# INTEGRA LIFESCIENCES

## ANNUAL REPORT 1996

# ENVISIONING . . . . .



# THEN CREATING

# REGENERATIVE MEDICINE

# INTEGRA LIFESCIENCES OVERVIEW

## VISION

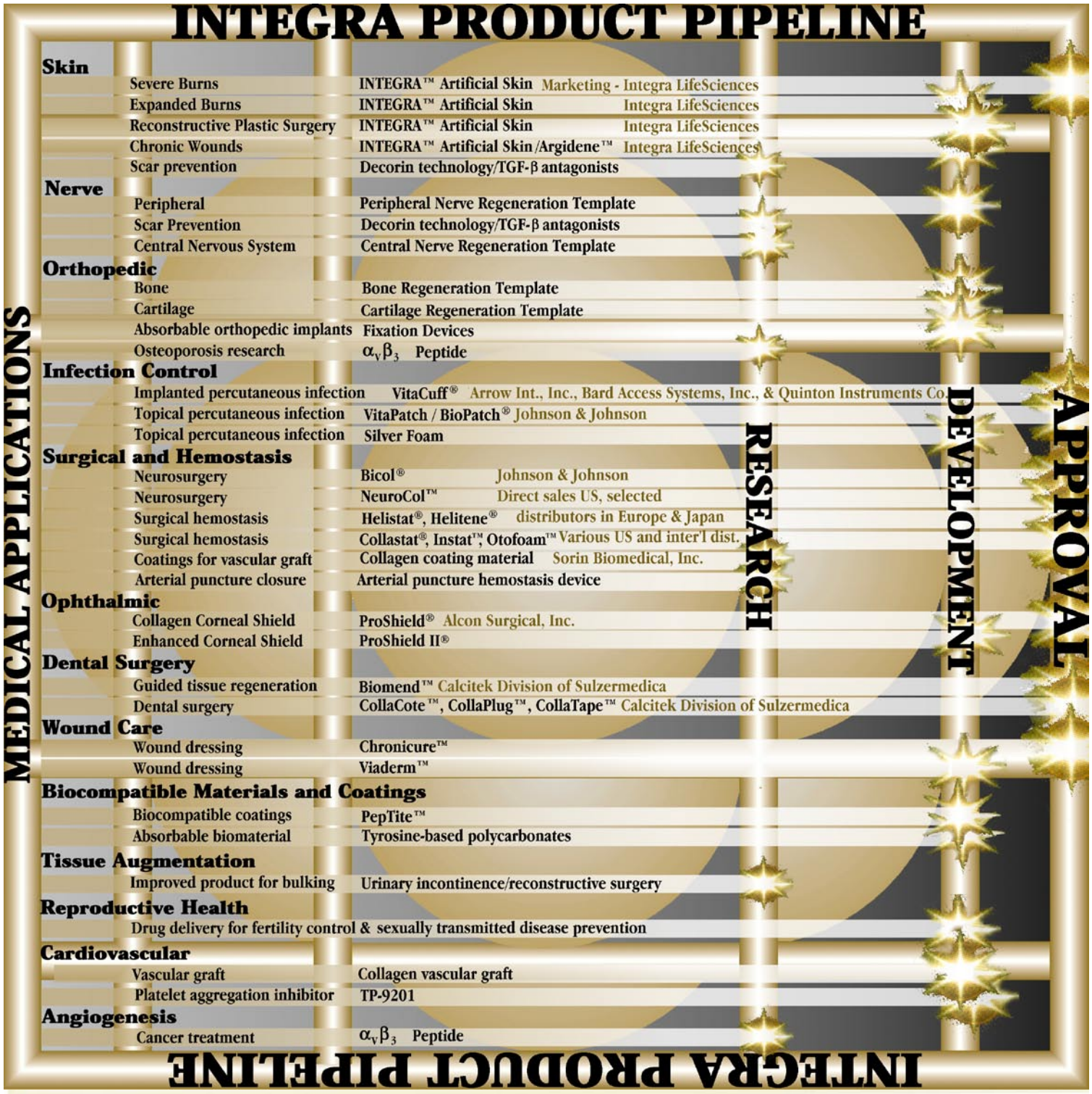
To establish Integra LifeSciences Corporation as the industry leader in meeting the demand for a wide range of implantable, absorbable tissue regeneration and other pharmacological products that target and control cell behavior within the patient's body.

## MISSION

Integra LifeSciences Corporation is dedicated to the acquisition, discovery and development of synergistic technologies for creating and marketing cost-effective, off-the-shelf, biosmart™, absorbable products designed to target and control cell behavior. Clinically, these products are implanted to regenerate specific body tissues and organs, or to cure or prevent a variety of diseases and age-associated conditions.

## 1996 ACCOMPLISHMENTS

- Achieved record sales and revenues.
- Received marketing approval from the United States Food and Drug Administration for INTEGRA™ Artificial Skin Dermal Regeneration Template™ for replacing severely burned skin.
- Named one of the year's "most notable breakthrough devices" approved for marketing by the FDA in 1996.
- Became the first company to reach the market with a commercially manufactured, cost-effective permanent regenerative skin replacement system for severe burns.
- Completed a $35 million public offering to support marketing efforts, clinical and preclinical studies, research and development programs to enhance our expanding product pipeline.
- Successfully completed worldwide training of over 600 surgeons in the use of INTEGRA™ Artificial Skin.
- Established ongoing exploration of expanded uses for INTEGRA™ Artificial Skin in plastic and reconstructive surgery, chronic wounds, and less severe burns.
- Successfully applied tissue regeneration technologies to cartilage, nerve and cardiovascular graft development programs.
- Launched commercial scale manufacturing of the Company's FDA inspected state-of-the-art tissue regeneration manufacturing facility.
- Became the first company to commercially produce and ship a high quality, cost-effective, off-the-shelf tissue regeneration product.
- Established a unique position by creating a type of basic operating system solution for technology development and products designed to target and control cell behavior for a broad range of desired medical results.
- Established a strategic patent portfolio containing more than 200 patents and nearly another 300 pending patent applications which protect our platform technologies, products and processes.
- Confirmed our business and technology strategy of bringing together proprietary synergistic technologies for targeted development
- Initiated enforcement of our strategic patent portfolio and proprietary rights with a pro-active corporate legal protection policy.
- Ended the year in a strong financial position with $34.3 million in cash equivalent and short-term cash balances.


INTEGRA PRODUCT PIPELINE
MEDICAL APPLICATIONS
RESEARCH
DEVELOPMENT
APPROVAL
Skin
Severe Burns
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Expanded Burns
INTEGRA™ Artificial Skin Integra LifeSciences
Reconstructive Plastic Surgery
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Chronic Wounds
INTEGRA™ Artificial Skin /Argidene™ Integra LifeSciences
Scar prevention
Decorin technology/TGF-β antagonists
Nerve
Peripheral
Peripheral Nerve Regeneration Template
Scar Prevention
Decorin technology/TGF-β antagonists
Central Nervous System
Central Nerve Regeneration Template
Orthopedic
Bone
Bone Regeneration Template
Cartilage
Cartilage Regeneration Template
Absorbable orthopedic implants
Fixation Devices
Osteoporosis research
$\alpha_v\beta_3$ Peptide
Infection Control
Implanted percutaneous infection
VitaCuff® Arrow Int., Inc., Bard Access Systems, Inc., & Quinton Instruments Co
Topical percutaneous infection
VitaPatch / BioPatch® Johnson & Johnson
Topical percutaneous infection
Silver Foam
Surgical and Hemostasis
Neurosurgery
Bicol® Johnson & Johnson
Neurosurgery
NeuroCol™ Direct sales US, selected
Surgical hemostasis
Helistat®, Helitene® distributors in Europe & Japan
Surgical hemostasis
Collastat®, Instat™, Otofoam™ Various US and inter'l dist.
Coatings for vascular graft
Collagen coating material Sorin Biomedical, Inc.
Arterial puncture closure
Arterial puncture hemostasis device
Ophthalmic
Collagen Corneal Shield
ProShield® Alcon Surgical, Inc.
Enhanced Corneal Shield
ProShield II®
Dental Surgery
Guided tissue regeneration
Biomend™ Calcitek Division of Sulzermedica
Dental surgery
CollaCote™, CollaPlug™, CollaTape™ Calcitek Division of Sulzermedica
Wound Care
Wound dressing
Chronicure™
Wound dressing
Viaderm™
Biocompatible Materials and Coatings
Biocompatible coatings
PepTite™
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Tyrosine-based polycarbonates
Tissue Augmentation
Improved product for bulking
Urinary incontinence/reconstructive surgery
Reproductive Health
Drug delivery for fertility control & sexually transmitted disease prevention
Cardiovascular
Vascular graft
Collagen vascular graft
Platelet aggregation inhibitor
TP-9201
Angiogenesis
Cancer treatment
$\alpha_v\beta_3$ Peptide
INTEGRA PRODUCT PIPELINE

# To Our Shareholders

I'm pleased to report that 1996 has been a record year of accomplishment and productivity. The FDA marketing approval, commercial manufacturing scale up, market introduction and clinical performance of **INTEGRA™ Artificial Skin Dermal Regeneration Template™**, has validated the Company's business and technology strategy that we developed and implemented over the past seven years. We are now well-positioned to take advantage of the growing need for safe, cost-effective, and clinically efficacious products designed to control the behavior of targeted cells within the patient's body, including additional tissue regeneration products for the practice of Regenerative Medicine.

## FDA Approval

In March 1996, **INTEGRA™ Artificial Skin** received marketing approval from the Food and Drug Administration for treating patients with severe burns — making us the first company to successfully develop and take an approved tissue regeneration product to market. The FDA's Center for Devices and Radiological Health named **INTEGRA™ Artificial Skin** among the year's "most notable breakthrough devices."

## Validated Manufacturing Facility

This was also the year that our 35,000 square foot Plainsboro facility was successfully inspected as a GMP manufacturing plant by the FDA for **INTEGRA™ Artificial Skin**. It is now a full-fledged commercial operation producing tissue regeneration products as well as our other medical products.

## Review and Organization of Technology

The review, organization, integration, and development of our broad and increasing portfolio of technologies is both disciplined and on-going. We believe that our technologies are valuable intellectual capital, playing as important a role as our financial and physical capital in providing truly sustainable earnings and growth. Our intellectual capital includes 206 issued patents with another 296 patents pending. Our platform technologies are organized into four overlapping categories — 1) Bioabsorbable and other materials, 2) Extracellular matrix and other specialized materials structures, 3) Materials as delivery vehicles for peptides, cells, growth factors, drugs and other actives, and 4) Actives. These provide support for our critical applications for tissue regeneration, our developing pharmacological applications, and additional opportunities for generating near-term and mid-term revenues from medical applications not associated with our core activity. The knowledge we have gained from our highly successful product development and launch of **INTEGRA™ Artificial Skin** coupled with the processes we have put in place represent yet another important asset for Integra. We have been able to identify and bring together our critical platform technology components to create a type of **basic operating system solution** to the problem of targeting and controlling selected cell behavior within the patient's body for both tissue regeneration and pharmacological application. In the science of controlling cell behavior, this proprietary knowledge and methodology is now also part of our intellectual assets, and thus enhances our ability to successfully bring to market a wide array of similarly designed tissue and organ regenerative products, as well as cell based pharmacological applications.

## $35 Million in Public Offering

Early in February 1996, Integra LifeSciences raised more than $35 million in a public offering, significantly strengthening our financial position. This, together with a clean balance sheet and a steadily increasing revenue stream, provides us with a sound financial base to roll-out our marketing, product development and clinical programs. Sound finances and a rich bank of intellectual capital puts Integra LifeSciences in a strong position to assess opportunities for important strategic alliances. In accordance with our strategic vision, our aim is to selectively cultivate strategic relationships which contribute meaningfully to our long-term objectives, and create sustained earnings and long-term growth.

## Domestic and International Sales of INTEGRA™ Artificial Skin

Since its market approval by the FDA, **INTEGRA™ Artificial Skin** gained further foreign approvals which now allow us to sell **INTEGRA™ Artificial Skin** in additional international markets. In the near future we expect **INTEGRA™ Artificial Skin** to be awarded the coveted CE Mark giving unrestricted access to the vast European Union market. To support these approvals, our marketing staff has trained more than 350 surgeons in the United States and Canada, as well as an additional 300 internationally. To date nearly 200 seriously burned patients in the United States and Canada have been treated with **INTEGRA™ Artificial Skin** and that number is rising steadily. The initial sales of **INTEGRA™ Artificial Skin** in 1996 were $3.1 million, 74 percent from domestic and 26 percent from international sales.

**INTEGRA™ Artificial Skin** is not just a new product but a new way of practicing medicine. It gives surgeons the ability to enable their patients' bodies to heal themselves in a way not previously thought possible. As with many new technologies, some surgeons are working with **INTEGRA™ Artificial Skin** on a limited basis. The initial patient results appear very good and we are seeing increased usage from new and repeat surgeons. To support sales we have been collecting cost-effectiveness and clinical results data to present to hospitals and third-party payers.

We also believe the increasing usage of **INTEGRA™ Artificial Skin** is partly due to the increasing positive attention being paid to it by professionals in the burn community. The public endorsements they have given to **INTEGRA™ Artificial Skin** have been covered by the media both in the United States and internationally. We look forward to further assessments of **INTEGRA™ Artificial Skin** presented in papers at professional symposiums and published in academic medical journals. We expect these to further support growing usage of **INTEGRA™ Artificial Skin**.

## Research and Development

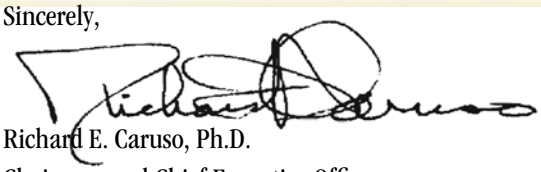
Our research and development program is directed toward several strategic objectives. We have brought together four categories of synergistic proprietary technologies for efficient development of products designed to target and control cell behavior. Our regenerative medicine products are designed to direct cells to regenerate specified tissues or organs within the patient's body. We are working in several areas to expand the applicability of **INTEGRA™ Artificial Skin**. Our cartilage, nerve and cardiovascular graft development is progressing well. We are receptive to partnering support for all three of these programs. We are pleased to report significant product development progress in our on-going partnership with Genetics Institute Inc. to regenerate bone in a process which combines recombinant human bone morphogenic protein-2 (rhBMP-2) with our absorbable collagen based structures. Pilot clinical studies provide evidence of safety and biological activity of the product in patients. Several larger, multicenter clinical trials were also initiated. Presently, the product is being tested in clinical studies in orthopedic, oral/maxillofacial and spine surgery. The success of our relationship with Genetics Institute, Inc. of Cambridge, Massachusetts further validates our strategy to combine safe absorbable materials, specialized structures and biological signals for targeted tissue regeneration.

For matrix medicine, our products are being designed to direct cells to prevent or cure diseases or age-associated disorders. Here our work is encouraging and we will seek strategic alliances for clinical development. The medical products we currently make and several new additional opportunities for products come from the same technologies. In these areas, we remain focused for near-term revenue opportunities.

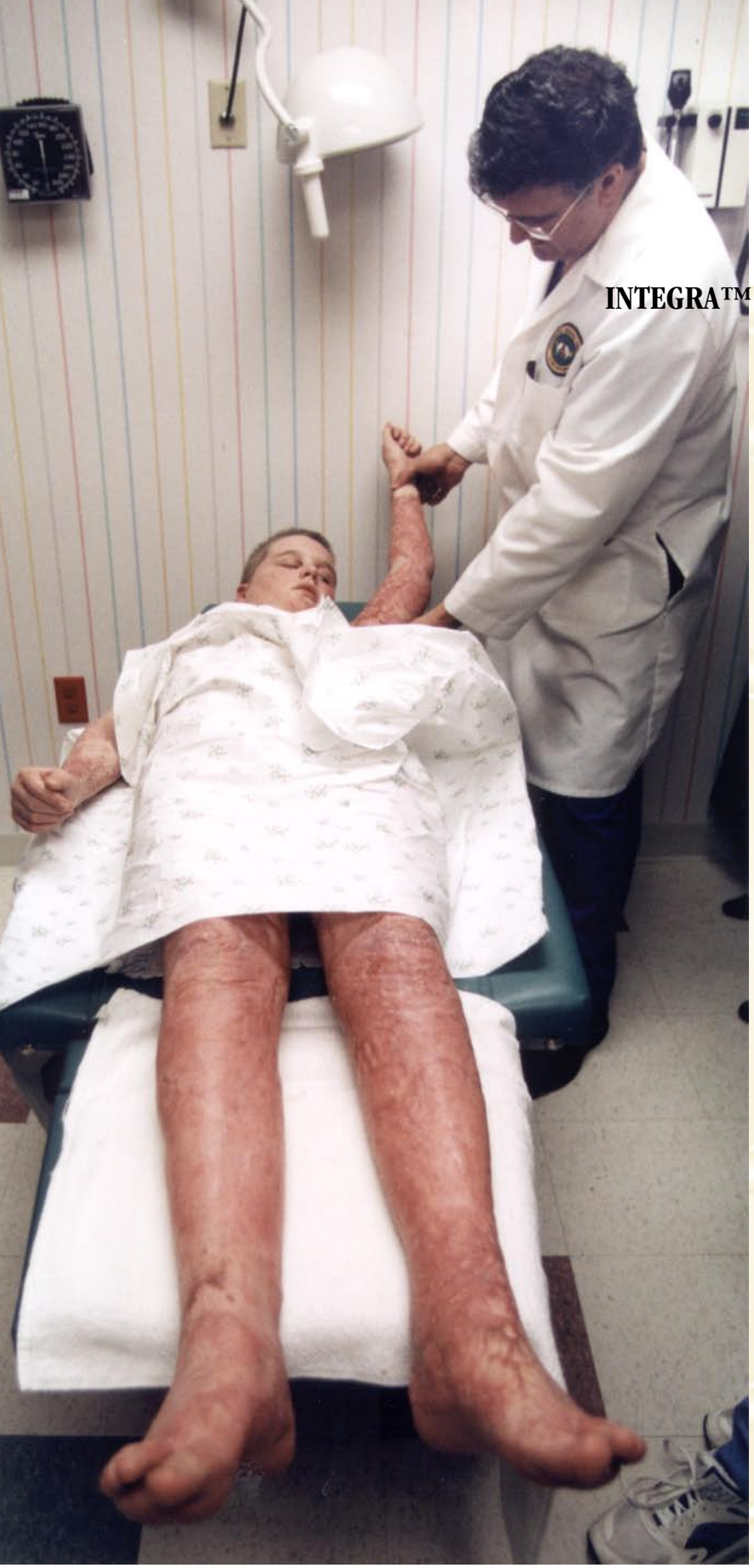
Most importantly, we have been able to direct our technology development toward a new class of medical products designed to target and control cell behavior. Much like a computer operating system is designed to control the functions of the computer, our biosmart™ products are being designed to control targeted cell behavior within the patient's body for a broad range of desired medical results.

This has indeed been a significant year for Integra LifeSciences. I would like to thank all of our shareholders for their continued support. I also express my appreciation to our associates for their energy and commitment, and the medical community for its participation in making tissue regeneration products and regenerative medicine a reality. We are now poised for even greater accomplishments in the future.

