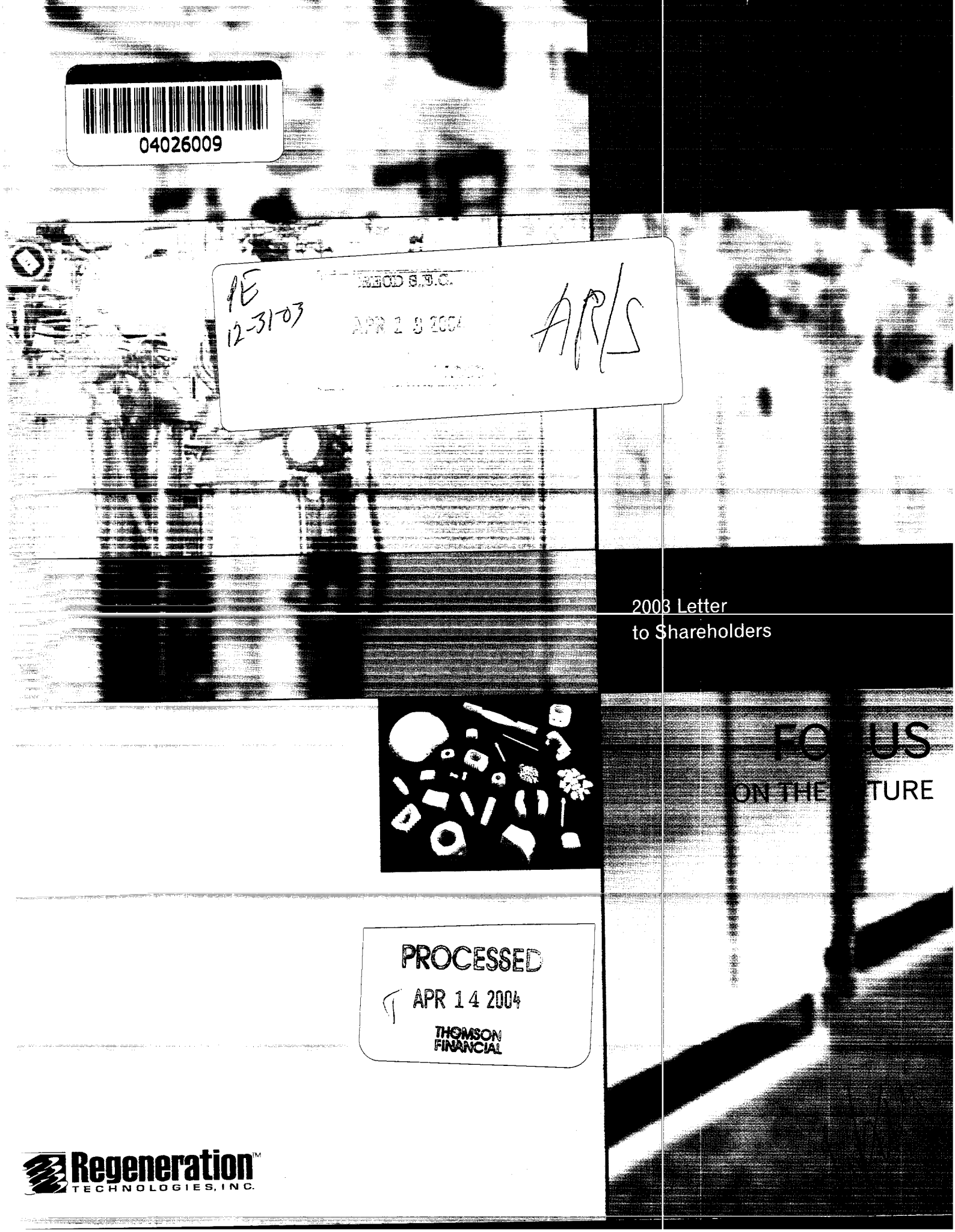


2003 Letter
to Shareholders

FOCUS
ON THE FUTURE

Regeneration™
TECHNOLOGIES, INC.

This Letter to Shareholders and the documents incorporated by reference contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations, estimates and projections about our industry, our management's beliefs and certain assumptions made by our management. Words such as "anticipates," "expects," "intends," "plans," believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. However, readers should carefully review the risk factors set forth in other reports or documents the registrant files from time to time with the Securities and Exchange Commission.

Regeneration Technologies' Vision Statement

We will be the leader in using the body to heal the body through the use of natural tissue and innovative technologies.

Our mission is to enhance the lives of patients by pioneering health solutions through regenerative medicine.

About Regeneration Technologies

Regeneration Technologies, Inc. processes human musculoskeletal and other tissues for use in orthopedic, cardiovascular and other surgeries with a commitment to science, safety and innovation. Surgeons then implant these allografts to repair a wide variety of bone and other tissue defects, including spinal vertebrae repair, musculoskeletal reconstruction, fracture repair, periodontal repair, urinary incontinence and heart valve disorders.

By processing allograft tissue into forms that can be used in many types of surgical procedures, RTI enables patients to benefit from the gift of donated tissues.

RTI also holds the patents on BioCleanse®, the only proven tissue sterilization process validated to eliminate viruses, bacteria, fungi and spores from tissue without impacting the structural or biomechanical integrity of the allograft. The company has distributed more than 400,000 implants sterilized with the BioCleanse process with zero incidence of infection. RTI is accredited by the American Association of Tissue Banks and was named a 2004 Technology Pioneer by the World Economic Forum.

The year 2003 was one of significant achievement for Regeneration Technologies, Inc. We made company history by setting record annual net revenue and net income. We received international recognition for our fiscal progress and our technological accomplishments by becoming part of the Russell® 2000 Index and by being named a 2004 Technology Pioneer by the World Economic Forum.

Our science, procedures and policies have been reviewed by an impressive list of agencies, both domestic and international, all with positive results. We officially launched our patented BioCleanse® Tissue Sterilization Process and a new standard of tissue sterility and safety to the medical world at the American Academy of Orthopaedic Surgeons meeting in February 2003. In July 2003 we were accredited by the American Association of Tissue Banks (AATB), and during the year we received International Organization for Standardization (ISO) certifications at a substantially more demanding standard specifically addressing the quality requirements of medical device companies.

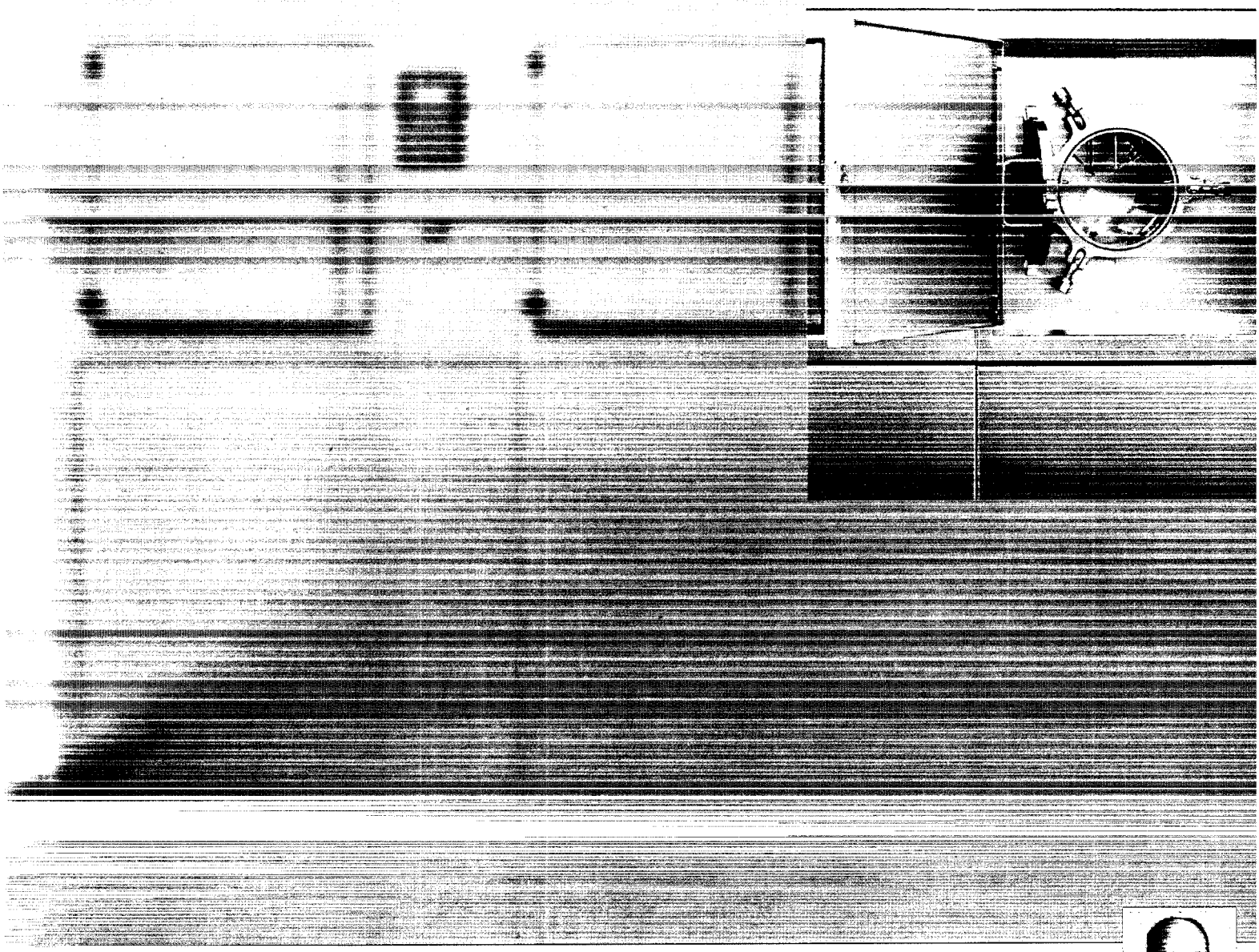
Looking back on these accomplishments, we see the first wave of success brought about by a solid foundation that will propel us into an exciting future.

