

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-K  
ANNUAL REPORT PURSUANT TO SECTION 13 OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended  
December 31, 1997

Commission File No. 0-26224

INTEGRA LIFESCIENCES CORPORATION  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
employer incorporation or organization)

51-0317849  
(I.R.S. employer  
identification no.)

105 Morgan Lane  
Plainsboro, New Jersey  
(Address of principal executive offices)

08536  
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$.01 per share  
(Title of class)

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

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

The aggregate market value of the registrant's Common Stock (its only voting stock) held by non-affiliates of the registrant as of March 20, 1998 was approximately \$43.8 million. (Reference is made to page 24 herein for a statement of the assumptions upon which this calculation is based.)

The number of shares of the registrant's Common Stock outstanding as of March 20, 1998 was 29,905,097.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement relating to its scheduled May 18, 1998 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

## PART I

### ITEM 1. BUSINESS

Integra LifeSciences Corporation (hereinafter referred to as "Integra" or the "Company") was incorporated as a Delaware corporation in June 1989. Integra develops, manufactures and markets medical devices, implants and biomaterials primarily used in the treatment of burns and skin defects, spinal and cranial disorders, orthopedics and other surgical applications. Integra seeks to be the world's leading company specializing in implantable medical and biopharmaceutical therapies to target and control cell behavior, and to build shareholder value by acquiring, discovering, and developing cost-effective, off-the-shelf products that satisfy unmet medical needs.

Headquartered in Plainsboro, New Jersey, with a facility in San Diego, California, Integra markets its products directly as well as through marketing partners and distributors both domestically and internationally in more than 29 countries. The Company's customers include burn, trauma, plastic and reconstructive surgeons, neurosurgeons, orthopedic surgeons, operating room nurses, private label purchasers, and hospital administrators. Integra's products include VitaCuff(TM), BioPatch(TM), BioMend(TM), and the Company's flagship product, the INTEGRA(TM) Artificial Skin, Dermal Regeneration Template(TM) Device ("INTEGRA(TM) Artificial Skin"), which was the first medical device specifically designed to enable the human body to regenerate functional dermal tissue to receive a Premarket Approval ("PMA") application from by the U.S. Food and Drug Administration ("FDA").

Cells, and the matrix that surrounds cells, are organized into tissues. Tissues are organized into organs, which perform essential functions of the body. During development and growth, cells normally produce an infrastructure, which consists of a variety of different proteins including collagen. The Company refers to this infrastructure of proteins and other molecules as the extra-cellular matrix ("ECM"). The ECM provides cells with structural support and biological signals so that they can function properly. Equally important, the ECM provides the integrity that is unique to certain tissues. For example, the matrix of bone is very hard and functions to support the weight of the body. Cartilage, found at sites where bone connects to bone, contains a different cell type and matrix organization that withstands extreme compression, yet allows for almost frictionless motion between the bones of a joint. Muscles, by contrast, consist of very specialized cells and matrix that are designed for movement, while skin is composed of cells and matrix that are tough yet flexible and protect the body against abrasion and water loss, as well as infection.

For cells to function normally within tissues, the cells must be attached (anchored) to, and interact with, the ECM proteins that surround them. When certain tissues become damaged, normal healthy cells attempt to repair the deficient site by moving into the damaged area, dividing, and depositing new matrix. However, the repaired tissue is often in the form of a scar, which consists of cells surrounded by excessive amounts of matrix. Scars do not function like normal tissue and often fail entirely.

The transplantation of tissues from human donors is restricted by the shortage of such tissues, the difficulty and expense of transportation, the risk of rejection, the danger of disease transmission and the requirement, in certain cases, for life-long use of immuno-suppressant drugs. The grafting of a patient's own tissue ("autografting") causes damage to the site where the healthy tissue is harvested and is of limited use for severely wounded patients who have a minimal amount of healthy tissue for grafting. Currently available biomaterials (such as metals, ceramics and plastics) used in permanent implantable devices (such as knee joints or heart valves) are commonly used, but tend to degrade after years in the body, potentially compromising long-term performance. The Company believes that its regenerative medicine technologies have the potential to provide safer, more effective and less expensive methods for replacing damaged or diseased tissues when compared to other currently available techniques.

The Company's business strategy has been to selectively acquire and further develop several platforms of synergistic biomaterials and ECM technologies. The Company uses the regenerative medicine technologies and proprietary processes it owns and licenses to fabricate devices manufactured from collagen and other components of the ECM. Once surgically implanted, these devices serve as temporary structures intended to support regeneration of functional tissues. These products are engineered precisely for specific tissues and are directed to be absorbed into

the body during the regeneration process. INTEGRA(TM) Artificial Skin is the first in a series of products that the Company is developing to regenerate a variety of body tissues, including the dura, peripheral nerve, bone, articular cartilage and cardiovascular graft.

The Company also develops, sells and has substantial manufacturing experience with FDA-regulated absorbable medical products that serve a broad range of applications, including drug delivery, surgical hemostasis (the control of bleeding), infection control, dental surgery and wound care. These products are sold primarily through marketing relationships with a number of established medical companies, including Arrow International, Inc., Bard Access Systems, Inc., the Calcitek Division of Sulzermedica ("Calcitek"), Johnson & Johnson Medical, Inc. ("J&J Medical"), Johnson & Johnson Professional, Inc. ("J&J Professional"), Quinton Instruments Co., and Sorin BioMedica, Inc. ("Sorin"). The Company's commercial products use many of the same biomaterials, manufacturing processes, and materials engineering techniques used to produce INTEGRA(TM) Artificial Skin.

The Company intends to further develop and commercialize pharmacological medical applications of its technologies, particularly those developed by the Company's Telios Pharmaceuticals, Inc. subsidiary ("Telios"). The Company refers to the pharmacological applications of its ECM technologies as Matrix Medicine(TM). This technology is directed to the treatment of human disease characterized by disruption of the normal interactions between cells and the ECM. Matrix Medicine(TM) development includes applications for anti-thrombotics, inhibitors of angiogenesis, prevention of fibrosis and the treatment of cancer. At present, the Company does not intend to enter human studies for these applications

without development partners.

The Company believes its management and scientific team, development and manufacturing experience, proprietary technological position and relationships with established medical institutions and other organizations position it to achieve its objectives. The Company's research implementation has been to maintain a relatively small core of scientists and researchers within the Company and to conduct a large portion of its research and product development through arrangements with independent medical research centers. The Company believes this provides a cost-effective approach to managing its research and product development efforts, while maintaining the ability to respond quickly and effectively to technological changes.

The Company is actively engaged in five business areas, each of which is described in detail below: (1) skin defects and burns; (2) neurosurgical; (3) orthopedic; (4) private label medical products; and (5) developing businesses and ventures.

#### Skin Defects and Burns

The Company's primary operating business is the repair of skin defects and burns where surgical intervention is required. This business encompasses INTEGRA(TM) Artificial Skin, the Company's leading commercial product, as well as a pipeline of new products including the development of a second generation of the Company's INTEGRA(TM) Artificial Skin utilizing a peptide/collagen matrix for enhanced healing, as well as a number of wound care products under development.

The Company believes the annual severe burn market is approximately \$75 million worldwide, and that the annual market for all burns and scar revision procedures is estimated to be \$350 million worldwide. Additional indications for plastic surgery and acute wound procedures increase the estimated market to over \$1 billion worldwide.

#### INTEGRA(TM) Artificial Skin

INTEGRA(TM) Artificial Skin is designed to enable the human body to regenerate functional dermal tissue. Human skin consists of the epidermis (the thin, outer layer which serves as a protective seal for the body) and the dermis (the thicker, layer underneath which provides structural strength and flexibility). The dermis also supports the viability of the epidermis through a vascular network.

The body normally responds to severe damage to the dermis by producing scar tissue in the wound area. This scar tissue is accompanied by contraction that pulls the edges of the wound closer which, while closing the wound, often permanently reduces flexibility. In severe cases, this contraction leads to a reduction in the range of motion for the patient, who subsequently requires extensive physical rehabilitation or reconstructive surgery. Physicians treating severe wounds, such as full-thickness burns, seek to minimize scarring and contraction. INTEGRA(TM) Artificial Skin was designed to minimize scar formation and wound contracture in full thickness skin defects.

INTEGRA(TM) Artificial Skin consists of two layers, a thin collagen-lycosaminoglycan ("GAG") sponge and a silicone membrane. The product is applied with the sponge layer in contact with the excised wound. The collagen-GAG sponge material serves as a template for the growth of new functional dermal tissue. The outer membrane layer acts as a temporary substitute for the epidermis to control water vapor transmission, prevent re-injury and minimize bacterial contamination.

INTEGRA(TM) Artificial Skin was approved by the FDA under a premarket approval application ("PMA") for the post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. In 1997, the FDA approved a PMA supplement extending the shelf life for INTEGRA(TM) Artificial Skin from one year to two years. The FDA's approval order includes requirements to provide a comprehensive practitioner training program and to conduct a post approval study at multiple clinical sites. The Company has contracted with 11 burn centers in the United States to participate in the post approval study, and currently has approximately 70 patients in the study. The Company offers its training program to all surgeons specializing in burns throughout the world, and has trained over 700 surgeons worldwide. The Company also offers programs to the entire hospital team, including operating room personnel, burn unit support staff, and hospital reimbursement specialists.

In 1996 and 1997, sales of INTEGRA(TM) Artificial Skin have been largely for the treatment of patients with life-threatening full-thickness or deep partial-thickness burns where conventional autograft is not available or not desirable due to the physiological condition of the patient. While the Company believes that burns are an important market for INTEGRA(TM) Artificial Skin, the Company is seeking to expand the approved indications for INTEGRA(TM) Artificial Skin in reconstructive surgery, acute wounds, closure following excision of skin cancers, and chronic wounds. Recently, the Company received CE Mark certification in Europe for INTEGRA(TM) Artificial Skin, which included an indication for reconstructive surgery and full thickness injuries. The broader reconstructive surgery indications include scar revision procedures, tumor and skin cancer resection, release of post-burn contractures, congenital skin defects and revision of hypertrophic and keloid scars.

With the CE mark certification, INTEGRA(TM) Artificial Skin is now approved in 29 countries, including Canada and the United States. The Company sells INTEGRA(TM) Artificial Skin through a direct technical sales organization in the United States, Canada, Ireland and the United Kingdom and through distributors in other international markets. Through its direct sales force and by working closely with its specialized international distributors, the Company maintains a continuous working relationship with clinicians in the field of burn care and reconstructive surgery. Integra believes these relationships are critical to the long-term success of any new generation product.

In 1997, the Company signed an exclusive importation and sales agreement for INTEGRA(TM) Artificial Skin in Japan with Century Medical Inc. ("CMI"). CMI is headquartered in Tokyo, with sales offices in Sapporo, Sendai, Nagoya, Osaka and Fukuoka. Over the past two decades, CMI has steadily expanded its medical products distribution business in Japan, and CMI's parent company, ITOCHU

Corporation, reported revenues of \$155 billion for 1997. Under this agreement, CMI is conducting a clinical trial in Japan at its own expense to obtain Japanese regulatory approvals for the sale of INTEGRA(TM) Artificial Skin in Japan.

INTEGRA(TM) Artificial Skin sales were \$6.0 million and \$3.1 million for the years ended December 31, 1997 and 1996, respectively and accounted for 43% and 28% of the Company's total product sales, respectively.

#### Product Development

The Company has begun development of a number of new products for its Surgical Skin Business. The most important of these is a second generation INTEGRA(TM) Artificial Skin which incorporates the proprietary (arginine-glycine-aspartic) amino acid peptide sequence ("RGD") which is part of the Company's Telios technology base. The Company expects this product to reduce significantly the healing time for full thickness skin repair.

In addition to the effort to expand indications for INTEGRA (TM) Artificial Skin, the Company is aggressively developing adjunctive products with value added strategies of particular significance to the wound care business. Additionally, as data is acquired on the clinical performance of INTEGRA(TM) Artificial Skin, that feedback is being utilized to generate potential product improvements necessary to provide the best regenerative dermal matrix product to Integra's customers.

## Neurosurgical Business

The neurosurgical business encompasses the Company's dural graft and peripheral nerve conduit products.

### Artificial Dural Graft

The dura mater is the tough connective tissue covering the brain and spinal cord. It acts as a physical barrier and contains the cerebrospinal fluid ("CSF"). There is frequently a need for dural grafts to cover defects in the dura mater resulting from neurosurgical procedures or other trauma. The Integra dural regeneration product prevents leakage of the CSF and guides the histotypic regeneration of the dural membrane without the adverse effects of scar formation associated with current, non-regenerative methods of dural repair. The collagen matrix is entirely resorbed via normal metabolic pathways during the process of dural regeneration. The Company's dural regeneration template has been implanted in over 600 patients that comprise two retrospective studies of the product's performance. The Company is currently evaluating several potential regulatory strategies for bring this product to market.

There are approximately 325,000 procedures performed worldwide annually where a dural graft is required. The Company believes the annual market size for this indication is potentially \$40 million. Additionally, the dural graft material is being clinically assessed for the prevention of fibrosis (adhesions) in spinal

surgery. The potential anti-fibrotic market in the U.S. comprises approximately 600,000 spinal and cranial procedures per year. The Company believes the annual market size for this indication is potentially \$200 million worldwide as an anti-adhesion material.

### Peripheral Nerve Conduit

Although peripheral nerves are one of the few tissues of the body that spontaneously regenerate, they fail, in the majority of cases, to make useful, functional connections. Consequently, peripheral nerve injuries often result in permanent loss of function. Currently, the only method of treatment for a severed peripheral nerve is microsurgical re-attachment. Integra's peripheral nerve regeneration conduit is a thin collagen tube designed to facilitate regeneration of the severed nerve and acts as a bridge between the severed nerve stumps. The collagen conduit supports nerve regeneration and is resorbed. There are approximately 20,000 procedures annually in the U.S. that involve severed peripheral nerves, and the Company believes the worldwide market could amount to approximately \$80 million.

Scar formation at the nerve repair site is the leading cause of failure in conventional nerve grafting techniques. The Company's collagen tube prevents scar formation and provides guided peripheral nerve regeneration. The Company's pre-clinical studies have demonstrated the closure of 5-cm gaps in peripheral nerves in non-human primates with restored nerve function. The Company initiated Phase I clinical trials in 1996 in Copenhagen, Denmark. Phase II trials are planned for the second quarter of 1998.

### Japanese Distribution

On March 12, 1998, Integra and CMI announced a strategic alliance for the export of the neurosurgical product line to Japan. This marks the third agreement for which CMI will receive rights to distribute Integra's proprietary medical devices in Japan.

Under the terms of this agreement, CMI will pay a licensing fee of \$1 million in the first quarter of 1998 and will invest \$4 million for 500,000 shares of Integra preferred stock in the second quarter of 1998. CMI will also underwrite all costs of the Japanese clinical trials and regulatory approval processes. This seven-year distribution contract begins on the date of regulatory approval in Japan.

## Product Development

Integra has an active research and development program to develop future generations of the dural graft and peripheral nerve products in addition to other regenerative products and technologies that will meet the future needs of the neuro-surgical community.

## Orthopedic

The Company's orthopedics business is predominantly in the development stage. The Company has a number of projects under way to develop products that support the regeneration of bone, cartilage and connective tissue. Collaborative projects include those being undertaken with J&J Professional, Inc. ("JJPI"), Genetics Institute, Inc. ("GI"), Sofamor/Danek Group, Inc. ("SDG") and the National Institute of Standards and Technology ("NIST").

## Bone Regeneration

The Company supplies GI with a collagen delivery matrix that is used in conjunction with GI's recombinant human bone morphogenic protein-2 (rhBMP-2) to stimulate bone regeneration at defect sites. Human clinical trials conducted by GI have shown the safety and biological activity of the product. GI has initiated additional larger trials. GI expects to continue testing the product in clinical studies for orthopedic, oral/maxillofacial and eventually spine surgery, the last in conjunction with SDG. The Company has an exclusive supply agreement with GI to provide commercial quantities of the collagen delivery matrix, should GI successfully commercialize its products.

## Cartilage Regeneration

More than 500,000 surgical procedures are performed annually for the treatment of traumatized articular cartilage. Damaged articular cartilage, which connects the skeletal joints, is associated with the onset of progressive pain, degeneration and, ultimately, long-term osteoarthritis. Conventional procedures for treating traumatic cartilage damage, such as debridement and drilling, do not stop joint surface degeneration and often require two or more surgeries.

The Company is developing a new device to allow in-vivo regeneration of the patient's own articular cartilage. This technology will allow the patient's own body to regenerate a smooth, weight-bearing surface. Conventional approaches result in the formation of fibrocartilage, which is rough and non-weight bearing over prolonged periods. Normal articular cartilage is not highly vascularized, and although it is metabolically active tissue, damaged cartilage generally does not effectively heal. The conventional procedure for treating traumatic damage to cartilage involves smoothing damaged portions of the tissue and removing free-floating material from the joint using arthroscopic surgery. While the objective of this procedure is to reduce pain and restore mobility, the long-term result of this procedure often is permanent reduction of joint mobility and an increased risk of developing osteoarthritis. The Company's objective in developing its cartilage-specific technology is to produce a product that provides the proper matrix system to allow the natural regeneration of the patient's cartilage, with full restoration of function and diminished risk of osteoarthritis.

The product under development would use the Company's peptide technology to create an enhanced template that would encourage cells to grow into the template once implanted into the patient. The Company's peptide portfolio includes bio-active agents designed to mimic natural ECM proteins to promote chondrocyte

cell adhesion, cell survival and other important cellular functions. The product under development will use this peptide technology to create an enhanced template that would recruit chondrocyte cells to the template once implanted. The template itself would employ proprietary designs based on multiple layers of collagen material of varying but tightly controlled densities and pore sizes to provide a scaffold for chondrocyte proliferation and hyaline cartilage formation. Simultaneously it would prevent the in-growth of unwanted cells that could lead to scar tissue formation. The Company anticipates that the device will be absorbed into the body over a period of several weeks. Pre-clinical studies involving several variations of the above protocols are in progress.

In February 1998, the Company announced the signing of a strategic alliance with JJPI to develop and market a new product to regenerate joint cartilage. Integra has agreed to develop an absorbable, collagen-based implant, designed in combination with its proprietary RGD peptide technology, that will allow the body to repair and regenerate articular cartilage found in the knee and other joints. JJPI will market the product worldwide. Under the terms of the agreement, JJPI will make payments up to \$13 million as Integra meets various milestones, and will fund all necessary development costs beyond the pre-clinical phase. Following successful development, Integra will be responsible for manufacturing the product and for future product development. JJPI is developing the arthroscopic instrumentation to be used in the surgeries.

The Company believes the product's sales potential, combined with the commitment from J&J's worldwide marketing and sales force, is a strong validation of the potential significance of the Telios RGD peptides. The product is being designed to help overcome the body's inherent deficiencies in regenerating articular cartilage by promoting the adhesion and function of cells in a manner that will have much wider clinical use. The Company believes that the combination of its collagen matrix technology with Telios' RGD peptide technology gives the Company a unique approach to accelerated cartilage repair. The product is being designed to be readily available and sterile off-the-shelf. The product's acellular technique does not require cell cultures. The Company expects these features to prove substantially more cost-effective than current options.