Sincerely,



Richard E. Caruso, Ph.D.
Chairman and Chief Executive Officer



# Marketing

## INTEGRA™ Artificial Skin Dermal Regeneration Template™

In 1996, **INTEGRA™ Artificial Skin** created a new standard of medical care: skin regeneration. For the thousands of people who suffer the trauma of severe full-thickness burns each year in America and throughout the world, there is now the opportunity for treatment that will direct the regeneration of their own skin.

In conjunction with the FDA's marketing approval for **INTEGRA™ Artificial Skin**, the validated manufacturing plant was inspected and qualified to make a high quality, medical grade product. A comprehensive training program for burn surgeons was developed and initiated.

Beginning in late Spring, 1996 and throughout the final quarters of the year we successfully rolled out this intensive training program which educated surgeons in the unique regenerative characteristics of **INTEGRA™ Artificial Skin** and the surgical procedures for its application. By year's end, 600 surgeons worldwide were qualified to use **INTEGRA™ Artificial Skin**, while another 75 have been trained in the United States in the first two months of 1997.

Of the 112 burn centers in the U.S. with a trained surgeon, more than 45 centers have already reordered **INTEGRA™ Artificial Skin**. More significantly, at the Spring 1997 national American Burn Association annual meeting in New York, more than ten burn surgeons presented the case results of their use of **INTEGRA™ Artificial Skin** for the more than 2,000 conference participants.

A number of surgeons in some of the country's major burn centers are participating in postapproval studies of **INTEGRA™ Artificial Skin**. This will provide important lessons for the professional burn community and help advance our efforts with **INTEGRA™ Artificial Skin** in less severe burns, plastic and reconstructive surgery, and chronic wounds.

Bryan's right leg (above) as treated with **INTEGRA™ Artificial Skin** is markedly smoother. His left leg has been treated with conventional autograft.

The Cincinnati Enquirer/Glenn Hartong

Along with working with surgeons at burn centers, we also work with administrators on reimbursement from insurance-payer groups. Managed care has created a cost-conscious environment within hospitals and by doctors. Currently, our efforts are to establish a clear reimbursement process for **INTEGRA™ Artificial Skin** at each burn center, and with major third-party payers.

We are particularly pleased at the clinical performance of this first tissue regeneration product and its demonstrated cost effectiveness. We are optimistic that broad clinical acceptance for its use will continue to occur and that it will become a standard of care in burn centers around the world.

## Medical Products

In addition to marketing and manufacturing **INTEGRA™ Artificial Skin**, the Company has developed a number of medical products which it markets internationally in partnership with pharmaceutical companies and specialized distributors.

VitaCuff and BioPatch are, respectively, implanted and topical percutaneous infection control products. The former is distributed by Arrow International, Inc., Bard Access Systems, Inc., and Quinton Instruments Co., and the latter by Johnson and Johnson, each under its own brand.

Integra has a range of surgical hemostasis products, including Collastat and Helistat. These have been manufactured for more than 14 years and are estimated to have been used safely with several hundred thousand patients. In this area we also manufacture a collagen coating for vascular grafts which we supply in partnership with Sorin Biomedical.

Alcon Surgical currently markets the Company's ophthalmic device, a collagen corneal shield , used to protect and lubricate the eye in conjunction with various ocular treatments.

Integra's dental surgical products are extensions of the Company's basic absorbable collagen hemostatic sponge technology. The three products, CollaCote™, CollaPlug™, and CollaTape™, provide for most of the hemostasis requirements in dental surgery. These are marketed by Calcitek, a division of Sulzermedica. Another of the Company's dental surgical products is Biomend™, an absorbable collagen membrane for guided tissue regeneration in periodontal surgery, also marketed by Calcitek.

The Company's Chronicure™ product is a wound exudate absorbent dressing used for management of chronic wounds and skin ulcers. Chronicure™ is manufactured by the Company and sold in the United States and internationally.

All of these other medical products contributed over $8 million in sales in 1996, with total product sales, including the initial sales of **INTEGRA™ Artificial Skin**, for the full year at $11.2 million.

# Tissue Regeneration - An Advanced Form of Tissue Engineering

For Regenerative Medicine, our Company's objective is to effectively solve urgent human medical needs caused by injury to human tissues and organs that are life-threatening and/or associated with serious disabilities. These medical needs are not effectively met by current products other than **INTEGRA™ Artificial Skin**. Yet, this area of medical practice is growing in importance due to an increase in life expectancy and an aging population.

Our immediate solution is to develop practical, cost-effective commercial tissue regeneration products like **INTEGRA™ Artificial Skin** that are designed to assist the patient's body to permanently regenerate an injured tissue or organ. These products are surgically implanted and directly enable targeted cells within the patient to grow his or her own functional human tissue, thus replacing the damaged or diseased tissue or organ.

Other companies have attempted to solve these problems by growing tissues in lab-type facilities for transplantation into the injured area ("Tissue Engineering") or have transplanted cultured cells to the damaged area in the hope that they would successfully repair the damage ("Cell Therapy"). The growth of tissue outside of the body has very serious drawbacks, including the unavailability of suitable autologous (from the same individual) cells, or the problems of rejection and cell death that occur when more available cells from human donors ("allogeneic cells") are substituted. Also, the manufacture of tissues outside of the body suffers from excessive manufacturing costs due to the complexity of this technology and the very high expense for tissue processing. The cell therapy approach to tissue replacement is also subject to limited availability of autologous cells as well as the absence of the appropriate functioning cells.

Because no one technology can do it all, our approach to the tissue replacement problem has been to identify, assemble and create an integrated technology based operating system for the development of tissue regeneration products that avoids the problems of manufacturing expense and impermanence which appear inherent in "tissue engineering" and "cell therapies."

We believe this differentiation is important because the medical care market accepts products that (a) serve a need, and (b) are efficacious, safe and cost-justified. Our assessment of examined technologies suggest that the implantation of an off-the-shelf, non-living biosmart™ absorbable device is a **simpler**, fundamentally **safer**, and more **cost-effective** way to regenerate a body tissue than current Tissue Engineering or Cell Therapy designed products. While there may be some tissues or organs that could require cell growth outside the patient's body in a production facility, our approach to this method is to use it only where required to assist BioSmart™ tissue regeneration products, in regenerating those particular tissues or organs.

A short-hand comparison would suggest that your Company is able to develop products like **INTEGRA™ Artificial Skin** that **turn the patient's own body into its own Tissue Engineering facility**. Integra does this with products that are designed to clinically target and control the behavior of the patient's cells.

## Tissue Engineering vs. Tissue Regeneration

| | | |
|---|---|---|
| **Definition** | Grow 3-D tissues in the lab | Grow tissue or organs within patients' bodies |
| **History** | From ability to grow cells in a single layer in a flask | From an integrated systems approach: materials • structures • vehicles • actives |
| **Function** | Implant tissue into body and expect it to function normally | BioSmart™ regeneration template implanted to aid the body's natural healing |
| **Safety** | Use of donor cells raises health concerns and rejection tissue | Base product materials have 15 years safety profile |
| **Manufacturing** | Expensive, artful process | Well-documented streamlined process producing reliable high-quality product |
| **Cost** | Potentially out of alignment with today's managed care | Cost-effective |

# Understanding the ExtraCellular Matrix (ECM) As the Body's Operating System for Cell Behavior

Successful tissue regeneration products for humans rely on the biochemistry of the human body's tissue specific **extracellular matrix (ECM)** and the characteristics of the cells which reside within. For organs or tissues, both hard (such as bone) and soft (such as skin), the ECM appears as a **honeycombed** or **lattice type structure** in which cells reside, providing strength and substance for tissues and organs. Importantly, the ECM for each tissue also **serves as a communication infrastructure for the embedded cells** and acts as one of the principal means that cells use to communicate with their surroundings.

Each tissue in the body has a specialized ECM. Each tissue specific ECM is a network of molecular fibers composed of carbohydrates and proteins with which tissue specific cells interact to form tissues and organs.

Each ECM, through its interaction with cell surface receptors and growth factors, **plays an important role in controlling the ways cells function and respond to injury and disease.**

Because of the critical physiological function of ECMs in tissues and organs of the body, the Company's broad understanding of how cells interact with the ECM provides an ideal basis for the development of an integrated technology development system for the Company's regenerative and pharmacological products. We recognize a demand for a wide range of ECM-based products that would target and control specific cell behavior for a variety of desired medical outcomes.

For therapeutic applications, our products will influence cells' ability to build a new matrix and at the same time control excess matrix production, as well as inhibit undesired cell-matrix interaction. To repair a patient's tissue or organ lost to damage or disease, the products must serve as a temporary ECM type analog. This substitute ECM functions to recruit appropriate targeted cells to infiltrate its structure and permits a new natural ECM, cells and resulting tissue or organ to regenerate while simultaneously being harmlessly absorbed by the patient's body.

**We understand the body's natural ECM to be its natural operating system for cell behavior.** To commercially develop a wide range of products to control cell behavior for tissue regeneration and pharmacological application, we envisioned an ECM-based operating system for technology development and specific biosmart™ products for targeted medical applications.

To create a **basic operating system solution** for the development of products that would control cell behavior for tissue regeneration and pharmacological application, we understand that **several technology components are required from diverse sciences** and that no one component could address all of the needs of the system. Our business and scientific strategies were developed with this vision in mind.

# ENVISIONING . . . . . THEN CREATING

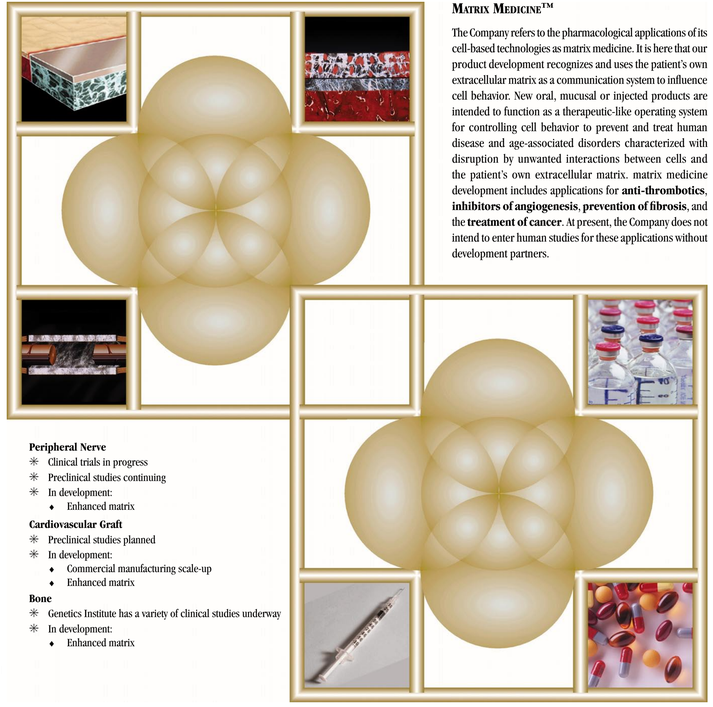
## INTEGRA'S BASIC OPERATING SYSTEM SOLUTION FOR TECHNOLOGY DEVELOPMENT AND PRODUCT PERFORMANCE

### REGENERATIVE MEDICINE

Products for regenerative medicine are developed from a synergy of two or more categories of platforms of technologies. Here, extracellular matrix analog products are surgically implanted at the prepared site of damage or disease. Like **INTEGRA™ Artificial Skin**, these lattice-like Biosmart™ products are designed to direct the cells of the patient's body to regenerate the targeted diseased or damaged tissue or organ. This process of tissue regeneration is also designed to consume the original implanted absorbable device leaving only the natural replacement tissue or organ regenerated by the patient's body. Currently, the Company has three additional tissue regeneration products in development for **peripheral nerves**, **cartilage**, and **cardiovascular graft** applications. In addition, the Company is developing several enhancements for **INTEGRA™ Artificial Skin** and intends to organize a central nervous system development project as an extension of the peripheral nerve project. The Company also has a strategeic collaborative relationship with Genetics Institute in advanced studies to regenerate **bone**.

**Skin**
- ✳ FDA Approval of PMA
- ✳ Currently marketing for severe burns
- ✳ Product variations in development:
  - ♦ Antimicrobial
  - ♦ Epidermal cell seeded
  - ♦ Dry sterile
  - ♦ Peptide enhanced
- ✳ Preclinical & clinical work in progress
  - ♦ Postapproval study for burns
  - ♦ Plastic and reconstructive study
  - ♦ Chronic wounds

**Cartilage**
- ✳ In development:
  - ♦ Dual layered matrix cell seeded
  - ♦ Dual layered matrix peptide enhanced
  - ♦ Surgical procedure
- ✳ Preclinical studies underway



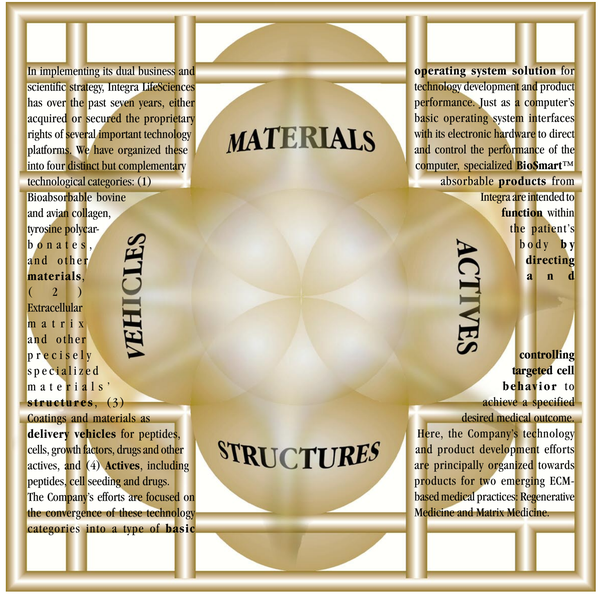
**Peripheral Nerve**
- ✳ Clinical trials in progress
- ✳ Preclinical studies continuing
- ✳ In development:
  - ♦ Enhanced matrix

**Cardiovascular Graft**
- ✳ Preclinical studies planned
- ✳ In development:
  - ♦ Commercial manufacturing scale-up
  - ♦ Enhanced matrix

**Bone**
- ✳ Genetics Institute has a variety of clinical studies underway
- ✳ In development:
  - ♦ Enhanced matrix

### MATRIX MEDICINE™

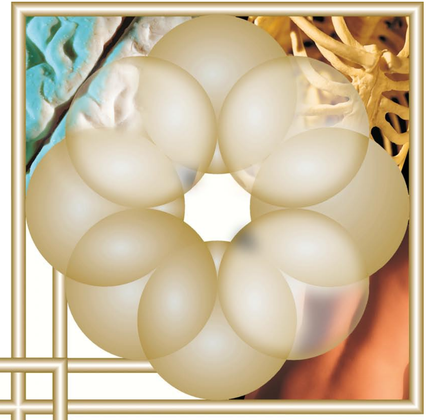
The Company refers to the pharmacological applications of its cell-based technologies as matrix medicine. It is here that our product development recognizes and uses the patient's own extracellular matrix as a communication system to influence cell behavior. New oral, mucusal or injected products are intended to function as a therapeutic-like operating system for controlling cell behavior to prevent and treat human disease and age-associated disorders characterized with disruption by unwanted interactions between cells and the patient's own extracellular matrix. matrix medicine 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.

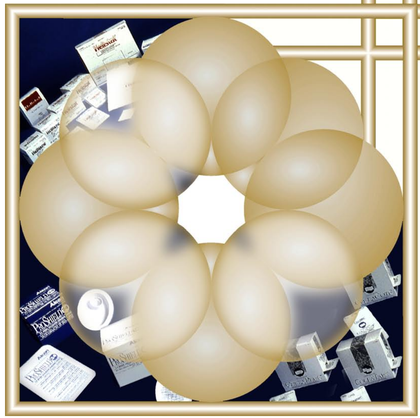



In implementing its dual business and scientific strategy, Integra LifeSciences has over the past seven years, either acquired or secured the proprietary rights of several important technology platforms. We have organized these into four distinct but complementary technological categories: (1) Bioabsorbable bovine and avian collagen, tyrosine polycarbonates, and other **materials**, (2) Extracellular matrix and other precisely specialized materials' **structures**, (3) Coatings and materials as **delivery vehicles** for peptides, cells, growth factors, drugs and other actives, and (4) **Actives**, including peptides, cell seeding and drugs. The Company's efforts are focused 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 **BioSmart™** absorbable **products** from Integra are intended to **function** within the patient's body **by directing and controlling targeted cell behavior** to achieve a specified desired medical outcome. Here, the Company's technology and product development efforts are principally organized towards products for two emerging ECM-based medical practices: Regenerative Medicine and Matrix Medicine.

### MEDICAL PRODUCTS

The Company's currently marketed Medical Products and substantial Other Opportunities for product development are derived from the same technology platforms and the product development system the Company has created. Here, one or more of the scientific components of a technology category are used independently or combined with one or more components of other categories for products. Currently, the Company has in excess of 15 medical products on the market which are distributed by several medical companies including Arrow, Bard, and Johnson & Johnson. The Company now has identified additional medical products for development.





### OTHER OPPORTUNITIES

Other opportunities for products based on the Company's four categories and several platforms of technologies are vast. In pursuing these opportunities, the Company is **focused** on those that have **near-term** and **mid-term revenue potential**, are being **funded by development partners**, or offer the lowest financial risk-adjusted highest **reward potential**. Examples of each of these are: bulk materials as additives, coatings or delivery systems, reproductive health applications, and tyrosine polycarbonates as new absorbable biomaterials for broad medical application.

- ✳ A variety of components or products for dermal application.
- ✳ Delivery systems for reproductive health applications.
- ✳ A new tyrosine polycarbonate absorbable material for broad medical application in the body. Initial applications include fixation and other orthopedic devices, antiadhesion and tissue substrates.

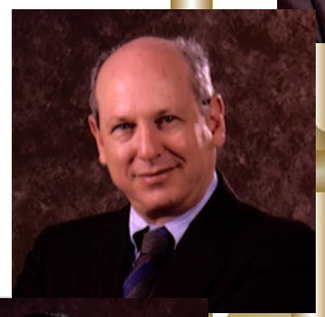
# Integra's Intellectual Capital And Shareholder Value

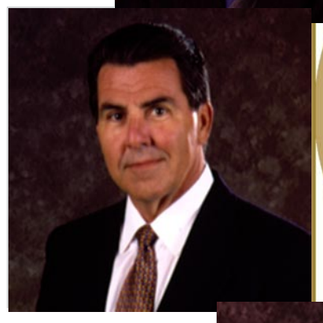
Integra LifeSciences' research and development activities and its **strategic portfolio of patents** and **proprietary technologies** are a significant part of its **intellectual capital.** We have more than 200 issued patents worldwide with nearly 300 more pending. We also have numerous proprietary value creating processes, including those developed in becoming the first to obtain FDA marketing approval for a skin regeneration product, and building and obtaining FDA inspection of our manufacturing facility in Plainsboro, NJ. As our technology and product development system is generic to cell behavior, so are our proprietary processes generic to a wide range of our existing products and those in development.

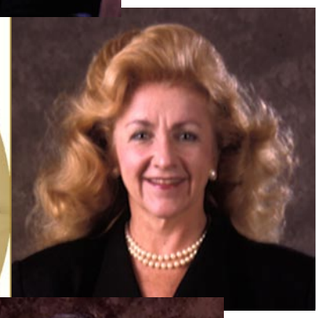
In 1996 we undertook a vigorous enforcement policy of selected patents, believing infringement is occurring. We intend to continue enforcement activity to insure that this aspect of our **intellectual capital** remains valuable. We also intend to continue to add to our patent portfolio as new discoveries are identified.