In the past two years, we have made significant and dramatic progress financially and operationally. At this time last year, we were just starting to see the effects of our operational and procurement efficiency programs. Today, RTI has grown strong in these areas. The year 2003 reflected the positive impact of our strategic initiatives in tissue safety, donor services and operating effectiveness.

Brian K. Hutchison
Chairman, President & CEO

03 Leadership Enhancements

l added Dr. Lennox Archibald, formerly of the Centers for Disease Control and Prevention, as Medical Director; a id seph Condon, formerly of Stryker Howmedica Osteonics, as Vice President of Operations to the senior staff.

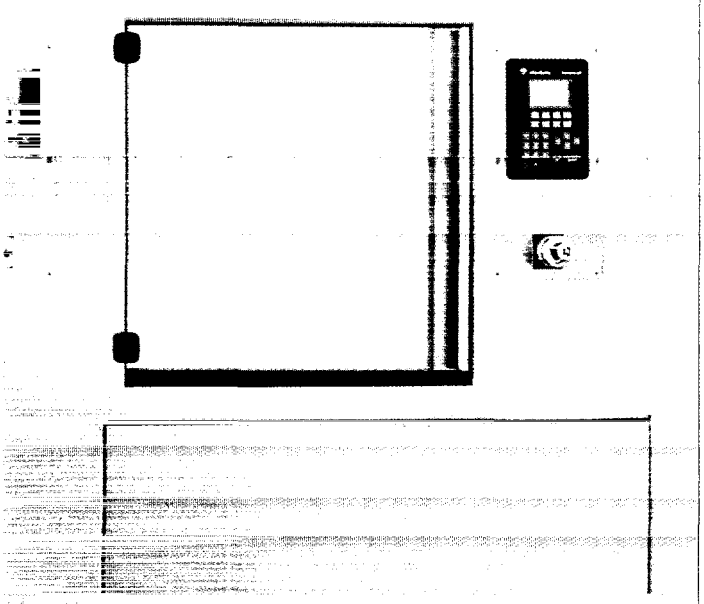


February 5

RTI officially launches the patented BioCleanse® Tissue Sterilization Process to the medical community at the American Academy of Orthopaedic Surgeons Annual Meeting in New Orleans. The official launch party featured former New York Mayor Rudy Giuliani speaking on safety and leadership.

allograft safety as we officially launched our Next-Generation BioCleanse® Tissue Sterilization Process and introduced an additional sterilization step for our structural allografts. Since March 1, our structural implants have been labeled "Sterile," indicating that they meet or exceed requirements for sterility per national and international standards. This label gives surgeons assurance the tissue they implant is free from bacteria, viruses, fungi and spores, along the same line as metal or synthetic implants and other medical products. BioCleanse is the only technology available today that sterilizes tissue, is scientifically and clinically proven to eliminate donor to recipient disease transmission risk, and preserves tissue strength and biocompatibility.

Commitment to Safety



he core of RTI's state-of-the-art processing facility is the BioCleanse® om, featuring fully automated equipment and technology.

Following the launch of our Next-Generation BioCleanse process, our company embarked on a national branding campaign, educating surgeons, nurses and infection control officers of the importance of allograft safety and the availability of sterile tissue. The adage "Demand sterile. Ask for BioCleanse." is being delivered to the medical community by RTI and our distributors. Our advances in tissue safety and sterilization are being noted across the scientific community as well—the development of BioCleanse was recognized on an international level when RTI was selected as one of 30 Technology Pioneers for 2004 by the World Economic Forum.

In addition to tissue sterilization, we still uphold the most stringent testing and screening standards and maintain one of the highest safety ratings in the industry for our allograft implants. This year we accomplished our goal of becoming accredited by the AATB, as well as renewing ISO 9001 and certification EN 46001 and received ISO 13485 certifications. By holding ourselves to a higher safety and quality standard, we not only exceed current regulatory requirements for our industry, but we already meet or exceed the current proposed Good Tissue Practices (GTPs) from the Food and Drug Administration.

March 1
RTI sends the first shipment of bone tissue labeled "Sterile." An innovation in tissue safety, RTI delivers bone tissue labeled "Sterile" indicating that it meets or exceeds requirements for sterility per national and international standards, providing the most complete measure of sterilization in the industry.

STERILE

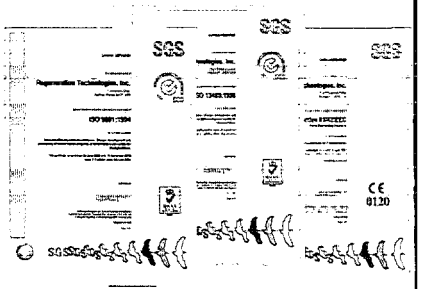
successful in the past year. Our national network of tissue procurement agencies provides services to donor families and education to their communities about the benefits of tissue donation. As a result of the diligence of our RTI Donor Services team, we were able to increase musculoskeletal tissue recoveries more than 17 percent, and we more than doubled cardiovascular recoveries over 2002 levels. More families generously chose the option of tissue donation, thereby helping hundreds of thousands of people who received life-saving and life-enhancing allograft implants.

Kari's husband Eric died April 7, 2003 in a motor vehicle accident that occurred as he and Kari—four months pregnant with their first child—were on their way to shop for baby items. Although Kari was injured in the crash, both she and her baby survived. Despite the anguish over losing her husband and suffering her own severe injuries, Kari made sure she carried out what she knew was Eric's wish—donation. The Barlaments' healthy daughter, Erica, was born in 2003 on her father's birthday, September 5.

Strength in Donor Services

As part of its donor education initiative, RTI Donor Services co-sponsored the National Coalition on Donation's first Rose Parade® float to raise awareness on organ and tissue donation. The float featured 22 organ and tissue donor families and recipients. Kari Barlament, the wife of a donor from Brillion, Wis., represented RTI Donor Services and tissue donor families nationwide as the only rider whose story focused solely on tissue donation.

We will continue our commitment to provide innovative biological solutions, adding value to the priceless gift of donated tissue by serving as the crucial link between the donor families and the patients in need of allograft implants.



June 24

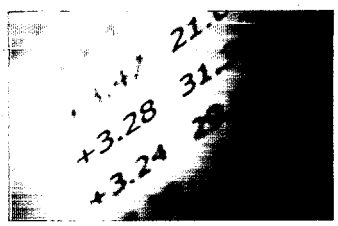
RTI renews ISO 9001 and certification EN 46001 and received ISO 13485 certifications. The ISO 13485 certification is a substantially more demanding standard specifically addressing the quality requirements of companies producing medical products. To obtain these important, internationally recognized certifications, RTI's quality system procedures were reviewed to ensure that the International Quality Standards have been addressed.

In 2003, RTI introduced an additional sterilization step for its Tutoplast® processed biological implants, setting a new standard for allograft safety.

Our state-of-the-art, pharmaceutical-grade processing facility allows us to improve the quality of our implants and increase our effectiveness in meeting surgeon demand. We are able to maximize the gift of donated tissue by ensuring that each donation helps as many recipients as possible. In 2003 we processed more than 165,000 implants, which will provide natural healing to the highest number of patients in the history of the company.

Meanwhile, we have improved our ability to consistently meet the demand for our implants. Throughout the year, we were able to expand our service level in meeting customer demand to historical levels. Looking forward to 2004, our goal is to expand distribution in each of our product lines by 20 percent.

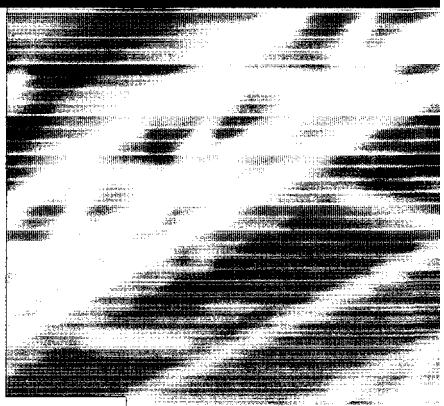
The continuation of our fiscal and operational efficiency programs allows us also to maximize our financial results. It is through these strong efficiency programs that we are able to control our costs and react quickly when business challenges arise.



July 10
RTI added to the Russell 2000® Index. The Russell 2000® Index, a leading U.S. equity index published by the Frank Russell Company, measures the performance of the small cap U.S. companies.

Focus on the Future

We are committed to maximizing future distribution growth in all product categories for 2004 and beyond. Our focus will consist of refining and expanding our distribution capabilities. Key initiatives for 2004 include developing our own biologics distribution group, forming new non-exclusive distribution arrangements and strengthening relationships with existing exclusive distributors. Through these initiatives, we will diversify our avenues to the medical community, ensuring that surgeons get the biological implants they need for their patients.



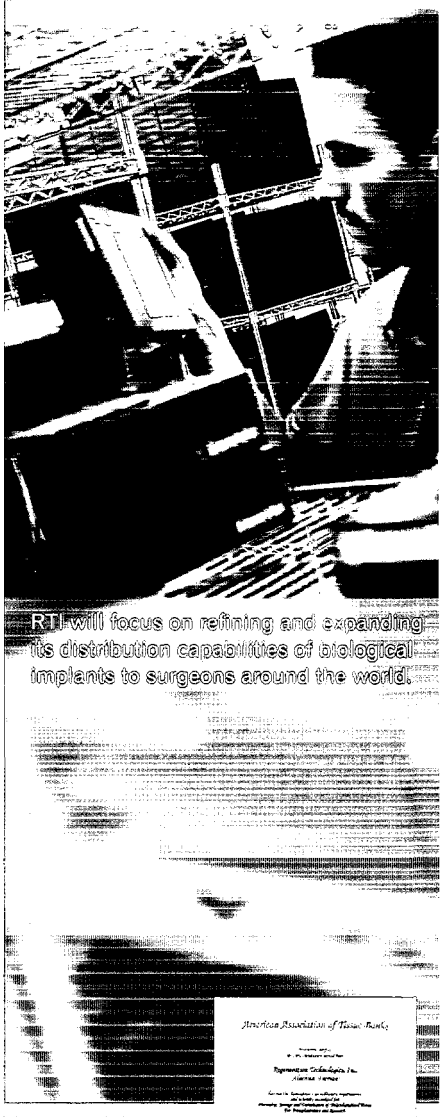
Diversifying Distribution

As we reviewed our existing distribution program in the second half of 2003, we found that while our fastest-growing product segments were aligned with strong distributors, there were other portions of our product categories that were not being served as well. In addition, with our increased operational effectiveness, we are now able to consistently meet the needs of our current distributors, which allows us to develop new products and expand in other areas of market demand.

