000 shares of our stock for an aggregate purchase price of $1.8 million under a previously authorized share repurchase program.

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 long-lived asset valuations and acquired in-process research and development charges, depreciation and amortization periods for long-lived assets, valuation allowances recorded against deferred tax assets, loss contingencies, and estimates of costs to complete performance obligations associated with research, licensing, and distribution arrangements for which revenue is accounted for using percentage of completion accounting. 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, determined on 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.

Long-Lived Assets. We review long-lived assets to be held and used, including property, plant, and equipment and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We evaluate the recoverability of long-lived assets to be held and used by comparing its carrying value with the projected undiscounted net cash flows applicable to the long-lived assets. If an impairment exists, we calculate the amount of such impairment based on the estimated fair value of the asset. We record impairments to long-lived assets to be disposed of based upon the fair value of the applicable assets. If future events that would trigger an impairment review occur or we change our estimates of projected future undiscounted net cash flows related to long-lived assets to be held and used, we may need to record an impairment charge.

Goodwill. Upon the adoption of Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets" in January 2002, our assessment of the recoverability of goodwill changed to a method based upon a comparison of the carrying value of the reporting units to which goodwill is assigned with its respective fair value. We completed our initial impairment review for goodwill as of June 30, 2002 and determined that our reporting unit goodwill was not impaired. If future events that would trigger an impairment review occur or we change our estimates of the fair value of our reporting units, we may need to record an impairment charge.



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.

Depreciation And Amortization Periods. We provide for depreciation and amortization using the straight-line method over the estimated useful lives of property, plant and equipment and other 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 these long-lived assets changes, we may change future depreciation and amortization expense.

Income Taxes. We recognize deferred tax assets and liabilities 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. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have considered our projections for future taxable earnings and the expected timing of the reversal of deductible temporary differences in determining the need for a valuation allowance. In 2002, this analysis resulted in our reducing the recorded valuation allowance by $23.4 million. In the event that we determine that we would be able to realize more or less than the recorded amount of net deferred tax assets, we would record an adjustment to the deferred tax asset valuation allowance in the period we make such a determination. We would record the adjustment in the earnings of such period or, to the extent the valuation allowance relates to tax benefits from the exercise of stock options, as a credit to additional paid-in capital.

Revenue Recognition. We recognize product sales when delivery has occurred and title has passed to the customer, there is a fixed or determinable sales price, and collectibility of that sales price is reasonably assured. We recognize research grant revenue when the related expenses are incurred. Under the terms of existing research grants, we are reimbursed for allowable direct and indirect research expenses. We recognize royalty revenue over the period our customers sell the royalty products and the amount earned by Integra is fixed and determinable. We recognize non-refundable fees received under research, licensing and distribution arrangements as revenue when received if we have no continuing obligations to the other party. For those arrangements where we have continuing performance obligations, we recognize revenue using the lesser of the amount of non-refundable cash received or the result achieved using percentage of completion accounting based upon our estimated cost to complete these obligations. If our estimates of the costs to complete these obligations change, we may change the amount of revenue we recognized for fees received under research, licensing and distribution arrangements where we have continuing performance obligations.

Loss Contingencies. We are subject to claims and lawsuits in the ordinary course of our business, including claims by employees or former employees and with respect to our products. 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.

Update to 2002 Annual Report on Form 10-K, Part IV, Item 15. Financial Statements

1. Financial Statements. The following financial statements and financial statement schedule are filed as a part of this report.



## REPORT OF INDEPENDENT ACCOUNTANTS

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, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Integra LifeSciences Holdings Corporation and Subsidiaries (the Company) at December 31, 2002 and 2001 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002, 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 more fully in Note 2 to the consolidated financial statements, in 2000 the Company changed its method of accounting for nonrefundable fees received under its various research, license and distribution agreements.

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 21, 2003, except Note 15
for which the date is March 17, 2003
and Notes 1 and 13 for which the
date is June 26, 2003.



INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

In thousands, except per share amounts

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| REVENUES | | | |
| Product revenue | $112,625 | $ 87,908 | $ 65,360 |
| Other revenue | 5,197 | 5,534 | 6,289 |
| Total revenue | 117,822 | 93,442 | 71,649 |
| COSTS AND EXPENSES | | | |
| Cost of product revenue | 45,772 | 36,014 | 29,511 |
| Research and development | 8,304 | 7,992 | 7,524 |
| Acquired in-process research and development | 2,328 | -- | -- |
| Selling and marketing | 25,118 | 20,322 | 15,371 |
| General and administrative | 15,469 | 12,044 | 28,483 |
| Amortization | 1,644 | 2,784 | 2,481 |
| Total costs and expenses | 98,635 | 79,156 | 83,370 |
| Operating income (loss) | 19,187 | 14,286 | (11,721) |
| Interest income (expense), net | 3,535 | 1,393 | (473) |
| Gain on dispositions of product lines | -- | -- | 1,146 |
| Other income (expense), net | 3 | (136) | 201 |
| Income (loss) before income taxes | 22,725 | 15,543 | (10,847) |

| | | | |
|---|---|---|---|
| Income tax expense (benefit) | (12,552) | (10,863) | 108 |
| Income (loss) before extraordinary loss and cumulative effect of accounting change | 35,277 | 26,406 | (10,955) |
| Extraordinary loss on early retirement of debt, net of income tax benefit | -- | (243) | -- |
| Cumulative effect of accounting change | -- | -- | (470) |
| Net income (loss) | $ 35,277 | $ 26,163 | $(11,425) |
| Basic net income (loss) per share before extraordinary loss and cumulative effect of accounting change | $ 1.21 | $ 1.09 | $ (0.95) |
| Basic net income (loss) per share | $ 1.21 | $ 1.08 | $ (0.97) |
| Diluted net income (loss) per share before extraordinary loss and cumulative effect of accounting change | $ 1.14 | $ 0.95 | $ (0.95) |
| Diluted net income (loss) per share | $ 1.14 | $ 0.94 | $ (0.97) |
| Weighted average common shares outstanding: | | | |
| Basic | 29,021 | 23,353 | 17,553 |
| Diluted | 30,895 | 27,796 | 17,553 |

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



INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONSOLIDATED BALANCE SHEETS

In thousands, except per share amounts

| | December 31, | |
|---|---|---|
| ASSETS | 2002 | 2001 |
| Current Assets: | | |
| Cash and cash equivalents | $ 43,583 | $ 44,518 |
| Short-term investments | 55,278 | 22,183 |
| Trade accounts receivable, net of allowances of $1,387 and $1,403 | 19,412 | 14,024 |
| Inventories | 28,502 | 24,329 |
| Prepaid expenses and other current assets | 5,498 | 2,898 |
| Total current assets | 152,273 | 107,952 |
| Noncurrent investments | 33,450 | 64,335 |
| Property, plant, and equipment, net | 16,556 | 11,662 |
| Deferred income taxes, net | 25,218 | 10,243 |
| Goodwill, net | 22,073 | 14,627 |
| Intangible assets, net | 23,091 | 16,898 |
| Other assets | 2,007 | 1,871 |

| | | |
|---|---|---|
| Total assets | $ 274,668 | $ 227,588 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Short-term debt | $ -- | $ 3,576 |
| Accounts payable, trade | 3,764 | 2,924 |
| Income taxes payable | -- | 1,481 |
| Customer advances and deposits | 7,908 | 4,843 |
| Deferred revenue | 816 | 772 |
| Accrued expenses and other current liabilities | 9,433 | 5,550 |
| Total current liabilities | 21,921 | 19,146 |
| Deferred revenue | 3,263 | 3,949 |
| Other liabilities | 1,887 | 437 |
| Total liabilities | 27,071 | 23,532 |
| Commitments and contingencies | | |
| Stockholders' Equity: | | |
| Preferred stock; $0.01 par value; 15,000 authorized shares; 0 and 54 Series C Convertible shares issued and outstanding | -- | 1 |
| Common stock; $.01 par value; 60,000 authorized shares; 27,204 and 26,129 issued and outstanding | 272 | 261 |
| Additional paid-in capital | 292,007 | 284,021 |
| Treasury stock, at cost; 106 and 6 shares | (1,812) | (51) |
| Other | (15) | (37) |
| Accumulated other comprehensive income (loss): | | |
| Unrealized gain on available-for-sale securities | 861 | 237 |
| Foreign currency translation adjustment | 1,618 | (776) |
| Minimum pension liability adjustment | (1,011) | -- |
| Accumulated deficit | (44,323) | (79,600) |
| Total stockholders' equity | 247,597 | 204,056 |
| Total liabilities and stockholders' equity | $ 274,668 | $ 227,588 |