The convergence of technologies from diverse sciences requires **experts from many fields**. In its development activities and to the extent feasible in its manufacturing and administration activities, Integra has emphasized a collaborative style of interpersonal relationships. A **collaborative environment** allows experts from diverse fields to share knowledge and make decisions using a mutually respectful **team-oriented approach**.

Integra believes its intellectual capital represents great wealth. However, unlike financial capital, intellectual capital remains largely invisible and difficult to assess. Integra believes that to **build shareholder value** successfully, it must skillfully leverage its intellectual capital and efficiently convert it into revenues, profits, and financial capital.



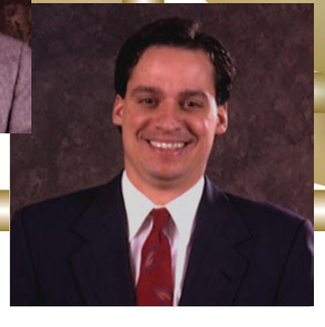


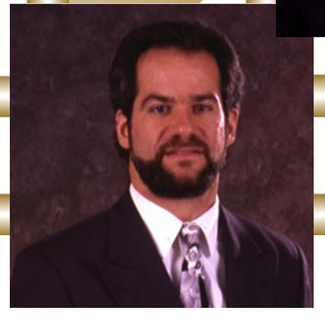


**Patent Portfolio**

**206** Patents Issued

**296** Patents Pending





Near-term opportunities to convert assets from our intellectual capital into financial capital and shareholder value include:

- Obtaining additional FDA approvals for applications of **INTEGRA™ Artificial Skin** for plastic and reconstructive surgery, and other indications;
- Continuing to develop and pursue **strategic opportunities** for our tissue regeneration projects including our cartilage, nerve and cardiovascular projects;
- Seeking partners for longer term **pharmacological applications** of our technologies to target and control cell behavior;
- Protecting and replenishing our **strategic patent portfolio** and proprietary processes;
- Pursuing **near-term revenue** opportunities in established materials-based and medical product markets.

## Corporate Information

### Annual Meeting

Integra LifeSciences Corporation will hold its fiscal 1997 Annual Meeting of Shareholders at 10:00 a.m., Monday, May 19, 1997, at the Princeton Marriott Hotel, Forrestal Village, Princeton, New Jersey.

### Transfer Agent

Chase Mellon Shareholder Services L.L.C.
New York, New York

### Independent Auditors

Coopers & Lybrand L.L.P.
Princeton, New Jersey

### Corporate Counsel

Drinker Biddle & Reath
Princeton, New Jersey

Shareholders may obtain, without charge, a copy of the Company's Annual Report on Form 10-K for 1996 upon written request delivered to:

Investor Relations
Integra LifeSciences Corporation
105 Morgan Lane
Plainsboro, New Jersey 08536

### Integra LifeSciences Corporation World Wide Web Address:

http://www.integra-ls.com

### Nasdaq National Market Symbol: IART

## Executive/Senior Officers

Richard E. Caruso, Ph.D.
Chairman, President and
Chief Executive Officer **

Frederick Cahn, Ph.D.
Senior Vice President, Technology

Andre P. Decarie
Senior Vice President,
Marketing and Sales

Michael D. Pierschbacher, Ph.D.
Senior Vice President,
Research and Development

George L. Brode, Ph.D.
Distinguished Research Fellow

Surendra P. Batra, Ph.D.
Vice President, Production Development

David B. Holtz
Vice President, Treasurer

Donald R. Nociolo
Vice President, Manufacturing Operations

Judith E. O'Grady, RN, MSN
Vice President, Regulatory Affairs

Robert G. Runckel
Vice President, International Marketing

## Outside Directors

Keith Bradley, Ph.D.
Director **,***
Professor of International Management and Director of Business Research,
The Open University Business School, Milton Keynes, England

William M. Goldstein, Esq.
Director and Secretary *
Managing Partner and
Chairman of the Tax Department, Drinker Biddle & Reath

Frederic V. Malek
Director
Chairman of Thayer Capital Partners

George W. McKinney, III, Ph.D
Director
President and Chief Executive Officer,
Gel Sciences, Inc. and
Managing Director, Beacon Venture Management Corporation

James M. Sullivan
Director *
Senior Vice President,
Marriott Lodging and Marriott Hotels, Resorts and Suites

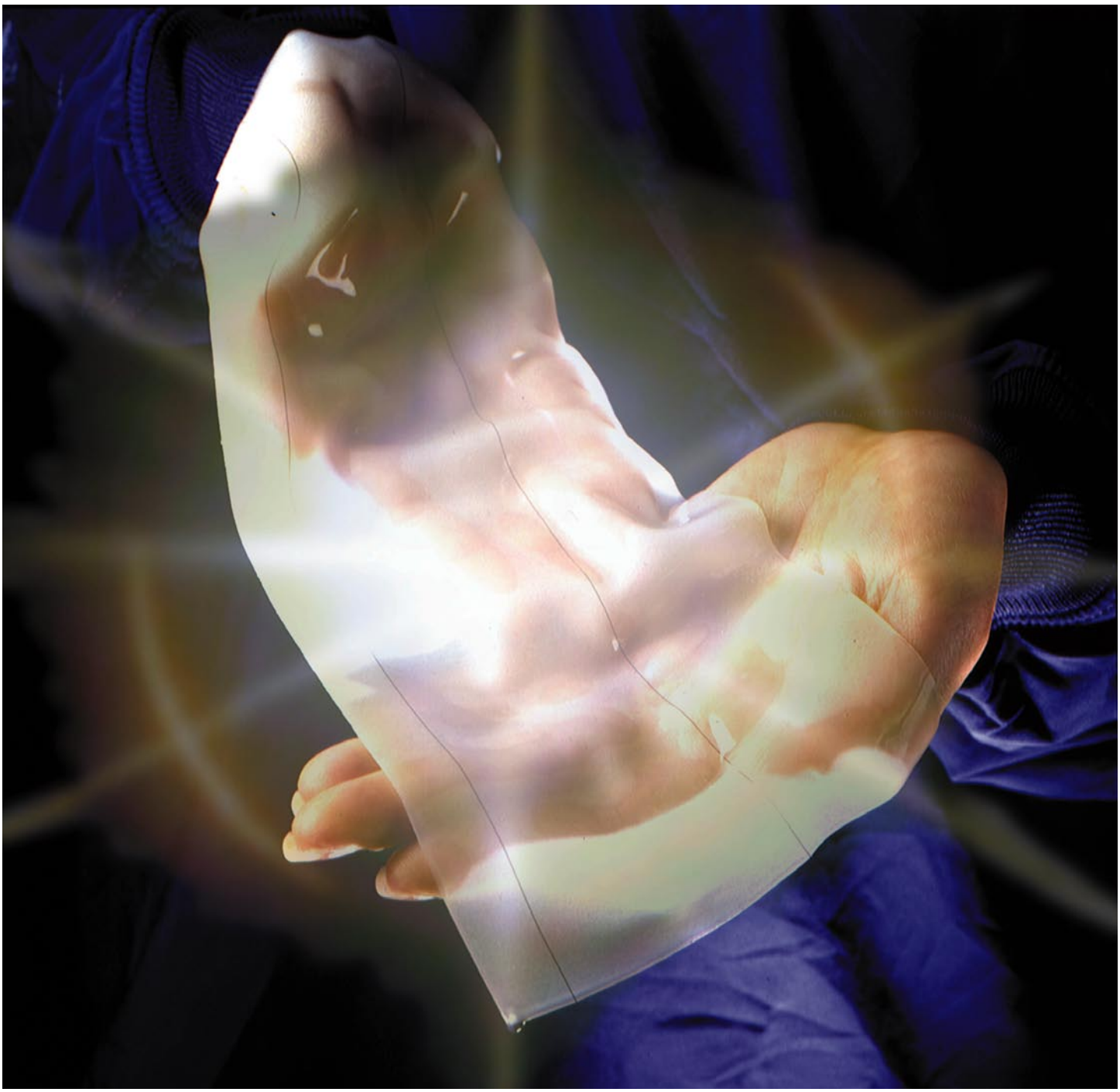
Edmund L. Zalinski, Ph.D.
Director ***
Retired, formerly Chairman of the Board,
American Capital Open End Funds

*Audit Committee Member
**Compensation Committee Member
***Stock Option Committee Member

## Creative Attribution

- ✳ Designed by Robyn A. Dormer of Integra LifeSciences Corporation
- ✳ Edited by Judy Brenna of Integra LifeSciences Corporation

# Envisioning then Creating . . . . .



# INTEGRA™ Artificial Skin

## The First Regenerative Medicine Product

# INTEGRA™ Artificial Skin named " . . . one of the notable breakthrough devices . . . of 1996 . . . "


**INTEGRA LIFESCIENCES CORPORATION**
**105 Morgan Lane**
**Plainsboro, New Jersey 08536**
**phone 609-275-0500 fax 609-799-3297**
**http://www.integra-ls.com**
**Nasdaq National Market Symbol: IART**

# INTEGRA LIFESCIENCES HOLDINGS CORP

## FORM 10-K
(Annual Report)

## Filed 3/28/1997 For Period Ending 12/31/1996

| | |
|---|---|
| Address | 311 C ENTERPRISE DRIVE |
| | PLAINSBORO, New Jersey 08536 |
| Telephone | 609-275-0500 |
| CIK | 0000917520 |
| Industry | Biotechnology & Drugs |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

# 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 Commission File No. 0-26224
December 31, 1996

# INTEGRA LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

| | |
|---|---|
| Delaware | 51-0317849 |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. employer identification no.) |
| 105 Morgan Lane<br>Plainsboro, New Jersey | 08536 |
| (Address of principal executive offices) | (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 21, 1997 was approximately $46,900,224. (Reference is made to page 29 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 21, 1997 was 29,630,496.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain portions of the registrant's definitive proxy statement relating to its scheduled May 19, 1997 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

## PART I

### ITEM 1. BUSINESS

**Summary**

Integra LifeSciences Corporation is dedicated to the acquisition, discovery and development of synergistic technologies for creating and marketing cost-effective, off-the-shelf, biosmart(TM), absorbable products designed to target and control cell behavior to regenerate specific body tissues and organs, or to treat a variety of disease and age-associated conditions. The Company's INTEGRA(TM) Artificial Skin, Dermal Regeneration Template(TM) Device ("INTEGRA Artificial Skin") is the first Premarket Approval Application (PMA) approved by the U.S. Food and Drug Administration (FDA) for a product which is specifically designed to enable the human body to replace a functional tissue that will not otherwise regenerate. The Company intends to use its proprietary technologies and biomaterials expertise to take advantage of the growing need for safe, cost-effective, and clinically efficacious products designed to control the behavior of targeted cells in the patient's body in the practice of Regenerative Medicine.

The tissues of humans and animals are comprised of cells imbedded in an infrastructure of proteins and other molecules, known as the extracellular matrix ("ECM"). The ECM provides cells with structural support and biological signals. Regenerative medicine technologies owned or licensed by the Company are used to fabricate Regeneration Template(TM) devices ("Regeneration Templates"), which are devices manufactured by the Company from collagen and other components of the ECM, using proprietary processes. Once surgically implanted, they serve as temporary structures that are intended to support regeneration of functional tissues. Regeneration Templates are precisely engineered for specific tissues and are designed to be absorbed into the body during the regeneration process. INTEGRA Artificial Skin is the first in a series of products that the Company is developing to regenerate a variety of body tissues, including articular cartilage, peripheral nerve, cardiovascular graft and, in cooperation with Genetics Institute, a subsidiary of American Home Products Corporation, bone.

The Company develops, sells and has substantial manufacturing experience with FDA-regulated absorbable medical products in addition to INTEGRA Artificial Skin, that serve a broad range of applications, including drug delivery, surgical hemostasis (to control bleeding), infection control, ophthalmic surgery, dental surgery and wound care. These products are sold primarily through marketing relationships with a number of established medical companies, including Alcon Surgical, Inc., Arrow International, Inc., Bard Access Systems, Inc., the Calcitek Division of Sulzermedica, Johnson & Johnson Medical Inc. and Sorin Biomedical, Inc. While these commercial products were not

specifically developed using the Company's advanced regenerative medicine technologies, they utilize many of the same biomaterials, manufacturing processes and materials engineering techniques.

In addition to the regenerative medicine applications of its proprietary technologies, the Company intends to further develop and commercialize pharmacological medical applications of its technologies. 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 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 with these applications without development partners.

The Company's business strategy has been to selectively acquire and further develop several platforms of synergistic biomaterials and ECM technologies. The Company's platform technologies organized into four overlapping categories -- 1) Bioabsorbable and other materials, 2) ECM and other specialized materials structures, 3) Materials as delivery vehicles for peptides, cells, growth factors, drugs and other actives, and 4) Actives
- -- provide support for our critical applications for tissue regeneration, our developing pharmacological applications, and additional opportunities for generating near-term and mid-term revenues from medical applications not associated with our core activity. The Company has been able to identify and bring together critical platform technology components to create a type of basic operating system solution to the problem of targeting and controlling selected cell behavior in the patients' body for both tissue regeneration and pharmacological application. The Company, possibly in alliance with strategic partners, intends to further develop those technologies that it believes are most commercially promising and to bring products to market or to license or sell such technologies or products to third parties. The Company believes its management and scientific team, development and manufacturing experience, proprietary technological position and relationships with established medical institutions and other organizations help 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.

**Regenerative Medicine**

In many cases, the human body will not regenerate diseased or injured tissues, such as the dermis. Regeneration Templates, when implanted into a wound site, provide a biosmart(TM) scaffold to support and guide cellular ingrowth intended to regenerate functional tissue. The Company uses proprietary

technologies and expertise to develop specialized Regeneration Templates intended to restore functional skin, articular cartilage, peripheral nerve, blood vessels, bone and, potentially, other human tissue.

The Company believes that its regenerative medicine technologies may provide potentially safer, more effective and less expensive methods for replacing damaged or diseased tissues when compared to other currently available techniques. For example, 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 autografting of tissue 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) have been commonly used, but tend to degrade after years in the body, compromising long-term performance.

The Company has several regenerative medicine products in various stages of development and production. Products sales of the Company's regenerative medicine products were $4.1 million, $580,000 and zero for the years ended December 31, 1996, 1995 and 1994. The Company currently has sales from two regenerative medicine products: INTEGRA Artificial Skin; and BioMend(TM) Absorbable Collagen Membrane. The following table summarizes the current status of the Company's regenerative medicine technologies:

Status and Target Indications of the Company's Regenerative Medicine Technologies

| TECHNOLOGY | TARGET CLINICAL APPLICATIONS | STATUS |
|---|---|---|
| INTEGRA(TM) Artificial Skin | Postexcisional 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 | Approval letter issued by the FDA in March 1996.<br><br>Foreign clearance to import to over 10 countries. |
| | Plastic and reconstructive applications | IDE submission planned for 1997 |
| BioMend(TM) Absorbable Collagen Membrane | Guided tissue regeneration in periodontal surgery | 510(k) clearance to market received August 1995 |
| Cartilage Regeneration | Restoration of functional articular cartilage in knee and other joints | Expanded preclinical study in progress, including several enhancements to include possible cell behavior modifications |
| Peripheral Nerve Regeneration | Regeneration of severed peripheral nerves | Completed preclinical study establishing effectiveness of technique; Phase I clinical trials commenced first quarter 1996 in Denmark |
| Bone Regeneration | Regeneration of bone in orthopedic, oral maxillofacial and spine surgery | Clinical studies conducted by Genetics Institute, Inc. |
| Cardiovascular Grafts | Regeneration of vascular grafts | Preclinical studies underway |

**INTEGRA(TM) Artificial Skin, Dermal Regeneration Template**

INTEGRA Artificial Skin is expected to be the Company's most significant near-term commercial regenerative product. The INTEGRA Artificial Skin technology 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 thicker dermis underneath,

which provides structural strength and flexibility and nourishes the epidermis through a vascular network. Current medical technology provides several methods for restoring epidermis on severely burned patients. However, the Company is not aware of any clinically proven method for regeneration of a functional dermis for such patients other than INTEGRA Artificial Skin.

The body normally responds to severe damage to the dermis by producing scar tissue in the wound area. This scar tissue formation 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 Artificial Skin consists of two layers, a thin collagen/glycosaminoglycan sponge and a silicone membrane. The product is applied with the sponge layer in contact with the wound. The collagen/ glycosaminoglycan 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 reinjury and minimize bacterial contamination.

The Company's PMA approval for INTEGRA Artificial Skin is indicated for the postexcisional 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. On March 1, 1996, the Company received notification from the FDA that its PMA application seeking permission to market INTEGRA Artificial Skin was approved. The FDA's approval order includes requirements to provide a comprehensive practitioners' training program and to conduct a post approval study at multiple clinical sites.

Potential Market for INTEGRA Artificial Skin. The initial market for INTEGRA Artificial Skin is 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. The majority of severely burned patients in the United States are treated in approximately 150 specialized burn care units. The sales of INTEGRA Artificial Skin are currently subject to a reportedly seasonal effect of burn incidents, which may be lower in the summer months.

While the Company believes that its primary market for INTEGRA Artificial Skin is its current indication, the Company is aware of additional cases for which INTEGRA Artificial Skin has been used. The Company is currently seeking to enhance and expand the indicational use of the INTEGRA Artificial Skin technology and intends to conduct additional clinical trials to demonstrate the safety and effectiveness of such technology in a broader range of indications than set forth in its PMA for INTEGRA Artificial Skin. Potential applications for such technology include reconstructive surgery, wound closure

following excision of skin cancer and other types of wounds.

Market Introduction of INTEGRA Artificial Skin. The Company has initiated the marketing of INTEGRA Artificial Skin through a direct technical sales organization in the United States, Canada, and the United Kingdom and through individual distributors in other foreign markets. The Company's training program has been offered to all physician members of the American Burns Association, as well as other physicians throughout the world. To date, over 350 surgeons in the United States and Canada, as well as an additional 300 surgeons internationally, have been trained in the use of INTEGRA Artificial Skin. The Company has also offered in-hospital training programs for operating room and burn unit personnel to further expand on the patient care involving INTEGRA Artificial Skin. The Company believes that INTEGRA Artificial Skin is not just a new product but a new way of practicing medicine, and as with many new technologies, some surgeons have started to use INTEGRA Artificial Skin only on a limited basis. The Company believes that the initial patient results have been positive, and as increased positive attention is given to these results further support for growing usage is expected to follow. In addition, the Company has been collecting data on the cost effectiveness as well as the clinical results to present to hospitals and third-party payers.

Production of INTEGRA Artificial Skin. The Company has completed construction and its validation of a commercial-scale manufacturing facility in Plainsboro, New Jersey to produce INTEGRA Artificial Skin, and the facility passed an FDA inspection for compliance with cGMP regulations. The shelf life of the product is currently one year when stored at refrigeration temperatures, and the Company is performing stability studies to increase its shelf life. The product is shipped to burn centers in the United States and Canada and is stored in the United Kingdom for direct United Kingdom sales. The product is also shipped to international distributors in Europe and the Far East for distribution through their established channels. The Company is currently manufacturing INTEGRA Artificial Skin in commercial quantities and believes it has sufficient capacity to generate significant product sales.