As a result, RTI will begin to develop our own biologics distribution group to better serve the marketplace. This group will be highly trained in the properties and benefits of biological, regenerative materials. The development of an independent distribution force is a long-term investment and a significant step that will have the greatest potential for impacting our business growth in the years to come. All implants that are not currently included in exclusive agreements will be handled by this new distribution group, along with other non-exclusive distributors, depending on the needs of each individual market.

To further diversify our distribution outlets, we also met with a number of companies in the latter part of 2003 to explore additional distribution agreements for RTI's expanded line of allograft implants. These discussions are ongoing and are focused on developing non-exclusive arrangements.

As we develop new distribution channels, we remain strongly committed to our exclusive distributors—Medtronic Sofamor Danek, Stryker Endoscopy, Exactech and C.R. Bard. RTI will work to continually maximize these exclusive arrangements to ensure mutually beneficial relationships with each distributor.

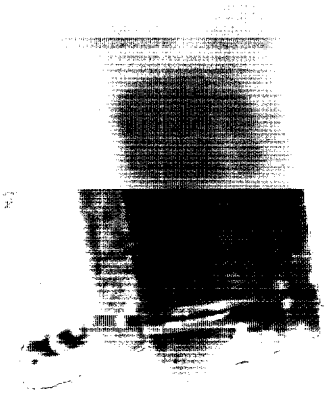


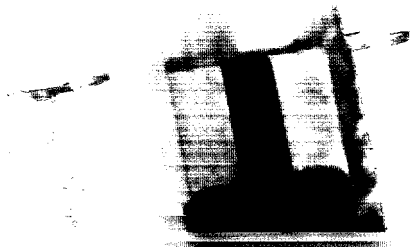
RTI will focus on refining and expanding its distribution capabilities of biological implants to surgeons around the world.

July 17
RTI is approved for accreditation by the American Association of Tissue Banks (AATB). The accreditation covers the processing, storage and distribution of musculoskeletal tissue for transplantation and research. Accreditation is awarded for a three-year term, after which RTI will apply for renewal.

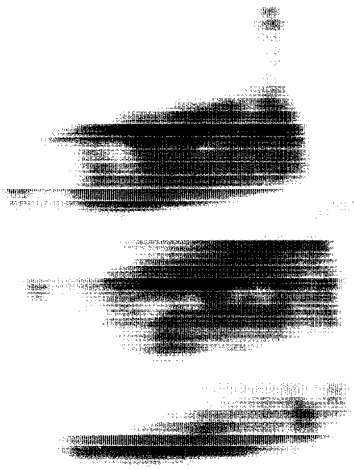
uture of RTI. We will continue to advance our operational and procurement programs and aise the bar for safety standards in the industry, while significantly increasing our focus on our expanding distribution and research and development initiatives.

Increasing Research and Development Resources





For 2004, RTI will almost double the financial resources of research and development to support its long-term product development plan.



The name Regeneration Technologies has been synonymous with cutting-edge science, industry-leading safety and premier innovation throughout company history. RTI pioneered the design of precision allograft, introducing the first machined allograft implant in the late 1990s, and has advanced allograft safety technology with the patented BioCleanse® Tissue Sterilization Process. In the years to come, RTI's tradition of innovation will continue.

In response to market demand and the availability of tissue for use in new implants, we have intensified our R&D efforts in the past year. Our scientists have made substantial progress on a number of exciting innovations in all of our current markets, as well as new markets such as trauma. During the second half of 2003, we developed a long-term product development plan to steadily introduce new implants that will become an ever-increasing component of our growth in revenues.

For 2004, we will almost double the financial resources of R&D to support this development plan. Our scientists are focusing their studies on delivering optimal regenerative medicine, by achieving higher levels of osteoinductivity and osteoconductivity through allograft, as well as expanding the uses of the BioCleanse technology to infuse healing pharmaceutical components into allograft implants.

In addition, we will be ready to launch the BioCleanse process for musculoskeletal soft tissue in 2004. Clinical trials have been advancing steadily, and preliminary findings show the implants are performing extremely well. As a company, we will continuously push the capabilities of the BioCleanse process to develop the safest and most effective implants possible.

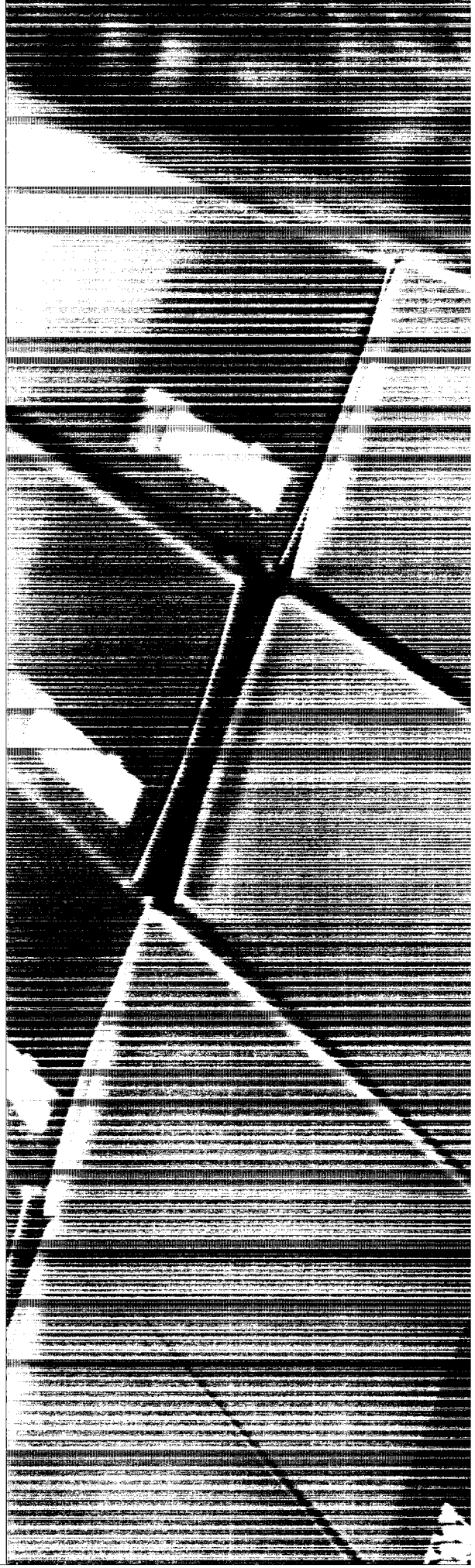
December 11
RTI selected as one of 30 Technology Pioneers for 2004 by the World Economic Forum for its advances in tissue sterilization. Technology Pioneers are companies chosen by the World Economic Forum that are developing and applying the most innovative and transformational technologies.

BIOCLEANSE™
TISSUE STERILIZATION PROCESS

findings show that demand for allograft and regenerative medicine is growing in an ever-stronger orthopedic market. Based upon market data and surgeon feedback, we have every indication that RTI has the right products, the right science and the right people to be the leader in this developing industry.

RTI is geared to develop sophisticated processing technology to accelerate the introduction of new tissue implants and to continuously raise the bar for tissue safety. Our goal for the coming year is to maximize our strengths and meet all business challenges with determination and resourcefulness. We intend to lead positive change in the tissue industry and drive awareness to the benefits of biological solutions. With our commitment to science, safety and innovation, we will enhance the lives of patients worldwide by pioneering health solutions through regenerative medicine.

Reflecting on the revolutionary accomplishments made by this company in its brief history, it is exciting to think of what is to come for RTI. With our donors' generosity, our employees' diligence, our distribution partners' commitment and our shareholders' support, we focus on the future and the achievements to come.



Brian K. Hutchison, Chairman
President & CEO
Regeneration Technologies, Inc.

Philip R. Chapman
President, Venad Administrative Services, Inc.
General Partner, Adler & Company

Peter F. Gearen, MD
Associate Professor
University of Florida College of Medicine

Michael J. Odrich
Managing Director
Lehman Brothers, Inc.

David J. Simpson
Executive Vice President
Stryker Corporation

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908-497-2300

Securities Exchange Commission Counsel
Fulbright & Jaworski
666 Fifth Avenue
31st Floor
New York, New York 10103
212-318-3076

Annual Shareholders' Meeting
Monday, April 26, 2004, 10:00 a.m. EDT
Hilton University of Florida Conference Center
1714 SW 34th St., Gainesville, FL 32607

Regeneration™
TECHNOLOGIES, INC.

Corporate Headquarters
621 Research Circle
Alachua, Florida 32615
386.418.8888

www.rtix.com

Science | Safety | Innovation

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☒ Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended **December 31, 2003**

or

☐ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the transition period from to

Commission file number: **0-31271**

REGENERATION TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**59-3466543**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

11621 Research Circle, Alachua, Florida 32615
(Address of Principal Executive Offices) (Zip Code)

(386) 418-8888
(Registrant's telephone number, including area code)

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 $0.001

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

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

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the Nasdaq Stock Market as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2003), was approximately $347.5 million.

The number of shares of Common Stock outstanding as of March 5, 2004, was 26,536,130.

DOCUMENTS INCORPORATED BY REFERENCE

As stated in Part III of this Annual Report on Form 10-K, portions of the registrant's definitive proxy statement for the registrant's 2004 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

REGENERATION TECHNOLOGIES, INC.