#### Tyrosine Polycarbonates Program

The Company is continuing the development of additional ECM technologies. The goal is to enhance the rate and quality of healing and tissue regeneration with synthetic biodegradable scaffolds to support cell attachment and growth. To this end, the Company is developing a new class of resorbable polycarbonates created through the polymerization of tyrosine, a naturally occurring amino acid. A well-defined and commercially scaleable manufacturing process is employed to prepare these materials. Device fabrication by traditional techniques such as compression molding and extrusion is readily achieved. The Company believes that this new biomaterial will be safe and effective in promoting full bone healing when implanted in damaged sites. The Company has licensed this patented technology from Rutgers University for all applications and continues to work in collaboration with the technology's inventor, Joachim Kohn, Ph.D. This material is currently being developed for orthopedic and tissue engineering applications

where strength and bone compatibility are critical issues for success of healing. The polymer when implanted in bone appears to be osteoconductive; it conducts bone onto and through the polymer implant. Further, because of the unique structure of the polymer, the biological breakdown products are non-acidic. Highly acidic by-products, which are typical of current commercial orthopedic implants, are a primary cause of sterile abscess which can lead to pain and even implant failure.

In 1997, the Company completed a pre-clinical animal study, funded by NIST and the Company. Toxicity studies completed have shown that the polymer is non-mutagenic and non-cytotoxic. No evidence of systemic toxicity, irritation, or sensitization was observed. The Company's development activities also include the use of biomaterials for drug delivery applications. In 1997, the Company was awarded a second \$2 million research and development grant from NIST for the development of new absorbable and biocompatible tyrosine-based polymer as a stand alone or in combination with RGD peptides to stimulate in-vivo cartilage regeneration.

The Company is also developing the polymers for incorporation into its other manufactured products. The Company has rights to use this material in wound closure and related drug delivery applications. There is the possibility of delivering growth factors and other biological response modifiers in a controlled manner in conjunction with the Company's skin regeneration, cartilage regeneration and nerve regeneration technologies. In addition, the technology may prove useful in surgical hemostasis and dental surgery applications where the sustained delivery of antibiotics at the surgical site could be beneficial. The Company's strategy is to pursue strategic partnership alliances to assist in the further development and commercialization of this technology.

#### Osteoporosis

Nearly 1.5 million Americans are afflicted with osteoporosis. It is estimated that there are nearly 300,000 new cases of osteoporotic hip fractures each year. The associated costs of osteoporosis approach \$10 billion each year. The Company is investigating a new therapeutic approach for the treatment of this disease based on its proprietary technologies developed at Telios. The approach prevents the attachment of bone dissolving osteoclasts to bone

tissue thereby slowing or preventing the disease. Pre-clinical studies have demonstrated the effectiveness of several proprietary peptides in preventing bone loss. Development efforts are continuing, as are efforts to identify an appropriate strategic partner to assist the Company in commercializing this technology.

#### Decorin for Fibrosis Control

The total U.S. market potential for adhesion prevention products is estimated at 4.5 million procedures worth approximately \$900 million. General surgery and gynecology comprise the largest segments with 40% and 38% shares, respectively. Medical Device International reports that there were over 400,000 adhesionolysis

procedures performed in 1995, nearly 240,000 of which were for gynecology-related indications.

It is estimated that by the year 2000, overall U.S. revenues for adhesion prevention devices will reach \$75-\$100 million--growing at a double-digit rate--equivalent to a market penetration of 15%. Although the adhesion prevention market is a potentially lucrative niche, it is unlikely that it will be able to support all the products and technologies currently available or under development. Nevertheless, there is a significant opportunity for a truly effective product. The Company's decorin-based product offers a unique approach to this problem by interrupting the mechanism of adhesion formation, rather than just providing a barrier that attempts to prevent tissues from "sticking to one another."

Decorin, a natural component of the ECM, is the body's natural regulator of the growth factor TGF-(beta). TGF-(beta) has many functions in the body including regulation of cell death, immune system interactions and wound healing. In the case of adhesion formation, a form of uncontrolled wound healing, when a tissue experiences trauma from accident, disease or surgery, the effected cells up-regulate the production of TGF-(beta). This causes a rapid and random deposition of ECM that ultimately results in scarring or fibrosis. When tissues are in close proximity to one another the fibrotic tissue attaches to other nearby tissues and an adhesion is formed. Decorin can bind this excess TGF-(beta) and stop the fibrosis cascade thereby actually preventing adhesions from ever starting.

The Company is in early-stage development of a variety of product forms (sprays, gels, films, solutions). The Company is seeking strategic partners to assist in the development of this technology, and it anticipates that preclinical studies will commence this year.

#### Private Label Medical Products

The Company develops and sells, primarily through licensing and distribution arrangements, a number of biomaterials-based medical products and devices for infection control, general surgery and dental surgery. These products accounted for approximately \$8.0 million, \$8.1 million and \$8.3 million of product sales for the Company during the years ended December 31, 1997, 1996 and 1995, respectively, representing approximately 57%, 72% and 100%, respectively, of the Company's product sales for such years.

The Company has pursued a strategy of developing new products, obtaining regulatory approvals, and distributing these products through marketing and distribution partnerships. Typically, these partnerships are with leading medical device companies that assist in developing the commercial potential of the Company's medical products. A substantial portion of the Company's medical products is sold to customers under the terms of multiple-year marketing and distribution agreements that provide for purchase and supply commitments on the part of the customer and the Company, respectively. In many cases, marketing customers have paid license fees to the Company for the marketing and distribution rights. In the absence of a suitable United States marketing partner for the Company's hemostasis product line, the Company has elected to sell certain portions of the hemostasis product line in the United States through a national network of specialized distributors.

Of the Company's total product sales during 1997, 1996 and 1995, customers accounting for more than 10% of total product sales included two customers accounting for 24%, three customers accounting for 42% and four customers accounting for 56%, respectively.

## Infection Control Products

The Company's patented VitaCuff(TM) product provides protection against infection arising from long-term catheters. VitaCuff(TM) consists of a silver nitrate impregnated collagen matrix ring, which is positioned on the catheter before placement. Once in place the collagen forms a seal at the point of entry, mechanically preventing microbial invasion along the catheter while at the same time releasing silver nitrate into the surrounding area. In this application, silver-nitrate functions as a highly effective, broad-spectrum anti-microbial agent. VitaCuff(TM) and related products are manufactured by the Company and marketed through Arrow International, Inc., Bard Access Systems, Inc. and Quinton Instruments.

The Company manufactures a patented wound dressing composed of a synthetic and biopolymer composite foam impregnated with an anti-microbial compound which is marketed by Ethicon, Inc., a Johnson & Johnson subsidiary, under the trade name BioPatch(TM). The product is applied over the entry point of any percutaneous device, such as orthopedic traction pins and epidural catheters, and serves to protect the area from bacterial growth for an extended period. In 1997, the Company extended its licensing and distribution agreement with Ethicon, Inc. for BioPatch(TM) and agreed to provide them with an exclusive license to its patents in this field. The Company has also developed a silver impregnated foam wound dressing which provides anti-microbial protection to prevent bacterial colonization leading to infection.

## Dental Surgery Products

The Company's dental surgery products are extensions of the Company's absorbable collagen hemostatic sponge technology (see below). Each of the three products, CollaCote(TM), CollaPlug(TM) and CollaTape(TM), has a unique dimension, shape and density and provides most of the hemostasis requirements encountered in dental surgery. Calcitek markets the Company's dental surgery products.

The Company has also developed BioMend(TM) Absorbable Collagen Membrane ("BioMend(TM)") for use in guided tissue regeneration in periodontal surgery. BioMend(TM) is inserted between the gum and the tooth after surgical treatment of periodontal disease. BioMend(TM) prevents the gum tissue from interfering with the regeneration of the periodontal ligament that holds the tooth in place. BioMend(TM) is intended to be absorbed into the patient after approximately four to seven weeks, avoiding the requirement for additional surgical procedures to remove a non-absorbable membrane. Calcitek also markets BioMend(TM).

## Surgical and Hemostasis Products

The Company's hemostasis products are used in surgical procedures to help control bleeding. The Company's absorbable collagen hemostatic sponge products consist of Helistat(TM) (Absorbable Collagen Hemostatic Sponge), Helitene(TM) (Absorbable Collagen Hemostatic Agent-Fibrillar Form), Collastat(TM) and related products. The Company's products have been manufactured for more than 15 years and are estimated to have been used in several hundred thousand patients. These products are manufactured by Integra and marketed in the United States through a network of specialized distributors. Outside of the United States, various international distributors sell the products. The Company introduced a new product under its Helistat(TM) line in 1997, a 1" x 9" collagen sponge strip for sternal hemostasis. The Company's Instat(TM) Products (absorbable collagen hemostatic agent in fibrillar form) are manufactured by the Company and marketed in the United States by Ethicon, Inc. In January 1998, the Company announced that it had signed an agreement with CMI for supply and distribution of the Company's Helistat(TM) and Helitene(TM) products in Japan. One variant of the Company's hemostasis product line is a collagen sponge sold by JJPI under the brand name Bicol(TM) that acts as a moistening agent to prevent drying of brain tissue and as a protective device to buffer the pressure of retractors in neuro-surgery.

The domestic market for hemostasis products is dominated by long standing, traditional products based on gelatin or cellulose technology. The Company's collagen technologies provide an effective control of surgical bleeding and are approved to be left in the body following completion of a surgical procedure.

## Biocompatible Coatings

As an extension of its surgical product line, the Company has developed a collagen vascular graft coating in conjunction with Sorin. This proprietary collagen coating provides an alternative to fabric vascular graft products, which require pre-clotting before use. The Company's product is easier to use because it eliminates the need for pre-clotting. The Company transferred the coating technology and pilot plant equipment to Sorin. Integra derives ongoing revenues from royalties and the sale of materials to Sorin.

The use of prosthetic device implants creates a variety of clinical problems, including inflammation, encapsulation, thrombosis and infection. These problems may be overcome by coating the surface of implanted materials with cell attachment sites which enable the natural development of tissue structure at the material-tissue interface providing for long-term, stable tissue integration.

The Company is developing PepTite(TM) Biocompatible Coating ("PepTite(TM)") designed to improve the biocompatibility of implantable materials. The coating contains the proprietary RGD peptide. The Company is conducting a number of pre-clinical in-vivo effectiveness studies in collaboration with various implant manufacturers. The Company has coated and is studying: (a) percutaneous access catheters to reduce thrombus formation; (b) polyester mesh to enhance endothelialization of arterial wall defect repairs and reduce inflammation in hernia and other fascial defects; (c) metal stents; (d) silicone implants to reduce or eliminate encapsulation of the implant; and (e) certain polymers

utilized in cardiovascular devices to reduce thrombogenicity and enhance tissue in-growth. The Company's strategy is to develop PepTite(TM) in collaboration with other medical device manufacturers.

## Developing Businesses and Ventures

The company has a number of developing businesses and ventures. These include a women's health initiative, an Artecovascular graft, a variety of Matrix Medicine(TM) products developed at Telios, including Decorin, and a project surrounding the regeneration of pancreatic islets.

### Women's Health Initiative

The Company is working with the Agency for Contraceptive Research and Development and the Population Council in the development of topical, trans-dermal and implantable drug delivery systems. These systems are intended to deliver steroids and other pharmaceuticals for reproductive health applications such as contraception, fertility enhancement and topical control of sexually transmitted disease. Products developed through these relationships are intended to be manufactured exclusively by the Company for worldwide distribution.

### Artecovascular Graft

In 1996, the Company formed Medicol Sciences, Ltd., a wholly-owned subsidiary in the Czech Republic ("Medicol"), and acquired rights to several patented processes relating to the development and manufacture of small diameter (less than 6 mm) vascular grafts. The technology employs a collagen-based matrix in conjunction with an open mesh Dacron fabric. Following sterilization, the resulting product can be implanted as a vascular graft. The Company also entered into a consulting agreement with Dr. Milan Krajicek, who is the inventor of the technology. The Company will be funding continued pre-clinical studies to determine the effectiveness of the graft in coronary artery by-pass surgery and for use in peripheral reconstruction procedures.

### Matrix Medicine: The Telios Product Pipeline

Integra acquired Telios in 1995 to commercialize Telios technologies relating to extracellular matrices and integrin-mediated activity, and in particular, their applications to tissue regeneration. Integra is developing Telios' findings and methodologies to enhance and accelerate development and commercialization of its products.

Telios's RGD peptide technology is a direct result of the pioneering work begun in the early 1980s by co-inventors Michael D. Pierschbacher, Ph.D., Integra's Senior Vice President and General Manager of Telios, and Erkki Ruoslahti, MD, President and CEO of The Burnham Institute. The patented RGD technology has been shown to have potential utility in a number of important and rapidly growing medical therapies. These include tissue regeneration, biocompatible coatings for

implantable medical devices, thrombosis (blood clotting), cancer treatment, immune system regulation, inflammation, and control of angiogenesis.

Peptides are small synthetic chains of amino acids that are designed to perform specific functions on cells. Peptides can be engineered to mimic very large natural matrix proteins that are found within tissues of the body. Peptides bind integrin receptors found on the surface of virtually all cells of the body. There are more than 20 such integrin types within this family of cell receptors. Integrins control cell attachment, growth, migration and differentiation. Cells present within tissues rely on specific integrin types during tissue regeneration. Small synthetic peptides can be designed to interact selectively with certain integrins to achieve differing outcomes by enhancing certain interactions between cells and matrix. When used in combination with a collagen scaffold, these peptides signal the appropriate cell-matrix functions through integrins and promote the formation of new tissue by guiding the attachment and growth of cells.

The Company's proprietary pharmacological applications of its technologies are intended to target and control the behavior of human cells through their interactions with the extracellular matrix. The Company refers to the clinical applications of these technologies as Matrix Medicine(TM), and is developing applications for the pharmacological treatment of serious human disease conditions, including diseases involving thrombosis, fibrosis and angiogenesis.

The Company's Matrix Medicine(TM) technologies are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid ("RGD") peptide sequence found in the majority of extracellular matrix proteins, including structural molecules and adhesion molecules that provide binding sites, structural support, and physiological information for the maintenance of normal cell function in the body. In 1997 additional significant patents that strengthen the Company's proprietary position in this technology were issued to The Burnham Institute. These patents are exclusively licensed to Integra through its Telios subsidiary.

The Company has in development new pharmacological products based on the interaction between the extracellular matrix and the integrin family of receptors that are present on virtually all cells in the body. The Company believes that many major diseases and disorders throughout the body, including many that are debilitating, life-threatening, costly and difficult or impossible to treat satisfactorily with existing therapies, involve the disruption or abnormality of the interaction of cells with the extracellular matrix. The Company's Matrix Medicine(TM) technologies are intended to modify the interaction of cells with the matrix in such a way as to provide new treatment strategies for a range of disorders. The Company is pursuing a strategy to identify clinical and market leaders in pharmacological areas to co-develop and license the Company's proprietary technologies and applications. The Company believes that such development and marketing relationships could result in a greater likelihood of commercialization of these opportunities by utilizing the skills of partners to complete clinical trials and market introduction, while allowing the Company to focus on pre-clinical development. Many of the Company's technologies are in the early stages of development and will require the commitment of substantial additional resources by the Company and its potential strategic partners prior to commercialization. There can be no assurance that the Company will be able to form strategic alliances or successfully develop

commercial products.

#### TP-9201 Platelet Aggregation Inhibitor for the Treatment of Stroke

The Company has developed a platelet aggregation inhibitor which has been demonstrated to be safe in a Phase I clinical trial and is now ready for Phase II dose ranging trials in patients. Platelets are small cells that circulate in the blood and have many important functions, one of which is related to the control of bleeding. Platelets prevent bleeding by first adhering to the vessel wall in a process called "platelet adhesion and spreading". In a secondary process of "platelet aggregation," platelets aggregate to form clumps. Without properly functioning platelets, dangerous bleeding can occur. In diseased or surgically damaged blood vessels, platelets can aggregate and restrict the vital supply of blood to the heart, brain and other organs and tissues. This condition, termed thrombosis, is a common hallmark of cardiovascular diseases such as heart attack and stroke, and can cause serious complications during and after surgical procedures. Two kinds of drugs currently available for the treatment of thrombotic diseases and conditions are anticoagulants and thrombolytics. Anticoagulants inhibit formation of clots and have both

preventive and therapeutic applications. Thrombolytics function by dissolving already existing clots. However, when the consequences of bleeding are severe, neither of these agents are generally recommended. Current approaches to thrombosis prevention that involve inhibition of platelet aggregation carry the risk of compromising the body's ability to control bleeding. Even minor bleeding, if allowed to go unchecked, can lead to life-threatening events such as stroke and other forms of internal hemorrhage.

The Company is developing a selective platelet aggregation inhibitor targeting the (alpha)IIb(beta)3 integrin receptor that appears on the surface of activated platelets and mediates their aggregation. A key technical challenge in the development of a (alpha)IIb(beta)3 inhibitor is to provide a molecule specific enough to allow the beneficial functions of (alpha)IIb(beta)3, such as those responsible for the primary event of platelet adhesion and spreading while at the same time inhibiting the negative effects caused by platelet aggregation. Anti-platelet agents without such characteristics prevent thrombosis but promote bleeding. ReoPro, an antibody that blocks the function of (alpha)IIb(beta)3 was approved by the FDA in 1996 for use to prevent thrombosis after angioplasty procedures. Eli Lilly, who markets this product, claims that the initial bleeding problems associated with this product can be controlled by carefully controlling the dosage. The Company has conducted pre-clinical studies that demonstrate TP-9201 doses that prevent unwanted platelet aggregation without reducing the platelets' ability to control capillary bleeding. The unique properties of this molecule are being developed for application in therapeutic areas where the separation of bleeding from anti-thrombotic effect is crucial.

The potential markets that could benefit from TP-9201 include: (a) unstable angina, as transient blockage of coronary arteries by blood clots, often preceding complete myocardial infarction; (b) restenosis, as reclosure of arteries, typically after angioplasty; (c) reocclusion, as reclosure of

arteries, typically after angioplasty or treatment of mild myocardial infarction with thrombolytics; and (d) ischemic stroke, as blockage of blood vessels supplying the brain, often resulting in permanent brain damage. Additionally, vascular synthetic grafts can cause thrombosis and have a tendency to leak blood. TP-9201 may be able to prevent thrombosis without increasing risk of bleeding associated with these grafts. Finally, problems associated with organ transplantation thrombosis, which occurs after reestablishing blood flow to the organ and results in blockage of the microvascular bed and organ failure, could be reduced with the use of TP-9201.

The Company believes that there are many procedures that may be addressed with the use of TP-9201 or future products developed from this technology. The Company intends to seek strategic alliances to further develop this technology. There can be no assurance that the Company will be able to form strategic alliances or successfully develop commercial products.

#### TGF-(Beta) Antagonists to Target Fibrosis and Cancer

Transforming Growth Factor Beta ("TGF-(beta)") is a class of growth factors (cytokines) that has widespread regulatory effects on many processes that are essential for normal health. Such processes include cell growth and differentiation, fetal development, immune regulation, inflammation and tissue repair. The Company believes that the importance of TGF-(beta) for human medicine is that an imbalance of TGF-(beta) underlies chronic inflammatory and fibrotic diseases, and contributes to tumor progression. The Company intends to develop TGF-(beta) antagonists that correct such TGF-(beta) imbalances. The Company has licensed from the Burnham Institute, as well as from the University of Utah, patents and patent applications relating to the control of TGF-(beta) activity. Potential medical applications of this technology include prevention of scarring following surgery or trauma and prevention or limitation of fibrosis of the kidney, lung, liver, skin, arteries and the central nervous system as well as potentially preventing drug resistance in tumors.

The Company has identified two primary therapeutic approaches to the control of TGF-(beta): human antibodies directed against TGF-(beta) and recombinant human decorin. Decorin is a natural regulator of TGF-(beta) activity and suppresses the production of TGF-(beta) in injured tissues. The Company's human antibody development program is being carried out under an agreement with Cambridge Antibody Technology Limited ("CAT"), under which CAT has already developed several human anti-TGF-(beta) antibodies that are presently under pre-clinical or clinical investigation. The Company has the right to market all dermal applications of these antibodies, including the treatment of dermal scarring. The Company has also developed cell lines expressing recombinant human decorin and is developing production procedures for decorin.