**BioMend(TM) Absorbable Collagen Membrane**

The Company has also developed BioMend(TM) Absorbable Collagen Membrane ("BioMend") for use in guided tissue regeneration in periodontal surgery. BioMend is inserted between the gum and the tooth after surgical treatment of periodontal disease. BioMend prevents the gum tissue from interfering with the regeneration of the periodontal ligament that holds the tooth in place. BioMend 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. FDA clearance to market BioMend under a Section 510(k) pre-market notification filing was obtained in August 1995. BioMend is marketed through the Calcitek Division of Sulzermedica. The Company's sales of BioMend may vary on a quarterly basis depending on the stocking levels at Calcitek.

**Cartilage Regeneration**

The Company is developing a Cartilage Regeneration Template(TM) to enable the regeneration of damaged articular cartilage. The Company has continued its support in the development of a proprietary cartilage regeneration therapy utilizing the patient's chondrocytes seeded into a collagen regeneration template. The Company has also expanded its efforts to include development of a proprietary cartilage collagen regeneration template that would utilize the Company's peptide technology, an active technology to enhance the regeneration process and potentially reduce or eliminate the need for chondrocyte seeding.

Normal articular cartilage does not have a vascular nutrient supply, 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 the functionality of the joint and an increased risk of developing osteoarthritis. The Company's objective in developing its technology is to produce a product that regenerates the patient's cartilage and restores function, thereby diminishing the risk or delaying the onset of osteoarthritis.

In one clinical protocol under development by the Company, chondrocytes will be taken from the patient during a diagnostic arthroscopic procedure, cultured outside the body with nutrients to promote cell proliferation, and then seeded into Cartilage Regeneration Templates. The Cartilage Regeneration Templates, bearing the regenerating cartilage, would then be shaped to match the damaged portion of the joint and implanted into the site using arthroscopic surgical techniques. After implantation, the Cartilage Regeneration Templates are intended to support the continued regeneration of the patient's own articular cartilage tissue. A second protocol under development would utilize the Company's peptide technology to create enhanced Cartilage Regeneration Templates that would signal chondrocyte cells to the template once implanted into the patient. The Cartilage Regeneration Templates employ proprietary designs using multiple layers of collagen material of varying densities that provide a scaffold for chondrocyte proliferation and cartilage formation, while

preventing the ingrowth of unwanted cells that could lead to scar tissue. It is anticipated that the collagen will be absorbed into the body over a period of several weeks. The peptide enhanced Cartilage Regeneration Templates would include bioactive agents designed to mimic natural ECM proteins to promote chondrocyte cell adhesion, cell survival and other important cellular functions. Preclinical studies involving several variations of the above protocols are in progress.

**Peripheral Nerve Regeneration**

The Company is developing a Peripheral Nerve Regeneration Template(TM) to facilitate the regeneration of severed peripheral nerves. Injuries to hands, arms, feet and legs that sever peripheral nerves result in the loss of sensation and normal motor control. Currently, there are only limited treatments available

for the repair of damaged peripheral nerves. Short gaps can be repaired by surgically reconnecting nerve endings. Conventional methods for repair of longer gaps require grafting nerve tissue that is removed from another part of the patient's body, resulting in loss of function and sensation in the location from which the nerve tissue is harvested.

The Company's Peripheral Nerve Regeneration Template is a thin collagen tube that serves as a conduit to facilitate regeneration of the severed nerve. The collagen tube is implanted and the severed ends of the nerve are inserted into the ends of the tube. The tube is intended to support guided regeneration of the nerve tissue down the length of the tube while being absorbed into the body.

Scar formation at the nerve repair site is the leading cause of failure in conventional nerve grafting techniques. The Company's collagen tube appears to prevent scar formation, to provide guided regeneration of nerve tissue and to prevent the ingrowth of surrounding tissue. The Company's preclinical studies have demonstrated the closure of 2cm gaps in peripheral nerves in non-human primates with restored nerve function. Preliminary results from an additional preclinical study indicate an ability to close 5cm gaps in peripheral nerves in non-human primates. The Company initiated Phase I clinical trials in 1996 in Copenhagen, Denmark and patient enrollment is proceeding. In addition to applications in hand surgery, the Company is exploring the use of this technology for the repair of nerve damage resulting from prostate surgery. The Company is continuing to develop variations of the Nerve Regeneration Template for enhanced performance. The Company knows of no companies that are currently conducting clinical studies on peripheral nerve repair.

**Bone Regeneration Matrix**

The Company supplies Genetics Institute, Inc. ("GI") with a collagen device that is used by GI in conjunction with GI's recombinant human bone morphorgenetic protein -2 (rhBMP-2) to stimulate tissue regeneration at bone defects. Pilot clinical studies conducted by GI have provided evidence of safety and biological activity of the product in patients. Several larger, multicenter clinical trials have also been initiated. Presently, the product is being tested in clinical studies in orthopedic, oral/maxillofacial and spine surgery. The Company has an exclusive supply agreement with GI to provide commercial quantities of the collagen device should GI successfully commercialize their products.

**Cardiovascular Graft Matrix**

In 1996, the Company formed a wholly-owned subsidiary in the Czech Republic and acquired rights to several patented processes involving the development of a cardiovascular graft matrix. The technology uses a collagen-based matrix structure which is surgically implanted as a vascular graft. The Company also entered into a consulting agreement with Dr. Milan Krajicek, who is the inventor of the technology, and will be funding continued preclinical development efforts.

**Possible Future Developments**

The Company believes that its regenerative medicine technologies may be applied to restore additional body tissues, and in the future it intends to explore such applications. The Company also believes that its absorbable biomaterials technology has significant potential as a vehicle for the delivery of drugs, peptides (a short chain of amino acids) and therapeutically beneficial proteins. The Company's scientists have collaborated with others to incorporate a variety of therapeutic agents, including anti-infectives, ECM components such as glycosaminoglycan and recombinant growth factors, into the Company's Regeneration Templates.

The Company is continuing the development of certain of its ECM technologies for the treatment of chronic wounds, partial-thickness burns and other applications. The goal is to enhance the rate of wound healing and tissue regeneration, as well as the quality of the resulting tissue, through the use of biodegradable scaffolds to direct cell attachment and migration. The Company is working at developing scaffolds in dry porous forms which can be made to persist in the tissue for various periods of time.

The Company continues to seek out new biomaterials for the application of its ECM technologies. To this end, the Company is developing a new class of polycarbonate created through the polymerization of tyrosine, a naturally-occurring amino acid. It is believed that this new biomaterial will be safe when implanted. The Company currently has a preclinical animal study in-process which has been funded by the National Institute of Science and Technology program and the Company. Patents covering this technology have been exclusively licensed from Rutgers University, and the Company works in close collaboration with the inventor, Joachim Kohn, Ph.D.

The Company's development activities also include the use of biomaterials for drug delivery applications. These applications are also being developed for incorporation into other Regeneration Template products manufactured by the Company. For instance, in surgical hemostasis, ophthalmic and dental surgery applications, the sustained delivery of antibiotics at the surgical site could be beneficial. There is also 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.

**Matrix Medicine**

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, 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 technologies are based on the interaction between a family of cell surface proteins called integrins and the arginine-glycine-aspartic acid peptide sequence found in many extracellular

matrix proteins, including (i) structural molecules, such as collagen, elastin and proteoglycans, that provide strength, mechanical support and a medium for diffusion of nutrients and other molecules and (ii) adhesion molecules, such as fibronectin, vitronectin and laminin, that provide binding sites between cells and these structural molecules.

The Company has in development new pharmacological products based on the interaction between the extracellular matrix and the integrin family. 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 matrix function. The Company's matrix medicine technologies are intended to modify or mimic matrix functions and 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 preclinical 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.

The following table summarizes the current status of three of the Company's matrix medicine technologies:

Status of Target Indications of Selected Matrix Medicine Technologies

| AGENT | POTENTIAL TARGET CLINICAL APPLICATIONS | STATUS |
|---|---|---|
| TP-9201 Platelet Aggregation Inhibitor | Acute unstable angina and other acute thrombotic indications, such as the prevention of abrupt closure of arteries following angioplasty or thrombolysis, stroke, reconstructive surgery, vascular grafts and organ transplantation, when they are accompanied by a risk of bleeding | Phase I human safety trial completed |
| TGF-(Beta) Antagonists | 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 | Preclinical development |
| (Alpha)v(Beta)3 Integrin Specific Peptides | Suppression of tumor growth and the spread of cancer through the blocking of this integrin found primarily on blood vessel sprouts | Preclinical development |

**TP-9201 Platelet Aggregation Inhibitor**

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." 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, without interfering with other platelet receptors. 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 preclinical 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 antithrombotic effect is crucial.

The following table identifies the potential markets that could benefit from TP-9201:

| CLINICAL INDICATION | MANIFESTATION |
|---|---|
| Unstable Angina | Transient blockage of coronary arteries by blood clots, often preceding complete myocardial infarction |
| Restenosis | Reclosure of arteries, typically after angioplasty |
| Reocclusion | Reclosure of arteries, typically after angioplasty or treatment of mild myocardial infarction with thrombolytics |
| Ischemic Stroke | Blockage of blood vessels supplying the brain, often resulting in permanent brain damage |
| Vascular | Synthetic grafts cause thrombosis, but also have a tendency to leak blood. TP-9201 may be able to prevent thrombosis without increasing risk of bleeding |
| Reconstructive Surgery | Microvascular thrombosis results in surgical failure, as does excessive bleeding (contraindicating current anticoagulants) |
| Organ Transplantation | Thrombosis after reestablishing blood flow to the organ results in blockage of the microvascular bed and organ failure |

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**

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 autoimmune and inflammatory disease and fibrotic diseases, and contributes to carcinogenesis. 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, 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.

The Company has identified three therapeutic approaches to the control of TGF-(Beta): human antibodies directed against TGF-(Beta); recombinant human decorin; and gene therapy delivery of 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 preclinical 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.

(Alpha)v(Beta)3 Integrin Specific Peptides

The Company has developed and licensed patent applications for technology to make peptides having specific binding affinity to different classes of integrins. The Company has a program to create integrin specific peptides and screen them for potential applications. The following integrins are being studied as potentially useful therapeutic targets in preclinical research:

| Target Integrin Class | Clinical Indications | Suggested Mechanism |
|---|---|---|
| (Alpha)IIb(Beta)3 | Thrombosis | Platelet aggregation |
| (Alpha)v(Beta)3 | Angiogenesis | (Alpha)v(Beta)3-mediated vascular cell migration |
| (Alpha)v(Beta)3 | Osteoporosis | (Alpha)v(Beta)3-mediated adhesion of bone-resorbing cells to bone |
| (Alpha)v(Beta)3 and/or (Alpha)IIb(Beta)3 | Restenosis | Smooth muscle cell migration and growth |
| (Alpha)v(Beta)3 and/or (Alpha)5(Beta)1 | Metastasis | Migration of carcinoma cells |
| (Alpha)5(Beta)1 and/or (Alpha)v(Beta)5 | Bone formation | Adhesion of bone-producing cells to bone |

The Company has developed lead compounds targeting (Alpha)v(Beta)3, (Alpha)v(Beta)5 and (Alpha)5(Beta)1, and is carrying out continuing preclinical research on these compounds through collaborative arrangements with academic laboratories experienced in the appropriate disease models. The Company intends to seek strategic alliances to further develop 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.

**Medical Products**

In addition to extensive research into extracellular matrix technologies conducted by the Company, the Company has developed and sells, either directly or through licensing and distribution arrangements, a variety of biomaterials-based medical products and devices that are not specifically based on the Company's regenerative medicine and matrix medicine technologies. These products are currently manufactured by the Company and are used internationally in infection control, surgery, ophthalmology, dentistry and wound care. These products accounted for approximately $7.1 million, $7.8 million and $7.0 million of revenue for the Company during the years ended December 31, 1996, 1995 and 1994, respectively, representing approximately 54%, 76% and 80%, respectively, of the Company's consolidated revenue for such periods.

The Company has pursued a strategy of developing marketing partnerships with leading medical companies to assist in developing the commercial potential of its medical products. The Company believes that such marketing partnerships allow it to concentrate its management and financial resources on the regenerative and pharmacological applications for its extracellular matrix technologies, while still realizing the commercial potential of its current 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 this product line in the United States through a national network of specialized distributors. Of the Company's total product sales for the years ended December 31, 1996, 1995 and 1994, three customers accounted for 42%, four customers accounted for 56% and four customers accounted for 62%, respectively. For the years ended December 31, 1995, 1994 and 1993, the Company's foreign sales were 16%, 11% and 13% of total product sales, respectively.

The table on the following page lists medical products currently

produced or under development by the Company, clinical applications and marketing partners, and is followed by descriptions of the products and their applications:

## Medical Products, Clinical Applications and Marketing Partners

| PRODUCTS/PRODUCTS IN DEVELOPMENT | YEAR INTRODUCED | CLINICAL APPLICATIONS | MARKETING PARTNER |
|---|---|---|---|
| Infection Control | | | |
| VitaCuff | 1987 | Implanted percutaneous infection control | Arrow International, Inc., Bard Access Systems, Inc. and Quinton Instruments Co. |
| VitaPatch/BioPatch | 1993 | Topical percutaneous infection control | Private label for Johnson & Johnson Medical Inc. |
| Surgical and Hemostasis | | | |
| Bicol | 1978 | Neurosurgery | Professional Division of Johnson & Johnson Inc. |
| Collastat, Instat, Otofoam | 1981, 1983<br>1983 | Surgical hemostasis | Various domestic and international distributors |
| Helistat, Helitene | 1985, 1987 | Surgical hemostasis | Direct sales in United States; Selected distributors in Europe and Japan |
| NeuroCol | 1993 | Neurosurgery | As immediately above |
| Collagen coating material | 1992 | Coating for vascular grafts | Sorin Biomedical, Inc. |
| Arterial puncture hemostasis device | In development | Hemostasis of arterial puncture after arterial catherization | N/A |
| Ophthalmic | | | |
| Collagen Corneal Shield | 1991 | Ophthalmic treatment | Alcon Surgical, Inc. |
| Dental Surgery | | | |
| CollaCote, CollaPlug, CollaTape | 1985 | Dental surgery | Calcitek Division of Sulzermedica |
| Wound Care<br>Chronicure / Viaderm | 1990 / In development | Wound dressing for chronic skin ulcers | Unresolved |
| Biocompatible Coatings<br>PepTite | In development | Improved biocompatibility of implantable materials | N/A |
| Orthopedics<br>Tyrosine-based polycarbonates | In development | Improved biocompatibility of orthopedic implants | N/A |
| Tissue Augmentation<br>Urinary incontinence | In development | Improved product for bulking of urinary sphincter | N/A |
| Reproductive Health | In development | Drug delivery for fertility control and sexually transmitted disease prevention | N/A |

**Infection Control Products**

The Company's VitaCuff product provides protection against infection arising from long-term catheters. VitaCuff consists of a silver-impregnated collagen matrix ring which is positioned on the catheter prior to 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 into the surrounding area. In this application, silver functions as a highly effective, broad spectrum antimicrobial agent.

VitaCuff and related products are manufactured by the Company and marketed through Arrow International, Inc., Bard Access Systems, Inc., Quinton Instruments Co. and through selected international distributors.

The Company's VitaPatch product is a wound dressing composed of a synthetic and biopolymer composite foam impregnated with an antimicrobial compound. 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 of time. There are no other dressings currently on the market with comparable antimicrobial protection. VitaPatch is marketed by Johnson & Johnson Medical Inc. under their trade name of BioPatch.

The Company has also developed a silver-impregnated foam wound dressing which provides antimicrobial protection to prevent bacterial colonization leading to infection. The Company is currently evaluating alternative marketing strategies for this product.

**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 of Helistat, Collastat and related products, have been manufactured for more than 15 years and are estimated to have been used with several hundred thousand patients without any severe adverse events being reported.

Products for the surgical hemostasis market are manufactured by the Company and marketed in the United States through a national network of specialized distributors and through various international distributors. Current approved products include Helistat (Absorbable Collagen Hemostatic Sponge) and Helitene (Absorbable Collagen Hemostatic Agent-Fibrillar Form). The Company introduced two new products under its Helistat line in 1996, a thicker 3"x4" sponge (7.0 mm thick for heavier bleeding applications) and a 1" x1 1/2" sponge (to control smaller bleeding sites for the dialysis market).

The Company's Bicol and NeuroCol collagen sponge products are porous matrices used in neurosurgery as moistening agents to prevent drying of brain tissue and as protective devices to buffer the pressure of retractors. The domestic market for moistening/protective devices is dominated by less effective, but lower cost gelatin or cellulose pads. Gelatin and cellulose pads hold less fluid, are more prone to drying and leave behind friable particles that must be irrigated and aspirated for removal. In contrast, the Company's collagen sponge provide absorption of fluid, exceptional wet strength and ease of handling by surgeons. Bicol is manufactured by the Company for the Johnson & Johnson Professional Division of Johnson & Johnson Inc. NeuroCol is manufactured by the Company and marketed with the Helistat line.

As an extension to the surgical product line, the Company has developed a collagen vascular graft coating in conjunction with Sorin Biomedical, Inc. 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 has transferred the coating technology and pilot plant equipment to Sorin Biomedical, and derives its revenues from royalties and the sale of materials to the manufacturer.

**Ophthalmic Products**

The Company's ophthalmic products are used to provide protection and lubrication of the eye in conjunction with various treatments for eye conditions. The Collagen Corneal Shield is a thin collagen film that resembles a contact lens. The Company is also developing a new version of corneal shields with enhanced performance and a viscoelastic material. These technologies have further potential to be used for a sustained delivery of various drugs to the eye. The Company's ophthalmic products are marketed by Alcon Surgical, Inc.

**Dental Surgery Products**

The Company's dental surgery products are extensions of the Company's basic absorbable collagen hemostatic sponge technology. Each of the three

products, CollaCote, CollaPlug and CollaTape, has a unique dimension, shape and density and provides most of the hemostasis requirements encountered in dental surgery. The Calcitek Division of Sulzermedica markets the Company's dental surgery products.

**Wound Care Products**

The Company's Chronicure product is a wound exudate absorbent dressing used for management of chronic wounds and skin ulcers, such as venous stasis ulcers, decubitus ulcers (bed sores) and diabetic ulcers. It is purified protein-hydrolysate of avian collagen. Chronicure is manufactured by the Company and sold in the United States and selected other countries. The Company is also developing a commercial-scale manufacturing process for its Viaderm product, which is also a wound exudate absorbent dressing.

**Biocompatible Coatings**

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") designed to improve the biocompatibility of implantable materials. The coating contains arginine-glycine-aspartic acid peptide sequence. A number of preclinical in vivo effectiveness studies were conducted in collaboration with various implant manufacturers. The Company coated and studied: percutaneous access catheters to reduce thrombus formation; polyester mesh to enhance endothelialization of arterial wall defect repairs and reduce inflammation in hernia and other fascial defects; silicone implants to reduce or eliminate encapsulation of the implant; and certain polymers utilized in cardiovascular devices to reduce

thrombogenicity and enhance tissue ingrowth. The Company's strategy is to develop PepTite in collaboration with medical device manufacturers.

**Orthopedics**

The Company has licensed proprietary technology from Rutgers University for a new class of polymer derived from tyrosine, a naturally-occurring amino acid. This material is currently being developed for orthopedic applications as a pure polymer and in composites with other reinforcing materials. In addition, the Company has rights to utilize this material in wound closure and related drug delivery applications. The polymer is presently undergoing animal safety testing. The Company's strategy is to locate an orthopedic partner to assist in the further development and commercialization of this technology.