FORM 10-K Annual Report
Table of Contents

PART I

This Annual Report on Form 10-K and the documents incorporated by reference contain forward-looking statements that have been made pursuant to the provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations, estimates and projections about our industry, our management's beliefs and certain assumptions made by our management. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "requires," "hopes," "may," "assumes," variations of such words and similar expressions are intended to identify such forward-looking statements. Do not unduly rely on forward-looking statements. These statements give our expectations about future performance, but are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Forward-looking statements speak only as of the date they are made, and unless required by law, we undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. BUSINESS.

Company Overview

We are a leader in the use of natural tissues and innovative technologies to produce allografts that repair and promote the natural healing of human bone and other human tissues and improve surgical outcomes. We process human musculoskeletal and other tissue, including bone, cartilage, tendon, ligament, dermal and cardiovascular tissue in producing our allografts. Surgeons then use these tissues to repair and promote the healing of a wide variety of bone and other tissue defects, including spinal vertebrae repair, musculoskeletal reconstruction, fracture repair, repairs to the jaw and related tissues, and heart valve disorders, among other conditions. Our allografts are distributed in all 50 states and in ten countries.

We provide a comprehensive portfolio of natural tissue products in a broad range of markets. We separate our allografts into four primary product lines: spinal, sports medicine, cardiovascular and other general orthopedic applications. The following table outlines the product lines we serve and the amount and percentage of our net revenues for the years ended December 31, 2003, 2002 and 2001:

	Year Ended December 31,					
	2003		2002		2001	
Market						
Spinal	$45,306	60.0%	$37,971	55.0%	$36,003	53.3%
Sports medicine	8,855	11.8%	10,028	14.5%	9,076	13.4%
Cardiovascular	5,141	6.8%	3,426	5.0%	811	1.2%
General orthopedic	14,229	18.8%	16,119	23.3%	19,696	29.2%
Other non-tissue	1,979	2.6%	1,516	2.2%	1,964	2.9%
Total	$75,510	100.0%	$69,060	100.0%	$67,550	100.0%

For additional financial information concerning our operating performance, please refer to Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of this report and our Consolidated Financial Statements in Part II, Item 8 of this report and incorporated herein by reference.

We distribute our allografts both within and outside the United States. Foreign distribution, primarily in Europe, accounted for 7.6%, 6.5% and 4.8% of our net revenues during the years ended December 31, 2003, 2002 and 2001, respectively.

We pursue a market-by-market approach to the distribution of our allografts, and establish strategic partnerships in order to increase our penetration in selected markets. We have exclusive distribution alliances

with Medtronic Sofamor Danek in the spinal market, Stryker Endoscopy for sports medicine applications and Exactech, Inc. in the bone paste market for general orthopedic uses. We also have a strategic collaboration with C.R. Bard, Inc. for certain urological applications. In the cardiovascular market and other markets that our allografts serve, we use a network of independent distributors.

Our BioCleanse™ process is a patented tissue sterilization process that is designed to add a measure of safety to our bone allografts by sterilizing the tissue and providing surgeons and patients allograft implants that are free of spores, fungi, bacteria and viruses. Before tissues are processed using the BioCleanse™ process, tissue recovery agencies perform a risk assessment on every potential donor, interview family members and evaluate the donor's medical records. All collected tissue is tested for the presence of viral or bacterial diseases. Bone tissue is sterilized through the BioCleanse™ process only after it has passed this screening and testing. The BioCleanse™ process is an automated multi-step cleansing process which first removes blood and fats, then chemically sterilizes the tissue, while maintaining the structural integrity and biocompatibility of the tissue. We believe that BioCleanse™ is the industry leading sterilization process and BioCleanse™ is the only tissue sterilization process for allografts that has been reviewed by the FDA.

On July 17, 2003, we were approved for accreditation by the American Association of Tissue Banks, or AATB, a nationally recognized association of the tissue banking industry. The accreditation covers the processing, storage and distribution of musculoskeletal tissue for transplantation research and informs users of our tissue that we are in compliance with the minimum safety guidelines of the association. Accreditation is for a three-year term, after which we will apply for renewal.

We were incorporated in 1997 in Florida as a wholly-owned subsidiary of Southeast Tissue Alliance, or SETA (formerly the University of Florida Tissue Bank, Inc.). We began operations on February 12, 1998 when SETA contributed to us its allograft manufacturing and processing operations, related equipment and technologies, distribution arrangements, research and development activities and certain other assets. At the time of our initial public offering in August 2000, we reincorporated in the State of Delaware. Our principal offices are located at 11621 Research Circle, Alachua, Florida, and our phone number is (386) 418-8888. Our Internet address is www.rtix.com. We make available, free of charge, on or through the investor relations portion of our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). These filings are also available on the SEC's website at www.sec.gov. Also available on our website is our Code of Ethics for Senior Financial Professionals, and the charters for our Audit Committee, Compensation Committee and Nominating and Governance Committee. Within the time period required by the SEC and Nasdaq, we will post any amendment to our Code of Ethics for our Senior Financial Professionals and any waiver of our Code of Conduct applicable to our senior financial professionals, executive officers and directors.

Industry Overview

Defects in bone and other human tissue can be caused by a variety of sources including trauma, congenital defect, aging, infectious disease, cancer and other similar conditions. The prevalent method used by surgeons to repair and promote the healing of defective tissue is surgery, principally through the use of surgical implants. When considering a surgical procedure for tissue repair, surgeons and patients face a number of treatment options including:

- metals and synthetics;
- "xenograft" tissue;
- "autograft" tissue; and
- "allograft" tissue.

Metals and Synthetics

Historically, the medical community has used metal and synthetic materials for implant procedures. Metal and synthetic technologies, however, have several shortcomings. One of the principal drawbacks to the use of

these materials is that they do not facilitate the body's natural tissue healing process known as "remodeling." Metal exhibits different properties than bone and one concern with its use in orthopedics is "stress shielding," where the bone adjoining the metal can become weak and fragile over time. This problem can be of particular concern to elderly patients who are more likely to suffer from osteoporosis. Additionally, a number of synthetics can wear away in the body, causing a negative immune system response. Other synthetics can chemically break down over time with negative biological and clinical consequences. Finally, some metal and synthetic products may need to be removed and/or replaced, requiring the expense and inconvenience of a second surgery.

Xenograft Tissue

Procedures using xenograft tissue, while not widely used in the United States at the present time other than for cardiac and vascular surgeries, involve recovering animal tissue, typically from cattle (bovine) or pigs (porcine), and then transplanting that recovered tissue into a human patient. Reasons for the limited use of xenografts in the United States include a higher risk of an adverse immune system response and the perceived risk of disease transmission. In the cardiovascular market, however, xenograft tissue is the most prevalent transplant tissue utilized in the United States.

Autografts and Allografts Tissue

Surgeons are increasingly utilizing autograft and allograft tissue in their surgical procedures to take advantage of their natural healing characteristics. Autograft procedures involve a surgeon harvesting tissue from one part of a patient's body for transplant to another part of the body. In contrast to autograft, allograft tissues are recovered from deceased human donors, processed for certain intended uses and then transplanted by a surgeon into the patient's body to make the needed repair.

Autografts and allografts are not only "osteoconductive," meaning they provide a scaffold for new bone to attach itself to, but, in contrast to metals and some synthetics, can be "osteoinductive" as well, meaning they stimulate the growth of new tissue. Because of the osteoinductive nature of allografts and autografts, they are eventually replaced by the patient's own bone through the remodeling process, typically over a one- to two-year period.

A significant drawback to autograft procedures is that they require an additional and potentially dangerous surgery to harvest the tissue from a second site in the patient's body. In 20% to 30% of autograft procedures, the site where the patient's tissue is harvested becomes painful and uncomfortable, a condition known as donor site morbidity. Additional complications can involve infection, nerve and arterial injury and joint instability. Moreover, a patient may not have sufficient quantities of quality autograft tissue for transplant procedures.

Our Products and Markets

We process tissue, including bone, cartilage, tendon, ligament, dermal, heart valves, and arteries and veins in producing our line of proprietary grafts. We separate our products into four primary markets: spinal, sports medicine, cardiovascular and other general orthopedic. Our current allografts range from material that is precision tooled for specific surgical applications to grafts conventionally processed for general surgical uses. The following table summarizes our allograft offerings in each of our product lines and distribution of these allografts.

Product Line	Allografts	Distribution
Spinal	— MD Series Threaded Bone Dowels — CORNERSTONE-SR cortical block — CORNERSTONE-Select cortical wedge — Assembled Cortical Cancellous Block allograft — Tangent Impacted Cortical Wedge — Precision Impacted Cortical Ring — OSTEOFIL Allograft Paste (frozen) — OSTEOFIL RT Allograft Paste (room temperature) — OSTEOFIL ICM Formed Allograft Paste — OSTEOFIL IC Moldable Allograft Paste	Medtronic Sofamor Danek
Sports medicine	— CorIS Cortical Bone Interference Screws — Pre-shaped bone-tendon-bone, Achilles tendons — Soft tissue tendons (gracilis, semitendinosus, tibialis) — Tendons with bone blocks (patellar and Achilles) — Meniscus grafts — Fresh osteochondral allografts — Cortical Bone Pins — Mini screws — HTO Wedges — AlloAnchor RC Allograft	Stryker Endoscopy, Network of independent distributors
Cardiovascular	— Cardiac • Valves • Conduits • Patches — Vascular • Veins • Arteries — SternalPaste Bone Graft	Network of independent distributors
General orthopedic and other	— Femoral heads — Ilium strips — Ilium blocks — Fibula rings — Femoral wedges — Cancellous/Cortical cancellous chips — Cancellous cubes — Cancellous blocks — Cortical/Cortical cancellous strips — Unicortical / Bicortical Dowels	Network of independent distributors, Medtronic Sofamor Danek, Stryker Endoscopy and Exactech, Inc.
	— Regenafil Injectable Bone Paste — Regenaform Moldable Bone Paste — Pericardium membrane — Opteform Moldable Bone Paste — OPTEFIL Flowable Bone Paste	Direct distribution and Exactech, Inc.
	— FasLata fascia lata allograft — Dermal allograft	C.R. Bard

Spinal

The spinal market for allografts includes bone implants and bone paste utilized in spinal fusion procedures. Our principal spinal allografts are our patented MD-Series Threaded Bone Dowels, our patent-pending Cornerstone SR Wedge, Tangent Impacted Cortical Wedge and Precision Impacted Cortical Ring. We also supply bone paste for the spinal fusion market through our Osteofil line of bone paste products. During 2003, we shipped over 95,000 spinal allograft units, including bone pastes, which accounted for $45.3 million of our net revenues. Our spinal allografts are marketed through our exclusive relationship with Medtronic Sofamor Danek, or "MSD".