## Drug Discovery Capability for Integrin Specific Compounds

The Company has developed integrin receptor and cell based assay systems which have been used to screen for and discover integrin specific drug candidates for clinical development. This capability has enabled the successful discovery of

the clinical development candidate TP-9201 (an anti-thrombotic compound that may be uniquely applicable to the treatment of stroke), an antagonist that effectively inhibited bone resorption in animal models of osteoporosis and a compound that effectively inhibits angiogenesis. Based on this experience, the Company is in a position to expand its drug discovery and screening programs and is seeking corporate partnerships for collaboration in this effort.

The following integrins are being studied as potentially useful therapeutic targets in pre-clinical research:

Target Integrin	Clinical Indications	Suggested Mechanism
(alpha)IIb(beta)3	Thrombosis	Platelet aggregation
(alpha)v(beta)3	Angiogenesis	Endothelial cell migration
(alpha)v(beta)3	Vascular grafts	Endothelial cell migration
(alpha)v(beta)3	Osteoporosis	Bone cell adhesion
(alpha)v(beta)3 and/or (alpha)IIb(beta)3	Restenosis	Smooth muscle cell proliferation
(alpha)v(beta)3 and/or (alpha)5(beta)1	Metastasis	Migration of cancer cells
(alpha)v(beta)3 and/or (alpha)v(beta)5	Bone formation	Adhesion of bone-producing cells to bone
(alpha)5(beta)1	Cell survival	Control of apoptosis

The Company has developed lead compounds targeting (alpha)IIb(beta)3, (alpha)v(beta)5, (alpha)v(beta)3 and (alpha)v(beta)1, and is carrying out continuing pre-clinical research on these compounds through collaborative arrangements with academic laboratories experienced in the appropriate disease models. The Company intends to seek strategic alliances to develop further the application of these compounds. There can be no assurance that the Company will be able to form strategic alliances or successfully develop commercial products.

## Pancreatic Islet Regeneration

The Company has an ongoing collaboration with Drs. Daniel Salomon and Bruce Torbet at The Scripps Research Institute for the development of Integra's proprietary technology to support the regeneration and long term survival of functioning pancreatic islets for the treatment of diabetes. By providing a synthetic extracellular matrix that supports the function of appropriate integrins, these researchers have shown in animal models that islet engraftment and vascularization can be achieved and that long term viability and glucose sensitivity can be maintained.

## Research Strategy

The Company has either acquired or secured the proprietary rights to several important scientific platforms. These platforms can be organized into four distinct but complementary technological categories: a) bioabsorbable and other materials; b) ECM and other specialized materials structures; c) materials as

delivery vehicles for peptides,

cells, growth factors, drugs and other actives; and d) actives. These technologies provide support for the Company's critical applications in tissue regeneration, developing pharmacological applications, and additional opportunities for generating near-term and mid-term revenues from medical applications. The Company has been able to identify and bring together critical platform technology components from which it wants to develop solutions to the problem of targeting and controlling selected cell behavior in the patient's body for both tissue regeneration and pharmacological application.

The Company focuses its efforts on the convergence of these technology categories into a type of "basic operating system solution" for technology development and product performance. Just as a computer's basic operating system interfaces with its electronic hardware to direct and control the performance of the computer, specialized absorbable products developed by the Company are intended to function in the patient's body by directing and controlling targeted cell behavior to achieve a specified desired medical result.

The Company's research focus is on technology development as opposed to early stage basic research. Toward that end, Integra focuses on the commercial and clinical utility of its products by encouraging early and close collaboration with clinicians. As an example, INTEGRA(TM) Artificial Skin is the result of a close collaboration between a surgeon and a materials scientist. The surgeon's ability to define the critical specifications of the product were essential prerequisites to the product development and demonstration of clinical utility in human clinical trials. Particularly critical were that the product be readily available "off the shelf" at the time of early wound excision for patients with life-threatening injury and that it be a permanent wound cover.

The Company's research implementation is to supplement a relatively small group of in-house scientists and researchers with collaborative links with a network of various hospitals and medical organizations which are centers of research in the Company's technologies. The Company believes this is a cost-effective way to obtain knowledge and expertise in the Company's technologies while maintaining an ability to respond quickly and effectively to technological change. To assist the Company in achieving its objectives, Integra has entered into collaborations, research and/or licensing arrangements with the following institutions: (a) Brigham & Women's Hospital, Inc., Boston, MA for INTEGRA(TM) Artificial Skin; (b) Cambridge Antibody Technology Limited, Cambridge, England, for product development of human TGF- (beta) antibodies; (c) Duke University Medical Center, Durham, NC for pre-clinical studies of collagen nerve graft tubes; (d) Eastern Virginia Medical School, Norfolk, VA for pre-clinical studies on polymers; (e) Agency for Contraceptive Research and Development, Norfolk, VA for topical fertility and sexually transmitted disease control; (f) Hospital for Joint Diseases Orthopedic Institute, New York, NY for pre-clinical studies on cartilage regeneration; (g) National Institute of Standards and Technology for resorbable polymers for orthopedic indications and tissue engineering; (h) The Burnham Institute, La Jolla, CA (formerly La Jolla Cancer Research Foundation) for basic research on integrin signaling pathways; (i) Massachusetts General

Hospital, Boston, MA for INTEGRA(TM) Artificial Skin studies; (j) Massachusetts Institute of Technology, Cambridge, MA for INTEGRA(TM) Artificial Skin studies; (k) Robert Wood Johnson Medical School, Piscataway, NJ for quality control methodology; (l) Rutgers University, Piscataway, NJ for tyrosine polycarbonate polymers for orthopedic applications and tissue engineering; (m) University Hospital Copenhagen, Denmark for clinical studies of collagen nerve graft tubes and resorbable polymers for tissue engineering; (n) J&J Professional, Inc. for articular cartilage regeneration; (o) Century Medical Inc., Japan for INTEGRA(TM) Artificial Skin and neuro-surgical product clinical trials in Japan; (p) The Scripps Research Institute in the areas of regenerating pancreas and stroke; and (q) University of Washington Engineered Biomaterials for bioengineering.

The Company spent approximately \$6.4 million, \$6.3 million and \$5.2 million during 1997, 1996 and 1995, respectively, on research and development activities. Research and development activities funded by government grants and contract development revenues amounted to \$500,000, \$1.1 million and \$1.1 million during 1997, 1996, and 1995, respectively.

#### Patents and Proprietary Rights

The Company's ability to compete effectively will depend, in part, on the clinical and commercial success of its development efforts and its ability to maintain the proprietary nature of its technologies and manufacturing processes. The Company pursues a policy of seeking patent protection for certain of its technology, products and product improvements both in the United States and in selected foreign countries. When appropriate, the Company has and plans to continue to enforce and defend its patent rights. The Company also relies upon trade

secrets, continuing technological innovations and licensing opportunities to develop and maintain its competitive position.

As of December 31, 1997, the Company owned or had exclusive license rights to 134 issued or allowed United States patents and 107 issued or allowed foreign patents, with pending United States patent applications and related foreign patent applications describing approximately 250 additional inventions. These patents and patent applications contain composition of matter, process and method of use claims for various fields of use, primarily involving regenerative medicine and related technologies. The Company files patent applications both in the United States and in foreign countries in order to protect both its products and technologies. In addition, the Company has various licenses to technologies patented by others. The patent position of biotechnology and pharmaceutical firms is highly uncertain, involves many complex legal, factual and technical issues and has recently been the subject of much litigation. There is no clear policy involving the breadth of claims allowed in such cases or the degree of protection afforded under such patents. As a result, there can be no assurance that patent applications relating to the Company's products or technologies will result in patents being issued, that patents issued or licensed to the Company will provide protection against competitors or that the Company will enjoy patent protection for any significant period of time. It is possible that

patents issued or licensed to the Company will be successfully challenged, or that patents issued to others may preclude the Company from commercializing its products under development.

Certain of the patents licensed by the Company for specific uses are licensed to other parties for use in certain fields or are sublicensed to other parties. Litigation to establish the validity of patents, to defend against infringement claims or to assert infringement claims against others, if required, can be lengthy and expensive. There can be no assurance that the products currently marketed or under development by the Company will not be found to infringe patents issued or licensed to others.

The Company's competitive position is also dependent upon unpatented trade secrets. The Company continues to develop a substantial database of information concerning its research and development. The Company has taken security measures to protect its data and is in the process of exploring ways to enhance further the security of its data. However, trade secrets are difficult to protect. There can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to the Company's trade secrets, that such trade secrets will not be disclosed, or that the Company can effectively protect its rights to unpatented trade secrets.

In an effort to protect its trade secrets, the Company has a policy of requiring its employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information developed or made known to the individual during the course of their relationship with the Company must be kept confidential, except in specified circumstances. There can be no assurance, however, that these agreements will provide meaningful protection for the Company's trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information.

#### Government Regulation

The Company's research and development activities and the manufacturing and marketing of the Company's existing and future products are subject to regulation by numerous governmental agencies in the United States and in other countries. The FDA and comparable agencies in other countries impose mandatory procedures and standards for the conduct of clinical trials and the production and marketing of products for diagnostic and human therapeutic use. The FDA product approval process has different regulations for drugs, biologics, and medical devices. The FDA currently classifies the Company's proposed regenerative medicine products as medical devices.

#### Review Process for Medical Devices

There are two types of FDA review/approval procedures for medical devices: a Premarket Notification Section 510(k) ("510(k)") and a Premarket Approval ("PMA") application. A 510(k) requires submission of

sufficient data to demonstrate substantial equivalence to a device marketed prior to May 28, 1976, or to a device marketed after that date which has been classified into Class I or Class II. Although the mandated period for FDA review is 90 days, actual review times can be substantially longer, and the sponsor cannot market the device until FDA clearance is obtained. For those devices that involve new technology and/or that present significant safety and effectiveness issues, 510(k) submissions may require significantly more time for FDA review and may require submission of more extensive safety and effectiveness data, including clinical trial data.

Among the conditions for clearance to market of a 510(k) submission is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's current Quality System Regulations. In complying with standards set forth in these regulations, manufacturers must expend time, money and effort for production and quality control to ensure full technical compliance at all times. Manufacturing establishments, both international and domestic, are also subject to inspections by or under the authority of the FDA. Although, at present, the FDA generally does not inspect such establishments prior to clearance of a 510(k) submission, it is establishing a program of conducting quality system inspections for new devices in the future as a standard practice.

The Medical Device Amendments of 1976 amended the Federal Food, Drug and Cosmetics Act to establish three regulatory classes for medical devices, based on the level of control required to assure safety and effectiveness. Class III Devices are defined as life-supporting and life-sustaining devices, devices of substantial importance in preventing impairment of human health or devices that present potentially unreasonable risk of illness or injury. Class III devices are those for which there is insufficient information to show that Class I or Class II controls can provide a reasonable assurance of safety or effectiveness. The PMA application review process for Class III devices was established to evaluate the safety and effectiveness of these devices on a product by product basis. Manufacturers that wish to market Class III devices must submit and receive approval of a PMA application from the FDA.

The FDA has substantial content and format requirements for PMA applications, which include clinical and non-clinical safety and effectiveness data, labeling, manufacturing processes and quality assurance programs. As part of the PMA application process, the PMA application may be referred to an FDA Advisory Panel for review. Additionally, final approval of the product is dependent on an inspection of the manufacturing facility for compliance with FDA Quality System Regulations.

All studies in humans for the purpose of investigating the safety and effectiveness of an investigational medical device must be conducted under the Investigational Device Exemption ("IDE") regulations. An IDE application to the FDA includes all preclinical biocompatibility testing, investigational protocols, patient informed consents, reports of all prior investigations, manufacturing and quality control information. It takes a number of years from initiation of the project until submission of a PMA application to the FDA, and requires the expenditure of substantial resources. If a PMA application is submitted, however, there can be no assurance on the length of time for the review process at the FDA or that the FDA will approve the PMA application.

Under either the 510(k) submission or PMA application process, manufacturing establishments, foreign and domestic, are subject to periodic inspections by the FDA for compliance with Quality System Regulations. The Company and each of its operating subsidiaries are subject to such inspections.

To gain approval for the use of a product for clinical indications other than those for which the product was initially evaluated or for significant changes to the product, further studies, including clinical trials and FDA approvals are required. In addition, for products with an approved PMA application, the FDA requires post-approval reporting and may require post approval surveillance programs to monitor the product's safety and effectiveness. Results of post approval programs may limit or expand the further marketing of the product.

## International Regulatory Requirements

The Company is preparing for the changing international regulatory environment. "ISO 9000" is an international recognized set of guidelines that are aimed at ensuring the manufacture and development of quality products. The Company was audited under ISO standards in 1997, and received certification to ISO9001, a full quality system. The Company is required to be audited on an annual basis by a recognized notified body to maintain certification. Companies that meet ISO standards are internationally recognized as functioning under a quality system. Approval of a product by regulatory authorities in international countries must be obtained prior to the commencement of marketing of the product in such countries. The requirements governing the conduct of clinical trials and product approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval of the PMA application. In June 1998, the European Union Medical Device Directive becomes effective, and all medical devices must meet the Medical Device Directive standards and receive CE mark certification. CE mark certification involves a comprehensive quality system program, and may require submission of data on a product to the notified body in Europe.

## Other United States Regulatory Requirements

In addition to the regulatory framework for product approvals, the Company is and may be subject to regulation under federal and state laws, including requirements regarding occupational health and safety; laboratory practices; and the use, handling and disposal of toxic or hazardous substances. The Company may also be subject to other present and possible future local, state, federal and foreign regulations.

The Company's research, development and manufacturing processes involve the controlled use of certain hazardous materials. The Company is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the

Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. Although the Company believes that it is in compliance in all material respects with applicable environmental laws and regulations, there can be no assurance that the Company will not incur significant costs to comply with environmental laws and regulations in the future, nor that the operations, business or assets of the Company will not be materially adversely affected by current or future environmental laws or regulations.

## Manufacturing

The Company's primary manufacturing facility is located in Plainsboro, New Jersey. The Company manufactures the majority of its medical products at this approximately 35,000 square foot FDA-registered and inspected facility which also serves as the Company's executive offices. The Company's commercial-scale manufacturing facility for INTEGRA(TM) Artificial Skin is at this location.

The basic material for many of the Company's medical and regenerative medicine products is principally purified collagen prepared from bovine tendon in a four-step process: (i) the raw material is processed with various enzymes and solvents to purify and render it non-immunogenic; (ii) the purified material is dispersed into suspensions appropriate for the manufacture of the different forms of collagen material and then dried using freeze drying techniques; (iii) the fibrous material yielded from the drying step is "cross-linked" through chemical bonding of overlying fibers, with different types and degrees of cross-linking being used for different products; and (iv) the bonded material is sized and packaged. The Company has installed equipment for the manufacture of bovine collagen-based products at its Plainsboro facility.

The Company also has a lease agreement for a four-building site consisting of approximately 25,000 square feet in West Chester, Pennsylvania. The West Chester facility and manufacturing assets were under renovation from 1994 through 1996. The Company has decided to reduce costs by shutting down the West Chester facility and consolidating the operations at the Plainsboro site. Through improved efficiencies, the Plainsboro facility is capable of handling these additional operations, as well as requirements from increased sales in the foreseeable future. The West Chester facility transition will occur during the early part of 1998, and the Company plans on transferring some associates to the Plainsboro facility.

The Company believes that its existing and renovated manufacturing facilities are adequate for the foreseeable future and, depending on product mix and pricing, can support the manufacturing for significant product sales. Further, the Company believes that suitable additional or alternative space will be available on commercially reasonable terms when needed in the future.

#### Competition

In general, the medical technology industry is subject to rapid, unpredictable and significant technological change. Competition from established

pharmaceutical and medical technology companies is intense. Competition also comes from early stage companies that have alternative technological solutions for the Company's primary clinical targets. New technologies are constantly being developed at universities and research institutions.

The Company's competitive position will depend on its ability to secure regulatory approval for its products, implement production and marketing plans, obtain patent protection and secure adequate capital resources. The Company is aware of several companies seeking to develop dermal replacement and other products that could, if successfully developed, potentially compete with the regenerative medicine technologies under development by the Company. A number of biotechnology, pharmaceutical and chemical companies are developing various types of wound healing treatments which are alternatives to tissue regeneration for some conditions, including chronic skin ulcers. These treatments employ a variety of approaches such as growth factors, tripeptides and wound dressings. The Company believes that some of these alternatives could be used in conjunction with the Company's products.

The Company competes primarily on the uniqueness of its technology and product features and on the quality and cost-effectiveness of its products. Many competitors or potential competitors have greater financial resources, research and development capabilities, and marketing and manufacturing experience than the Company. While there can be no assurance that the Company's products and technology will not become obsolete, the Company believes that it occupies a unique position in its industry because INTEGRA(TM) Artificial Skin was the first regenerative product approved by the FDA and due to the Company's strong patent portfolio covering the field of regeneration.

The Company is aware of several companies seeking to develop products that could, if successful and approved, compete with the regenerative medicine technologies under development by the Company. Several of these companies have products that may compete with INTEGRA(TM) Artificial Skin, including LifeCell Corporation (see "Item 3. Legal Proceedings" below), Genzyme Tissue Repair (a division of Genzyme Corporation), Advanced Tissue Sciences, Inc., Organogenesis, Inc. and Ortec International, Inc. LifeCell Corporation and Genzyme Tissue Repair are currently not subject to FDA regulation because they involve the processing of human cells and tissues and, therefore, are not currently subject to the costs and expenses and the potential delays associated with the FDA approval process.

The Company believes that expansion of its markets will be enhanced by the entry of additional competitors. During the last year several new products have been approved by the FDA or have moved closer to final approval. These include products by Johnson & Johnson (Regranex), Advanced Tissue Sciences, Inc. (Dermagraft) and Organogenesis, Inc. (Apligraf), Regranex is a growth factor based wound healing compound which competes with the Company's technologies at Telios. Dermagraft and Apligraf are dermal replacement products targeted primarily at chronic wounds. Dermagraft received a recommendation for approval from the FDA Advisory Panel on January 29, 1998 for treatment of diabetic ulcers. Graftskin is composed of donor human cells, bovine collagen and other ingredients and received a recommendation for approval from a FDA Advisory Panel on January 29, 1998 for treatment of venous stasis ulcers. The Company believes that success of these products in the market will offer an opportunity for Integra's technologies in the future. Ultimately, therefore, the Company's

competitive position will depend both on the size of the market for its products and on the sales and marketing strength established by the

Company and its corporate partners. The breadth of the Company's technologies allows it to compete in a wide range of possible solutions to the problem of repair of damaged tissue.

## Employees

The Company regards its employees as one of its most important assets. The competitive advantage of life sciences companies depends on a committed workforce, sound management processes and systems that maximize utilization of each employee's technical knowledge. The Company has developed such systems and processes in order to allow it to manage and market effectively its intellectual capital. To foster employee commitment the Company has implemented incentive plans that provide its employees the opportunity to invest and benefit from the Company's success. The Company is dedicated to building on these principles as it moves forward.

At December 31, 1997, the Company employed 166 full-time people (including temporary and part-time employees) of which 58 are engaged in production and production support (including warehouse, engineering, and facilities personnel), 15 in quality assurance/quality control, 35 in research and development, 10 in regulatory and clinical affairs, 21 in sales/marketing and 27 in administration and finance. None of the Company's employees is subject to a collective bargaining agreement.