**Tissue Augmentation**

The Company is developing an injectable biomaterial to augment the urinary sphincter to address the problem of urinary incontinence. The material is currently undergoing comparative evaluation with commercially available injectables in various preclinical in vivo and in vitro models.

**Reproductive Health**

The Company is working with the Agency for Contraceptive Research and Development and the Population Council in the development of topical, transdermal and implantable drug delivery systems 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.

**Research Strategy**

The Company has either acquired or secured the proprietary rights of several important scientific platforms. These platforms can be organized into four distinct but complementary technological categories: (1) Bioabsorbable and other materials, (2) Extracellular matrix and other specialized materials structures, (3) Materials as delivery vehicles for peptides, cells, growth factors, drugs and other actives, and (4) Actives. The Company's efforts are focused 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 biosmart(TM) 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. Here, the Company's technology and product development efforts are principally organized towards products for two emerging cell-based medical practices: Regenerative Medicine and Matrix Medicine.

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 technology. The Company believes this is a cost-effective way of obtaining know-how and expertise in the Company's technologies while maintaining an ability to respond quickly and effectively to technological changes.

The Company identifies, develops and combines complimentary technologies including biomaterials, cell culture, and growth and differentation factors. To assist the Company in achieving this, it has collaborative, research and/or licensing arrangements with the following institutions:

Summary of Collaborative, Research and/or Licensing Arrangements

| Institution | Project/Product | Sponsor |
|---|---|---|
| Brigham & Women's Hospital, Inc.<br>Boston, MA | INTEGRA Artificial Skin studies | The Company |
| Cambridge Antibody Technology Limited<br>Cambridge, UK | Product development of human TGF-(Beta) antibodies | CAT |
| Duke University Medical Center<br>Durham, NC | Preclinical studies of collagen nerve graft tubes | National Institutes of Health; The Company |
| Eastern Virginia Medical School<br>Norfolk, VA | Preclinical Studies on polymers for topical fertility and sexually transmitted disease control | Agency for Contraceptive Research and Development |
| Hospital for Joint Diseases Orthopaedic Institute<br>New York, NY | Preclinical studies on cartilage regeneration; preclinical studies on tyrosine polycarbonates for orthopedic applications | National Institutes of Health; National Institute of Standards and Technology; The Company |
| The Burnham Institute (formerly La Jolla Cancer Research Foundation)<br>La Jolla, CA | License Agreement concerning basic research on extracellular matrix | The Burnham Institute; The Company |
| Massachusetts General Hospital<br>Boston, MA | INTEGRA Artificial Skin studies | The Company |
| Massachusetts Institute of Technology<br>Cambridge, MA | INTEGRA Artificial Skin studies | The Company |
| Robert Wood Johnson Medical School Piscataway, NJ<br>Rutgers University<br>Piscataway, NJ | Quality control methodology<br>Tyrosine polycarbonate polymers for orthopedic applications | The Company<br>National Institutes of Health; National Institute of Standards and Technology |
| University Hospital<br>Copenhagen, Denmark | Clinical studies of collagen nerve graft tubes | The Company |

The Company spent approximately $6.3 million, $5.2 million and $3.1 million for the years ended December 31, 1996, 1995 and 1994, respectively, on research and development activities. Research and development activities funded by government grants and contract development revenues amounted to $1.1 million, $1.1 million and $1.3 million for the years ended December 31, 1996, 1995, and 1994, respectively.

The Company's research is focused on technology development as opposed to early stage basic research. Further, the research and development policy of the Company attempts to ensure that every promising technological concept has substantive commercial and clinical utility. To promote this, the Company encourages early and close collaboration with clinicians. An example is INTEGRA Artificial Skin, which was the result of a collaboration between a surgeon and a materials scientist. The ability of the surgeon to define the critical specifications of the product, especially that it be available "off the shelf" immediately at the time of early wound excision for patients with life-threatening injury and that it be a permanent wound cover, were essential prerequisites to the product development and demonstration of clinical utility in human clinical trials.

**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 technology, products and product improvements both in the United States and in selected foreign countries. When determined 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, 1996, the Company owned or had exclusive license rights to 107 issued or allowed United States patents and 99 issued or allowed foreign patents, with pending United States patent applications and related foreign patent applications describing approximately 300 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.

In response to a request by the Company, the United States Patent and Trademark Office ("USPTO") declared an interference on November 15, 1993 to determine who was first to invent cyclic arginine-glycine-aspartic acid peptides among several pharmaceutical companies and the Burnham Institute, from whom the Company received its rights. Based upon the records of the USPTO, the patent application to which the Company has rights was the first to be filed among those filed by the parties to the interference. Nevertheless, there can be no assurance that the discovery in question was made first by

scientists at the Burnham Institute. The granting of a patent covering cyclic arginine-glycine-aspartic acid peptides to a third party would have an adverse impact on the Company's ability to develop its TP-9201 peptide and other cyclic arginine-glycine-aspartic acid peptides under development by the Company. Furthermore, there can be no assurance as to the timing, cost, or outcome of the pending interference.

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 for 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.

**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 has completed an addition of approximately 10,000 square foot and a commercial-scale manufacturing facility for INTEGRA Artificial Skin at this location.

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 renovation is in its final phase and the Company has

commenced manufacturing commercial medical products at this facility.

The Company has invested approximately $7.8 million in property and equipment over the last three years, excluding property and equipment acquired in connection with business acquisitions. A substantial portion of this investment was in facility and major equipment additions and renovations at the Company's Plainsboro and West Chester facilities.

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 basic material for the Company's Chronicure and Viaderm wound care products is hydrolyzed collagen from an avian source. The Company processes this biomaterial into a gel-like substance for further external processing monitored by the Company. The Company has installed equipment for the manufacture of bovine collagen-based products at its Plainsboro facility and avian collagen-based products at its West Chester, Pennsylvania facility. Certain spray drying and packaging operations for the Company's avian collagen-based products are performed by outside contractors.

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 universities, research institutions and pharmaceutical, chemical and biotechnology companies is intense. Many competitors or potential competitors have greater financial resources, research and development capabilities and marketing and manufacturing experience than the Company. 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 being developed 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 following table presents the status of products known to the Company which are on the market or under development that might compete with INTEGRA Artificial Skin:

**Competition for INTEGRA Artificial Skin**

| COMPANY | TECHNOLOGY/PRODUCT | STATUS | CURRENTLY SUBJECT TO FDA REGULATION |
|---|---|---|---|
| LifeCell Corporation | Processed cadaver skin | On market | No |
| Genzyme Tissue Repair Division of Genzyme Corporation | Cultured epidermal autograft | On market | No |
| Cell Culture Technology | Cultured epidermal autograft | On market | No |
| Advanced Tissue Sciences, Inc. | Polymer mesh temporary dressing with cultured cells | On market | Yes |
| Organogenesis, Inc. | Cultured cells in collagen matrix | PMA submitted for venous stasis ulcers | Yes |
| Ortec International, Inc. | Cell-seeded collagen matrix | In IDE clinical phase evaluation | Yes |

Certain of the Company's competitors, such as LifeCell Corporation, Genzyme Tissue Repair and Cell Culture Technology, have developed technologies involving processed cadaver skin or cultured epidermal autograft that 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. Two other companies, Advanced Tissue Sciences, Inc. and Organogenesis, Inc., have been granted expedited FDA review for their skin substitutes, Dermagraft-TC and Graftskin, respectively. Dermagraft-TC is a synthetic polymer mesh with cultured human cells that can be used as a temporary dressing until a graft of the patient's own skin can be used. Dermagraft-TC received FDA approval during the first quarter of 1997. Graftskin is composed of donor human cells, bovine collagen and other ingredients. A number of other biotechnology companies are

also developing wound-healing factors to speed the rate of healing of chronic skin ulcers. These products may be competitive or complementary to INTEGRA Artificial Skin.

The Company competes primarily on the uniqueness of its technology and product features, and on the quality and cost-effectiveness of its products and development effort. The Company believes that the first dermal replacement product to reach the United States market benefits from a competitive advantage over later entrants in the market. The Company believes that INTEGRA Artificial Skin is the first dermal replacement product for severe burns approved by the FDA.

There can be no assurance that developments by the Company's competitors or potential competitors will not render the Company's technology or proposed applications of its technology obsolete.

**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 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 time frame 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 Good Manufacturing Practice ("cGMP") 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 foreign 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 cGMP 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 cGMP regulations.

All studies in humans for the purpose of investigating the safety and effectiveness of an investigational medical device must be conducted under the IDE regulations. An IDE application to the FDA includes all preclinical biocompatibility testing, investigational protocol, patient informed consent forms, 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 cGMP 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 is scheduled to be audited under ISO standards during the first half of 1997. Companies that meet ISO standards are internationally recognized as functioning under a quality system. Seventeen countries have adopted ISO 9000 for medical products. Approval of a product by regulatory authorities in foreign 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 addition to the Company's efforts to become ISO 9000 certified, the Company has obtained or is actively pursuing foreign registrations in selected markets for the majority of its product lines. The Company has numerous certificates of export for its complete line of medical products.

**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.

**Employees**

The Company believes that its employees are one of its most important assets. The competitive advantage of life sciences companies depends on a committed workforce, sound management processes and systems which 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. The investment in such systems makes the Company less vulnerable if and when specific employees leave. To foster employee commitment the Company has implemented incentive plans so that employees have an important stake in the Company's shares and benefit from the Company's success. The Company is dedicated to building on these principles as it moves forward.

At December 31, 1996, the Company employed 129 people, of which 52 are engaged in production and production support, 14 in quality assurance/quality control, 21 in research and development, four in regulatory and clinical affairs, 17 in sales/marketing and 21 in administration and finance. None of the Company's employees are subject to a collective bargaining agreement.

**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 which expires in October 2012, and a lease for approximately 25,000 square feet of production, administration and warehouse space in West Chester, Pennsylvania which expires in April 1999, with three five-year renewal options. In 1996, the Company entered into a five year lease for approximately 7,400 square feet of administrative and laboratory space located in San Diego, California.

**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. The Company intends to defend the counterclaim vigorously.

On or about July 18, 1996, Telios Pharmaceuticals, Inc.("Telios"), a wholly-owned subsidiary of Company, 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 the Burnham Institute 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, 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 counter suit asking for an award of defendants' reasonable attorney fees.

On March 27, 1996, Telios filed a motion in the United State Bankruptcy Court for the Southern District of California, in the Telios chapter 11 case, No. 95-00770-H11, regarding "cure" requirements for assumed executory contracts with The University of Utah and The University of Utah Research Foundation (collectively, the "University"). The motion seeks to resolve certain disputes concerning Telios' licensing rights under a certain License Agreement and Research Agreement entered into between Telios and the University. In addition, on March 22, 1996, the University filed a complaint against Telios in the United States District Court for the District of Utah, styled as Case No. 2:96CV-0262W, seeking a declaration that the Research Agreement and License Agreement were terminated or terminable. In January 1997, the parties stipulated to the court to postpone the any trial pending continued settlement discussions.

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

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

**Additional Information**

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

**Executive Officers of the Company**

The executive officers of 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. Mr. Holtz 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. | 53 | Chairman, President and Chief Executive Officer |
| Frederick Cahn, Ph.D. | 54 | Senior Vice President, Technology |
| Andre P. Decarie | 51 | Senior Vice President, Marketing and Sales |
| Michael D. Pierschbacher, Ph.D. | 45 | Senior Vice President, Research and Development |
| David B. Holtz | 30 | Vice President, Treasurer |
| Donald Nociolo | 34 | Vice President, Operations |
| Judith E. O'Grady | 46 | Vice President, Regulatory Affairs |

**Executive Officers**

Richard E. Caruso, Ph.D. founded the Company and is the Chairman, 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. Prior to 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.

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. He was appointed to his current position after the acquisition of Biomat by the Company in April 1993. Prior to 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, Marketing and Sales, 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 October 1988 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. Prior to joining Telios as a full-time employee in October 1988, he was a staff scientist at the Burnham Institute for five years. Dr. Pierschbacher is a member of the adjunct staff of the Burnham Institute. 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.

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. Prior to joining the Company, Mr. Holtz was an associate with Coopers & Lybrand 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 of our customers. Mr. Nociolo has seven years experience working in engineering and manufacturing 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 and 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.

## PART II

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

The Company's Common Stock began trading on The Nasdaq National Market on August 16, 1995 under the symbol IART. The following table represents the high and low sales prices for the Company's Common Stock for each quarter since its initial trading date.

| | HIGH | LOW |
|---|---|---|
| 1995 | | |
| Third Quarter | $10.00 | $4.50 |
| Fourth Quarter | $ 8.75 | $6.00 |
| 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 21, 1997 was $4.00. 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 21, 1997 was approximately 729, which includes stockholders whose shares were held in nominee name. The number of beneficial stockholders at that date was over 7,600.

**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. The nine month period ended December 31, 1992 reflects the period subsequent to the March 31, 1992 purchase of all of the Company's common stock by an affiliate of Dr. Richard E. Caruso, the controlling stockholder of the Company.

| | Years Ended December 31, | | | | Nine Months Ended |
|---|---|---|---|---|---|
| | 1996 | 1995 | 1994 | 1993 | December 31,1992 |
| | (In thousands, except per share data) | | | | |
| Statement of Operations Data (1) | | | | | |
| Product sales | $11,210 | $ 8,356 | $ 6,958 | $ 3,950 | $ 1,352 |
| Research grants | 1,072 | 1,064 | 912 | 300 | 90 |
| Product license fees | 500 | 520 | 200 | 300 | ---- |
| Royalty income | 290 | 239 | 174 | 125 | 4 |
| Contract product development | 76 | 50 | 417 | 101 | 31 |
| Total revenue | 13,148 | 10,229 | 8,661 | 4,776 | 1,477 |
| Cost of product sales | 6,671 | 4,850 | 4,402 | 2,535 | 940 |
| Research and development | 6,294 | 5,191 | 3,085 | 2,170 | 282 |
| Selling, general and administrative | 9,630 | 6,097 | 3,505 | 2,576 | 992 |
| Acquired in-process research and development (2) | ---- | 19,593 | (275) | 20,642 | ---- |
| Total costs and expenses | 22,595 | 35,731 | 10,717 | 27,923 | 2,214 |
| Operating loss | (9,447) | (25,502) | (2,056) | (23,147) | (737) |
| Interest income | 1,799 | 283 | 221 | 12 | 39 |
| Interest expense | ---- | (188) | (64) | (218) | (135) |
| Other income (expense) | 120 | 5 | (1) | 19 | 15 |
| Net loss | $(7,528) | $(25,402) | $(1,900) | $(23,334) | $ (818) |
| Net loss per share | $ (.27) | $ (1.21) | $ (.10) | $ (1.41) | $ (.06) |
| Weighted average number of common shares outstanding | 28,114 | 21,073 | 19,035 | 16,583 | 14,450 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 1996 | 1995 | 1994 | 1993 | 1992 |
| | (In thousands) | | | | |
| Balance Sheet Data (1) | | | | | |
| Cash, cash equivalents and short-term investments | $ 34,276 | $ 5,710 | $ 3,331 | $ 5,066 | $ 1,213 |
| Working capital | 37,936 | 7,476 | 3,610 | 3,488 | 1,340 |
| Total assets | 48,741 | 19,378 | 13,703 | 10,043 | 2,442 |
| Long-term debt | ---- | ---- | 1,754 | 3,224 | 1,635 |
| Accumulated deficit (2) | (58,981) | (51,454) | (26,052) | (24,152) | (818) |
| Total stockholders' equity | 46,384 | 17,427 | 9,275 | 3,559 | 92 |

(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 from these periods are not directly comparable. See Notes 1 and 12 of the Company's consolidated financial statements included elsewhere in this Report.

(2) 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 is dedicated to the acquisition, discovery and development of synergistic technologies for creating and marketing cost-effective, off-the-shelf, bio-absorbable products designed to regenerate specific body tissues and organs, or treat many cell-based diseases or age-associated

conditions. 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 the years presented below may not be directly comparable.

The following discussion contains trend information and other forward-looking statements related to the future use and sales of 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 "Factors That May Affect Future Results of Operations" below.

**Results of Operations**

**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(TM) Artificial Skin ("INTEGRA") in 1996 compared to minimal sales in the prior year. Approximately 71% of INTEGRA sales in 1996 were in the United States following the product's marketing approval from the FDA in March, 1996. During 1996, 65 burn centers and hospitals throughout the United States and Canada purchased INTEGRA. INTEGRA export sales were to 13 countries in Europe and Asia. The Company believes that the primary application of INTEGRA has been for patients with severe life-threatening burns, but is aware of its application in reconstructive procedures. The continued growth of INTEGRA sales will depend on the Company's ability to increase its customer base (primarily burns centers and hospital burn units) as well as increase the number of patients treated and the amount of product used per patient. Factors that the Company believes affect this growth include continued physician training prior to product use, the continued collection of pharma-economic data to address product reimbursement issues and the publication and discussion of positive clinical results within the physician community.

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. The Company has resolved the production difficulties in the ophthalmic product line and began shipping product to its marketing partner in the first quarter of 1997. Approximately 42% and 56% of the Company's product sales were to three customers in 1996 and four customers in 1995, respectively. Because a significant portion of the Company's products (other than INTEGRA) are sold to marketing partners, quarter-to-quarter sales in medical products can vary significantly. 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 National Institute of Science and Technology (NIST) grant. The NIST grant was completed as of December 31, 1996. Grant revenue is expected to be lower in 1997 unless additional grants are awarded to the Company. 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 receieved 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 different periods of 1996. Due to the high fixed costs of the manufacturing facility for INTEGRA, the Company is anticipating higher unit 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. The Company continues to seek contract manufacturing opportunities to increase utilization of its capacity.

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. 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. The Company expects the level of research and development expenditures in 1997 to be higher than in 1996 as expenditures related to the post-approval study for INTEGRA and other clinical and pre-clinical trials expand. These trials are expected 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, general and administrative expense increased 58% from $6.1 million in 1995 to $9.6 million in 1996 due in part to an increase of $1.6 million in general and administrative expense incurred by the Company's Telios operation. Sales and marketing expenses increased by $1.8 million 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 has 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. A significant portion of Telios' administrative expense involves the maintainance of its intellectual property and expenditures related to patent infringement litigation. The Company is involved in an infringement litigation case that is in its early stages, and the Company anticipates incurring continued significant expenditures during 1997 related to this matter. The Company is anticipating selling, general and administrative expense to remain higher than 1996 levels due to the ongoing introduction and marketing of INTEGRA and Telios' 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.

**1995 Compared to 1994**

The Company's net loss increased from $1.9 million in 1994 to $25.4 million in 1995. Included in the 1995 loss is $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 18% from $8.7 million in 1994 to $10.2 million in 1995 primarily as a result of an increase in medical product sales of $1.4 million. Medical product sales increased from $7 million in 1994 to $8.4 million in 1995 with increases in the Company's surgical and hemostasis, dental and ophthalmic product lines. The increases in surgical and hemostasis product sales were largely the result of increases in unit volume associated with the Company's direct marketing efforts and one of the Company's marketing and distribution agreements. Dental product sales increased as a result of initial stocking orders for the Company's BioMend product, which received FDA marketing clearance in August 1995. The Company's ophthalmic product also showed an increase in unit volume sold to the Company's marketing partner. The Company commenced foreign sales of INTEGRA in the third quarter of 1995 and had limited sales in 1995 in connection with the product's introduction at foreign training conferences. The Company's total export foreign sales increased from $926,000 in 1994 to $945,000 in 1995 with a significant shift in revenues from supplying a raw material component to a marketing partner (76% of foreign sales in 1994) to direct marketing of the Company's surgical and hemostasis product line (56% of foreign sales in 1995).