Our MD-Series Threaded Bone Dowels are used to help restore the anatomical relationships in the lumbar area of the spine between vertebral bodies and the open spaces within vertebral bodies, known as foramen. Our dowels are threaded, providing rigid interface above and below the vertebral body, allowing the surgeon to restore normal alignment and provide greater stability. Our Cornerstone SR Wedge is used in similar cases in the cervical area of the spine. Our Tangent Impacted Cortical Wedge and Precision Impacted Cortical Ring allografts are specially designed and contoured to promote stability and minimize disruption of the spine.

We currently have several assembled spinal allografts in development for use in spinal fusion surgery.

Sports Medicine

Many repetitive use and sports-related injuries can be addressed with allograft implants. The most prevalent surgeries include repairs to the anterior cruciate ligament, or ACL in the knee, or rotator cuff, in the shoulder. Our principal sports medicine allografts are patent-pending pre-shaped tendons for ligament reconstruction, interference screws for ligament fixation and our cartilage allografts for knee reconstruction. Many of our sports medicine allografts are precision tooled and shaped to fit surgeon's requirements, designed for specific instrumentation, making them easier and/or faster to implant. During 2003, we shipped over 11,000 sports medicine allografts which accounted for $8.9 million of our net revenues. Our sports medicine allografts are marketed in the United States through our exclusive relationship with Stryker Endoscopy.

We currently are completing our development of the BioCleanse™ sterilization process for our soft tissue sports medicine allografts. In addition, we are developing versions of existing precision tooled allografts derived from bovine tissue.

Cardiovascular

The cardiovascular allograft market includes transplantation of human heart valves and vascular tissue as an alternative to mechanical, synthetic or xenograft substitutes.

We acquired our cardiovascular allograft capability with our acquisition of Alabama Tissue Center in 2000. Our principal cardiovascular allograft is our heart valve allograft, which surgeons use to replace a patient's own heart valve during coronary surgery. During 2003, we shipped over 1,200 cardiovascular allograft units, including heart valves, vascular tissue and sternal paste, which accounted for approximately $5.1 million of our net revenues. We distribute our cardiovascular allografts through an independent distribution network.

General Orthopedic

Bone Paste. Surgeons principally use our bone paste allografts, which are composed of demineralized bone matrix and biologic gel carrier, in fracture treatment, bone and joint reconstruction and periodontal applications, such as jaw repairs. Our bone paste allografts for general orthopedic use are marketed through our Optefil and Opteform lines through an exclusive relationship with Exactech.

Conventional Allografts. Our conventional allograft business includes a wide variety of allograft categories including our osteoarticular grafts, such as our frozen femoral heads which are used for cancer treatment procedures and hip and knee reconstruction. We also produce certain types of blended and milled bone allografts, such as our demineralized bone matrix, cortical cancellous chips and ground cancellous chips, used in total hip and knee replacements and for various injuries. Additionally, we produce various types of fashioned bone, such as our fibular wedges and iliac crest wedges, used for various orthopedic procedures, as well as various soft tissue implants used for ligament and articulating surface repair. In 2003, we shipped over 42,000 general orthopedic allografts which accounted for $14.2 million of our net revenues.

The BioCleanse Tissue Sterilization Solution

We have developed and recently launched in the United States the BioCleanse tissue sterilization process, which is an FDA reviewed, automated, pharmaceutical grade chemical sterilization process for musculoskeletal bone. This process is fully validated to kill or inactivate all classes of conventional pathogens, viruses, microbes, bacteria and fungi. Our BioCleanse process is able to remove greater than 99% of the blood, fats, lipids and other unwanted materials from the tissue we process, a figure that is significantly in excess of traditional processing. We believe the removal of blood, fat, lipids and other unwanted materials results in faster patient healing because it eliminates the need for the patient's body to remove these substances using natural processes following surgery. An important element of the BioCleanse process is that while it removes unwanted materials embedded within the tissue, it maintains the tissue's structural integrity and compression strength. Studies have shown that tissue sterilized with BioCleanse maintains the same compression strength as untreated tissue and has significantly greater compression strength than tissue treated with other sterilization processes.

Our BioCleanse process is currently used exclusively on our bone allografts, however, based on our successful studies using soft tissue, we believe that the BioCleanse process is equally applicable to soft tissue including cardiovascular grafts. In addition to the safety advantage of BioCleanse, it provides us with a number of significant research and development opportunities, including the ability to sterilize xenograft tissue and to introduce bone-growth factors and anti-bacterial, anti-viral and cancer fighting agents into our allografts.

Tissue Recovery

Tissue recovery is the actual removal of tissue from a donor only after receiving appropriate familial consent. Tissue recovery personnel aseptically recover tissue within 24 hours for musculoskeletal tissue and 12 hours for cardiovascular tissue following a donor's death, using surgical instruments and sterile techniques similar to those used in hospitals for routine surgery. Recovered tissue is placed on wet or dry ice and then transported by the donor recovery agency to the tissue processor or possibly a research institution.

Under U.S. law, human tissue cannot be sold. However, the law permits the recovery of some costs, such as those involved in recovering, processing and storing tissue and costs related to the advancement of tissue processing technologies, all types of activities in which we are involved.

Our network of donor recovery groups recovers a variety of tissue types from donors including the fibula, femur, tibia, humerus, ilium, pericardium, fascia lata, dermis, hearts for valves and blood vessels. Once we receive tissue that has been screened at our tissue recovery centers we re-screen this recovered material to guard against transmittable diseases. This screening process includes evaluation of risk on the basis of donor medical history, lifestyle, interviews with the donor's family and physical examination of the donor. We also perform biomedical testing and culturing at various stages during the processing of tissue, using FDA licensed tests and other tests for known viruses and pathogens.

We have relationships with over thirty tissue donor centers across the country. Southeast Tissue Alliance, or SETA (formerly the University of Florida Tissue Bank, Inc.) which is our largest recovery group, supplied us

with approximately 28% of our total tissue during 2003. Our three largest donor recovery groups together recovered approximately 51% of our total tissue during this period.

Due to the limitations in the availability of human donor tissue, we continue to investigate methods of rendering xenograft tissue (tissue recovered from non-human sources) biocompatible for implant to humans while not adversely affecting tissue strength. Grafts processed from xenograft tissue would be regulated by the FDA as devices and we would be required to obtain approval or licenses from the FDA prior to marketing in the United States.

Marketing and Distribution

Our allografts are distributed in all 50 states and in ten countries internationally. We pursue a market-by-market approach to distribution, including strategic relationships in selected markets, in order to increase our penetration of these markets.

Medtronic Sofamor Danek, serves as our exclusive worldwide distributor for allograft tissue and bone paste for use in spinal surgery. On June 1, 2002, we entered into a new license and distribution agreement with MSD which replaced the two existing agreements between the two companies. As under the prior agreements, MSD remains our exclusive distributor in the spinal market and we remain responsible for processing and related regulatory compliance related to screening, testing and processing of this tissue. Under the new agreement, MSD is now responsible for the distribution of available tissue and regulatory compliance related to distribution, as well training and consultation with surgeons and conducting certain marketing activities. In addition, under the new agreement, MSD pays us license and service fees of approximately 40% to 50% of the listed average net distribution fee for specialty tissue allografts and bone paste for use in spinal surgery. As a result, effective November 1, 2002, we no longer pay management service fees to MSD with respect to distribution activities. Accordingly, all distribution revenues related to the MSD agreement, including during periods prior to our new arrangement, are reflected as net revenues in the financial statement. The new agreement also provides that MSD has the right to become the exclusive distributor for new allografts we develop for use in the spine. The two companies have agreed to negotiate in good faith for MSD to have exclusive distribution rights with respect to any other allografts intended for use outside the spine. The new agreement is for an initial term expiring June 1, 2014, subject to earlier termination under certain limited circumstances.

Effective January 1, 2003, we entered into an exclusive License and Distribution Services Agreement with Stryker Endoscopy, a division of Stryker Corporation, to serve as the exclusive distributor, in the United States, of allografts we process for use in sports medicine applications, including reconstruction and repair of the knee, hip, shoulder, wrist, elbow, foot and ankle. Prior to this agreement, we distributed these allografts through a network of independent distributors. Under the agreement, Stryker Endoscopy pays us license and service fees based on a percentage of the listed average net distribution fee. Our line of sports medicine allograft products includes menisci, pre-shaped tendons, precision-tooled anchors, screws and pins, and fresh osteochondral allografts. Under the agreement, we remain responsible for processing and delivery of the relevant tissue and related regulatory compliance. Stryker Endoscopy is responsible for distribution of available tissue, managing customer orders and invoicing, as well as customer education and certain marketing activities. The agreement also provides that each party must first offer the other party the opportunity to pursue the development and/or distribution of any new product covered by the agreement. The agreement is for an initial term ending December 31, 2004 and is automatically renewable for one year periods thereafter unless prior notice is given by either party.

Exactech, Inc., or Exactech, serves as our exclusive worldwide distributor for bone paste products for general orthopedic procedures. Effective July 1, 2002, we entered into a new license and distribution agreement with Exactech which replaced the existing agreement between the two companies. The agreement expands Exactech's distribution rights to both moldable and flowable bone paste. The original agreement was limited to moldable bone paste products. Under the new agreement, we remain responsible for processing bone paste

allograft tissue and related regulatory compliance. Exactech will continue distribution of available bone paste products and regulatory compliance related to distribution. Under the agreement, Exactech will pay us license and service fees based on a percentage of the listed average net distribution fee for bone paste used in non-spinal orthopedic procedures. We also are required to pay Exactech a small percentage of the fees we receive with respect to our moldable bone pastes distributed by others. The agreement is for an initial term expiring June 30, 2014, subject to earlier termination under certain limited circumstances.