## Forward Looking Statements

This report contains trend information and other forward-looking statements related to the future use and sales of the Company's products, potential markets for the Company's products, anticipated expenditure levels compared to historical amounts and the Company's plans for its research and development efforts. Such statements are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995 and involve risks and uncertainties which may cause results to differ materially from those set forth in these statements. Potential risks and uncertainties include, without limitation, those mentioned in this report and, in particular, those mentioned under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Factors That May Affect Future Results of Operations".

## ITEM 2. PROPERTIES

The Company has a lease for approximately 35,000 square feet for its principal administrative, marketing, manufacturing and product development activities in Plainsboro, New Jersey that expires in October 2012. It also holds a lease for approximately 25,000 square feet of production, administration and warehouse space in West Chester, Pennsylvania that expires in April 1999, with three five-year renewal options. The Company has decided to suspend its operations at the West Chester, Pennsylvania facility. The Company's Telios Pharmaceutical,

Inc. subsidiary leases approximately 18,600 square feet of administrative and laboratory space located in San Diego, California under a lease that expires in October 2004. The Company also leases several smaller facilities to support additional administrative and storage operations.

## ITEM 3. LEGAL PROCEEDINGS

In January 1994, ABS LifeSciences, Inc., a wholly-owned subsidiary of the Company, entered into a five-year distribution agreement with the distributor of the Company's Chronicure product pursuant to which the distributor is obligated to purchase certain minimum quantities of wound care products. In October 1995, the Company's subsidiary filed a complaint in the United States District Court for the District of New Jersey claiming the distributor breached the distribution agreement by, among other things, not paying the subsidiary for certain products delivered. In November 1995, the distributor filed an affirmative defense and counterclaim alleging, among other things, fraudulent misrepresentation and breach of contract and seeking damages of approximately \$1.2 million plus unspecified punitive damages. During 1997, the case was inactive and dismissed by the court based on a tentative settlement with leave to reinstate on the request of either party. However, the Company has not been able to consummate an acceptable settlement and has submitted a request to reinstate the case. The Company intends to continue to defend the counterclaim.

On or about July 18, 1996, Telios filed a patent infringement lawsuit against three parties: Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps. The lawsuit was filed in the U.S. District Court for the Southern District of California. The complaint charges, among other things, that the defendant Merck KGaA "willfully and deliberately induced, and continues to willfully and deliberately induce, defendants Scripps Research Institute and Dr. David A. Cheresh to infringe United States Letters Patent No. 4,729,255." This patent is one of a group of five patents granted to Burnham and licensed by Telios that are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid (known as "RGD") peptide sequence found in many extracellular matrix proteins. The Company is pursuing numerous medical applications of the RGD technology in the fields of anti-thrombotic agents, cancer, osteoporosis, and a cell adhesive coating designed to improve the performance of

implantable devices and their acceptance by the body. The defendants have filed a countersuit asking for an award of defendants' reasonable attorney fees.

In August 1995, Telios received confirmation of its Chapter 11 plan of reorganization in the United States Bankruptcy Court for the Southern District of California. Under the plan, Telios assumed a certain License Agreement and a certain Research Agreement entered into with the University of Utah and the University of Utah Research Foundation ("University") in 1991. On March 27, 1996, Telios filed a motion with the bankruptcy court for a determination as to whether there were any "cure" requirements for the assumed contracts with the University (the "Motion"). In the meantime, on March 22, 1996, the University

filed a complaint against Telios in the United States District Court for the District of Utah seeking a declaration that the License Agreement and Research Agreement were terminated or terminable. The District Court case was subsequently dismissed in light of the pending Motion in the bankruptcy court. In November 1997, the bankruptcy court entered an order decreeing that Telios' license to certain of the patents and technology rights under the License Agreement had been reduced to a non-exclusive license. However, the court did not terminate the license. In addition, Telios still retains an exclusive license to certain patents, technology and rights to make, use and sell licensed products thereunder, which have been exclusively sublicensed by Telios to Cambridge Antibody Technology, Limited. A hearing has been set for May 27, 1998 to determine whether Telios has licensing rights to a certain new invention disclosed by the University under the License Agreement and/or the Research Agreement.

On or about November 4, 1997, Integra (Artificial Skin) Corporation ("IASC"), a wholly-owned subsidiary of the Company, and the Massachusetts Institute of Technology ("MIT") filed a patent infringement lawsuit against LifeCell Corporation ("LifeCell") alleging that LifeCell infringed United States Patent Nos. 4,458,678 and 4,505,266 through the making, using and selling of its AlloDerm(R) and/or XenoDerm(TM) products. The suit was filed in the United States District Court for the District of Massachusetts. The patents in suit are licensed by MIT to IASC and relate to treating wounds with products which encourage tissue regeneration. LifeCell has filed counterclaims seeking declaratory judgments of non-infringement and patent invalidity and also claims that MIT and IASC are barred from recovery under the doctrines of laches, patent misuse and unclean hands alleging, among other things, that MIT and IASC filed this suit solely to disrupt LifeCell's November 1997 stock offering. LifeCell has filed a motion to transfer this action to the United States District Court for the Southern District of Texas which motion MIT and IASC are opposing. The Company intends to vigorously pursue its claims and vigorously defend against LifeCell's counterclaims and affirmative defenses.

On or about December 10, 1997, LifeCell filed a complaint against MIT and IASC in Texas state court claiming tortious interference, business and product disparagement, unfair competition, civil conspiracy and violation of the Texas Free Enterprise and Antitrust Act based upon the contention that MIT and IASC filed the patent infringement suit in Massachusetts in order to interfere with LifeCell's November 1997 stock offering. LifeCell is seeking unspecified actual monetary damages in an amount not less than \$12 million together with treble damages, unspecified punitive damages, and other relief. MIT and IASC removed this case to the United States District Court for the Southern District of Texas and have filed a motion to transfer it to United States District Court in Massachusetts. LifeCell filed a motion to remand the case back to Texas state court which motion MIT and IASC are opposing. MIT and IASC have also filed motions to dismiss the case for lack of personal jurisdiction and to stay discovery. The Company also intends to vigorously defend against this suit.

The ultimate liability of the cases disclosed above cannot now be determined because of the considerable uncertainties that exist. The Company's financial statements do not reflect any significant amounts related to possible unfavorable outcomes of these matters. The Company intends to continue its vigorous defense of these matters. However, it is possible that the Company's results of operations, financial position and cash flows in a particular period

could be materially affected by these contingencies.

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

Pursuant to a written consent dated December 27, 1997, the holders of 18,428,836 shares, or approximately 61.6%, of the Company's issued and outstanding shares of Common Stock approved the following: (i) an amendment to the Company's 1996 Incentive Stock Option and Non-Qualified Stock Option Plan (the "Plan") increasing the maximum number of options that may be issued under the Plan to an individual over any one-year period from 300,000 to 1,000,000; (ii) the grant to Stuart M. Essig, the Company's President and Chief Executive Officer, of an option under the Plan to purchase

1,000,000 shares of Common Stock; and (iii) the grant to Mr. Essig of restricted units pursuant to which he is to acquire an additional 2,000,000 shares of Common Stock. These approvals were obtained pursuant to Section 228 of the Delaware General Corporation Law, subject to the expiration of twenty (20) days following the mailing on February 24, 1998 of an Information Statement to the Company's stockholders as required under the Securities Exchange Act of 1934, as amended.

#### Additional Information

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

The executive officers of the Company serve at the discretion of the Board of Directors. The only family relationship between any of the executive officers of the Company is between Dr. Caruso and Mr. Holtz, who is the nephew of Dr. Caruso.

The following information indicates the position and age of the Company's executive officers as of the date of this report and their previous business experience.

Name	Age	Position
Richard E. Caruso, Ph.D.	54	Chairman
Stuart M. Essig, Ph.D.	36	President and Chief Executive Officer
George W. McKinney, Ph.D.	54	Vice Chairman, Executive Vice President and Chief Operating Officer
Frederick Cahn, Ph.D.	55	Senior Vice President, Technology
Andre P. Decarie	52	Senior Vice President, Corporate Development
Michael D. Pierschbacher, Ph.D.	46	Senior Vice President and General Manager, Telios
Surendra P. Batra, Ph.D.	51	Vice President, Product Research
Carlos Blanco, M.D.	62	Vice President, Medical Director
David B. Holtz	31	Vice President, Treasurer
Donald Nociolo	35	Vice President, Operations
Judith E. O'Grady	47	Vice President, Regulatory Affairs
Robert D. Paltridge	40	Vice President, North American Sales
Robert G. Runckel	52	Vice President, Marketing and International Sales

#### Executive Officers

Richard E. Caruso, Ph.D. founded the Company and is the Chairman of the Board of Directors. Until December 1997, Mr. Caruso also served as President and Chief Executive Officer. From 1969 to 1992, Dr. Caruso was a principal of LFC Financial Corporation, a major entrepreneurial financing company located in Radnor, Pennsylvania. When he left in 1992, he was a director of the company and held the position of Executive Vice President. He has 25 years experience in finance and entrepreneurial ventures. Before joining LFC Financial Corporation, Dr. Caruso was associated with Price Waterhouse & Co. in Philadelphia, Pa. Dr. Caruso has served as a director or trustee of the following organizations: American Capital Open End Mutual Funds, LFC Financial Corporation, 202 Data Systems, Tenley Enterprises, Inc., and London School of Economics Business Performance Group. He is currently a director of Susquehanna University, The Baum School of Art, Uncommon Individual Foundation (Founder) and the Company. He received a BS degree from Susquehanna University, an MSBA degree from Bucknell University, and a Ph.D. degree from the London School of Economics, University of London (UK). Dr. Caruso is also a certified public accountant.

Stuart M. Essig, Ph.D. has served the Company as President and Chief Executive Officer since December 1997. Mr. Essig was elected by the Board of Directors as the Company's President and Chief Executive Officer and appointed to the Board in December 1997. Before joining the Company, Mr. Essig supervised the medical technology practice at Goldman, Sachs & Co. as a managing director. Mr. Essig has ten years of broad health care experience at Goldman Sachs serving as a senior merger and acquisitions advisor to a broad range of domestic and international medical technology, pharmaceutical and biotechnology clients. Mr. Essig received an A.B. degree from the Woodrow Wilson School of Public and International Affairs at Princeton University, and an MBA and a Ph.D. degree in Financial Economics from the University of Chicago, Graduate School of Business. Mr. Essig also serves on the Board of Directors of Neuromedical Systems, Inc., a Medical diagnostics products company.

George W. McKinney, Ph.D. has served the Company as Vice Chairman, Executive Vice President and Chief Operating Officer since May 1997 and as a member of the Board of Directors since December 1992. Between 1990 and 1997, Dr. McKinney was Managing Director of Beacon Venture Management Corporation, a venture capital firm. Between 1992 and 1997, Dr. McKinney also served as President and Chief Executive Officer of Gel Sciences, Inc. and GelMed, Inc., a privately held specialty materials firm with development programs in both the industrial and Medical products field. From 1983 to 1989, Dr. McKinney was a Managing Director at American Research & Development, a venture capital firm. Between 1986 and 1989, he also served as President and Chief Executive Officer of American Superconductor, Inc. (NASDAQ: AMSC), a development stage firm in the specialty materials field. From 1965 to 1983, Dr. McKinney worked for Corning Glass Works (now Corning, Inc.), a specialty materials firm, in a variety of manufacturing, engineering, and financial positions. At Corning, he served as President of Corning Designs, a subsidiary which he founded, as Secretary to the Management Committee, as Director of Business Development and Planning, as Treasurer, International, as Assistant Treasurer, Domestic, and as Financial and Control Manager for the Engineering Division. Dr. McKinney holds a S.B. from MIT in Management and a Ph.D. from Stanford University in Strategic Planning.

Frederick Cahn, Ph.D. has served the Company as Vice President for Technology from 1993 to September 1995 and as Senior Vice President of Technology since September 1995. Between 1987 and 1993, Dr. Cahn was President and Founder of Biomat Corporation. The Company appointed him to his current position after the acquisition of Biomat in April 1993. Before founding Biomat, Dr. Cahn served as Senior Scientist at Digilab Division of Bio-Rad Laboratories developing software and methods for chemical analysis and quality control for semiconductor and medical diagnostic applications. From 1980 to 1984, Dr. Cahn was Senior Scientist for New England Digital Corporation developing acoustic research and digital signal processing products. From 1988 to the present, he carried out various research duties as a Research Affiliate with the Massachusetts Institute of Technology, including a project to demonstrate the feasibility of porous microcarriers for mass culture of mammalian cells. Dr. Cahn received a BA degree in Physics and Biology from the University of California at Berkeley, and a Ph.D. degree in Biophysics from the Massachusetts Institute of Technology.

Andre P. Decarie, Senior Vice President, Corporate Development, joined the Company as Vice President of Marketing in 1993. Mr. Decarie has been active in the medical industry for over 20 years, both in senior management positions and in private consulting. He was Vice President of Sales for Surgical Laser Technologies and Vice President of Marketing for Hemostatic Surgery Corporation. He spent over 14 years at United States Surgical Corporation in a variety of national and international assignments, including sales, marketing and product development. In 1990, as Director of Continuing Medical Education for USSC, he led the group which guided the training of over 15,000 surgeons in the US and hundreds of international surgeons, in techniques of Minimally Invasive Surgery. He is a member of the ASCRS Research Foundation, and a member of their Gold Eagle Society. Mr. Decarie holds a BBA degree in Marketing from the University of Miami.

Michael D. Pierschbacher, Ph.D. joined the Company in October 1995 as Senior Vice President, Research and Development. Dr. Pierschbacher served Telios, which was acquired by the Company in connection with the reorganization of Telios

under Chapter 11 of the Bankruptcy Code, as Senior Vice President and Scientific Director from June 1987 to September 1995. He was a co-founder of Telios in May 1987 and is the co-discoverer and developer of Telios' matrix peptide technology. Before joining Telios as a full-time employee in October 1988, he was a staff scientist at the Burnham Institute for five years and remained on staff there in an adjunct capacity until the end of 1997. He received his post-doctoral training at Scripps Clinical and Research Foundation and at the Burnham Institute. Dr. Pierschbacher received his Ph.D. in Biochemistry from the University of Missouri.

Surendra P. Batra, Ph.D. has served the Company as Vice President for Product Research since January 1992. Between 1991-1992 Dr. Batra was a Research and Development Manager at ABS LifeSciences, a subsidiary of Integra LifeSciences. Dr. Batra has worked in the field of protein biochemistry, enzymology, biomaterials, tissue regeneration and implantable materials, for 15 years and has published ten (10) research articles. Prior to joining Integra LifeSciences, Dr. Batra served with Semex Medical, Inc. as a Senior Scientist Group Leader in biomaterials development, specializing in wound care, ophthalmology, drug delivery and implantables. Before coming to the United States, Dr. Batra taught medical biochemistry for eight (8) years in a reputable medical school in New Delhi, India. Dr. Batra received an MS Chemistry degree from the University of Meerut, India; an MS in Medical Biochemistry from Delhi University, India and a Ph.D. in Physiology and Biochemistry from the Reading University in the U.K.

Carlos Blanco, M.D. joined the Company full time in May 1997 and serves as the Company's Vice President, Medical Director. He had previously served as a consultant and senior advisor to the Company. From 1985 to 1996, Dr. Blanco was employed by Marion Laboratories and its successor companies Marion Merrell Dow, Inc. and Hoechst Marion Roussel, holding positions as Director, International Marketing; Director, Medical Marketing; Director, Marketing Relations for Wound Care; and Medical Director, Wound Care. While at Marion, Dr. Blanco was instrumental in the development of INTEGRA(TM) Artificial Skin. Prior to working for Marion, Dr. Blanco served in several companies in the wound care business, most notably for 15 years with The Purdue Frederick Company, where he served as Director, Clinical Research and Director, Burn/Wound Programs. Dr. Blanco is on the Board of Directors for the Wound Healing Society, Chairman of Ad hoc Committee of the International Society of Burn Injuries, Chairman of the Industry Relations Committee Wound Healing Society and the Board of Trustees of the American Burn Association. Dr. Blanco received his medical degree from Seville Medical School in Seville, Spain and his BS degree from Colegio del Carmen, Melilla, Spain.

David B. Holtz joined the Company as the Controller in 1993 and has served as Vice President, Treasurer since March 1997. His responsibilities include managing all accounting and information systems functions. He is also responsible for the preparation of the Company's Securities and Exchange Commission filings and federal and state tax returns. Before joining the Company, Mr. Holtz was an associate with Coopers & Lybrand, L.L.P. in Philadelphia and Cono Leasing Corporation, a private leasing company. He received a BS degree in Business Administration from Susquehanna University in 1989 and is a certified public accountant.

Donald Nociolo joined the Company as Director, Manufacturing in 1994 and has served as Vice President, Operations since March 1997. His responsibilities include managing all manufacturing operations to ensure on-time shipment of GMP produced and high quality product to all customers. Mr. Nociolo has over ten years experience working in engineering and manufacturing management in the Medical device industry. Six of those years were spent working at Ethicon, Inc., Johnson & Johnson's suture division. Mr. Nociolo received a BS degree in Industrial Engineering from Rutgers University and an MBA in Industrial Management from Fairleigh Dickinson University.

Judith E. O'Grady has served as Vice President of Regulatory Affairs for the Company, or a predecessor company, since 1988. Included in her responsibilities are clinical research and quality assurance functions. Ms. O'Grady has worked in the areas of Medical devices and collagen technology for the past 15 years. Between 1988 and 1992, she held the position of Vice President of Regulatory Affairs with Colla-Tec, Inc., a predecessor to the Company, and from 1981 to 1988 with American Biomaterials Company and American Medical Products/Delmed. Earlier in her career, she served as a Clinical Research Associate with Surgikos, a Johnson & Johnson subsidiary. Ms. O'Grady received a BS degree in Nursing from Marquette University and an MS degree in Nursing from Boston University. Ms. O'Grady is a member of the Board of Directors of the State of New Jersey League for Nursing.

Robert D. Paltridge joined the Company as National Sales Director in February 1995 and has served as Vice President, North American Sales since September 1997. His responsibilities include managing the sales activities of INTEGRA(TM) Artificial Skin and the Helistat(TM) and Helitene(TM) collagen hemostatic agents in North America along with negotiating contracts with national group purchasing organizations. Mr. Paltridge has 15 years of sales/sales management experience in the medical device industry. Before joining the Company, he was National Sales Manager at Strato Medical, a division of Pfizer, Inc. He received a BS degree in Business Administration from Rutgers University.

Robert G. Runckel joined the Company in 1988 and serves as Vice President, Marketing and International Sales. Mr. Runckel has 27 years experience in healthcare sales and marketing, including significant international experience. From 1988 to 1992, he served in a similar position with Colla-Tec, Inc., a predecessor of the Company, and American Biomaterials Corporation. Before that, Mr. Runckel served as Sales Manager of Becton Dickinson Pharmaceutical Systems and as Marketing Manager, Asia, Africa and Australia for the International Group of Becton Dickinson and Co., a world-wide manufacturer of medical and laboratory devices and diagnostics. He received a B.A. degree in Chemistry from the University of Oregon.

## PART II

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

The Company's Common Stock trades on The Nasdaq National Market under the symbol IART. The following table represents the high and low sales prices for the Company's Common Stock for each quarter for the last two years.

	HIGH	LOW
1997		
First Quarter	\$5.875	\$3.00
Second Quarter	\$4.75	\$2.50
Third Quarter	\$5.125	\$3.125
Fourth Quarter	\$4.625	\$2.9375
1996		
First Quarter	\$13.50	\$6.375
Second Quarter	\$13.00	\$8.75
Third Quarter	\$11.75	\$4.125
Fourth Quarter	\$7.00	\$4.25

The closing price for the Common Stock on March 20, 1998 was \$4.6875. For purposes of calculating the aggregate market value of the shares of Common Stock of the Company held by nonaffiliates, as shown on the cover page of this report, it has been assumed that all the outstanding shares were held by nonaffiliates except for the shares held by directors and executive officers of the Company and stockholders owning 10% or more of outstanding shares. However, this should not be deemed to constitute an admission that all such persons are, in fact, affiliates of the Company. Further information concerning ownership of the Company's Common Stock by executive officers, directors and principal stockholders will be included in the Company's definitive proxy statement to be filed with the Securities and Exchange Commission.