Research grant revenue increased from $912,000 in 1994 to $1.1 million in 1995. The Company's largest grant is from the National Institute of Science and Technology, which increased from $431,000 in 1994 to $660,000 in 1995. The Company received several new grants in 1995, which were offset by decreases in two Small Business Innovation Research grants that provided funding in 1994. A substantial portion of licensing revenue in 1994 and 1995 was related to the Company's BioMend product, which is exclusively marketed through the Calcitek Division of Sulzermedica. Contract product development funding declined by $367,000 from 1994 to 1995 as a result of the expiration of funding for development efforts on the Company's ophthalmic product line.

Cost of product sales increased 10% from $4.4 million (63% of product sales) in 1994 to $4.9 million (58% of product sales) in 1995. The decrease in cost of product sales as a percentage of sales was due primarily to costs incurred during 1994 related to the transfer of manufacturing equipment and related materials from the Company's Menlo Park, California facility to its Plainsboro, New Jersey facility and increases in unit volume output in 1995. The decrease was partially offset by an increase in costs in the fourth quarter of 1995 related to production capacity for INTEGRA at the Company's Plainsboro, New Jersey facility as well as increased capacity at the Company's West Chester, Pennsylvania facility.

Research and development expense increased 68% from $3.1 million in 1994 to $5.2 million in 1995, due in part to $1.2 million of research and development expense incurred by Telios since the Company's acquisition of Telios in August 1995. The remaining $900,000 increase was due to costs associated with the addition of full-time research and development staff, increased expenditures for outside contract research, additional lab supplies and equipment, and consultants for research and product development activities related to the Company's regenerative medicine technologies. The majority of these expenditures

were associated with the validation of manufacturing and quality assurance processes for INTEGRA and expenditures funded under research grants.

Selling, general and administrative expense increased 74% from $3.5 million in 1994 to $6.1 million in 1995 with $700,000 of the increase resulting from administrative expenses incurred by Telios during the post-acquisition period. The remaining $1.9 million was largely attributable to $1.1 million of additional sales and marketing expenses resulting from the introduction of selected medical product lines in international markets, the development of marketing and training materials for INTEGRA and the establishment in the third quarter of 1994 of a direct surgical sales force to market certain medical product lines domestically. Additional administrative expenditures in 1995 included $300,000 for legal and accounting fees and governmental filing fees incurred in connection with the registration of the Company's common stock under the Securities Exchange Act of 1934 and the Company's listing on the Nasdaq National Market. The remaining $500,000 of increases during 1995 consisted of additional administrative costs, primarily related to the operation of the Company's West Chester, Pennsylvania facility for a full year compared to a six-month period in 1994, and the hiring of additional regulatory and administrative support personnel at the Company's Plainsboro, New Jersey facility.

Interest income increased by $62,000 from 1994 to 1995 due to higher cash balances following the Telios acquisition. Interest expense increased by approximately $124,000 from 1994 to 1995 as a result of higher outstanding balances under the Company's revolving line of credit (the "Revolving Credit") from an affiliate of Dr. Richard E. Caruso, the controlling stockholder of the Company, through September of 1995.

**Liquidity and Capital Resources**

The Company has funded its operations to date primarily through private and public offerings of its common stock, revenues from sales of existing products, research grants from government agencies, development agreements with major industrial companies, borrowings under the Revolving Credit 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. As a result of the offering, the outstanding balance of $10,000 on the Revolving Credit was paid and the Revolving Credit terminated in accordance with its terms.

At December 31, 1996, the Company had cash, cash equivalents and short-term investments of $34.3 million representing a $28.6 million increase from December 31, 1995. The Company's principal sources of liquidity in 1996 were the receipt of $35.6 million in net proceeds from an underwritten public offering of its common stock, $790,000 from the exercise of stock options under the Company's stock option plans and $300,000 from the sale of fixed assets. The principal uses of funds during 1996 were $8.0 million for operations which included $1.3 million and $1.1 million in the growth of inventory and accounts

receivable, respectively, and $1.2 million in purchases of property and equipment.

The Company's principal sources of liquidity in 1995 were cash acquired in the Telios acquisition of $10.4 million after payment of bankruptcy claims, $1.9 million in borrowings under the Revolving Credit and $1.0 million from a private placement of common stock. The principal uses of funds in 1995 were $5.6 million for operations, $2.9 million for plant and equipment and $2.2 million for repayments on the Revolving Credit.

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. There can be no assurance that the Company will be able to generate sufficient revenues to obtain profitability.

**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 patient's length of hospital stay. However, the cost of the product does require the healthcare provider to incur a higher initial cost than is customary under most 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 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 has filed a patent infringement lawsuit against three parties charging that there is a willful and deliberate infringement on a patent licensed by the Company from The Burnham Institute. This litigation, 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.

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 the assesment of 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, 1996, the Company had net operating loss carryforwards of approximately $22 million and $13 million for federal and state income tax purposes, respectively, to offset future taxable income, if any, which expire through 2011 and 2003, respectively. At December 31, 1996, 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 2002 and 2009. 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 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 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 on an international basis. The Company is currently evaluating the new statement and the impact of adoption of SFAS 128 on the Company's financial statements is not presently known. This statement is effective for financial statements for periods ending after December 15, 1997 and requires restatement of all prior period earnings or losses per share data presented.

**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 19, 1997, 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.



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) |

| Exhibit Number | Description | Location |
|---|---|---|
| 3.2 | Amended and Restated By-laws of the Company | (2) (Exh. 3.2) |
| 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 | License Agreement between Smith & Nephew Consolidated Inc. and Vitaphore Corporation dated as of December 31, 1993 | (2) (Exh. 10.3) |
| 10.4 | Research and License Agreement between the Brigham and Women's Hospital, Inc. and the Company dated as of January 1, 1995 | (2) (Exh. 10.4) |
| 10.5 | Exclusive License Agreement between the Company and Rutgers University dated as of December 31, 1994 | (2) (Exh. 10.5) |
| 10.6 | License Agreement for Adhesion Peptides Technology between La Jolla Cancer Research Foundation and Telios dated as of June 24, 1987 | (2) (Exh. 10.6) |
| 10.7(a) | Letter of Intent among Cambridge Antibody Technology Limited ("CAT"), Telios and the Company dated May 10, 1995 | (2) (Exh. 10.7(a)) |
| 10.7(b) | Strategic Alliance and Technology Agreement dated as of June 23, 1995 between CAT and Telios and consented to by the Company | (2) (Exh. 10.7(b)) |
| 10.8 | Technology Development and License Agreement between Union Carbide and the Company dated as of April 30, 1993 | (2) (Exh. 10.8) |
| 10.9 | Research Agreement between Helitrex Inc., American Biomaterials Corporation and Dr. Roger Madison dated as of May 30, 1986, as extended by and between the Company and Duke University dated as of January 1, 1995 | (2) (Exh. 10.9) |
| 10.10 | Development Agreement between Boston Scientific Corporation and Colla-Tec, Inc. dated as of December 29, 1993 | (2) (Exh. 10.10) |
| 10.11 | OEM Manufacturing and Supply Agreement between Boston Scientific Corporation and Colla-Tec, Inc. dated as of December 29, 1993 | (2) (Exh. 10.11) |
| 10.12 | Supply Agreement between Genetics Institute, Inc. and the Company dated as of April 1, 1994 | (2) (Exh. 10.12) |
| 10.13 | Employment Agreement between the Company and Andre P. Decarie dated as of June 10, 1993 * | (2) (Exh. 10.13) |
| 10.14 | Employment Agreement between the Company and Robert J. Towarnicki dated as of July 1, 1992 * | (2) (Exh. 10.14) |

| Exhibit Number | Description | Location |
|---|---|---|
| 10.15 | Employment Agreement between the Company and John R. Emery dated as of December 6, 1994 * | (2) (Exh. 10.15) |
| 10.16 | Employment Agreement between the Company and Frederick Cahn dated as of December 31, 1992 * | (2) (Exh. 10.16) |
| 10.17 | Letter Agreement between the Company and Ioannis V. Yannas, Ph.D. dated as of December 31, 1992 regarding the provision of Consulting and Technology Services | (2) (Exh. 10.17) |
| 10.18 | Registration Rights Agreement between the Company and Manor Care, Inc. dated as of April 28, 1995 | (2) (Exh. 10.18) |
| 10.19 | Registration Rights Agreement between the Company and Edmund L. Zalinski dated as of August 31, 1994 | (2) (Exh. 10.19) |
| 10.20 | Registration Rights Agreement between the Company and Edmund L. Zalinski Company dated as of August 31, 1994 | (2) (Exh. 10.20) |
| 10.21 | Registration Rights Agreement between the Company and Elliot-Lewis Corporation dated as of August 31, 1994 | (2) (Exh. 10.21) |
| 10.22 | Registration Rights Agreement between the Company and Steven Dadio dated as of August 31, 1994 | (2) (Exh. 10.22) |
| 10.23 | Registration Rights Agreement between the Company and William R. Sautter dated as of August 31, 1994 | (2) (Exh. 10.23) |
| 10.24 | Registration Rights Agreement between the Company and Alcon Laboratories, Inc. dated as of April 22, 1994 | (2) (Exh. 10.24) |
| 10.25 | Registration Rights Agreement between the Company and Genetics Institute, Inc. dated as of April 26, 1994 | (2) (Exh. 10.25) |
| 10.26 | Registration Rights Agreement between the Company and Boston Scientific Corporation dated as of December 29, 1993 | (2) (Exh. 10.26) |
| 10.27(a) | Stockholder Rights Agreement between the Company and Union Carbide dated as of April 30, 1993 ("Carbide Agreement") | (2) (Exh. 10.27(a)) |
| 10.27(b) | Amendment dated November 30, 1993 to Carbide Agreement | (2) (Exh. 10.27(b)) |
| 10.28 | 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) |
| 10.29 | 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) |
| 10.30 | 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) |
| 10.31 | 1992 Stock Option Plan * | (2) (Exh. 10.31) |

| Exhibit Number | Description | Location |
|---|---|---|
| 10.32 | 1993 Incentive Stock Option and Non-Qualified Stock Option Plan * | (2) (Exh. 10.32) |
| 10.33 | Loan and Security Agreement between the Company and Provco Leasing Corporation dated as of June 30, 1993, as amended December 31, 1994, February 8, 1995 and June 8, 1995 | (2) (Exh. 10.33) |
| 10.34 | Letter Agreement between the Company and Provco Leasing Corporation dated as of June 8, 1995 regarding debt conversion | (2) (Exh. 10.34) |
| 10.35 | Warrant Agreement between the Company and Boston Scientific Corporation dated as of December 29, 1993 | (2) (Exh. 10.35) |
| 10.36 | Registration Rights Agreement between the Company and Provco Leasing Corporation dated as of April 30, 1995 | (2) (Exh. 10.37) |
| 10.37 | 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) |
| 10.38 | 1996 Incentive Stock Option and Non-Qualified Stock Option Plan* | (5) (Exh. 4.3) |
| 11 | Statement re: Computation of Per Share Earnings | (1) |
| 21 | Subsidiaries of the Company | (1) |
| 24 | Powers of Attorney | (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 Registration Statement on Form S-8 (File No. 333-06577) which became effective on June 22, 1996.

(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.

[Coopers & Lybrand Letterhead]

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, 1996 and 1995, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 1996. 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, 1996 and 1995, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1996 in conformity with generally accepted accounting principles.

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

Princeton, New Jersey
February 21, 1997

INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | December 31, 1996 | December 31, 1995 |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 11,761,925 | $ 4,512,434 |
| Short-term investments | 22,514,221 | 1,197,812 |
| Accounts receivable, net of allowance for doubtful accounts of $227,815 and $253,843 as of December 31, 1996 and 1995, respectively | 2,902,201 | 1,768,099 |
| Inventories | 2,634,950 | 1,372,313 |
| Prepaid expenses and other current assets | 338,175 | 468,547 |
| Total current assets | 40,151,472 | 9,319,205 |
| Property and equipment, net | 8,553,845 | 9,605,796 |
| Intangibles and other assets | 36,100 | 452,719 |
| Total assets | $ 48,741,417 | $ 19,377,720 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable, trade | $ 161,836 | $ 321,304 |
| Accrued expenses and other current liabilities | 2,053,558 | 1,511,508 |
| Short-term debt - related party | - | 10,314 |
| Total current liabilities | 2,215,394 | 1,843,126 |
| Other liabilities | 141,988 | 107,908 |
| Total liabilities | 2,357,382 | 1,951,034 |
| Commitments and contingencies | | |
| Stockholders' Equity: | | |
| Preferred stock, $.01 par value (15,000,000 authorized shares; no shares issued or outstanding) | - | - |
| Common stock, $.01 par value (60,000,000 authorized shares; 28,551,315 and 23,493,916 issued and outstanding at December 31, 1996 and 1995, respectively) | 285,513 | 234,939 |
| Additional paid-in capital | 105,447,248 | 68,730,310 |
| Unearned compensation related to stock options | (327,994) | - |
| Notes receivable - related parties | (34,875) | (84,875) |
| Unrealized loss on available-for-sale investments | (4,436) | - |
| Accumulated deficit | (58,981,421) | (51,453,688) |
| Total stockholders' equity | 46,384,035 | 17,426,686 |
| Total liabilities and stockholders' equity | $ 48,741,417 | $ 19,377,720 |

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

**INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 1996 | 1995 | 1994 |
| REVENUE | | | |
| Product sales | $ 11,209,980 | $ 8,355,961 | $ 6,958,491 |
| Research grants | 1,072,528 | 1,063,476 | 911,626 |
| Product license fees | 500,000 | 520,000 | 200,000 |
| Royalties | 289,921 | 239,389 | 174,142 |
| Contract product development | 76,136 | 50,300 | 416,982 |
| Total revenue | 13,148,565 | 10,229,126 | 8,661,241 |
| COSTS AND EXPENSES | | | |
| Cost of product sales | 6,671,158 | 4,850,366 | 4,402,341 |
| Research and development | 6,293,617 | 5,190,495 | 3,085,368 |
| Selling, general and administrative | 9,630,485 | 6,097,376 | 3,504,989 |
| Acquired in-process research and development | - | 19,592,567 | (275,630) |
| Total costs and expenses | 22,595,260 | 35,730,804 | 10,717,068 |
| Operating loss | (9,446,695) | (25,501,678) | (2,055,827) |
| Interest income | 1,798,918 | 282,604 | 220,799 |
| Interest expense - related party | (126) | (187,897) | (63,704) |
| Other income (expense) | 120,170 | 5,387 | (969) |
| Net loss | $ (7,527,733) | $ (25,401,584) | $ (1,899,701) |
| Net loss per share | $ (0.27) | $ (1.21) | $ (0.10) |
| Weighted average number of common and common equivalent shares outstanding | 28,113,869 | 21,073,214 | 19,035,147 |

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

**INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 1996 | 1995 | 1994 |
| OPERATING ACTIVITIES: | | | |
| Net loss | $ (7,527,733) | $ (25,401,584) | $ (1,899,701) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 2,058,724 | 1,394,422 | 709,232 |
| (Gain) loss on sale of assets | (136,462) | (5,387) | 969 |
| Loss on sale of investments | 26,176 | - | - |
| Amortization of discount and interest on investments | (954,832) | (20,968) | - |
| Acquired in-process research and development | - | 19,592,567 | (275,630) |
| Common stock issued and amortization of unearned compensation | 83,194 | 70,000 | 82,900 |
| Deferred revenue | (10,650) | (350,000) | (150,000) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (1,134,102) | (175,450) | (739,870) |
| Inventories | (1,262,637) | (423,312) | (219,329) |
| Prepaid and other current assets | 130,372 | 252,201 | (215,110) |
| Non-current assets | 159,478 | 9,825 | (16,119) |
| Accounts payable, accrued expenses and other liabilities | 601,916 | (584,796) | (383,569) |
| Net cash used in operating activities | (7,966,556) | (5,642,482) | (3,106,227) |
| INVESTING ACTIVITIES: | | | |
| Proceeds from the sales/maturities of investments | 21,138,142 | - | - |
| Purchases of investments | (41,530,331) | (1,176,844) | - |
| Purchases of property and equipment | (1,171,884) | (2,924,720) | (3,739,956) |
| Proceeds from sale of assets | 304,037 | 12,628 | 10,330 |
| Cash acquired in business acquisitions | - | 13,116,670 | - |
| Payments of acquired bankruptcy claims and acquisition costs | (10,409) | (2,940,763) | - |
| Net cash provided by (used in) investing activities | (21,270,445) | 6,086,971 | (3,729,626) |
| FINANCING ACTIVITIES: | | | |
| Proceeds from sales of common stock | 35,661,463 | 1,000,001 | 7,500,000 |
| Proceeds from exercised stock options | 785,343 | 70,662 | - |
| Payments of long-term debt | (10,314) | (2,181,578) | (4,245,220) |
| Proceeds from long-term debt | - | 1,937,897 | 1,813,704 |
| Notes receivable - related parties | 50,000 | - | 32,890 |
| Other financing activities | - | (90,482) | - |
| Net cash provided by financing activities | 36,486,492 | 736,500 | 5,101,374 |
| Net increase (decrease) in cash and cash equivalents | 7,249,491 | 1,180,989 | (1,734,479) |
| Cash and cash equivalents at beginning of period | 4,512,434 | 3,331,445 | 5,065,924 |
| Cash and cash equivalents at end of period | $ 11,761,925 | $ 4,512,434 | $ 3,331,445 |

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

**INTEGRA LIFESCIENCES CORPORATION AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

| | Common Stock Shares | Common Stock Amount | Additional Paid-In Capital | Notes Receivable-Related Parties |
|---|---|---|---|---|
| Balance, December 31, 1993..... | 18,466,455 | $ 184,665 | $27,644,139 | $(117,765) |
| Sale of common stock..... | 937,500 | 9,375 | 7,490,625 | - |
| Issuance of common stock for services rendered..... | 10,000 | 100 | 82,800 | - |
| Decrease in notes receivable... | - | - | - | 32,890 |
| Net loss..... | - | - | - | - |
| Balance, December 31, 1994..... | 19,413,955 | 194,140 | 35,217,564 | (84,875) |
| Sale of common stock..... | 115,607 | 1,156 | 998,845 | - |
| Issuance of common stock for services rendered..... | 8,000 | 8 | 69,920 | - |
| Conversion of Revolving Credit. | 173,411 | 1,734 | 1,498,271 | - |
| Business acquisition..... | 3,573,743 | 35,737 | 30,877,140 | - |
| Issuance of common stock under stock option plans..... | 209,200 | 2,092 | 68,570 | - |
| Net loss..... | - | - | - | - |
| Balance, December 31, 1995..... | 23,493,916 | 234,939 | 68,730,310 | (84,875) |
| Public offering of common stock..... | 4,671,250 | 46,713 | 35,524,268 | - |
| Issuance of common stock under stock option plans..... | 386,149 | 3,861 | 781,482 | - |
| Unearned compensation related to stock options..... | - | - | 411,188 | - |
| Amortization of unearned compensation..... | - | - | - | - |
| Decrease in notes receivable... | - | - | - | 50,000 |
| Unrealized loss on investments..... | - | - | - | - |
| Net loss..... | - | - | - | - |
| Balance, December 31, 1996..... | 28,551,315 | $ 285,513 | $105,447,248 | $(34,875) |

| | Unearned Compensation Related to Stock | Unrealized (Loss) on Investments | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|
| Balance, December 31, 1993..... | $ - | $ - | $(24,152,403) | $3,558,636 |
| Sale of common stock..... | - | - | - | 7,500,000 |
| Issuance of common stock for services rendered..... | - | - | - | 82,900 |
| Decrease in notes receivable... | - | - | - | 32,890 |
| Net loss..... | - | - | (1,899,701) | (1,899,701) |
| Balance, December 31, 1994..... | - | - | (26,052,104) | 9,274,725 |
| Sale of common stock..... | - | - | - | 1,000,001 |
| Issuance of common stock for services rendered..... | - | - | - | 70,000 |
| Conversion of Revolving Credit. | - | - | - | 1,500,005 |
| Business acquisition..... | - | - | - | 30,912,877 |
| Issuance of common stock under stock option plans..... | - | - | - | 70,662 |
| Net loss..... | - | - | (25,401,584) | (25,401,584) |
| Balance, December 31, 1995..... | - | - | (51,453,688) | 17,426,686 |

| | | | | |
|---|---|---|---|---|
| Public offering of common stock | - | - | - | 35,570,981 |
| Issuance of common stock under stock option plans..... | - | - | - | 785,343 |
| Unearned compensation related to stock options..... | (411,188) | - | - | - |
| Amortization of unearned compensation..... | 83,194 | - | - | 83,194 |
| Decrease in notes receivable... | - | - | - | 50,000 |
| Unrealized loss on investments. | - | (4,436) | - | (4,436) |
| Net loss..... | - | - | (7,527,733) | (7,527,733) |
| Balance, December 31, 1996..... | $(327,994) | $ (4,436) | $(58,981,421) | $46,384,035 |

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

1. BUSINESS

Integra LifeSciences Corporation and Subsidiaries (collectively, the "Company") intends to commercialize products in the emerging new extracellular matrix and biomaterials-based science of regenerative medicine, an enabling science that encourages the directed regeneration of new physiological body tissues and organs. The science makes use of the Company's proprietary specialized extracellular matrices which it calls Regeneration Template(TM) Devices. These are a form of biomaterial-based scaffolding, which enables the growth and regeneration of natural functioning substitute tissues and organs. With few exceptions, the human body will not ordinarily regenerate a substitute for its own diseased or damaged tissue or organs. The Company also has extracellular matrix based technologies which may allow for the therapeutic treatment of a wide range of cell based diseases.