In the United States, we have 14 independent distributors specializing in general orthopedics, which distribute our allografts through approximately 100 representatives, complemented by our marketing staff of 10 people. Internationally, we have five distributors that distribute our allografts through approximately 75 representatives. This network distributes conventional tissue directly to hospitals and surgeons in their exclusive territory. Distributors and representatives receive compensation for the revenues they generate.

In the urological market, C.R. Bard serves as the exclusive distributor for our urological allografts. Under this agreement, we may ship our urological allografts directly to C.R. Bard's customers or to C.R. Bard for their direct distribution. In return, we receive reimbursement for shipping charges and a transfer fee as a percentage of the amount charged to the customer. In order to remain our exclusive distributor of these allografts, C.R. Bard must meet a specific annual distribution quota. C.R. Bard has an exclusive 90-day right to negotiate an agreement for the distribution of any new technology, invention, process or application we may develop in the future for the treatment of "urinary voiding dysfunction or pelvic tissue defects." This agreement expires in June 2008, subject to a provision providing for automatic renewal.

In the cardiovascular market, we distribute heart valve, vascular tissue and sternal bone paste allografts through 13 cardiovascular distributors, using approximately 40 representatives within the United States.

Research and Development

We plan to continue to develop new allografts and technologies within the spinal, cardiovascular, sports medicine and orthopedic markets and to develop additional tissue-related technologies for other markets. We will do this by building on our core technology platforms: BioCleanse, precision machined and assembled grafts, and tissue mediated induction. As of December 31, 2003, our research and development staff consisted of 17 professional and technical personnel.

In 2003, we developed a long-term product development plan to steadily introduce new products which we expect will become an ever-increasing component of our revenues. In 2004, we expect to almost double the financial resources in our research and development efforts to support this development plan. Our scientists are focusing their studies on delivering optimal regenerative medicine by achieving higher levels of osteoinductivity and osteoconductivity through allograft, as well as expanding the uses of the BioCleanse technology to infuse healing pharmaceutical components into allograft implants. We are geared to develop sophisticated processing technology to accelerate the introduction of new tissue implants and to continuously raise the bar for tissue safety.

In addition, in 2004, we will be ready to launch the BioCleanse process for musculosketal soft tissue. Clinical trials have been advancing steadily, and preliminary findings show the implants are performing well. In addition, we are experimenting with the use of the BioCleanse process on cardiovascular tissue and loading bone growth factors, as well as antimicrobial and cancer-fighting agents into our allografts. We will continue to expand upon the ability of our BioCleanse process to render various tissues sterile, biocompatible and nonimmunogenic. We have received the CE mark in Europe for seven xenograft cortical and cancellous bone constructs processed by the BioCleanse process. We intend to continue to expand our xenograft program to other tissue types and configurations.

We continue to develop our precision machined and assembled technology to produce novel graft types previously not possible due to the naturally occurring anatomical constraints of human tissue. Our assembled

technology allows us to produce optimal graft configurations and expand the offering of allograft tissues into previously unmet applications. Assembled technology consists of the construction of grafts from subassemblies enabling the manufacture of more grafts as well as more complex constructs for broader surgical indications. Additionally, tissue that was previously unusable due to anatomical limitations on bone thickness, shape or quality can now be formed into implantable grafts.

We hold an active research grant from the National Institute of Standards and Technology to investigate the utilization of musculoskeletal tissue grafts as a vehicle for gene delivery.

Intellectual Property

Our business depends upon the significant know-how and proprietary technology we have developed. To protect this know-how and proprietary technology, we rely on a combination of trade secret laws, patents, trademarks and confidentiality agreements. The effect of these intellectual property rights is to define zones of exclusive use of the covered intellectual property.

Presently, our United States patent holdings include patents relating to or covering: BioCleanse, our proprietary method of cleaning, sterilizing and virally inactivating donor tissue; our MD-Series cortical bone dowel; the use of the interference screw technology; our segmentally demineralized graft; and claims directed toward our demineralized stent or conduit technology. Presently, our foreign patent holdings include: our MD-Series cortical bone dowel technology and our demineralized stent technology. The duration of patent rights generally is 20 years from the date of filing of priority application, while trademarks, once registered, essentially are perpetual. We also have patent applications pending in the U.S. (including continuation and divisional applications), and corresponding foreign patent applications pending in various countries including, but not limited to, Canada, Mexico, Japan, Australia and the European Union. In addition, we rely on our substantial body of know-how, including proprietary tissue recovery techniques and processes, research and development, tissue processing and quality assurance.

Competition

Competition in the bone and tissue reconstruction and healing industry is intense and subject to rapid technological change and evolving industry requirements and standards. Companies within the industry compete on the basis of design of related instrumentation, efficacy of products, relationships with the surgical community, depth of range of implants, scientific and clinical results, and pricing. Allograft implants compete with autograft, metals and synthetic tissues, as well as with alternative medical procedures such as xenografts.

Our principal competitors in the conventional allograft market include the Musculoskeletal Transplant Foundation, or MTF, the American Red Cross Tissue Services, AlloSource and LifeNet. Among our competitors in precision tooled allograft are Osteotech, MTF, LifeNet, and Tutogen. Other companies who process bone pastes include Osteotech, AlloSource, GenSci Regeneration Sciences, Wright Medical Technologies, and MTF. Among the companies that market devices used for soft tissue anchoring in bladder neck suspensions are Mentor, Ethicon (a division of Johnson & Johnson), Boston Scientific, Smith & Nephew and C.R. Bard. In the cardiovascular tissue market, CryoLife and LifeNet are our principal competitors distributing human heart valves and vascular tissue. American Red Cross and Northwest Tissue Service Center also compete in this market.

Government Regulation

Government regulation plays a significant role in the processing and distribution of allografts. The recovery, production, testing, labeling, storage, record keeping, approval, marketing, advertising and promotion of allografts are governed or influenced by the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and/or other federal and state statutes and regulations. Failure to comply with applicable requirements could result in fines, injunctions, civil penalties, recall or seizure of products, suspension of production, inability to

market current products, criminal prosecution, and/or refusal of the government to authorize the marketing of new products. In addition to being registered as a tissue bank with the FDA, we also are licensed by the states of New York, Florida, California and Maryland. These states have regulations similar to the FDA covering donor screening and tissue processing.

We currently market allografts that are subject to the FDA's "Human Tissue Intended for Transplantation" and Subparts A and B of "Human Cells, Tissues, and Cellular and Tissue-Based Products" regulations. Under these regulations, we are required to perform donor screening and infectious disease testing and to document this screening and testing for each donor from whom we process tissue. The FDA has authority under the rules to inspect human tissue processing facilities, and to detain, recall, or destroy tissues for which appropriate documentation is not available. We are not required to obtain pre-market approval or clearance from the FDA for allografts that meet the regulation's definition of "human tissue."

In January 2001, the FDA issued a final rule requiring tissue processors to register with the agency and list their tissue products. This is a preliminary step to the FDA issuing its proposed comprehensive tissue regulations titled "Current Good Tissue Practices for Manufacturers of Human Cellular and Tissue Based Products." This proposed regulation is presently under review and we expect finalization to be published in 2004. We are currently an FDA registered tissue processor.

The FDA may regulate certain allografts as medical devices, drugs, or biologics, which would require that we obtain approval or product licensure from the FDA. This would occur in those cases where the allograft is deemed to have been "more than minimally manipulated or indicated for nonhomologous use." In general, "homologous use" occurs when tissue is used for the same basic function that it fulfilled in the donor. The definitional criteria for making these determinations appear in the FDA's rules. If the FDA decides that certain of our current or future allografts are more than minimally manipulated or indicated for nonhomologous use, it would require licensure, approval or clearances of those allografts. Allografts requiring such approval are subject to pervasive and continuing regulation by the FDA. We would be required to list these allografts as a drug, as a medical device, or as a biologic, and to manufacture them in specifically registered or licensed facilities in accordance with FDA regulation "Current Good Manufacturing Practices." We would also be subject to post-marketing surveillance and reporting requirements. In addition, our manufacturing facilities and processes would be subject to periodic inspection to assess compliance with Current Good Manufacturing Practices. Depending on the nature and extent of any FDA decision applicable to our allografts, further distribution of the affected products could be interrupted for a substantial period of time, which would reduce our revenues and hurt our profitability. Our labeling and promotional activities would be subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of drugs, devices and biologics is also subject to more intensive regulation than is the case for human tissue products.

On March 12, 2002, we and other tissue processors were advised by the FDA that our bone paste allografts would be subject to regulation as medical devices under the 510(k) pre-market notification process. We submitted the required documentation to the FDA in August 2002 and are awaiting clearance. We and other processors are permitted to continue distributing these allografts while going through this process.

Heart valve allografts are regulated by the FDA as medical devices. The FDA permits entities that processed and distributed heart valve allografts before June 26, 1991 to continue distributing heart valve allografts without obtaining 510(k) clearance or pre-market approval from the FDA. Our heart valve allografts are covered by this "grandfather" policy provided these heart valves are processed and labeled in the same manner as they were prior to June 26, 1991. Any changes to processes or labels would subject heart valves to the pre-market approval process as a medical device.

Our tissue processing generates by-products classified as medical hazardous waste by the U.S. Environmental Protection Agency and the Florida Department of Environmental Protection. All such by-products must be segregated and properly disposed of in compliance with applicable environmental regulations.

Employees

As of December 31, 2003, we had a total of 358 full-time employees. The following chart shows the number of our employees involved in the various aspects of our business:

Department	Number of Employees
Tissue Processing and Manufacturing	211
Tissue Recovery	48
Distribution and Marketing	16
Research and Development	17
General and Administrative	66

Risk Factors

An investment in our common stock involves a high degree of risk. You should consider each of the risks and uncertainties described in this section and all of the other information in this document before deciding to invest in our common stock. Any of the risk factors we describe below could severely harm our business, financial condition and results of operations. The market price of our common stock could decline if any of these risks or uncertainties develop into actual events. You may lose all or part of the money you paid to buy our common stock.