The Company does not currently pay any cash dividends on its Common Stock and does not anticipate paying dividends in the foreseeable future.

The number of stockholders of record as of March 20, 1998 was approximately 833, which includes stockholders whose shares were held in nominee name. The number of beneficial stockholders at that date was over 6,700.

In March 1998, the Company announced that its Board of Directors authorized a common stock repurchase program. The share repurchase program of up to 500,000 shares (pre-split) was effective immediately. Under the terms of the share repurchase plan, the Company is allowed to repurchase up to 500,000 of its outstanding shares of common stock effective immediately. The share repurchase plan allows the Company to make repurchases from time to time during 1998 in the open market or through privately negotiated transactions. Repurchased common shares will be added to the Company's treasury shares. The timing of any share repurchase will be dictated by overall financial and market conditions and other corporate considerations.

The Board also approved, subject to shareholder approval, a one-for-two reverse stock split of the Company's common stock. The reverse stock split is subject to stockholder approval at the annual shareholders meeting scheduled for May 18, 1998.

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## ITEM 6. SELECTED FINANCIAL DATA

The following data has been selected by the Company and derived from consolidated financial statements that have been audited by Coopers & Lybrand LLP, independent accountants. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with the Company's consolidated financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this report.

	Years Ended December 31,				
	1997	1996	1995	1994	1993
	-----				
	(In thousands, except per share data)				
Statement of Operations Data (1)					
Product sales.....	\$ 14,001	\$11,210	\$ 8,356	\$ 6,958	\$ 3,950
Other revenue.....	745	1,938	1,873	1,703	826
	-----				
Total revenue.....	14,746	13,148	10,229	8,661	4,776
	-----				
Cost of product sales.....	7,027	6,671	4,850	4,402	2,535
Research and development.....	6,406	6,294	5,191	3,085	2,170
Selling and marketing.....	5,460	4,310	2,455	1,335	677
General and administrative (2).....	14,764	5,320	3,642	2,170	1,899
Acquired in-process research and development (3)	-----	-----	19,593	(275)	20,642
	-----				
Total costs and expenses.....	33,657	22,595	35,731	10,717	27,923
	-----				

Operating loss.....	(18,911)	(9,447)	(25,502)	(2,056)	(23,147)
Interest income.....	1,771	1,799	283	221	12
Interest expense.....	----	----	(188)	(64)	(218)
Other income (expense) .....	176	120	5	(1)	19
	-----	-----	-----	-----	-----
Net loss.....	<u>\$(16,964)</u>	<u>\$(7,528)</u>	<u>\$(25,402)</u>	<u>\$(1,900)</u>	<u>\$(23,334)</u>
	=====	=====	=====	=====	=====
Basic and diluted net loss per share.....	<u>\$ (.57)</u>	<u>\$ (.27)</u>	<u>\$ (1.21)</u>	<u>\$ (.10)</u>	<u>\$ (1.41)</u>
	=====	=====	=====	=====	=====
Weighted average number of common shares outstanding.....	<u>29,620</u>	<u>28,114</u>	<u>21,073</u>	<u>19,035</u>	<u>16,583</u>
	=====	=====	=====	=====	=====

	December 31,				
	1997	1996	1995	1994	1993
	----	----	----	----	----
Balance Sheet Data (1)			(In thousands)		
Cash, cash equivalents and short-term investments	\$ 26,272	\$ 34,276	\$ 5,710	\$ 3,331	\$ 5,066
Working capital.....	29,407	37,936	7,476	3,610	3,488
Total assets.....	38,356	48,741	19,378	13,703	10,043
Long-term debt.....	----	----	----	1,754	3,224
Accumulated deficit.....	(75,945)	(58,981)	(51,453)	(26,051)	(24,151)
Total stockholders' equity.....	35,755	46,384	17,427	9,275	3,559

(1) As the result of the Company's acquisitions of Vitaphore Corporation in April 1993, Biomat Corporation in June 1993, another company's 50% interest in a joint venture with Vitaphore Corporation in December 1993 and Telios Pharmaceuticals, Inc. in August 1995, the consolidated financial results for the periods prior to 1997 are not directly comparable.

(2) In December 1997, general and administrative expense included the following two non-cash charges: (i) \$1.0 million related to an asset impairment charge; and (ii) \$5.9 million related to an equity-based signing bonus for the Company's President and Chief Executive Officer.

(3) As a result of the required use of purchase accounting, the 1993 loss included \$20.6 million of acquired in-process research and development which was charged to expense at the date of the Company's acquisitions in 1993, and the 1995 loss included \$19.6 million of acquired in-process research and development which was charged to expense at the date of the Company's acquisition of Telios Pharmaceuticals, Inc.

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

The following discussion should be read in conjunction with the Company's consolidated financial statements, the notes thereto and the other financial information included elsewhere in this report.

General

The Company has developed principally by combining existing businesses, acquiring synergistic technologies and forming strategic business and technological alliances. As a result of the Company's acquisition of Telios Pharmaceuticals, Inc. ("Telios") in August 1995, the consolidated financial results for 1995 and 1996 may not be directly comparable.

Results of Operations

1997 Compared to 1996

The Company's net loss increased from \$7.5 million in 1996 to \$17.0 million in 1997. The 1997 loss included two non-cash charges totaling \$6.9 million, which are included in general and administrative expense.

Total revenues increased 12% from \$13.1 million in 1996 to \$14.7 million in 1997 as increases in product sales offset decreases in other revenues. Product sales increased 25% from \$11.2 million to \$14.0 million due to \$6.0 million in sales of INTEGRA(TM) Artificial Skin ("INTEGRA") in 1997 compared to \$3.1 in 1996. The Company's export sales increased 11% from \$1.9 million to \$2.1 million as INTEGRA export sales increased by \$860,000. Approximately 72% of INTEGRA sales in 1996 were in North America compared to 71% in 1996, following the product's marketing approval from the FDA in March 1996. In 1997, 114 burn centers and hospitals throughout North America purchased INTEGRA compared to 65 burn centers and hospitals in 1996. The Company's international sales included INTEGRA sales to 20 countries throughout the world.

The primary application of INTEGRA has been for patients with severe life-threatening burns. The Company is also aware of its application in reconstructive and wound healing procedures and is continuing to focus its strategy on expanding the approved indications for use of INTEGRA. The Company believes that INTEGRA can offer improved clinical results compared to existing treatments for relief of painful scars, wound contractures and hypertrophic scarring. The Company believes that the following factors will have the greatest influence on the use and sale of INTEGRA: (i) physician training prior to product use; (ii) the collection of pharma-economic data to address product reimbursement issues; (iii) the publication of positive clinical results, and (iv) the Company's ability to obtain regulatory approvals for expanded indications.

Sales of the Company's private label and other medical products decreased from \$8.1 million in 1996 to \$8.0 million in 1997. Decreases in the Company's infection control and surgical and hemostasis product lines were offset by increases in its dental product line and other contract manufacturing. The dental product line increase was the result of increased orders from the Company's marketing partner for the BioMend product, which was introduced in August 1995. The decrease in the surgical and hemostasis product line, which includes products sold to marketing partners and products marketed directly, was due to lower unit volume from international distributors and customers.

During 1997, the Company's distribution agreement for its ophthalmic products was terminated, and the Company has discontinued the product line. In January 1998, the Company decided to suspend operations at its leased West Chester, Pennsylvania facility, and as a result has discontinued its avian collagen wound care product line and its contract manufacturing activities. The Company's ophthalmic, avian collagen and contract manufacturing revenues accounted for less than 5% of product sales in 1997 and 1996. Customers representing greater than 10% of sales included two customers equaling 24% in 1997 and three customers equaling 42% in 1996. Because a significant portion of the Company's private label and other medical products are sold to marketing partners and

distributors, quarter-to-quarter sales in medical products can vary significantly.

Other revenue, which includes grant revenue, license fees, contract development revenue and royalties, declined from \$1.9 million in 1996 to \$745,000 in 1997. Grant revenue declined by \$590,000 as a large portion of 1996 revenue came from a three-year \$2.0 million National Institute of Standards and Technology (NIST) grant which was completed in 1996. Licensing revenue also declined as the Company received a \$500,000 license fee in 1996 in an agreement with Cambridge Antibody Technology Limited involving a human antibody development program. The Company expects its other revenues to increase from 1997 due to the following: (i) the Company has signed a licensing and distribution agreement with Century Medical, Inc. for the Company's Dura regeneration product which included a \$1.0 million licensing fee in March 1998; (ii) the Company has signed a development agreement with Johnson & Johnson Professional, Inc. to develop an absorbable, collagen-based implant designed in combination with a proprietary RGD-peptide for cartilage regeneration; and (iii) the Company has been awarded a new three-year \$2 million NIST grant to develop absorbable biocompatible polymers in combination with RGD peptides specifically designed to stimulate in vivo cartilage regeneration. The Company continues to seek additional research grants, licensing arrangements and development funding for several of its technologies and programs, although the timing and amount of such revenue, if any, can not be predicted.

Cost of product sales increased 5% from \$6.7 million (60% of product sales) in 1996 to \$7.0 million (50% of product sales) in 1997. The dollar increase in cost of product sales is due to higher product sales. Cost of product sales as a percentage of sales decreased due to lower inventory write-offs related to certain medical product production difficulties in 1996, improved capacity utilization for INTEGRA, and increased sales in higher margin products. Due to the high fixed costs of the manufacturing facility for INTEGRA, the Company is anticipating higher per unit product costs until there is a requirement for higher production volume. The Company believes its current capacity to produce INTEGRA and its other medical products is sufficient to support significant growth, and the utilization of this capacity will affect its gross margin on product sales. In January 1998, the Company decided to discontinue its production operations at the West Chester, Pennsylvania leased facility. The Company anticipates lower production operating costs during 1998 as a result of this closing.

Research and development expense increased from \$6.3 million in 1996 to \$6.4 million in 1997. Increases in research and development expenditures associated with clinical costs for the Company's post-approval study of INTEGRA offset declines in pre-clinical costs associated with the Company's absorbable biocompatible polymer program. Continuing expenditures include costs associated with efforts focusing on combining the Company's biomaterials technologies with those acquired in the Telios acquisition. The Company expects the level of research and development expenditures in 1998 to be higher than in 1997 as expenditures related to the post-approval study for INTEGRA continue, and other clinical and pre-clinical efforts expand. These efforts will continue to focus on additional clinical indications for INTEGRA and on the Company's other regenerative and matrix medicine technologies. The amount of resources allocated to fund particular research and development efforts will vary depending upon a number of factors, including the progress of development of the Company's

technologies, changing competitive conditions and determinations with respect to the commercial potential of the Company's technologies.

Selling and marketing expense increased 27% from \$4.3 million in 1996 to \$5.5 million in 1997 as the Company continued to focus its efforts on the domestic and international market introduction of INTEGRA. During 1997, the Company expanded its network of domestic and international regional managers for the sales of INTEGRA. The Company is anticipating a continued increase in selling and marketing costs associated with INTEGRA, including costs associated with introduction of INTEGRA into additional markets and for additional indications.

General and administrative expense was \$14.8 million in 1997 and included two non-cash charges in the fourth quarter. The Company incurred a \$1.0 million asset impairment charge associated with certain leasehold improvements at its leased West Chester, Pennsylvania, and a \$5.9 million charge related to an equity-based signing bonus for the Company's new President and Chief Executive Officer. Excluding these charges, general and administrative expense increased 48% from \$5.3 million in 1996 to \$7.9 million in 1997. Significant increases include the addition of several senior executives and costs related to the continued maintenance of the Company's intellectual property and patent infringement litigation. The Company is involved in two patent infringement litigation cases that are in their early stages, and the Company anticipates incurring continued significant expenditures during 1998 related to these matters.

Other income, net, which primarily includes interest income, was \$1.9 million in 1996 and 1997 as the decline in interest income from lower investment balances was offset by income from other items.

#### 1996 Compared to 1995

The Company's net loss decreased from \$25.4 million in 1995 to \$7.5 million in 1996. As a result of the required use of purchase accounting, the Company's 1995 loss included approximately \$19.6 million of acquired in-process research and development that was charged to expense at the date of the Company's acquisition of Telios.

Total revenues increased 28% from \$10.2 million in 1995 to \$13.1 million in 1996 primarily as a result of an increase in product sales. Product sales increased 34% from \$8.4 million to \$11.2 million due to \$3.1 million in sales of INTEGRA in 1996 compared to minimal sales in the prior year. Approximately 71% of INTEGRA sales in 1996 were in the United States following its marketing approval from the FDA in March 1996, and included sales to 65 burn centers and hospitals throughout the United States and Canada. INTEGRA export sales were to 13 countries in Europe and Asia. Product sales of the Company's other medical devices decreased from \$8.4 million in 1995 to \$8.1 million in 1996. Decreases in the Company's ophthalmic and surgical and hemostasis product lines were partially offset by increases in its infection control and dental product lines. The ophthalmic product line decrease was due to production difficulties, which

delayed product shipments during the second half of 1996. The decrease in the surgical and hemostasis product line, which includes products sold to marketing partners and products marketed directly, was due to lower unit volumes as well as lower unit pricing on the products marketed directly. The infection control and dental product line increases were the result of increases in orders from marketing partners for the Company's BioPatch and BioMend products. Approximately 42% and 56% of the Company's product sales were to three customers in 1996 and four customers in 1995, respectively. The Company's export sales (including INTEGRA) increased 98% from \$945,000 to \$1.9 million as INTEGRA export sales increased by \$860,000.

Other revenue, which includes grant revenue, license fees, contract development revenue and royalties, was \$1.9 million in 1996 and 1995. Grant revenue in both periods was approximately \$1.1 million, the

largest portion of which came from a three year \$2.0 million NIST grant. The NIST grant was completed as of December 31, 1996. The Company received a \$500,000 license fee in 1996 as part of an agreement with Cambridge Antibody Technology Limited involving a human antibody development program. The Company also received a \$500,000 license fee in 1995 from the Calcitek Division of Sulzermedica when the Company's BioMend product received FDA marketing clearance. The Company continues to seek research grants, licensing arrangements and development funding for several of its technologies, although the timing and amount of such revenue, if any, can not be predicted.

Cost of product sales increased 38% from \$4.9 million (58% of product sales) in 1995 to \$6.7 million (60% of product sales) in 1996. The dollar increase in cost of product sales is due to higher product sales and an increase in manufacturing capacity associated with INTEGRA and with the Company's West Chester, Pennsylvania facility. The INTEGRA production facility and additional capacity at the West Chester facility came on-line during the last quarter of 1995. Cost of product sales as a percentage of sales increased due to inventory write-offs related to certain medical product production difficulties and lower capacity utilization for INTEGRA product during 1996.

Research and development expense increased 21% from \$5.2 million in 1995 to \$6.3 million in 1996, due to an increase of \$1.4 million in research and development expenses incurred by the Company's Telios operation, which was acquired in August 1995. Research and development expenditures at Telios include costs associated with efforts focusing on combining the Company's existing technologies with those acquired in the acquisition. The Company's research and development efforts involving INTEGRA decreased significantly from 1995 to 1996 as a result of the transfer of the product to manufacturing. Additional increases in other research and development projects partially offset the decrease related to the INTEGRA transfer. These increases included costs associated with the addition of full-time and part-time research and development staff and increased expenditures for outside contract activities.

Selling and marketing expense increased 76% from \$2.5 million in 1995 to \$4.3 million in 1996 as a result of the domestic and international market

introduction of INTEGRA. The Company was required by the FDA to train all surgeons prior to their use of INTEGRA, and as of December 31, 1996 the Company had trained approximately 600 surgeons worldwide. During 1996, the Company also established a network of domestic and international regional managers for the sales of INTEGRA. INTEGRA training and selling cost increases were partially offset by a decrease in costs resulting from a reduction in the size of the Company's direct sales force for certain other medical product lines.

General and administrative expense increased 46% from \$3.6 million in 1995 to \$5.3 million in 1996 largely due to increases in costs involving the maintenance of intellectual property and expenditures related to patent infringement litigation.

Other income, net, which primarily includes interest income and interest expense, increased from \$100,000 in 1995 to \$1.9 million in 1996 largely due to \$1.8 million in interest earned in 1996 on the net proceeds of the Company's underwritten public offering.

#### Liquidity and Capital Resources

The Company has funded its operations to date primarily through private and public offerings of its securities, revenues from sales of existing products, research grants from government agencies, development agreements with major industrial companies, borrowings under a revolving credit line and cash acquired in connection with the Telios acquisition. On February 1, 1996, the Company completed an underwritten public offering of 4,671,250 shares of its common stock, which resulted in approximately \$35.6 million in net proceeds to the Company.

At December 31, 1997, the Company had cash, cash equivalents and short-term investments of \$26.3 million representing an \$8.0 million decrease from December 31, 1996. The principal uses of funds during 1997 were \$7.9 million for operations and \$770,000 in purchases of property and equipment.

Under the Company's stock repurchase program (see Item 5. "Market Price for Registrant's Common Equity and Related Stockholder Matters"), the Company may utilize from time to time its available cash to repurchase the Company's common stock on the open market. The amount and timing of any share repurchases will depend on market conditions as well as the Company's cash position.

In March 1998, the Company entered into a series of agreements under which it will issue 500,000 shares of preferred stock for \$4.0 million during the second quarter of 1998. The newly issued series of preferred stock will carry an annual dividend of 2%, and each preferred share will be convertible into one share of the Company's common stock. The Company anticipates it will continue to use its liquid assets to fund operations until sufficient revenues can be generated through product sales and collaborative arrangements. In addition, the Company may continue to raise additional funding through the use of private or public offerings. There can be no assurance that the Company will be able to generate sufficient revenues to obtain profitability or raise additional funding in

equity transactions.

#### Factors That May Affect Future Results of Operations

The Company believes that the following important factors, among others, have affected, and in the future could affect, the Company's results of operations and could cause the Company's future results to differ materially from its historical results and those expressed in any forward-looking statements made by the Company.

- o The Company believes that its INTEGRA product represents a relatively new method of treatment, and as such, it is difficult to estimate the potential market and potential revenue growth for the product. The Company also believes that INTEGRA provides a substantial enhancement over existing treatment alternatives for its current indication, which is the treatment of severe burns. The Company believes that INTEGRA provides longer-term financial savings and other health benefits by reducing the number of required procedures and the length of the patient's hospital stay. However, the cost of the product does require the healthcare provider to incur a higher initial cost than is customary under traditional treatment options. In addition, the health care industry in general is under continued cost containment pressures from government health administration authorities, private health insurers and other organizations. Should the Company be unable to demonstrate these savings to the healthcare provider market and others, the Company may experience lower than anticipated revenue growth and a resulting adverse effect on its business, financial condition and results of operations.
- o Because a significant portion of the Company's historical medical product sales have been to a small number of marketing partners, the loss of one of these customers could have a negative impact on revenues. The Company also depends on third party distributors for several products domestically and internationally. The Company's revenues and gross profit margins for these products are dependent on the continuing efforts of these marketing partners and third party distributors. The Company believes that its current relationships with customers regarding these products is satisfactory.
- o There can be no assurance that the Company's planned research and development efforts will lead to commercially successful products. Many of the Company's technologies are in the early stages of development and will require the commitment of substantial additional resources by the Company and its potential strategic partners prior to commercialization. There can be no assurance that any such potential products will be successfully developed on a timely basis, if at all, be safe and effective in clinical trials, meet applicable regulatory standards and receive necessary regulatory approvals, be produced in commercial quantities at acceptable costs, or be successfully marketed and achieve customer acceptance. There can also be no assurance that the Company's current plans for clinical trials to expand the indication of use for INTEGRA will result in an expanded indication or achieve a greater market acceptance. Costs due to regulatory delays or demands, unexpected adverse side

effects or insufficient therapeutic effectiveness would prevent or significantly slow development and commercialization efforts and could have a material adverse effect on the Company.