In addition to its efforts to commercialize its biomaterials and extracellular matrix technologies, the Company utilizes its same base of medical biomaterials, proprietary technologies and expertise to manufacture and sell directly or through distribution arrangements over a dozen medical products which serve diverse medical markets including surgical hemostasis, ophthalmic, wound care, dental and infection control.

The Company has developed principally by combining existing businesses, acquiring synergistic technologies and forming strategic business and technological alliances. It acquired ABS LifeSciences Inc. (formerly Applied Biomedical Sciences, Inc.) and its wholly-owned subsidiary Medimatrix, Inc. in November 1990; Colla-Tec, Inc. (formerly a subsidiary of Marion Merrell Dow, Inc.) in June 1991; and certain technologies obtained from the Wound Care Division of Marion Merrell Dow, Inc. incorporated as Integra (Artificial Skin) Corp. in August 1991. The Company acquired Vitaphore Corporation (formerly a subsidiary of Union Carbide Chemical and Plastics Company, Inc.) as of April 30, 1993; substantially all of the assets and liabilities of Biomat Corporation incorporated as Biomaterials Corporation as of June 30, 1993; and Smith & Nephew Medical Limited's 50% interest in a joint venture with Vitaphore Corporation as of December 31, 1993. In August 1995, the Company acquired Telios Pharmaceuticals, Inc.("Telios").

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. 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 is 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**

On January 1, 1994, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities". There was no effect on income from the adoption of this Standard. 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.

**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. 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 which 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.

**Intangible Assets**

Acquired intangible assets are stated at cost and are amortized using the straight-line method over their estimated useful lives. The Company acquired an intangible asset in December 1993 which has been amortized over three years. For the years ended December 31, 1996, 1995 and 1994, the Company's amortization expense was $99,804.

**Income Taxes**

The Company follows the provisions of SFAS 109, "Accounting for Income Taxes". Under the asset and liability method required by SFAS 109, 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.

**Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and short-term investments which are held at major financial institutions and trade receivables. The Company's products are sold on an uncollateralized basis and on credit terms based upon a credit risk assessment of each customer. The Company's principal customers are generally well established and in some cases are industry leaders, or are affiliated with industry leaders, in the sales and marketing of medical devices. The Company's provision for doubtful accounts receivable for the years ended December 31, 1996, 1995 and 1994 were $204,505, $185,316, and $70,524, respectively. Amounts written off for the years ended December 31, 1996, 1995 and 1994 were $230,533, $10,765 and $39,000, respectively.

**Loss per Share**

Net loss per share is based on the weighted average number of common and common equivalent shares outstanding during the periods. Options and warrants have been excluded in the calculation of common and common equivalent shares as they are antidilutive.

**New Accounting Pronouncements**

Effective January 1, 1996, the Company adopted SFAS 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of", which requires companies to review their long-lived assets and certain identifiable intangibles (collectively, "Long-Lived Assets") for impairment whenever events or changes in circumstances indicate that the carrying value of a Long-Lived Asset may not be recoverable. The Company's adoption of SFAS 121

did not have a material impact on its financial position or results of operations.

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.

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 on an international basis. The Company is currently evaluating the new statement and the impact of adoption of SFAS 128 on the Company's financial statements is not presently known. This statement is effective for financial statements for periods ending after December 15, 1997 and requires restatement of all prior period earnings or losses per share data presented.

**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 1994 and 1995 amounts have been reclassified to conform to the 1996 presentation.

3. INVESTMENTS

The Company's current investment balances are classified as available for sale and have maturities within one year. For the twelve months ended December 31, 1996, securities were sold for proceeds of $3,938,142 and a net loss of $26,176. Investment balances as of December 31, 1996 were as follows:

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| U.S. Government securities..... | $ 2,019,213 | $ -- | $ (5,441) | $ 2,013,772 |
| U.S. Government agency securities..... | 20,499,444 | 13,040 | (12,035) | 20,500,449 |
| Total investments..... | $ 22,518,657 | $ 13,040 | $ (17,476) | 22,514,221 |

4. INVENTORIES

Inventories consist of the following:

| | December 31, | |
|---|---|---|
| | 1996 | 1995 |
| Finished goods | $1,006,596 | $ 480,343 |
| Work-in-process | 1,270,252 | 516,840 |
| Raw materials | 358,102 | 375,130 |
| | $2,634,950 | $1,372,313 |

5. PROPERTY AND EQUIPMENT

Property and equipment, net, consists of the following:

| | December 31, | |
|---|---|---|
| | 1996 | 1995 |
| Machinery and equipment | $ 4,763,409 | $ 4,546,880 |
| Furniture and fixtures | 206,823 | 232,969 |
| Leasehold improvements | 7,270,410 | 6,865,841 |
| Construction in progress | -- | 295,882 |
| | 12,240,642 | 11,941,572 |
| Less: Accumulated depreciation and amortization | (3,686,797) | (2,335,776) |
| | $ 8,553,845 | $ 9,605,796 |

Depreciation and amortization expense for the years ended December 31, 1996, 1995 and 1994 was $1,958,905, $1,294,618, and $609,428, respectively.

6. CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 1996 | 1995 |
| Legal fees | $ 661,046 | $ 315,514 |
| Contract research | 375,052 | 188,423 |
| Accrued royalties | 215,682 | 18,583 |
| Customer Advances | 204,478 | -- |
| Vacation | 174,124 | 174,689 |
| Fixed asset purchases | -- | 97,355 |
| Other | 423,176 | 716,944 |
| | $2,053,558 | $1,511,508 |

During the fourth quarter of 1994, the Company reduced an accrual for a plant closing by $275,630 to reflect a reduction in anticipated costs associated with closing such facility. The change in accounting estimate is reflected as a reduction in acquired in-process research and development.

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 the majority shareholder of the Company. The Revolving Credit was collateralized by certain tangible and intangible assets of the Company and all of the capital stock of the Company's subsidiaries.

In June 1995, $1,500,005 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. Outstanding principal and interest was to be paid to the Lender and the Revolving Credit was to expire the earlier of (a) August 15, 1996, (b) the closing of an initial public offering of equity securities by the Company, or (c) the Company's private placement or placements of equity securities which nets to the Company an aggregate of $20,000,000.

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 value of $1,000,001.

In April 1994, in private placement transactions, the Company sold a total of 750,000 shares of its common stock, 375,000 shares each to Alcon Laboratories, Inc. ("Alcon") and Genetics Institute, Inc. ("GI") at a per share price of $8.00 for an aggregate value of $6,000,000.

In June 1994, in private placement transactions, the Company sold a total of 187,500 shares of common stock, 125,000 shares for $1,000,000 to a contractor and its affiliates and 62,500 shares for $500,000 to a director of the Company.

In December 1994, the Company issued to Rutgers University ("Rutgers") 10,000 shares of its common stock in connection with the licensing of certain technologies from Rutgers. Such amount was expensed in 1994.

**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.

**Massachusetts Institute of Technology Warrant**

As partial consideration for a technology license entered into with Massachusetts Institute of Technology ("MIT") (see Note 14), the Company granted to MIT a warrant (the "MIT Warrant") to purchase 45,000 shares of the Company's common stock at an exercise price of $7.50 per share. The exercise price increased by $1.00 per share on May 1, 1994 and an additional $1.00 per share on May 1, 1995. The MIT Warrant expired unexercised on December 31, 1996.

**Stockholders' Rights**

As stockholders of the Company, Union Carbide Corporation, BSC, Alcon and GI are entitled to registration rights.

**Notes Receivable - Related Parties**

Notes receivable - related parties at December 31, 1996 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, 1996, the Company has 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 adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation." 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 $83,194 for the year ended December 31, 1996. Had compensation cost for the Company's stock option plans been determined based on the fair value at the grant date for awards in 1996 and 1995 consistent with the provisions of SFAS No. 123, the Company's net loss and net loss per share would have increased to the pro forma amounts indicated below:

| | 1996 | 1995 |
|---|---|---|
| Net loss | $ (7,527,733) | $(25,401,584) |
| Proforma net loss | $ (8,258,931) | $(25,721,841) |
| Net loss per share | $ (0.27) | $ (1.21) |
| Proforma net loss per share | $ (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:

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

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 five 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 Plan become exercisable over specified periods, generally within five years from the date of grant. As of December 31, 1996, no options were granted under the 1996 Plan.

For the three years ended December 31, 1996, option activity for all the plans was as follows:

| | Weighted-Average Exercise Price | Shares |
|---|---|---|
| December 31, 1993, Outstanding | 1.49 | 3,140,250 |
| Granted | 7.80 | 451,500 |
| Canceled | 0.75 | (764,687) |
| December 31, 1994, Outstanding | 2.64 | 2,827,063 |
| December 31, 1994, Exercisable | 1.55 | 1,408,676 |
| Granted | 8.59 | 979,500 |
| Exercised | 0.34 | (209,200) |
| Canceled | 7.48 | (262,473) |
| December 31, 1995, Outstanding | 4.16 | 3,334,890 |
| December 31, 1995, Exercisable | 2.06 | 1,683,948 |
| Granted | 9.77 | 209,250 |
| Exercised | 2.03 | (386,149) |
| Canceled | 8.38 | (347,860) |
| December 31, 1996, Outstanding | 4.34 | 2,810,131 |
| December 31, 1996, Exercisable | 2.82 | 1,899,979 |
| December 31, 1996, Available for Grant | | 2,144,520 |

All options granted under the 1992 and 1993 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 1996 and 1995 were as follows:

| | 1996 | | 1995 | |
|---|---|---|---|---|
| Exercise price: | Exercise Price | Fair Value | Exercise Price | Fair Value |
| Equal to market value of stock: | $ 10.68 | $ 4.52 | $ 8.57 | $ 3.90 |
| In excess of market value of stock: | 8.55 | 3.24 | 8.65 | 3.30 |

The following table summarizes information about the outstanding and exercisable stock options at December 31, 1996:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number as of 12/31/96 | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price | Number as of 12/31/96 | Weighted-Average Exercise Price |
| $ 0.265 | 1,351,767 | 0.7 year | $ 0.265 | 1,243,791 | $ 0.265 |
| 5.00 to 8.00 | 745,334 | 2.4 years | 7.21 | 451,823 | 7.08 |
| $8.65 to $12.50 | 713,030 | 3.8 years | 9.08 | 204,365 | 8.96 |
| | 2,810,131 | | | 1,899,979 | |

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 the Majority Shareholder 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 the majority shareholder and are leased and otherwise made available for use by 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 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.

The Company is required to pay for utilities, taxes, insurance and maintenance at its principal leased facilities. The Company also leases facilities for storage under short-term agreements in both California and Pennsylvania. Future minimum lease payments under operating leases at December 31, 1996 were as follows:

| | Related Parties | Third Parties | Total |
|---|---|---|---|
| 1997 | $ 369,000 | $138,000 | $ 507,000 |
| 1998 | 390,000 | 137,000 | 527,000 |
| 1999 | 270,000 | 143,000 | 413,000 |
| 2000 | 210,000 | 148,000 | 358,000 |
| 2001 | 210,000 | 63,000 | 273,000 |
| Thereafter | 2,584,000 | -- | 2,584,000 |
| Total minimum lease payments | $4,033,000 | $629,000 | $4,662,000 |

Total rental expense for the years ended December 31, 1996, 1995 and 1994 was $654,000, $468,000 and $618,000, respectively.

11. INCOME TAXES

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

| | December 31, | |
|---|---|---|
| | 1996 | 1995 |
| Net operating loss and tax credit carryforwards | $ 26,371,000 | $ 22,956,000 |
| Inventory reserves and capitalization | 1,051,000 | 378,000 |
| Other | 1,335,000 | 207,000 |
| Depreciation | 196,000 | -- |
| Total deferred tax assets before valuation allowance | 28,953,000 | 23,541,000 |
| Valuation allowance | (28,953,000) | (23,468,000) |
| Net deferred tax assets | -- | 73,000 |
| Depreciation | -- | (73,000) |
| Total deferred tax liabilities | -- | (73,000) |
| Net deferred tax asset | $ -- | $ -- |

A reconciliation of the United States Federal statutory rate to the Company's effective tax rate for the years ended December 31, 1996, 1995 and 1994 is as follows:

| | 1996 | 1995 | 1994 |
|---|---|---|---|
| Federal statutory rate | (34.0%) | (34.0%) | (34.0%) |
| Expenses not deductible for tax purposes: | | | |
| Acquired in-process research and development | -- | 26.3% | (4.9%) |
| Other | 1.3% | (1.3%) | 2.3% |
| Increase in valuation allowance for deferred tax assets and net operating losses not recognized | 32.7% | 9.0% | 36.6% |
| Effective tax rate | -- | -- | -- |

At December 31, 1996, the Company has net operating loss carryforwards of approximately $22 million and $13 million for federal and state income tax purposes, respectively, to offset future taxable income, if any, which expire through 2011 and 2003, respectively.

At December 31, 1996, 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 2002 and 2009. 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 the Internal Revenue Code of 1986, as amended, Section 382 and other provisions of the Internal Revenue Code and its applicable regulations.

12. BUSINESS ACQUISITIONS

**Telios Pharmaceuticals, Inc.**

On April 11, 1995, the Company entered into an acquisition agreement with 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 $30,912,877, 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 acquisition was accounted for by the purchase method of accounting and, accordingly, the purchase price and the expenses associated with the acquisition have been allocated to the assets acquired and the liabilities assumed at the date of acquisition as follows:

| | |
|---|---|
| Cash and cash equivalents | $ 13,116,670 |
| Accounts receivable | 74,879 |
| Prepaid expenses | 343,868 |
| Fixed assets | 1,309,975 |
| Other assets | 9,413 |
| In-process research and development | 19,592,567 |
| Accounts payable and accrued liabilities | (576,141) |
| Bankruptcy claims | (2,717,373) |
| | $ 31,153,858 |

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.

The unaudited pro forma summary information presents the consolidated results of operations as if the acquisition had occurred at the beginning of the year ended December 31, 1995:

| | |
|---|---|
| Total revenue | $ 10,261,000 |
| Net loss | $ (10,640,000) |
| Net loss pershare | $ (.47) |

The unaudited pro forma summary information was prepared based on assumptions that the Company deems appropriate, but the results are not necessarily indicative of those that might have occurred had the acquisition actually occurred at the beginning of the year presented. Telios' results of operations and cash flows are included in the consolidated financial statements effective August 16, 1995.

**Colla-Tec, Inc.**

As partial consideration for its 1991 acquisition of Colla-Tec from Marion Merrell Dow, Inc. ("MMDI"), MMDI is entitled to receive contingent deferred

consideration payable in either cash or in common stock of Colla-Tec, at the election of MMDI, based upon the sales of certain Colla-Tec products during each year of the deferral period (the five-year period commencing July 1, 1991 and ending June 30, 1996). The yearly contingent amount is calculated as the aggregate of (i) 3% of eligible sales in excess of $2,500,000 and up to $5,000,000, (ii) 5% of eligible sales in excess of $5,000,000 and up to $10,000,000, and (iii) 3% of eligible sales in excess of $10,000,000 during each deferral year period.

Payment of any contingent deferred consideration in the form of cash will be made in five equal annual installments upon the conclusion of the deferral period, subject to restrictions on the available cash flow of Colla-Tec. Payment of any contingent deferred consideration in the form of common stock shall not exceed 5% of the then outstanding common stock of Colla-Tec. The final contingent amount calculated as of June 30, 1996 was not material.

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, 1996, 1995 and 1994, the Company's discretionary matching was based on a percentage of salary reduction elections per eligible participant, and totaled $32,900, $20,800 and $11,700, respectively. No discretionary profit sharing contribution was made in any year.

14. ROYALTIES, LICENSE AND DEVELOPMENT AGREEMENTS

**MIT Patents**

In 1991, 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. The Company's financial statements do not reflect any cost for this acquisition of regenerative medical technology.

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 (see Note 8) and royalties on product sales. For the year ended December 31, 1996, the Company accrued royalties on approximately $3.1 million of Integra (TM) Artificial Skin product sales.

**Rutgers Agreement**

In 1993, the Company acquired an option to license from 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, $2,000,000 grant to fund the development of this technology. In December 1994, the Company exercised its option and entered into a license agreement with Rutgers (see Note 8), which grants 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, 1996, the Company has not commercialized products under such agreements that would be subject to royalties.

**Brigham and Women's Hospital, Inc.**

In January 1995, the Company acquired the rights to develop, manufacture and sell products resulting from cultural epithelial autograft methods patented by the Brigham and Women's Hospital, Inc., for which the Company funded a limited one-year research effort and 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**

In October 1996, the Company was awarded a second one-year grant for $170,000 in 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. The Company has the right to negotiate distribution agreements for any products developed through this collaboration.