We depend heavily upon a limited number of sources of human tissue, and any failure to obtain tissue from these sources in a timely manner will interfere with our ability to process and distribute allografts.

The limited supply of human tissue has at times limited our growth, and may not be sufficient to meet our future needs. In addition, due to seasonal changes in mortality rates, some scarce tissues that we use for our allografts are at times in particularly short supply. Other factors, some of which are unpredictable, such as negative publicity and regulatory actions in our industry also can unexpectedly reduce the available supply of tissue.

We rely on donor recovery groups for our tissue supply. Donor recovery groups are part of relatively complex relationships. They provide support to donor families, are regulated by the FDA, and are often affiliated with hospitals, universities or organ procurement groups. Our relationships with donor recovery groups, which are critical to our supply of tissue, can be affected by relationships they have with other organizations. Any negative impact of the regulatory and disease transmission issues facing the industry, as well as the negative publicity that these issues create, could have an impact on our ability to negotiate favorable contracts with recovery groups.

Southeast Tissue Alliance, or SETA, our largest donor recovery group, supplied us with approximately 28% of our total tissue for the year ended December 31, 2003. Our three largest recovery groups together supplied approximately 51% of our total tissue for the year ended December 31, 2003. If we were to lose any one of these three sources of tissue, the impact on our operating results would be material.

We cannot be sure that our supply of tissue will continue to be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain tissue from our current sources sufficient to meet our needs, we may not be able to locate additional replacement sources of tissue on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of tissue would significantly hurt our revenues. We expect our revenues would decline in proportion to any decline in tissue supply.

If we fail to maintain our existing strategic relationships or are unable to identify additional distributors of our allografts, our revenues may decrease.

We currently derive the majority of our revenues through our relationships with three companies, Medtronic Sofamor Danek, or MSD, Stryker Endoscopy and Exactech, Inc. For the year ended December 31, 2003, we derived approximately 60%, 6%, and 6%, respectively, of our net revenues from distribution by MSD, Stryker Endoscopy, and Exactech.

MSD provides nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for our line of spinal allografts. If our relationship with MSD is terminated for any reason and we are unable to replace the relationship with other means of distribution, our revenues would be negatively impacted.

We may need to obtain the assistance of additional distributors to market and distribute our new allografts and technologies, as well as to market and distribute our existing allografts and technologies to new market segments or geographical areas. We may not be able to find additional distributors who will agree to and successfully market and distribute our allografts and technologies on commercially reasonable terms, if at all. If we are unable to establish new distribution relationships on favorable terms, our revenues may decline.

If we fail to achieve and maintain the high processing standards that our allografts require or if we are unable to develop processing capacity as required, our commercial opportunity will be reduced or eliminated.

Our allografts require careful calibration and precise, high-quality processing. Achieving precision and quality control requires skill and diligence by our personnel. If we fail to achieve and maintain these high processing standards, including avoiding processing errors, design defects or component failures:

- we could be forced to recall, withdraw or suspend distribution of our allografts;
- our allografts and technologies could fail quality assurance and performance tests;
- production and deliveries of our allografts could be delayed or cancelled; and
- our processing costs could increase.

Further, to be successful, we will need to manage our processing capacity related to tissue recovery and demand for our allografts. It may be difficult for us to match our processing capacity to demand due to problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures, and lack of skilled personnel. If we are unable to process and produce our allografts on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if we experience unanticipated technological problems or delays in processing, it will reduce our net revenues and increase our cost per allograft processed.

Our allografts and technologies could become subject to significantly greater regulation by the FDA, which could disrupt our business.

The FDA and several states have statutory authority to regulate allograft processing and allograft-based materials. The FDA could identify deficiencies in future inspections of our facilities or promulgate future regulatory rulings that could potentially disrupt our business, hurting our profitability.

For example, in mid-2001, the FDA reviewed our BioCleanse process after the FDA raised concerns about the process in a letter to us dated May 3, 2001. While the FDA concluded that the compliance portion of its review of our BioCleanse process in January 2002 and determined we were in compliance with existing FDA requirements and that no regulatory action was warranted, the possibility always exists that the FDA could raise concerns with these or other aspects of our business. The FDA's decision, that no regulatory action was warranted, does not constitute a formal approval of our BioCleanse process and the FDA is free to raise the same or similar concerns in the future.

If any of our allografts falls under the FDA's definitions of "more than minimally manipulated or indicated for nonhomologous use," we would be required to obtain medical device approval or clearance or biologics licenses, which could require clinical testing. Disapproval of our license applications and restricted distribution of any of our allografts, which may become subject to pre-market approval, may result. The FDA could require post-market testing and surveillance to monitor the effects of such allografts, could restrict the commercial applications of these allografts, and could conduct periodic inspections of our facility and our suppliers' facilities. Delays encountered during the FDA approval process could shorten the patent protection period during which we have the exclusive right to commercialize such technologies or could allow others to come to market with similar technologies before us.

On March 12, 2002, we and other tissue processors were advised by the FDA that our bone paste allografts would be subject to regulation as medical devices under the 510(k) pre-marketing notification process. In its letter, the FDA stated that it would issue guidance on the required submissions for this process "in the near future." We have submitted 510(k) applications for our bone paste allografts, and are working through the review process with the FDA. Under the 510(k) pre-market notification process, we have submitted an application containing data supporting the "substantial equivalence" of our allografts to a device marketed prior to the enactment of the Medical Device Amendments of 1976 or to a device legally marketed after that statute's enactment. If we do not receive FDA clearance to continue marketing these allografts, it could have a material and adverse effect on our revenues and our profitability.

Some of our proposed grafts will contain tissue derived from animals, commonly referred to as xenografts. Xenografts are medical devices that are subject to pre-market approval or clearance by the FDA. We may not receive FDA approval or clearance to market these grafts.

Proposed FDA regulations of human cellular and tissue-based products, titled "Good Tissue Practices," would regulate all stages of allograft processing, from procurement of tissue to distribution of final allografts. These proposed regulations will potentially increase regulatory scrutiny within our industry and this could lead to increased enforcement action affecting the conduct of our business. In addition, the effect of this regulation on recovery agencies which supply us with tissue may be significant and lead to additional costs of recovery activities. These costs may translate into increased costs to us, as we compensate the recovery agencies based on their cost of recovery.

Other regulatory entities include state agencies with statutes covering tissue banking. Of particular relevance to our business are regulations issued by Florida, New York, California and Maryland. Most states do not currently have tissue banking regulations. However, recent incidents of allograft related infections in the industry may stimulate the development of regulation in other states. It is possible that others may make allegations against us or against donor recovery groups or tissue banks, including those with which we have a relationship, about non-compliance with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action, or could cause negative publicity for our business and our industry.

Our industry is subject to additional local, state, federal and international government regulations and any increased regulations of our current or future activities could significantly increase the cost of doing business, thereby reducing our profitability.

Some aspects of our business are subject to additional local, state, federal or international regulation. Changes in the laws or new interpretations of existing laws could negatively affect our business, revenues or prospects, and increase the costs associated with conducting our business. In particular, the procurement and transplantation of allograft tissue is subject to federal regulation under the National Organ Transplant Act, or NOTA, a criminal statute that prohibits the purchase and sale of human organs, including bone and other tissue. NOTA permits the payment of reasonable expenses associated with the transportation, processing, preservation, quality control and storage of human tissue, which are the types of services we perform. If in the future NOTA

were amended or interpreted in a way that makes us unable to include some of these costs in the amounts we charge our customers, it could reduce our revenues and therefore hurt our business. It is possible that more restrictive interpretations or expansions of NOTA could be adopted in the future which could require us to change one or more aspects of our business, at a substantial cost, in order to continue to comply with this statute.

A variety of additional local, state, federal and international government laws and regulations govern our business, including those relating to the storage, handling, generation, manufacture and disposal of medical wastes from the processing of tissue. If we fail to conduct our business in compliance with these laws and regulations, we could be subject to significant liabilities. We could be subject to significant liabilities arising from hazardous biological materials for which our insurance may not be adequate. Moreover, such insurance may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which could harm our financial condition and liquidity.

Our success will depend on the continued acceptance of our allografts and technologies by the medical community.

Our new allografts, technologies or enhancements to existing allografts may never achieve broad market acceptance, which can be affected by numerous factors, including:

- lack of clinical acceptance of our allografts and technologies;
- introduction of competitive tissue repair treatment options which render our allografts and technologies too expensive or obsolete;
- lack of availability of third-party reimbursement; and
- difficulty training surgeons in the use of our allografts and technologies.

Market acceptance will also depend on our ability to demonstrate that our existing and new allografts and technologies are an attractive alternative to existing tissue repair treatment options. Our ability to do so will depend on surgeons' evaluations of the clinical safety, efficacy, ease of use, reliability and cost-effectiveness of these tissue repair options and technologies. For example, we believe that some in the medical community have lingering concerns over the risk of disease transmission through the use of allografts.

Furthermore, we believe that even if the medical community generally accepts our allografts and technologies, recommendations and endorsements by influential surgeons will be important to the commercial success of our allografts and technologies. If our allografts and technologies are not broadly accepted in the marketplace, we may not achieve a competitive position in the market.

Rapid technological changes will affect us and our customers, which could result in reduced demand for our allografts.

Technologies change rapidly in our industry and there are frequent introductions of new technologies. For example, steady improvements have been made in synthetic human tissue substitutes which compete with our allografts. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human tissue. If one of our competitors successfully introduces synthetic technologies using recombinant technologies, which stimulate the growth of tissue surrounding an implant, it could result in a decline in demand for allografts. Although our growth strategy contemplates introducing new allografts and technologies, the development of these new allografts and technologies is a complex and uncertain process, requiring a high level of innovation, as well as the ability to accurately predict future technology and market trends. The allografts we currently have in development will require significant additional development, investment and testing. We may need to undertake costly and time-consuming efforts to achieve these objectives. We may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new

technologies or enhancements to existing allografts in a timely and cost-effective manner, if at all. If we are unable to achieve the improvements in our allografts necessary for their successful commercialization, the demand for our allografts will suffer.