- o The Company depends substantially on its ability to obtain patents (by license or otherwise), maintain trade secrets and operate without infringing on the intellectual property rights of third parties. The patent position of biotechnology and pharmaceutical firms is highly uncertain, involves many complex legal, factual and technical issues and has recently been the subject of much litigation. There can be no assurance that patent applications relating to the Company's products and technologies will result in patents being issued, that patents issued or licensed by the Company will provide protection against competitors or that the Company will enjoy patent protection for any significant period of time. The Company is currently involved in two patent infringement lawsuits. These litigation suits, as well as any possible future litigation, can be lengthy and expensive, and there can be no assurance as to the timing, cost or eventual outcome of such litigation. The Company's business may be adversely affected if it is unsuccessful in protecting its patents and proprietary rights. In addition, the Company is the defendant in several lawsuits claiming damages that, if decided against the Company, could have a material adverse effect on the financial position of the Company. The Company believes these lawsuits are without merit and will continue its defense against these suits.
- o The markets for the Company's actual and proposed products and their intended use are characterized by rapidly changing technology. Competition in the general area of medical technology is intense and is expected to increase. There are many companies in the medical field that have substantially greater capital resources, research and development staffs and facilities than the Company. There is a risk that technological developments will render actual and proposed products or technologies of the Company non-competitive, uneconomical or obsolete. As a result, the Company's growth and future financial performance depend in part upon its ability to introduce new products and enhance existing products to meet the latest technological advances. Failure by the Company to anticipate or respond adequately to changes in technology and market factors could have a material adverse effect on the Company's business.
- o The Company has developed by acquiring or securing a number of synergistic companies and technologies. There are certain risks associated with business and technology acquisitions, including incorrectly assessing the value of assets and future prospects, the extent of possible liabilities and the anticipated costs of incorporating acquired businesses into the Company. Although the Company is frequently in discussions with others relating to the possible technology acquisitions and related matters, it does not currently have any agreement or understanding with respect to any acquisitions or any material technology transfers. Because these types of transactions involve risks and could involve the issuance of the Company's equity, any business or technology acquisition could have a material affect on the Company's business.

The above factors are not meant to represent an exhaustive list of the risks and uncertainties associated with the Company's business. These factors as well as other factors may affect the Company's future results and the Company's stock price, particularly on a quarterly basis. Finally, because the Company participates in a highly dynamic industry, its stock price is often subject to significant volatility.

#### Other Matters

At December 31, 1997, the Company had net operating loss carryforwards of approximately \$36 million and \$28 million for federal and state income tax purposes, respectively, to offset future taxable income, if any, which expire through 2012 and 2004, respectively. At December 31, 1997, several of the Company's subsidiaries had unused net operating loss and tax credit carryforwards arising from periods prior to the Company's ownership. The net operating loss carryforwards (excluding Telios) of

approximately \$10 million for federal income tax purposes expire between 2000 and 2005. The Company's Telios subsidiary has generated approximately \$84 million of net operating losses, which expire between 2002 and 2010. The amount of Telios' net operating loss that is available and the Company's ability to utilize such loss is dependent on the determined value of Telios at the date of acquisition. The Company's has valuation allowance of \$37.5 million against all deferred tax assets, including the net operating losses, due to the uncertainty of realization. The timing and manner in which these net operating losses may be utilized in any year by the Company are severely limited by the Internal Revenue Code of 1986, as amended, Section 382 and other provisions of the Internal Revenue Code and its applicable regulations.

In June 1997, the Financial Accounting Standards Board issued SFAS 130, "Reporting Comprehensive Income," which established standards for reporting comprehensive income and its components (revenues, expenses, gains and losses) in the financial statements. SFAS 131, "Disclosures about Segments of an Enterprise and Related Information," was also issued in June 1997, and replaces existing segment disclosure requirements and requires certain financial information regarding operating segments on the basis used internally by management to evaluate segment performance. These statements will affect disclosure and presentation in the financial statements but will have no impact on the Company's consolidated financial position, liquidity, cash flows or results of operations. The Company will adopt SFAS 130 and 131 in the first quarter of 1998 and year-end 1998, respectively.

The Company believes that its financial and operational systems, with limited modifications, will function properly with respect to dates in the year 2000 and thereafter. The Company estimates that the costs associated with the Year 2000 issue will be insignificant and as such will not have a material impact on the Company's financial position or operating results.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements specified by this Item, together with the report thereon of Coopers & Lybrand L.L.P., are presented following Item 14 of this report.

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

Not applicable.

PART III

INCORPORATED BY REFERENCE

The information called for by Item 10 "Directors and Executive Officers of the Registrant" (other than the information concerning executive officers set forth after Item 4 herein), Item 11 "Executive Compensation", Item 12 "Security Ownership of Certain Beneficial Owners and Management" and Item 13 "Certain Relationships and Related Transactions" is incorporated herein by reference to the Company's definitive proxy statement for its Annual Meeting of Stockholders scheduled to be held on May 18, 1998, which definitive proxy statement is expected to be filed with the Commission not later than 120 days after the end of the fiscal year to which this report relates.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

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

1. Financial Statements. The following financial statements are filed as a part of this report. All schedules are omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

Report of Independent Accountants.....	F-1
Consolidated Balance Sheets as of December 31, 1997 and 1996.....	F-2
Consolidated Statements of Operations for the years ended December 31, 1997, 1996 and 1995.....	F-3
Consolidated Statements of Cash Flows for the years ended December 31, 1997, 1996 and 1995.....	F-4
Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 1997, 1996 and 1995.....	F-5
Notes to Consolidated Financial Statements.....	F-6

2. Exhibits.

Exhibit Number -----	Description -----	Location -----
2.1(a)	Acquisition Agreement between Telios Pharmaceuticals, Inc. and the Company dated as of April 11, 1995, as amended May 10, 1995	(2) (Exh. 2.1(a))
2.1(b)	Amendment Nos. 2 and 3 to Acquisition Agreement dated as of July 6, 1995 and July 14, 1995, respectively	(2) (Exh. 2.1(b))

2.1(c)	Amendment No. 4 to Acquisition Agreement dated as of August 14, 1995	(3) (Exh. 2.2)
2.2(a)	Combined Disclosure Statement and Plan of Reorganization dated as of March 31, 1995 Jointly Proposed by Telios Pharmaceuticals, Inc. and the Company (as modified through May 16, 1995) (the "Plan")	(2) (Exh. 2.2(a))
2.2(b)	Modifications to the Plan	(2) (Exh. 2.2(b))
2.2(c)	Order of the United States Bankruptcy Court for the Southern District of California dated July 21, 1995 confirming the Plan	(2) (Exh. 2.2(c))
3.1	Amended and Restated Certificate of Incorporation of the Company	(2) (Exh.3.1)
3.2	Amended and Restated By-laws of the Company	(5) (Exh. 3)
10.1	License Agreement between MIT and the Company dated as of December 29, 1993	(2) (Exh. 10.1)
10.2	License & Research Agreement between ABS LifeSciences, Inc. and Hospital for Joint Diseases Orthopaedic Institute dated as of December 26, 1990, as amended on May 9, 1992 and January 12, 1995	(2) (Exh. 10.2)
10.3	Exclusive License Agreement between the Company and Rutgers University dated as of December 31, 1994	(2) (Exh. 10.5)
10.4	License Agreement for Adhesion Peptides Technology between La Jolla Cancer Research Foundation and Telios dated as of June 24, 1987	(2) (Exh. 10.6)
10.5	Registration Rights Agreement between the Company and Boston Scientific Corporation dated as of December 29, 1993	(2) (Exh. 10.26)
10.6(a)	Stockholder Rights Agreement between the Company and Union Carbide dated as of April 30, 1993 ("Carbide Agreement")	(2) (Exh. 10.27(a))

10.6(b)	Amendment dated November 30, 1993 to Carbide Agreement	(2) (Exh. 10.27(b))
10.7	Real Estate Lease & Usage Agreement between BHP Diagnostics, Inc., Medicus Technologies, Inc., Integra, Ltd. and the Company dated as of May 1, 1994	(2) (Exh. 10.28)
10.8	Shared Facilities Usage Agreement Between BHP Diagnostics, Inc., Medicus Technologies, Inc. and Integra, Ltd. and the Company dated as of May 1, 1994	(2) (Exh. 10.29)
10.9	Lease between Plainsboro Associates and American Biomaterials Corporation dated as of April 16, 1985, as assigned to Colla-Tec, Inc. on October 24, 1989 and as amended through November 1, 1992	(2) (Exh. 10.30)
10.10	1992 Stock Option Plan *	(2) (Exh. 10.31)
10.11	1993 Incentive Stock Option and Non-Qualified Stock Option Plan *	(2) (Exh. 10.32)
10.12	Warrant Agreement between the Company and Boston Scientific Corporation dated as of December 29, 1993	(2) (Exh. 10.35)
10.13	Form of Indemnification Agreement between the Company and [ ] dated August 16, 1995, including a schedule identifying the individuals that are a party to such Indemnification Agreements	(4)
10.14	Employment Agreement dated December 27, 1997 between Integra LifeSciences Corporation and Stuart M. Essig*	(5) (Exh. 10.1)
10.15	Restricted Units Agreement dated December 27, 1997 by and between Integra LifeSciences Corporation and Stuart M. Essig*	(5) (Exh. 10.3)
10.16	Integra LifeSciences Corporation 1996 Incentive Stock Option and Non-Qualified Stock Option Plan (as amended through December 27, 1997)*	(5) (Exh. 10.4)
10.17	Indemnity letter agreement dated December 27, 1997 from Integra LifeSciences Corporation to Stuart M. Essig*	(5) (Exh. 10.5)
21	Subsidiaries of the Company	(1)
23	Consent of Independent Accountants	(1)
27	Financial Data Schedule	(1)

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

(1) Filed herewith.

(2) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form 10/A (File No. 0-26224) which became effective on August 8, 1995.

- (3) Incorporated by reference to the indicated exhibit to the Company's Report on Form 10-Q for the quarter ended June 30, 1995.
- (4) Incorporated by reference to the indicated exhibit to the Company's Registration Statement on Form S-1 (File No. 33-98698) which became effective on January 24, 1996.
- (5) Incorporated by reference to the indicated exhibit to the Company's Report on Form 8-K file with the Commission on February 3, 1998.

(b) Reports on Form 8-K

The Company did not file any reports on Form 8-K during the last quarter of the fiscal year covered by this report.

REPORT OF INDEPENDENT ACCOUNTANTS

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

We have audited the accompanying consolidated balance sheets of Integra LifeSciences Corporation and Subsidiaries as of December 31, 1997 and 1996, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 1997. 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 in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Integra LifeSciences Corporation and Subsidiaries as of December 31, 1997 and 1996, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1997 in conformity with generally accepted accounting principles.

/s/ Coopers & Lybrand, L.L.P.

Princeton, New Jersey  
February 27, 1998, except for the second paragraph of Note 19  
for which the date is March 12, 1998

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	December 31,	
In thousands	1997	1996
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents.....	\$ 2,083	\$ 11,762
Short-term investments.....	24,189	22,514
Accounts receivable, net of allowances of \$390 and \$228.....	2,780	2,902
Inventories.....	2,350	2,635
Prepaid expenses and other current assets.....	400	338
	-----	-----
Total current assets.....	31,802	40,151
Property and equipment, net.....	6,414	8,554
Other assets.....	140	36
	-----	-----
Total assets.....	\$ 38,356	\$ 48,741
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable, trade.....	\$ 541	\$ 162
Accrued expenses and other current liabilities.....	1,854	2,053
	-----	-----
Total current liabilities.....	2,395	2,215
Other liabilities.....	206	142
	-----	-----
Total liabilities.....	2,601	2,357
	-----	-----
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$.01 par value (15,000 authorized shares; no shares issued or outstanding).....	---	---
Common stock, \$.01 par value (60,000 authorized shares; 29,903 and 28,551 issued and outstanding at December 31, 1997 and 1996, respectively).....	299	285
Additional paid-in capital.....	111,728	105,447
Unearned compensation related to stock options.....	(266)	(328)
Notes receivable - related party.....	(35)	(35)
Unrealized loss on available-for-sale investments.....	(26)	(4)
Accumulated deficit.....	(75,945)	(58,981)
	-----	-----
Total stockholders' equity.....	35,755	46,384
	-----	-----
Total liabilities and stockholders' equity.....	\$ 38,356	\$ 48,741
	=====	=====

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

In thousands

Years Ended December 31,

	1997	1996	1995
	----	----	----
<b>REVENUE</b>			
Product sales.....	\$ 14,001	\$ 11,210	\$ 8,356
Research grants.....	485	1,072	1,064
Product license fees.....	14	500	520
Royalties.....	246	290	239
Contract product development.....	---	76	50
	-----	-----	-----
Total revenue.....	14,746	13,148	10,229
	=====	=====	=====
<b>COSTS AND EXPENSES</b>			
Cost of product sales.....	7,027	6,671	4,850
Research and development.....	6,406	6,294	5,191
Selling and marketing.....	5,460	4,310	2,455
General and administrative.....	14,764	5,320	3,642
Acquired in-process research and development.....	---	---	19,593
	-----	-----	-----
Total costs and expenses.....	33,657	22,595	35,731
Operating loss.....	(18,911)	(9,447)	(25,502)
Interest income.....	1,771	1,799	283
Interest expense - related party.....	---	---	(188)
Other income.....	176	120	5
	-----	-----	-----
Net loss.....	\$ (16,964)	\$ (7,528)	\$ (25,402)
	=====	=====	=====
Basic and diluted net loss per share.....	\$ (0.57)	\$ (0.27)	\$ (1.21)
	=====	=====	=====
Weighted average number of common and common equivalent shares outstanding....	29,620	28,114	21,073
	=====	=====	=====

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands

	Years Ended December 31,		
	1997	1996	1995
<b>OPERATING ACTIVITIES:</b>			
Net loss.....	\$ (16,964)	\$ (7,528)	\$ (25,402)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	1,903	2,059	1,394
(Gain) loss on sale of assets.....	(162)	(136)	(5)
Loss on sale of investments.....	---	26	---
Amortization of discount and interest on investments.....	(126)	(955)	(21)
Acquired in-process research and development.....	---	---	19,593
Common stock and restricted units issued.....	5,875	---	70
Amortization of unearned compensation.....	123	83	---
Provision for impairment of leasehold improvements.....	1,021	---	---
Deferred revenue.....	---	(10)	(350)
Changes in operating assets and liabilities:			
Accounts receivable.....	122	(1,134)	(176)
Inventories.....	285	(1,263)	(423)
Prepaid and other current assets.....	(62)	130	252
Non-current assets.....	(81)	159	10
Accounts payable, accrued expenses and other liabilities.....	187	602	(585)
	-----	-----	-----
Net cash used in operating activities.....	(7,879)	(7,967)	(5,643)
	-----	-----	-----
<b>INVESTING ACTIVITIES:</b>			
Proceeds from the sales/maturities of investments.....	35,500	21,138	---
Purchases of investments.....	(37,071)	(41,530)	(1,177)
Purchases of property and equipment.....	(770)	(1,172)	(2,925)
Proceeds from sale of assets and other.....	183	304	13
Cash acquired in business acquisitions.....	---	---	13,117
Payments of acquired bankruptcy claims and acquisition costs.....	---	(10)	(2,941)
	-----	-----	-----
Net cash (used in) provided by investing activities.....	(2,158)	(21,270)	6,087
	-----	-----	-----
<b>FINANCING ACTIVITIES:</b>			
Proceeds from sales of common stock.....	---	35,662	1,000
Proceeds from exercised stock options.....	358	785	71
Payments of long-term debt.....	---	(10)	(2,182)
Proceeds from long-term debt.....	---	---	1,938
Notes receivable - related parties.....	---	50	---
Other financing activities.....	---	---	(90)
	-----	-----	-----
Net cash provided by financing activities.....	358	36,487	737
	-----	-----	-----
Net (decrease) increase in cash and cash equivalents.....	(9,679)	7,250	1,181
Cash and cash equivalents at beginning of period.....	11,762	4,512	3,331
	-----	-----	-----
Cash and cash equivalents at end of period.....	\$ 2,083	\$ 11,762	\$ 4,512
	=====	=====	=====

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

In thousands

	Common Shares	Stock Amount	Additional Paid-In Capital	Notes Receivable Related Parties	Unearned Compensation Related to Stock Options	Unrealized (Loss) on Investments	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 1994.....	19,414	194	\$ 35,218	\$ (85)	---	---	\$(26,051)	\$ 9,276
Sale of common stock.....	116	1	999	---	---	---	---	1,000
Issuance of common stock for services rendered.....	8	---	70	---	---	---	---	70
Conversion of revolving credit line....	173	2	1,498	---	---	---	---	1,500
Business acquisition.....	3,574	36	30,877	---	---	---	---	30,913
Issuance of common stock under stock option plans.....	209	2	68	---	---	---	---	70
Net loss.....	---	---	---	---	---	---	(25,402)	(25,402)
Balance, December 31, 1995.....	23,494	235	68,730	(85)	---	---	(51,453)	17,427
Public offering of common stock.....	4,671	47	35,524	---	---	---	---	35,571
Issuance of common stock under stock option plans.....	386	3	782	---	---	---	---	785
Unearned compensation related to non-employee stock option.....	---	---	411	---	(411)	---	---	---
Amortization of unearned compensation..	---	---	---	---	83	---	---	83
Decrease in notes receivable.....	---	---	---	50	---	---	---	50
Unrealized loss on investments.....	---	---	---	---	---	(4)	---	(4)
Net loss.....	---	---	---	---	---	---	(7,528)	(7,528)
Balance, December 31, 1996.....	28,551	285	105,447	(35)	(328)	(4)	(58,981)	46,384
Issuance of common stock under stock option plans.....	1,352	14	345	---	---	---	---	359
Unearned compensation related to non-employee stock options.....	---	---	61	---	(61)	---	---	---
Amortization of unearned compensation..	---	---	---	---	123	---	---	123
Issuance of restricted units.....	---	---	5,875	---	---	---	---	5,875
Unrealized loss on investments.....	---	---	---	---	---	(22)	---	(22)
Net loss.....	---	---	---	---	---	---	(16,964)	(16,964)
Balance, December 31, 1997.....	29,903	\$ 299	\$ 111,728	\$ (35)	\$ (266)	\$ (26)	\$(75,945)	\$35,755

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS

Integra LifeSciences Corporation (the "Company") develops, manufactures and markets medical devices, implants and biomaterials primarily used in the treatment of burns and skin defects, spinal and cranial disorders, orthopedics, private label medical products, and other surgical applications. The Company seeks to be the world's leading company specializing in implantable medical and biopharmaceutical therapies to target and control cell behavior.

There are certain risks and uncertainties inherent in the Company's business. The Company has incurred net operating losses since inception and expects to continue to incur such losses unless and until product sales and collaborative arrangements generate sufficient revenue to fund continuing operations. There can be no assurance that the Company's research and development efforts will result in commercially successful products or that the Company will be granted regulatory approvals for its products. The Company's business is characterized by rapidly changing technology and intense competition. There is a risk that technological developments will render actual and proposed products or technologies of the Company non-competitive, uneconomical or obsolete. There are certain risks associated with the Company's product sales being comprised of a few significant products. In addition, the Company is subject to various other risks and uncertainties common within its industry which could have a material adverse effect on its business.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents are primarily composed of money market mutual funds, repurchase agreements and U.S. Government securities. The carrying values of these instruments reflect their approximate fair values.