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



INTEGRA LIFESCIENCES HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| OPERATING ACTIVITIES: | | | |
| Net income (loss) | $ 35,277 | $ 26,163 | $(11,425) |
| Adjustments to reconcile net income (loss) to net cash | | | |

| | | | |
|---|---|---|---|
| provided by (used in) operating activities: | | | |
| Depreciation and amortization | 5,020 | 5,959 | 5,357 |
| Loss (gain) on sale of product line and other assets | 28 | -- | (1,316) |
| In process research and development charge | 2,328 | -- | -- |
| Loss on early retirement of debt | -- | 256 | -- |
| Deferred tax benefit | (13,401) | (12,085) | -- |
| Amortization of discount and premium on investments | 2,142 | 298 | (181) |
| Stock based compensation | 31 | 29 | 13,587 |
| Other, net | 129 | 158 | 43 |
| Changes in assets and liabilities, net of business acquisitions: | | | |
| Accounts receivable | (2,109) | 98 | (3,475) |
| Inventories | 1,153 | (6,987) | (3,061) |
| Prepaid expenses and other current assets | (1,131) | (1,443) | (571) |
| Non-current assets | 185 | 1,858 | (3,565) |
| Accounts payable, accrued expenses and other liabilities | (90) | (941) | 2,831 |
| Customer advances and deposits | 2,565 | 4,020 | (3,078) |
| Deferred revenue | (142) | (1,682) | (106) |
| Net cash provided by (used in) operating activities | $ 31,985 | 15,701 | (4,960) |
| INVESTING ACTIVITIES: | | | |
| Proceeds from sale of product line and other assets | -- | -- | 1,600 |
| Proceeds from the maturities of investments | 35,402 | 3,000 | 16,981 |
| Purchases of available for sale investments | (39,113) | (88,533) | (13,391) |
| Purchases of property and equipment | (2,254) | (2,860) | (3,268) |
| Cash used in business acquisitions, net of cash acquired | (25,015) | (6,348) | (16,187) |
| Loans made | -- | -- | (238) |
| Net cash used in investing activities | $(30,980) | (94,741) | (14,503) |
| FINANCING ACTIVITIES: | | | |
| Net proceeds (repayments) from revolving credit facility | -- | (3,147) | 3,143 |
| Repayments of term loan | (3,600) | (7,705) | (2,250) |
| Repayment of note payable | -- | (2,800) | -- |
| Proceeds from sales of preferred stock and warrants | -- | -- | 5,375 |
| Proceeds from the issuance of common stock | -- | 113,433 | 5,000 |
| Proceeds from exercise of common stock purchase warrants | -- | 3,616 | 50 |
| Proceeds from stock issued under employee benefit plans | 3,323 | 6,060 | 3,156 |
| Purchases of treasury stock | (1,761) | -- | (170) |
| Collection of related party note receivable | -- | -- | 35 |
| Preferred stock dividends paid | -- | -- | (67) |
| Net cash (used in) provided by financing activities | $ (2,038) | 109,457 | 14,272 |
| Effect of exchange rate changes on cash and cash equivalents | 98 | 15 | (24) |
| Net increase (decrease) in cash and cash equivalents | $ (935) | 30,432 | (5,215) |
| Cash and cash equivalents at beginning of period | 44,518 | 14,086 | 19,301 |
| Cash and cash equivalents at end of period | $ 43,583 | $ 44,518 | $ 14,086 |
| Cash paid during the year for interest | $ 20 | $ 778 | $ 922 |
| Cash paid during the ye | | | |