**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 $1,000,000 per year. In addition, a royalty based on net sales of product containing licensed technology is payable to Burnham. As of December 31, 1996, the Company has not commercialized products that would be subject to royalties.

**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. The Company received, in January 1996, a $500,000 licensing fee and is entitled to market any dermal application products developed with royalties payable to CAT. The Company will receive royalties upon the sale by CAT of licensed products other than those directed at dermal applications.

**Other Royalty, License and Development Agreements**

The Company has multiple-year agreements to (i) exclusively develop, manufacture and sell to Alcon certain collagen-based devices currently in development for use in the field of ophthalmics, for which the Company had product development

revenue in 1994 of $393,000, and (ii) supply certain existing collagen-based devices to GI for use with GI's recombinant bone morphogenic protein technology.

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. The Company intends to defend the counterclaim vigorously.

On or about July 18, 1996, Telios Pharmaceuticals, Inc.("Telios"), a wholly-owned subsidiary of Company, 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, 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 counter suit asking for an award of defendants' reasonable attorney fees.

On March 27, 1996, Telios filed a motion in the United State Bankruptcy Court for the Southern District of California, in the Telios chapter 11 case, No. 95-00770-H11, regarding "cure" requirements for assumed executory contracts with The University of Utah and The University of Utah Research Foundation (collectively, the "University"). The motion seeks to resolve certain disputes concerning Telios' licensing rights under a certain License Agreement and Research Agreement entered into between Telios and the University. In addition, on March 22, 1996, the University filed a complaint against Telios in the United States District Court for the District of Utah, styled as Case No. 2:96CV-0262W, seeking a declaration that the Research Agreement and License Agreement were terminated or terminable. In January 1997, the parties stipulated to the court to postpone the any trial pending continued settlement discussions.

The financial statements do not reflect any amounts related to these matters.

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 $1,296,000.

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 $346,000, $581,000 and $141,000 for the years ended December 31, 1996, 1995 and 1994, respectively.

At December 31, 1996, the Company has employment agreements with three employees that expire at specified dates through 1997 and require the Company to make total aggregate payments in the amount of $250,000.

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 | 1996 | 1995 | 1994 |
|---|---|---|---|
| Customer A | 15% | 21% | 27% |
| Customer B | 15% | -- | -- |
| Customer C | 12% | 12% | -- |
| Customer D | -- | 12% | 10% |
| Customer E | -- | 11% | 15% |
| Customer F | -- | -- | 10% |
| | 42% | 56% | 62% |

For the years ended December 31, 1996, 1995 and 1994, the Company's foreign

export sales, primarily to Europe and Japan, were 16%, 11% and 13% of total product sales, respectively.

18. SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for interest, excluding capitalized interest of $78,599 in 1994, was $314, $187,583 and $416,621 for the years ended December 31, 1996, 1995 and 1994, respectively. There was no cash paid for income taxes during the periods presented.

Included in other current liabilities at December 31, 1995 is $97,355 related to fixed asset additions and leasehold improvements which were paid after year end.

In connection with the August 1995 acquisition of Telios, the Company issued 3,573,743 of its common stock with an aggregate value of $30,912,877 (see Note 12).

In 1995, the Company and the Lender (see Note 7) agreed to convert $1,500,005 of the Revolving Credit to common stock at a price of $8.65 per share.

In 1994, a contractor for the Company provided $945,896 of financing under a line of credit.

Common stock of the Company valued at $82,900 was issued to Rutgers in connection with a licensing agreement in 1994. Common stock of the Company valued at $70,000 was issued to two investment banks for advisory services rendered during 1995.

As part of an executive compensation agreement, notes receivable-related parties of $120,000 were forgiven, $60,000 of which was a non-cash transaction for the year ended December 31, 1994.

## 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/ Richard E. Caruso, Ph.D.*
*Richard E. Caruso, 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 28th day of March, 1996.

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

* Richard E. Caruso, Ph.D., pursuant to a Power of Attorney executed by each of the directors and officers noted above and filed with the Securities and Exchange Commission as Exhibit 24 to this Annual Report on Form 10-K, by signing his name hereto, does hereby sign and execute this Annual Report on Form 10-K on behalf of each of the persons noted above, in the capacities indicated, and does hereby sign and execute this Annual Report on Form 10-K on his own behalf, in the capacities indicated.

*/s/ Richard E. Caruso, Ph.D.*
*Richard E. Caruso, Ph.D.*

## EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 2.1(a) | Acquisition Agreement between Telios Pharmaceuticals, Inc. and the Company dated as of April 11, 1995, as amended May 10, 1995 (2) |
| 2.1(b) | Amendment Nos. 2 and 3 to Acquisition Agreement dated as of July 6, 1995 and July 14, 1995, respectively (2) |
| 2.1(c) | Amendment No. 4 to Acquisition Agreement dated as of August 14, 1995 (3) |
| 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) |
| 2.2(b) | Modifications to the Plan (2) |
| 2.2(c) | Order of the United States Bankruptcy Court for the Southern District of California dated July 21, 1995 confirming the Plan (2) |
| 3.1 | Amended and Restated Certificate of Incorporation of the Company (2) |
| 3.2 | Amended and Restated By-laws of the Company (2) |
| 10.1 | License Agreement between MIT and the Company dated as of December 29, 1993 (2) |
| 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) |
| 10.3 | License Agreement between Smith & Nephew Consolidated Inc. and Vitaphore Corporation dated as of December 31, 1993 (2) |
| 10.4 | Research and License Agreement between the Brigham and Women's Hospital, Inc. and the Company dated as of January 1, 1995 (2) |
| 10.5 | Exclusive License Agreement between the Company and Rutgers University dated as of December 31, 1994 (2) |

| Exhibit Number | Description |
|---|---|
| 10.6 | License Agreement for Adhesion Peptides Technology between La Jolla Cancer Research Foundation and Telios dated as of June 24, 1987 (2) |
| 10.7(a) | Letter of Intent among Cambridge Antibody Technology Limited ("CAT"), Telios and the Company dated May 10, 1995 (2) |
| 10.7(b) | Strategic Alliance and Technology Agreement dated as of June 23, 1995 between CAT and Telios and consented to by the Company (2) |
| 10.8 | Technology Development and License Agreement between Union Carbide and the Company dated as of April 30, 1993 (2) |
| 10.9 | Research Agreement between Helitrex Inc., American Biomaterials Corporation and Dr. Roger Madison dated as of May 30, 1986, as extended by and between the Company and Duke University dated as of January 1, 1995 (2) |
| 10.10 | Development Agreement between Boston Scientific Corporation and Colla-Tec, Inc. dated as of December 29, 1993 (2) |
| 10.11 | OEM Manufacturing and Supply Agreement between Boston Scientific Corporation and Colla-Tec, Inc. dated as of December 29, 1993 (2) |
| 10.12 | Supply Agreement between Genetics Institute, Inc. and the Company dated as of April 1, 1994 (2) |
| 10.13 | Employment Agreement between the Company and Andre P. Decarie dated as of June 10, 1993 * (2) |
| 10.14 | Employment Agreement between the Company and Robert J. Towarnicki dated as of July 1, 1992 * (2) |
| 10.15 | Employment Agreement between the Company and John R. Emery dated as of December 6, 1994 * (2) |
| 10.16 | Employment Agreement between the Company and Frederick Cahn dated as of December 31, 1992 * (2) |
| 10.17 | Letter Agreement between the Company and Ioannis V. Yannas, Ph.D. dated as of December 31, 1992 regarding the provision of Consulting and Technology Services (2) |
| 10.18 | Registration Rights Agreement between the Company and Manor Care, Inc. dated as of April 28, 1995 (2) |
| 10.19 | Registration Rights Agreement between the Company and Edmund L. Zalinski dated as of August 31, 1994 (2) |

| Exhibit Number | Description |
|---|---|
| 10.20 | Registration Rights Agreement between the Company and Edmund L. Zalinski Company dated as of August 31, 1994 (2) |
| 10.21 | Registration Rights Agreement between the Company and Elliot-Lewis Corporation dated as of August 31, 1994 (2) |
| 10.22 | Registration Rights Agreement between the Company and Steven Dadio dated as of August 31, 1994 (2) |
| 10.23 | Registration Rights Agreement between the Company and William R. Sautter dated as of August 31, 1994 (2) |
| 10.24 | Registration Rights Agreement between the Company and Alcon Laboratories, Inc. dated as of April 22, 1994 (2) |
| 10.25 | Registration Rights Agreement between the Company and Genetics Institute, Inc. dated as of April 26, 1994 (2) |
| 10.26 | Registration Rights Agreement between the Company and Boston Scientific Corporation dated as of December 29, 1993 (2) |
| 10.27(a) | Stockholder Rights Agreement between the Company and Union Carbide dated as of April 30, 1993 ("Carbide Agreement") (2) |
| 10.27(b) | Amendment dated November 30, 1993 to Carbide Agreement (2) |
| 10.28 | Real Estate Lease & Usage Agreement between BHP Diagnostics, Inc., Medicus Technologies, Inc., Integra, Ltd. and the Company dated as of May 1, 1994 (2) |
| 10.29 | Shared Facilities Usage Agreement Between BHP Diagnostics, Inc., Medicus Technologies, Inc. and Integra, Ltd. and the Company dated as of May 1, 1994 (2) |
| 10.30 | 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) |
| 10.31 | 1992 Stock Option Plan * (2) |
| 10.32 | 1993 Incentive Stock Option and Non-Qualified Stock Option Plan * (2) |
| 10.33 | Loan and Security Agreement between the Company and Provco Leasing Corporation dated as of June 30, 1993, as amended December 31, 1994, February 8, 1995 and June 8, 1995 (2) |

| Exhibit Number | Description |
|---|---|
| 10.34 | Letter Agreement between the Company and Provco Leasing Corporation dated as of June 8, 1995 regarding debt conversion (2) |
| 10.35 | Warrant Agreement between the Company and Boston Scientific Corporation dated as of December 29, 1993 (2) |
| 10.36 | Registration Rights Agreement between the Company and Provco Leasing Corporation dated as of April 30, 1995 (2) |
| 10.37 | 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) |
| 10.38 | 1996 Incentive Stock Option and Non-Qualified Stock Option Plan* (5) |
| 11 | Statement re: Computation of Per Share Earnings (1) |
| 21 | Subsidiaries of the Company (1) |
| 23 | Consent of Independent Accountants (1) |
| 24 | Powers of Attorney (1) |
| 27 | Financial Data Schedule (1) |

* Indicates a management contract or compensatory plan or arrangement.

(1) Filed herewith.

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

(3) Incorporated by reference to the indicated exhibit to the Company's 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 Registration Statement on Form S-8 (File No. 333-06577) which became effective on June 22, 1996.

**Exhibit 11**

## Statement of Computation of Per Share Amounts

| | Year Ended December 31, 1996 | Year Ended December 31, 1995 | Year Ended December 31, 1994 |
|---|---|---|---|
| Primary: | | | |
| Net loss for the period | $ (7,527,733) | $ (25,401,584) | $ (1,899,701) |
| Weighted average number of shares of common stock outstanding | 28,113,869 | 21,073,214 | 19,035,147 |
| Shares issuable upon exercise of outstanding options and warrants | ---- | ---- | ---- |
| Shares assumed to be acquired in accordance with the treasury stock method | ---- | ---- | ---- |
| Shares used in computing per share income | 28,113,869 | 21,073,214 | 19,035,147 |
| Net loss per share | $ (.27) | $ (1.21) | $ (.10) |
| Fully Diluted: | | | |
| Net income (loss) for the period | $ (7,527,733) | $ (25,401,584) | $ (1,899,701) |
| Weighted average number of shares of common stock outstanding | 28,113,869 | 21,073,214 | 19,035,147 |
| Shares issuable upon exercise of outstanding options and warrants | 3,345,601 | 3,326,564 | 3,879,766 |
| Shares assumed to be acquired in accordance with the treasury stock method | (1,733,586) | (1,454,700) | (1,274,844) |
| Shares used in computing per share income | 29,725,884 | 22,945,078 | 21,640,069 |
| Net income (loss) per share | $ (.25) | $ (1.11) | $ (.09) |

**Exhibit 21**

## 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. | Biomaterials Corporation | Delaware |
| 5. | Colla-Tec, Inc. | Delaware |
| 6. | Integra (Artifical Skin) Corp. | Delaware |
| 7. | Integra LifeSciences Surgical Products Corporation | Delaware |
| 8. | Integra LifeSciences I, Ltd. | Delaware |
| 9. | Intellectual Properties Corporation | Delaware |
| 10. | Medicol Sciences, spol. s r.o. | Czech Republic |
| 11. | Medicus Technologies, Inc. | Delaware |
| 12. | Vitaphore Corporation | Delaware |
| 13. | Telios Pharmaceuticals, Inc. | Delaware |

**Exhibit 23**

[Coopers & Lybrand L.L.P. Letterhead]

## CONSENT OF INDEPENDENT ACCOUNTANTS

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 21, 1997 on our audits of the consolidated financial statements of Integra LifeSciences Corporation and Subsidiaries as of December 31, 1996 and 1995, and for each of the three years in the period ended December 31, 1996, which report is included in the Corporation's 1996 Annual Report on Form 10-K.

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

*Princeton, New Jersey*
*March 26, 1997*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that the person whose signature appears below constitutes and appoints Richard E. Caruso, and William M. Goldstein, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to do any and all acts, including the execution of documents, which said attorneys, or either of them, may deem necessary or advisable to enable Integra LifeSciences Corporation (the "Company") to comply with the Securities Exchange Act of 1934, as amended, and the rules and regulations and requirements of the Securities and Exchange Commission, in connection with the filing under such Act of an annual report of the Company on Form 10-K for the year ended December 31, 1996, including the power and authority to sign in the name and on behalf of the undersigned, in any and all capacities in which the signature of the undersigned would be appropriate, such annual report and any and all amendments thereto and generally to do and perform all things necessary to be done in the premises as fully and effectually in all respects as the undersigned could do if personally present.

IN WITNESS WHEREOF, the undersigned has hereunto set his hand this 28th day of March, 1997.

*/s/ William M. Goldstein,*
*----------*
*William M. Goldstein, Esq.*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that the person whose signature appears below constitutes and appoints Richard E. Caruso, and William M. Goldstein, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to do any and all acts, including the execution of documents, which said attorneys, or either of them, may deem necessary or advisable to enable Integra LifeSciences Corporation (the "Company") to comply with the Securities Exchange Act of 1934, as amended, and the rules and regulations and requirements of the Securities and Exchange Commission, in connection with the filing under such Act of an annual report of the Company on Form 10-K for the year ended December 31, 1996, including the power and authority to sign in the name and on behalf of the undersigned, in any and all capacities in which the signature of the undersigned would be appropriate, such annual report and any and all amendments thereto and generally to do and perform all things necessary to be done in the premises as fully and effectually in all respects as the undersigned could do if personally present.

IN WITNESS WHEREOF, the undersigned has hereunto set his hand this 28th day of March, 1997.

*/s/ Frederic V. Malek*
*----------*
*Frederic V. Malek*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that the person whose signature appears below constitutes and appoints Richard E. Caruso, and William M. Goldstein, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to do any and all acts, including the execution of documents, which said attorneys, or either of them, may deem necessary or advisable to enable Integra LifeSciences Corporation (the "Company") to comply with the Securities Exchange Act of 1934, as amended, and the rules and regulations and requirements of the Securities and Exchange Commission, in connection with the filing under such Act of an annual report of the Company on Form 10-K for the year ended December 31, 1996, including the power and authority to sign in the name and on behalf of the undersigned, in any and all capacities in which the signature of the undersigned would be appropriate, such annual report and any and all amendments thereto and generally to do and perform all things necessary to be done in the premises as fully and effectually in all respects as the undersigned could do if personally present.

IN WITNESS WHEREOF, the undersigned has hereunto set his hand this 28th day of March, 1997.

*/s/ George McKinney, III*
*----------*
*George McKinney, III, Ph.D.*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that the person whose signature appears below constitutes and appoints Richard E. Caruso, and William M. Goldstein, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to do any and all acts, including the execution of documents, which said attorneys, or either of them, may deem necessary or advisable to enable Integra LifeSciences Corporation (the "Company") to comply with the Securities Exchange Act of 1934, as amended, and the rules and regulations and requirements of the Securities and Exchange Commission, in connection with the filing under such Act of an annual report of the Company on Form 10-K for the year ended December 31, 1996, including the power and authority to sign in the name and on behalf of the undersigned, in any and all capacities in which the signature of the undersigned would be appropriate, such annual report and any and all amendments thereto and generally to do and perform all things necessary to be done in the premises as fully and effectually in all respects as the undersigned could do if personally present.

IN WITNESS WHEREOF, the undersigned has hereunto set his hand this 28th day of March, 1997.

*/s/ James M. Sullivan*
*----------*
*James M. Sullivan*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that the person whose signature appears below constitutes and appoints Richard E. Caruso, and William M. Goldstein, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, to do any and all acts, including the execution of documents, which said attorneys, or either of them, may deem necessary or advisable to enable Integra LifeSciences Corporation (the "Company") to comply with the Securities Exchange Act of 1934, as amended, and the rules and regulations and requirements of the Securities and Exchange Commission, in connection with the filing under such Act of an annual report of the Company on Form 10-K for the year ended December 31, 1996, including the power and authority to sign in the name and on behalf of the undersigned, in any and all capacities in which the signature of the undersigned would be appropriate, such annual report and any and all amendments thereto and generally to do and perform all things necessary to be done in the premises as fully and effectually in all respects as the undersigned could do if personally present.

IN WITNESS WHEREOF, the undersigned has hereunto set his hand this 28th day of March, 1997.

*/s/ Edmund L. Zalinski*
*----------*
*Edmund L. Zalinski, Ph.D.*

**ARTICLE 5**

| | |
|---|---|
| PERIOD TYPE | 12 MOS |
| FISCAL YEAR END | DEC 31 1996 |
| PERIOD START | JAN 01 1996 |
| PERIOD END | DEC 31 1996 |
| CASH | 11,761,925 |
| SECURITIES | 22,514,221 |
| RECEIVABLES | 2,902,201 |
| ALLOWANCES | 0 |
| INVENTORY | 2,634,950 |
| CURRENT ASSETS | 40,151,472 |
| PP&E | 12,240,642 |
| DEPRECIATION | 3,686,797 |
| TOTAL ASSETS | 48,741,417 |
| CURRENT LIABILITIES | 2,215,394 |
| BONDS | 0 |
| PREFERRED MANDATORY | 0 |
| PREFERRED | 0 |
| COMMON | 285,513 |
| OTHER SE | 46,098,522 |
| TOTAL LIABILITY AND EQUITY | 48,741,417 |
| SALES | 11,209,980 |
| TOTAL REVENUES | 13,148,565 |
| CGS | 6,671,158 |
| TOTAL COSTS | 6,671,158 |
| OTHER EXPENSES | 0 |
| LOSS PROVISION | 0 |
| INTEREST EXPENSE | 126 |
| INCOME PRETAX | (7,527,733) |
| INCOME TAX | 0 |
| INCOME CONTINUING | (7,527,733) |
| DISCONTINUED | 0 |
| EXTRAORDINARY | 0 |
| CHANGES | 0 |
| NET INCOME | (7,527,733) |
| EPS PRIMARY | (.27) |
| EPS DILUTED | (.27) |