Investments

The Company's current investment policy is to invest available cash balances in high quality debt securities with maturities not to exceed 18 months. Realized gains and losses are determined on the specific identification cost basis.

The accompanying notes are an integral part  
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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Liquidity

The Company completed a public offering in February 1996, resulting in net proceeds of \$35.6 million (see Note 8). The Company believes that current cash balances and funds available from existing revenue sources will be sufficient to finance the Company's anticipated operations for at least the next twelve months. The Company may in the future seek to issue equity securities or enter into other financing arrangements with strategic partners to raise funds in excess of its anticipated liquidity and capital requirements.

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.

Property and Equipment

Purchases of property and equipment are stated at cost. The Company provides for depreciation using the straight-line method over the estimated useful lives of the assets, which are estimated to be between 3 and 15 years. Leasehold improvements are amortized using the straight-line method over the minimum lease term or the life of the asset whichever is shorter. The cost of major additions and improvements is capitalized. Maintenance and repair costs that do not improve or extend the lives of the respective assets are charged to operations as incurred. When depreciable assets are retired or sold, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in operations.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the statement of operations in the period that includes the enactment date.

Research and Development

Research and development costs are expensed in the period in which they are incurred.

Revenue Recognition

The Company's product revenue is recognized at the time that products are shipped. Research grant revenue and contract product development revenue are recognized when the related expenses are incurred. Under the terms of current research grants, the Company is reimbursed for allowable direct and indirect research expenses. Product licensing fees are recognized when earned, which is when all related commitments have been satisfied. Royalty revenue is recognized when the Company's marketing and distribution partners sell royalty products.

The accompanying notes are an integral part  
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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents, short-term investments held at major financial institutions and accounts receivable. The Company's products are sold on an uncollateralized basis and on credit terms based upon a credit risk assessment of each customer. The Company's provisions for doubtful accounts receivable for the years ended December 31, 1997, 1996 and 1995 were \$318,000, \$205,000 and \$185,000, respectively. Amounts written off for the years ended December 31, 1997, 1996 and 1995 were \$156,000, \$231,000 and \$11,000, respectively.

Loss per Share

In February 1997, the Financial Accounting Standards Board issued SFAS 128, "Earnings per Share," which simplifies existing computational guidelines, revises disclosure requirements and increases the comparability of earnings per share data (EPS) on an international basis. Under SFAS 128, basic EPS excludes dilution and is computed by dividing net income by the weighted-average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then share in the earnings of the entity. The Company has not included options and warrants to purchase common stock at \$2.9375 to \$12.50 per share of 3,778,000, 3,516,000 and 4,041,000 for the years ended December 31, 1997, 1996 and 1995, respectively, in the diluted per share computation as the result is antidilutive. The Restricted Units issued by the Company (see Note 8) are included in the weighted average calculation because no further consideration is due related to the issuance of the underlying common shares.

Stock Based Compensation

Effective January 1, 1996, the Company adopted SFAS 123, "Accounting for Stock-Based Compensation". SFAS 123 encourages, but does not require, companies to recognize compensation expense for grants of stock, stock options, and other equity instruments to employees based on fair value accounting rules. SFAS 123 does require companies that choose not to adopt the fair value accounting rules

to disclose pro forma net income (loss) and earnings (loss) per share data under the new method. The Company has adopted the disclosure-only provisions of SFAS 123.

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Recent Accounting Pronouncements

In June 1997, the Financial Accounting Standards Board issued SFAS 130, "Reporting Comprehensive Income," which established standards for reporting comprehensive income and its components (revenues, expenses, gains and losses) in the financial statements. SFAS 131, "Disclosures about Segments of an Enterprise and Related Information," was also issued in June 1997 and replaces existing segment disclosure requirements and requires certain financial information regarding operating segments on the basis used internally by management to evaluate segment performance. These statements will affect disclosure and presentation in the financial statements but will have no impact on the Company's consolidated financial position, liquidity, cash flows or results of operations. The Company will adopt SFAS 130 and 131 in the first quarter of 1998 and year-end 1998, respectively.

Preparation of Financial Statements

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosures of contingent assets and liabilities, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Reclassifications

Certain 1996 and 1995 amounts have been reclassified to conform to the 1997 presentation.

3. INVESTMENTS

The Company's current investment balances are classified as available for sale and have maturities within one year. The Company held all securities until maturity (or call) during the twelve months ended December 31, 1997. For the twelve months ended December 31, 1996, securities were sold for proceeds of \$3,938,000 and a net loss of \$26,000. Investment balances as of December 31, 1997 and 1996 were as follows:

In thousands	Amortized Cost ----	Unrealized Gains -----	Unrealized Losses -----	Fair Value -----
1997:				
U.S. Government agency securities.....	\$ 24,215 =====	\$ --- =====	\$ (26) =====	\$ 24,189 =====
1996:				
U.S. Government securities.....	\$ 2,019	\$ ---	\$ (5)	\$ 2,014
U.S. Government agency securities.....	20,499 -----	13 -----	(12) -----	20,500 -----
Total investments.....	\$ 22,518 =====	\$ 13 =====	\$ (17) =====	\$ 22,514 =====

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

4. INVENTORIES

Inventories consist of the following:

In thousands	December 31,	
	1997	1996
Finished goods.....	\$ 773	\$ 1,007
Work-in-process.....	1,251	1,270
Raw materials.....	326	358
	\$ 2,350	\$ 2,635
	=====	=====

5. PROPERTY AND EQUIPMENT

Property and equipment, net, consists of the following:

In thousands	December 31,	
	1997	1996
Machinery and equipment.....	\$ 4,107	\$ 4,764
Furniture and fixtures.....	221	207
Leasehold improvements.....	6,550	7,270
	10,878	12,241
Less: Accumulated depreciation and amortization.....	(4,464)	(3,687)
	\$ 6,414	\$ 8,554

Depreciation and amortization expense for the years ended December 31, 1997, 1996 and 1995 was \$1,903,000 \$1,959,000 and \$1,295,000, respectively.

6. CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

In thousands	December 31,	
	1997	1996
Legal fees.....	\$ 471	\$ 661
Contract research.....	252	375
Accrued royalties.....	49	216
Customer advances.....	12	205
Vacation.....	214	174
Other.....	856	422
	\$ 1,854	\$ 2,053
	=====	=====

The accompanying notes are an integral part  
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7. LONG-TERM DEBT

Related Party

In connection with the Company's February 1996 public offering, the Company's \$3,500,000 revolving credit facility, as amended (the "Revolving Credit"), from a related party (the "Lender") expired. The Lender was a corporation whose shareholders are trusts whose beneficiaries include beneficiaries of a principal shareholder of the Company.

In June 1995, \$1,500,000 of the outstanding principal balance was converted into common stock of the Company at a price of \$8.65 per share and the amount committed under the Revolving Credit was reduced from \$5,000,000 to \$3,500,000.

Interest on the outstanding principal amount of the Revolving Credit was computed at twelve percent (12%) per annum. During the term of the Revolving Credit, amounts may have been borrowed, repaid and reborrowed. The outstanding principal and interest was paid to the Lender when the Revolving Credit expired in February 1996.

8. STOCKHOLDERS' EQUITY

Common Stock Transactions

On February 1, 1996, the Company completed the issuance of 4,671,250 shares of its common stock through a public offering, resulting in net proceeds of approximately \$35.6 million.

In April 1995, in a private placement transaction, the Company sold 115,607 shares of its common stock to Manor Care, Inc. at a price of \$8.65 per share for an aggregate of \$1,000,000.

Restricted Units

In December 1997, the Company issued 2,000,000 restricted units ("Restricted Units") as a fully vested equity based signing bonus to the Company's new President and Chief Executive Officer ("Executive"). Each Restricted Unit represents the right to receive one share of the Company's common stock. The shares of common stock underlying the restricted units ("Unit Shares") shall be delivered to Executive on January 1, 2002 if Executive is employed by the Company on December 31, 2001. If, prior to December 31, 2001, (a) Executive's employment with the Company is terminated for cause or (b) he voluntarily leaves his employment with the Company (other than for good reason or due to disability), the Unit Shares shall be distributed to Executive on January 1, 2018. In connection with the Restricted Units, the Company incurred a non-cash compensation charge of \$5,875,000 in the fourth quarter of 1997, which is included in general and administrative expenses.

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Warrants

Boston Scientific Warrant

In conjunction with a 1993 private placement of 695,894 shares of the Company's common stock to Boston Scientific Corporation ("BSC"), the Company sold for additional consideration and issued to BSC a warrant (the "BSC Warrant") to purchase 695,894 shares of the Company's common stock at an exercise price of \$7.185 per share. The BSC Warrant is exercisable through January 31, 2000.

Stockholders' Rights

As stockholders of the Company, Union Carbide Corporation and BSC are entitled to registration rights. Executive also has registration rights with respect to the Units Shares underlying the Restricted Units.

Notes Receivable - Related Parties

Notes receivable - related party at December 31, 1997 is a recourse note due from a former officer of the Company with a specified maturity date in October 1998. The note is collateralized by shares of the Company.

9. STOCK OPTIONS

As of December 31, 1997, the Company had three stock option plans, the 1992 Stock Option Plan (the "1992 Plan"), the 1993 Incentive Stock Option and Non-Qualified Stock Option Plan (the "1993 Plan") and the 1996 Incentive Stock Option and Non-Qualified Stock Option Plan (the "1996 Plan").

The Company has reserved 2,550,000 shares of common stock for issuance under the 1992 Plan. The 1992 Plan permits the Company to grant both incentive and non-qualified stock options to designated directors, officers, employees and associates of the Company. Options become exercisable over specified periods, generally 2% or less per month, and generally expire in five or ten years from the date of grant. The Company has reserved 1,500,000 shares of common stock for issuance under each of the 1993 and 1996 Plans. The 1993 and 1996 Plans permit the Company to grant both incentive and non-qualified stock options to designated directors, officers, employees and associates of the Company. Options issued under the 1993 and 1996 Plans become exercisable over specified periods, generally within five years from the date of grant.

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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
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In May 1997, the Company's Stock Option Committee and Board of Directors approved an option exchange program pursuant to which employees with options having an exercise price in excess of \$4.00 per share under the Company's Stock Option Plans could elect to exchange such options for new stock options with an exercise of \$4.00. Under the exchange program, (i) the number of replacement options issued in exchange for the original options was determined by the utilization of a formula based on the percentage decrease in exercise price from the original grant (not to exceed 25% of the original options and excluding the first 1,000 options), (ii) the replacement options expiration dates were adjusted to one year later than the original options expiration dates, and (iii) the vesting terms of the replacement options were adjusted to proportionately reflect the decrease in options, when applicable. Under the exchange program, 1,084,484 options with exercise prices ranging from \$4.25 to \$12.50 were exchanged for 891,623 options granted with an exercise price of \$4.00, which was in excess of the closing market price at the date of exchange.

The Company has adopted the disclosure-only provisions of SFAS 123, and accordingly no compensation cost has been recognized for the stock option plans except the amortization of unearned compensation related to options granted to outside consultants which amounted to \$123,000 and \$83,000 for the year ended December 31, 1997 and 1996, respectively. Had the compensation cost for the Company's stock option plans been determined based on the fair value at the grant date for awards in 1997, 1996 and 1995 consistent with the provisions of SFAS No. 123, the Company's net loss and basic and diluted net loss per share would have increased to the pro forma amounts indicated below:

In thousands, except per share data

	1997	1996	1995
	----	----	----
Net loss.....	\$ (16,964)	\$ (7,528)	\$ (25,402)
Proforma net loss.....	(17,777)	(8,259)	(25,722)
Basic and diluted net loss per share.....	\$ (0.57)	\$ (0.27)	\$ (1.21)
Proforma basic and diluted net loss per share.....	(0.60)	(0.29)	(1.22)

As options vest over a varying number of years, and awards are generally made each year, the proforma impacts shown here may not be representative of future proforma expense amounts. The proforma additional compensation expense was calculated based on the fair value of each option grant using the Black-Scholes model with the following weighted-average assumptions:

	1997	1996	1995
	----	----	----
Dividend yield.....	-0-	-0-	-0-
Expected volatility.....	80%	60%	60%
Risk free interest rate.....	6.2%	6.1%	6.2%
Expected option lives.....	3 years	3 years	3 years

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

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the three years ended December 31, 1997, option activity for all the plans was as follows:

Shares in thousands	Weighted-Average Exercise Price -----	Shares -----
December 31, 1994, Outstanding.....	\$ 2.64	2,827 =====
December 31, 1994, Exercisable.....	1.55	1,409 =====
Granted.....	8.59	980
Exercised.....	0.34	(209)
Canceled.....	7.48	(263)
		-----
December 31, 1995, Outstanding.....	4.16	3,335 =====
December 31, 1995, Exercisable.....	2.06	1,684 =====
Granted.....	9.77	209
Exercised.....	2.03	(386)
Canceled.....	8.38	(348)
		-----
December 31, 1996, Outstanding.....	4.34	2,810 =====
December 31, 1996, Exercisable.....	2.82	1,900 =====
Granted.....	3.55	2,986
Exercised.....	0.26	(1,352)
Canceled.....	7.76	(1,362)
		-----
December 31, 1997, Outstanding.....	3.84	3,082 =====
December 31, 1997, Exercisable.....	4.68	787 =====
December 31, 1997, Available for Grant.....		521 =====

All options granted under the Plans were at the common stock's fair market value or greater at the dates of grant. The weighted average exercise price and fair market value of options granted in 1997, 1996 and 1995 were as follows:

	In Excess of Market Price -----		Equal to Market Price -----	
	Exercise Price -----	Fair Value -----	Exercise Price -----	Fair Value -----
Year-ended 1997	\$ 4.04	\$ 1.93	\$ 3.22	\$ 2.13
Year-ended 1996	8.55	3.24	10.68	4.52
Year-ended 1995	8.65	3.30	8.57	3.90

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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes information about the outstanding and exercisable stock options at December 31, 1997:

Options in thousands	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number as of 12/31/97	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number as of 12/31/97	Weighted- Average Exercise Price
\$2.9375 - \$3.9375	1,421	8.5 years	\$ 2.98	23	\$ 3.23
\$4.00 to \$5.25	1,481	3.9 years	4.02	651	4.00
\$6.53 to \$11.50	180	2.5 years	9.20	113	8.84
	----- 3,082 =====			----- 787 ===	

10. LEASES

The Company leases all of its facilities through noncancelable operating lease agreements. In November 1992, a corporation whose shareholders are trusts whose beneficiaries include beneficiaries of a principal shareholder of the Company, acquired from independent third parties a 50% interest in the general partnership from which the Company leases its approximately 35,000 square foot administrative, manufacturing, research and principal warehouse facility in Plainsboro, New Jersey.

The lease provides for rent escalations of 13.3%, 10.1% and 8.5% in the years 1997, 2002 and 2007, respectively, and expires in October 2012. The total amount of the minimum lease payments related to the New Jersey facility is being charged to expense on the straight-line method over the term of the lease. In 1995, the Company completed constructing, as a leasehold improvement, a 10,000 square foot addition to the building.

In 1994, the Company leased and otherwise obtained the use of a four building, approximately 25,000 square foot medical facility in West Chester, Pennsylvania. The facilities were acquired in April 1994 by a related party of a principal shareholder of the Company and are leased and otherwise made available for use to the Company as of May 1, 1994. The lease agreement provides that the Company is obligated to pay monthly non-escalating fixed amounts for the facility for a period of five years, with three five-year options to extend the lease. The intent of the lease agreement is to make available to the Company additional freeze drying facilities and other production assets as well as warehouse and administrative space.

In January 1998, the Company decided to suspend its operations at its West Chester, Pennsylvania facility. Under SFAS 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of", the Company is required to review its long-lived assets and certain identifiable intangibles (collectively, "Long-Lived Assets") for impairment whenever events or changes in circumstances indicate that the future cash flows do not recover the carrying value of the Long-Lived Assets. The Company incurred an asset impairment charge of \$1,021,000 in the fourth quarter of 1997, included in general and administrative expense, related to certain leasehold improvements made at the West Chester facility. The Company believes the future cash flows generated by this facility will not support the carrying value of the leasehold improvements.

The accompanying notes are an integral part  
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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
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In 1996, the Company leased 7,400 square feet of administrative and laboratory space in San Diego, California under a five-year lease agreement that provides for monthly payments with annual escalations. In 1997, the Company leased an additional 11,200 square feet of space at the San Diego site to increase its laboratory and administrative operations.

The Company is required to pay for utilities, taxes, insurance and maintenance at its principal leased facilities. The Company also leases facilities additional space for administrative support activities and storage under short-term agreements in New Jersey, California and Pennsylvania. Future minimum lease payments under operating leases at December 31, 1997 were as follows:

In thousands	Related Parties	Third Parties	Total
	-----	-----	-----
1998	\$ 390	\$ 387	\$ 777
1999	270	442	712
2000	210	453	663
2001	210	469	679
2002	213	479	692
Thereafter	2,430	887	3,317
	-----	-----	-----
Total minimum lease Payments	\$ 3,723	\$ 3,117	\$ 6,840
	=====	=====	=====

Total rental expense for the years ended December 31, 1997, 1996 and 1995 was \$640,000, \$654,000 and \$468,000, respectively, and included \$390,000, \$390,000 and \$210,000 in related party expense for the years ended December 31, 1997, 1996 and 1995, respectively.

11. INCOME TAXES

The temporary differences which give rise to deferred tax assets and (liabilities) are presented below:

In thousands	December 31,	
	----- 1997	----- 1996
	-----	-----
Net operating loss and tax credit carryforwards	\$ 31,974	\$ 26,371
Inventory reserves and capitalization	1,402	1,051
Other	3,406	1,335
Depreciation	682	196
	-----	-----
Total deferred tax assets before valuation allowance	37,464	28,953
Valuation allowance	(37,464)	(28,953)
	-----	-----
Net deferred tax assets	----	----
Depreciation	----	----
Total deferred tax liabilities	----	----
	-----	-----
Net deferred tax asset	\$ ----	\$ ----
	=====	=====

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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
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The Company's valuation allowance of \$37.5 million was provided against the deferred tax assets due to the uncertainty of realization.

A reconciliation of the United States federal statutory rate to the Company's effective tax rate for the years ended December 31, 1997, 1996 and 1995 is as follows:

	1997	1996	1995
Federal statutory rate	(34.0%)	(34.0%)	(34.0%)
Expenses not deductible for tax purposes:			
Acquired in-process research and Development	--	--	26.3%
Other	1.4%	1.3%	(1.3%)
Increase in valuation allowance for deferred tax assets and net operating losses not recognized	32.6%	32.7%	9.0%
	---	---	---
Effective tax rate	-----	-----	-----

At December 31, 1997, the Company had net operating loss carryforwards of approximately \$36 million and \$28 million for federal and state income tax

purposes, respectively, to offset future taxable income, if any, which expire through 2012 and 2004, respectively.

At December 31, 1997, several of the Company's subsidiaries have unused net operating loss and tax credit carryforwards arising from periods prior to the Company's ownership. The net operating loss carryforwards (excluding Telios) of approximately \$10 million for federal income tax purposes expire between 2000 and 2005. The Company's Telios subsidiary has generated approximately \$84 million of net operating losses, which expire between 2002 and 2010. The amount of Telios' net operating losses that are available and the Company's ability to utilize such losses is dependent on the determined value of Telios at the date of acquisition. The timing and manner in which these net operating losses may be utilized in any year by the Company are severely limited by Section 382 and other provisions of the Internal Revenue Code of 1986, as amended, and its applicable regulations.

12. BUSINESS ACQUISITIONS

Telios Pharmaceuticals, Inc.

On April 11, 1995, the Company entered into an acquisition agreement with Telios Pharmaceuticals, Inc. ("Telios") setting forth the terms and conditions under which the Company would acquire all of the outstanding equity securities of Telios. On July 21, 1995, the United States Bankruptcy Court for the Southern District of California (the "Bankruptcy Court") confirmed the Combined Disclosure Statement and Plan of Reorganization (the "Plan") proposed by Telios and the Company. Effective August 15, 1995, the Company acquired Telios by issuing 3,573,743 shares of the Company's common stock valued at \$30,913,000, or \$8.65 per share. The Company's shares and certain cash disbursements were made in conjunction with the confirmation of the Plan under US bankruptcy laws and pursuant to Section 1145 of the Bankruptcy Code.

The accompanying notes are an integral part  
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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
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The acquisition was accounted for by the purchase method of accounting and, accordingly, the purchase price and the expenses associated with the acquisition were allocated to the assets acquired and the liabilities assumed at the date of acquisition as follows:

In thousands:

Cash and cash equivalents.....	\$ 13,117
Accounts receivable.....	75
Prepaid expenses.....	344
Fixed assets.....	1,310
Other assets.....	9
In-process research and development.....	19,592
Accounts payable and accrued liabilities.....	(576)
Bankruptcy claims.....	(2,717)
	-----
	\$ 31,154

The acquired in-process research and development had no alternative use and was charged to expense at the date of acquisition. The bankruptcy claim liabilities include pre-petition and post-petition claims, which have been satisfied in cash after the acquisition date.

13. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) Profit Sharing Plan and Trust ("401(k) Plan") for eligible employees and their beneficiaries. All employees are eligible to participate in the plan once they become full-time employees and attain the age of 21. The 401(k) Plan provides for employee contributions through a salary reduction election. Employer discretionary matching and discretionary profit sharing contributions, which are determined annually by the Company, vest over a six-year period of service. For the years ended December 31, 1997, 1996 and 1995, the Company's discretionary matching was based on a percentage of salary reduction elections per eligible participant, and totaled \$35,000, \$33,000 and \$21,000, respectively. No discretionary profit sharing contribution was made in any year.

14. ROYALTIES, LICENSE AND DEVELOPMENT AGREEMENTS

MIT Patents

In 1991, Marion Merrell Dow, Inc. ("MMDI"), assigned to the Company its interest in certain license agreements between MMDI and MIT (the "MMDI Agreement") which gave MMDI exclusive access to patent rights for use in the field of regenerative medicine. MMDI also granted to the Company a worldwide exclusive license to utilize certain technology necessary to continue the development and commercialization of the patent rights that are the subject of the MMDI Agreement. The first product that the Company has commercialized under the MMDI Agreement is the INTEGRA(TM) Artificial Skin product. As consideration for the rights and license granted to the Company, the Company has agreed to pay to MMDI royalties equal to a percentage of the net sales of any products subject to the MMDI Agreement.

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INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES  
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As a result of the 1993 acquisition of substantially all of the assets of Biomat Corporation, the Company acquired rights to certain other MIT technology for use in fields related to regenerative medicine (the "Biomat License Agreement"). In December 1993, the Company entered into a license agreement with MIT (the "Integra License Agreement") in which (i) the Company and MIT agreed to amend and restate the MMDI Agreement and the Biomat License Agreement, (ii) MIT granted the Company an exclusive license to additional patent rights with broad use in the field of regenerative medicine, and (iii) MIT modified the consideration payable by the Company to MIT for access to all MIT technology subject to such license. The Integra License Agreement provides for payments to MIT in the form of a common stock warrant and royalties on product sales. For the year ended December 31, 1997 and 1996, the Company accrued royalties based on the sales of INTEGRA(TM) Artificial Skin of approximately \$6.0 million and \$3.1 million, respectively.

Rutgers University Agreements

In 1993, the Company acquired an option to license from Rutgers University ("Rutgers") patents describing a certain class of biodegradable polymers for medical applications. As consideration for the option, the Company paid Rutgers an option fee, which has been expensed, and agreed to fund a limited one-year research program at Rutgers to evaluate the technology.

In 1993, the Company applied for, and was awarded by the United States Department of Commerce, a three-year, \$2 million grant to fund the development of this technology. In December 1994, the Company exercised its option and entered into a license agreement with Rutgers which granted to the Company certain exclusive proprietary rights for development and provides for the Company to pay to Rutgers a percentage royalty on the sale of all products commercialized under the license agreement. As of December 31, 1997, the Company has not commercialized products under such agreements that would be subject to royalties.

In October 1997, the Company was notified that its application for an award from the United States Department of Commerce to fund additional work on a related class of biodegradable was awarded. This award is a three-year, \$2 million grant scheduled to begin in April 1998.

The Burnham Institute

The Company has an agreement with The Burnham Institute ("Burnham"), formerly the La Jolla Cancer Research Foundation, which grants it an exclusive license to Burnham's adhesion peptide technology and a right of first refusal to obtain a license on other technology. The term of the license agreement is for the life of the related patent rights. Any patent applications, issued patents or improvements related to Burnham's technology, but made by the Company, belong to and are owned by Burnham and are exclusively licensed to the Company. The licensing agreement includes a commitment to pay Burnham 20% of all option and license fees and milestone payments paid by sublicensees up to an aggregate of \$1 million per year. In addition, a royalty based on net sales of product containing licensed technology is payable to Burnham. As of December 31, 1997, the Company has not commercialized products that would be subject to royalties.

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Brigham and Women's Hospital, Inc.

In 1995, the Company acquired the rights to develop, manufacture and sell products resulting from cultured epithelial autograft methods patented by the Brigham and Women's Hospital, Inc., for which the Company funds a limited research effort and will pay a royalty on the sales of any products that may be commercialized from the use of these technologies. The Company plans to continue funding research efforts on this technology.

CONRAD

The Company is continuing its collaboration with the Eastern Virginia Medical School to further develop polymer based materials for use in reproductive health applications under the Contraceptive Research and Development (CONRAD) program. Under the collaboration, CONRAD provides the Company with grant funding to cover a portion of the expenditures under the program. The Company has the right to negotiate distribution agreements for any products developed through this collaboration.

Cambridge Antibody Technology Limited

In January 1996, the Company and Cambridge Antibody Technology Limited ("CAT") entered into an agreement consisting of a license to CAT of certain rights to use anti-TGF-(beta) antibodies for the treatment of fibrotic diseases and the granting of a right of first refusal to CAT for certain rights relating to decorin, a molecule believed to mediate the production of TGF-(beta) in humans and animals. Under the agreement, the Company received a \$500,000 licensing fee and is entitled to market any dermal application products developed with royalties payable to CAT. The Company will also receive royalties upon the sale by CAT of licensed products other than those directed at dermal applications.

Genetics Institute, Inc. and Sofamor/Danek Group, Inc.

The Company supplies GI with a collagen delivery matrix that is used in conjunction with GI's recombinant human bone morphogenic protein-2 (rhBMP-2) to stimulate bone regeneration. Human clinical trials conducted by GI have shown the safety and biological activity of the product and GI has initiated additional larger trials. Sofamor/Danek Group, Inc. ("SDG"), GI and the Company are jointly developing specialized delivery matrices for the release of rhBMP-2 in the spine. These matrices can be used alone or in conjunction with SDG spinal cages. Human trials have begun and these matrices can be used alone or in

conjunction with SDG's spinal cages. The Company has an exclusive supply agreement with GI to provide commercial quantities of the collagen delivery matrix, should GI successfully commercialize its products.

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Johnson & Johnson Professional, Inc.

In February 1998, the Company announced the signing of a strategic alliance with J&J Professional, Inc. to develop and market a new product to regenerate articular cartilage. The Company will develop an absorbable, collagen-based implant designed in combination with a proprietary RGD peptide. J&J Professional, Inc. will develop the arthroscopic instrumentation used in the surgery and will market the combined products worldwide. Under the terms of the agreement, J&J Professional, Inc. will make payments up to \$13 million as the Company meets various milestones, and will fund all necessary development costs beyond the pre-clinical phase. Following successful development, the Company will be responsible for manufacturing the product and for future new product development.

Other Royalty, License and Development Agreements

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

15. LEGAL MATTERS

In January 1994, ABS LifeSciences, Inc., a wholly-owned subsidiary of the Company, entered into a five-year distribution agreement with the distributor of the Company's Chronicure product pursuant to which the distributor is obligated to purchase certain minimum quantities of wound care products. In October 1995, the Company's subsidiary filed a complaint in the United States District Court for the District of New Jersey claiming the distributor breached the distribution agreement by, among other things, not paying the subsidiary for certain products delivered. In November 1995, the distributor filed an affirmative defense and counterclaim alleging, among other things, fraudulent misrepresentation and breach of contract and seeking damages of approximately \$1.2 million plus unspecified punitive damages. During 1997, the case was inactive and dismissed by the court based on a tentative settlement with leave to reinstate on the request of either party. However, the Company has not been able to consummate an acceptable settlement and has submitted a request to

reinstate the case. The Company intends to continue to defend the counterclaim.

On or about July 18, 1996, Telios filed a patent infringement lawsuit against three parties: Merck KGaA, a German corporation, Scripps Research Institute, a California nonprofit corporation, and David A. Cheresh, Ph.D., a research scientist with Scripps. The lawsuit was filed in the U.S. District Court for the Southern District of California. The complaint charges, among other things, that the defendant Merck KGaA "willfully and deliberately induced, and continues to willfully and deliberately induce, defendants Scripps Research Institute and Dr. David A. Cheresh to infringe United States Letters Patent No. 4,729,255." This patent is one of a group of five patents granted to Burnham and licensed by Telios that are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid (known as "RGD") peptide sequence found in many extracellular matrix proteins. The Company is pursuing numerous medical applications of the RGD technology in the fields of anti-thrombic agents, cancer,

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osteoporosis, and a cell adhesive coating designed to improve the performance of implantable devices and their acceptance by the body. The defendants have filed a countersuit asking for an award of defendants' reasonable attorney fees.

In August 1995, Telios received confirmation of its Chapter 11 plan of reorganization in the United States Bankruptcy Court for the Southern District of California. Under the plan, Telios assumed a certain License Agreement and a certain Research Agreement entered into with the University of Utah and the University of Utah Research Foundation ("University") in 1991. On March 27, 1996, Telios filed a motion with the bankruptcy court for a determination as to whether there were any "cure" requirements for the assumed contracts with the University (the "Motion"). In the meantime, on March 22, 1996, the University filed a complaint against Telios in the United States District Court for the District of Utah seeking a declaration that the License Agreement and Research Agreement were terminated or terminable. The District Court case was subsequently dismissed in light of the pending Motion in the bankruptcy court. In November 1997, the bankruptcy court entered an order decreeing that Telios' license to certain of the patents and technology rights under the License Agreement had been reduced to a non-exclusive license. However, the court did not terminate the license. In addition, Telios still retains an exclusive license to certain patents, technology and rights to make, use and sell licensed products thereunder, which have been exclusively sublicensed by Telios to Cambridge Antibody Technology, Limited. A hearing has been set for May 27, 1998 to determine whether Telios has licensing rights to a certain new invention disclosed by the University under the License Agreement and/or the Research Agreement.

On or about November 4, 1997, Integra (Artificial Skin) Corporation ("IASC"), a wholly-owned subsidiary of the Company, and the Massachusetts Institute of Technology ("MIT") filed a patent infringement lawsuit against LifeCell

Corporation ("LifeCell") alleging that LifeCell infringed United States Patent Nos. 4,458,678 and 4,505,266 through the making, using and selling of its AlloDerm(R) and/or XenoDerm(TM) products. The suit was filed in the United States District Court for the District of Massachusetts. The patents in suit are licensed by MIT to IASC and relate to treating wounds with products which encourage tissue regeneration. LifeCell has filed counterclaims seeking declaratory judgments of non-infringement and patent invalidity and also claims that MIT and IASC are barred from recovery under the doctrines of laches, patent misuse and unclean hands alleging, among other things, that MIT and IASC filed this suit solely to disrupt LifeCell's November 1997 stock offering. LifeCell has filed a motion to transfer this action to the United States District Court for the Southern District of Texas which motion MIT and IASC are opposing. The Company intends to vigorously pursue its claims and vigorously defend against LifeCell's counterclaims and affirmative defenses.

On or about December 10, 1997, LifeCell filed a complaint against MIT and IASC in Texas state court claiming tortious interference, business and product disparagement, unfair competition, civil conspiracy and violation of the Texas Free Enterprise and Antitrust Act based upon the contention that MIT and IASC filed the patent infringement suit in Massachusetts in order to interfere with LifeCell's November 1997 stock offering. LifeCell is seeking unspecified actual monetary damages in an amount not less than \$12 million together with treble damages, unspecified punitive damages, and other relief. MIT and IASC removed this case to the United

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States District Court for the Southern District of Texas and have filed a motion to transfer it to United States District Court in Massachusetts. LifeCell filed a motion to remand the case back to Texas state court which motion MIT and IASC are opposing. MIT and IASC have also filed motions to dismiss the case for lack of personal jurisdiction and to stay discovery. The Company also intends to vigorously defend against this suit.

The ultimate liability of the cases disclosed above cannot now be determined because of the considerable uncertainties that exist. The Company's financial statements do not reflect any significant amounts related to possible unfavorable outcomes of these matters. The Company intends to continue its vigorous defense of these matters. However, it is possible that the Company's results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies.

16. CONSULTING AND EMPLOYMENT AGREEMENTS

The Company has several consulting agreements with research and other professional specialists. The Company's agreements with its consultants require payments through March 2005 in the aggregate amount of \$1.1 million.

A member of the Company's board of directors is a partner of a law firm which provides services to the Company. Amounts paid by the Company for services rendered were \$72,000, \$346,000 and \$581,000 for the years ended December 31, 1997, 1996 and 1995, respectively.

At December 31, 1997, the Company had employment agreements with five employees that expire at specified dates through 2001 and require the Company to make total aggregate minimum payments in the amount of \$2.5 million.

17. MAJOR CUSTOMER DATA

A portion of the Company's products are sold to customers under the terms of multiple-year marketing and distribution agreements that provide for purchase and supply commitments on the part of the customer and the Company, respectively. In many cases marketing customers have paid license fees to the Company for the marketing and distribution rights. The following table represents customers that accounted for over 10% of product sales in one or more years:

Customer	1997	1996	1995
-----	----	----	----
Customer A	13%	15%	21%
Customer B	--	15%	--
Customer C	11%	12%	12%
Customer D	--	--	12%
Customer E	--	--	11%
	-----	-----	-----
	24%	42%	56%

For the years ended December 31, 1997, 1996 and 1995, the Company's foreign export sales, primarily to Europe and Japan, were 14%, 16% and 11% of total product sales, respectively.

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The Company's product sales consists of several products that make up a large percentage of the total, including the Company's Integra Artificial Skin product which accounted for 43% of product sales for the period ended December 31, 1997.

18. SUPPLEMENTAL CASH FLOW INFORMATION

Included in other current liabilities at December 31, 1997 is \$57,000 related to fixed asset additions and leasehold improvements that were paid after year-end.

Cash paid for interest expense was \$188,000 for the year ended December 31, 1995. There was no cash paid for income taxes during the periods presented.

In connection with the August 1995 acquisition of Telios, the Company issued 3,573,743 shares of its common stock with an aggregate value of \$30,913,000 (see Note 12).

In 1995, the Company and the Lender (see Note 7) agreed to convert \$1,500,000 of the Revolving Credit to common stock at a price of \$8.65 per share.

Common stock of the Company valued at \$70,000 was issued to two investment banks for advisory services rendered during 1995.

19. Subsequent Events

Stock Repurchase Program

In February 1998, the Company's Board of Directors authorized a common stock repurchase program of up to 500,000 shares, effective immediately. The share repurchase plan allows the Company to make repurchases from time to time during 1998 in the open market or through privately negotiated transactions. Repurchased common shares will be added to the Company's treasury shares. The timing of any share repurchase will be dictated by overall financial and market conditions and other corporate considerations.

Century Medical, Inc.

On March 12, 1998, the Company entered into a series of agreements with Century Medical, Inc. ("CMI"), a wholly-owned subsidiary of ITOCHU Corporation, under which CMI will distribute the Company's neuro-surgery products in Japan. Under the agreements, CMI will pay an up-front non-refundable licensing fee of \$1.0 million in the first quarter of 1998 and purchase 500,000 shares of newly issued preferred stock of the Company for \$4.0 million in the second quarter of 1998. CMI will also underwrite all costs of the Japanese clinical trials and regulatory approval processes.

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

SIGNATURES

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

INTEGRA LIFESCIENCES CORPORATION

By: /s/ Stuart M. Essig, Ph.D.

-----  
Stuart M. Essig, Ph.D.  
President

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons, in the capacities indicated, on the 30th day of March, 1998.

Signature -----	Title -----
/s/ Richard E. Caruso ----- Richard E. Caruso, Ph.D.	Chairman of the Board
/s/ Stuart M. Essig ----- Stuart M. Essig, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ George W. McKinney ----- George W. McKinney, III, Ph.D.	Vice Chairman, Chief Operating Officer and Director
/s/ David B. Holtz ----- David B. Holtz	Vice President, Treasurer (Principal Financial and Accounting Officer)
/s/ Keith Bradley ----- Keith Bradley, Ph.D.	Director
/s/ William M. Goldstein ----- William M. Goldstein, Esq.	Director
/s/ Frederic V. Malek ----- Frederic V. Malek	Director
/s/ James M. Sullivan ----- James M. Sullivan	Director
/s/ Edmund L. Zalinski ----- Edmund L. Zalinski, Ph.D.	Director

Subsidiaries of Integra LifeSciences Corporation

Name of Subsidiary -----	State of Incorporation -----
1. ABS LifeSciences, Inc.	Delaware
2. Advanced Reproductive Health Corporation	Delaware
3. Applied Regenerative Technologies, Inc.	Delaware
4. Colla-Tec, Inc.	Delaware
5. Integra (Artificial Skin) Corporation	Delaware
6. Integra LifeSciences Surgical Products Corporation	Delaware
7. Integra LifeSciences I, Ltd.	Delaware
8. Intellectual Properties and Asset Corporation	Delaware
9. LifeSciences Corporate Holdings Corporation	Delaware
10. LifeSciences Services Corporation	Delaware
11. Medicol Sciences, spol. s.r.o.	Czech Republic
12. Medicus Technologies, Inc.	Delaware
13. Telios Pharmaceuticals, Inc.	Delaware
14. Vitaphore Corporation	Delaware

CONSENT OF INDEPENDENT AUDITORS

We consent to the incorporation by reference in the registration statement of Integra LifeSciences Corporation and Subsidiaries on Form S-8 (File No. 333-06577) of our report dated February 27, 1998, except for the second paragraph of Note 19, for which the date is March 12, 1998, on our audits of the consolidated financial statements of Integra LifeSciences Corporation and Subsidiaries as of December 31, 1997 and 1996, and for each of the three years in the period ended December 31, 1997, which report is included in the Corporation's 1997 Annual Report on Form 10-K.

/s/ Coopers & Lybrand, L.L.P.

Princeton, New Jersey  
March 30, 1998

YEAR  
DEC-31-1997  
JAN-01-1997  
DEC-31-1997

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	24,189	
	2,780	
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	2,350	
31,802		10,878
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	38,356	
2,395		0
0		0
		299
	35,456	
38,356		
	14,001	
	14,746	
		7,027
	7,027	
	0	
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	(16,964)	
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	(16,964)	
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	(.57)	