We face intense competition, which could result in reduced acceptance and demand for our allografts and technologies.

The medical technology/biotechnology industry is intensely competitive. We compete with companies in the United States and internationally that engage in the development and production of medical technologies and processes including:

- biotechnology, orthopedic, pharmaceutical, biomaterial and other companies;
- academic and scientific institutions; and
- public and private research organizations.

Many of our competitors have much greater financial, technical, research, marketing, distribution, service and other resources than we have. Moreover, our competitors may offer a broader array of tissue repair treatment products and technologies or may have greater name recognition than we do in the marketplace. For example, we compete with a number of divisions of Johnson & Johnson, a company with significantly greater resources and brand recognition than we have. Our competitors, including several development stage companies, may develop or market technologies that are more effective or commercially attractive than ours, or that may render our technologies obsolete. For example, the successful development of a synthetic tissue product that permits remodeling of bones could result in a decline in the demand for allograft-based products and technologies.

We have to resolve our outstanding differences with Medtronic Sofamor Danek.

At December 31, 2003, we had a recorded liability to MSD of $10.7 million, for management service fee obligations which were recognized under the terms of the prior distribution agreement. We are disputing certain components of the recorded liability to MSD, which has primarily focused on the contractual terms and, among other things, responsibilities of the parties relative to losses on consignment inventories and uncollected accounts receivable. We, along with MSD, have attempted for over a year, to resolve these issues in a manner that addressed the needs of the two companies. We have been unable to reach an agreement with MSD with respect to the amount owed. The current distribution agreement calls for MSD and us to enter into arbitration to settle the dispute if a settlement cannot otherwise be reached. We are in discussions with MSD to resolve these matters and to improve our current distribution agreement. Management believes that the ultimate settlement of these matters will not exceed the liability provided for in the Company's consolidated financial statements, however, there can be no assurance that this will occur.

If we do not manage the medical release of donor tissue into processing in an efficient manner, it could affect our profitability.

There are many factors which affect the level and timing of donor medical releases, such as effectiveness of donor screening performed by our donor recovery groups, the timely receipt, recording and review of required medical documentation, and employee loss and turnover in our medical records department. Some of our donor recovery groups are also processors who provide us with partially processed tissues which they have already determined to be medically suitable for processing. Therefore, these sources provide a higher level of documentation than those that perform donor recovery alone. Although we strive for the timely medical release of tissue, while at the same time maximizing safety for our employees and for tissue recipients, our internal policies may sacrifice timely release of tissue in favor of safety. We continue to review our internal policies in order to provide the best framework for medical releases, however we can provide no assurance that releases will occur at levels which maximize our processing efficiency and minimize our cost per allograft processed.

Negative publicity concerning methods of tissue recovery and screening of donor tissue in our industry could reduce demand for our allografts and impact the supply of available donor tissue.

Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of our allografts. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies.

Potential patients may not distinguish our allografts, technologies and the tissue recovery and the processing procedures we have in place, from those of our competitors or others engaged in tissue recovery. In addition, families of potential donors may become reluctant to agree to donate tissue to for-profit tissue processors.

If our patents and the other means we use to protect our intellectual property prove to be inadequate, our competitors could exploit our intellectual property to compete more effectively against us.

The law of patents and trade secrets is constantly evolving and often involves complex legal and factual questions. The U.S. government may deny or significantly reduce the coverage we seek in our patent applications before or after a patent is issued. We therefore cannot be sure that any particular patent we apply for will be issued, that the scope of the patent protection will be comprehensive enough to provide adequate protection from similar technologies which may compete with ours, that interference proceedings regarding any of our patent applications will not be filed, or that we will achieve any other competitive advantage from a patent. In addition, it is possible that one or more of our patents will be held invalid if challenged or that others will claim rights in or ownership of our patents and other proprietary rights. If any of these events occur, our competitors may be able to use our intellectual property to compete more effectively against us.

Because patent applications are secret until patents are actually issued (or until 18 months after a patent application has been filed) and the publication of discoveries in the scientific or patent literature lags behind actual discoveries, we cannot be certain that our patent application was the first application filed covering a particular invention. If another party's rights to an invention are superior to ours, we may not be able to obtain a license to use that party's invention on commercially reasonable terms, if at all. In addition, our competitors, many of which have greater resources than we do, could obtain patents that will prevent, limit or interfere with our ability to make use of our inventions either in the United States or in international markets. Further, the laws of some foreign countries do not always protect our intellectual property rights to the same extent as the laws of the United States. Litigation or regulatory proceedings in the United States or foreign countries also may be necessary to enforce our patent or other intellectual property rights or to determine the scope and validity of our competitors' proprietary rights. These proceedings can be costly, result in development delays, and divert our management's attention from our business.

We also rely upon unpatented proprietary techniques and processes in tissue recovery, research and development, tissue processing and quality assurance. It is possible that others will independently develop technology similar to ours or otherwise gain access to or disclose our proprietary technologies. We may not be able to meaningfully protect our rights in these proprietary technologies, which would reduce our ability to compete.

In 1996, a law was passed in the United States that limits the enforcement of patents covering the performance of surgical or medical procedures on a human body. This law prevents medical practitioners and health care entities who practice these procedures, not otherwise covered by a patented procedure, from being sued for patent infringement. Therefore, depending upon how these limitations are interpreted by the courts, they could have a material adverse effect on our ability to enforce any of our proprietary methods or procedures deemed to be surgical or medical procedures.

Our success will depend in part on our ability to operate without infringing on or misappropriating the proprietary rights of others, and if we are unable to do so we may be liable for damages.

We cannot be certain that U.S. or foreign patents or patent applications of other companies do not exist or will not be issued that would prevent us from commercializing our allografts and technologies. Third parties may sue us for infringing or misappropriating their patent or other intellectual property rights. Intellectual property litigation is costly. If we do not prevail in litigation, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license requiring us to make royalty payments. It is possible that a required license will not be available to us on commercially acceptable terms, if at all. In addition, a required license may be non-exclusive, and therefore our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around another company's patent, we may be unable to make use of some of the affected technologies or distribute the affected allografts which would negatively impact our revenues.

We or our competitors may be exposed to product liability claims which could cause us to be liable for damages or cause investors to think we will be liable for similar claims in the future.

The development of allografts and technologies for human tissue repair and treatment entails an inherent risk of product liability claims, and substantial product liability claims may be asserted against us. We may not have adequate insurance coverage for any future claims that arise. Moreover, insurance covering our business may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which would harm our financial condition and liquidity. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. In addition, claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain surgeon endorsement of our allografts or to expand our business.

If we are not successful in expanding our distribution activities into international markets, we will not be able to pursue one of our strategies for increasing our revenues.

Our current and planned international distribution strategies vary by market, as well as within each country in which we operate. For example, we distribute only a portion of our line of allografts within each country. Our international operations will be subject to a number of risks which may vary from the risks we face in the United States, including:

- the need to obtain regulatory approvals in additional foreign countries before we can offer our grafts and technologies for use;
- longer distribution-to-collection cycles, as well as difficulty in collecting amounts owed to us;
- dependence on local distributors;
- limited protection of intellectual property rights;
- fluctuations in the values of foreign currencies; and
- political and economic instability.

If third-party payors fail to provide appropriate levels of reimbursement for the use of our allografts, our revenues would be adversely affected.

Political, economic and regulatory influences subject the healthcare industry in the United States to fundamental change. Any new federal or state legislation could result in significant changes in the availability, delivery, pricing or payment for healthcare services and products. While we cannot predict what form any new legislation will take, it is possible that any significant healthcare legislation, if adopted, could lower the amounts paid to us for our services, which would decrease our revenues. Our revenues depend largely on the

reimbursement of patients' medical expenses by government health care programs and private health insurers. Governments and private insurers closely examine medical procedures incorporating new technologies to determine whether the procedures will be covered by payment, and if so, the level of payment which may apply. We cannot be sure that third-party payors will continue to reimburse us or provide payment at levels which will be profitable to us.

The value of our investment in Organ Recovery Systems, Inc. is dependent on the financial success of this new venture.

We own 1,285,347 shares of convertible preferred stock issued by Organ Recovery Systems, Inc., or ORS, a privately held company, for which the purchase price was $5.25 million. ORS is organized for the purpose of advancing organ transplantation technology. Realization of our investment in ORS is dependent upon ORS's successful execution of its operational strategies and the continued industry acceptance of its current and future product developments. If ORS does not successfully execute its operational strategies and recognize long-term profitability, the value of our investment could be impaired which could have a negative effect on our financial statements for the period in which the impairment occurs.

Item 2. PROPERTIES.

Our physical facilities, located in Alachua, Florida, near metropolitan Gainesville, include three new buildings on approximately 21 acres of property we own, including a 65,000 square foot manufacturing facility, a 50,000 square foot office building and a 20,000 square foot commons building. These facilities include 30 clean-rooms for tissue processing and packaging, eight single-donor BioCleanse sterilization chambers, freezers for storage of tissue and laboratory facilities.

We currently have a separate BioCleanse processing unit and laboratory operations in approximately 4,000 square feet of leased space related to xenograft research. The monthly rent was $4,000 and the lease expired on January 31, 2004. We entered into an extension on the lease for an additional year, to January 31, 2005, which includes additional space of 2,100 square feet for $9,000 per month.

We also lease additional warehousing facilities in Alachua. The monthly rent is $5,000 and the lease expires on February 28, 2005.

Our new manufacturing facility will increase our capacity for tissue processing. We intend for this new facility to meet the FDA's Current Good Manufacturing Practices requirements and believe it will also allow us to be designated as an FDA approved medical device manufacturer if necessary.

Our wholly owned subsidiary, Alabama Tissue Center, operates from a leased space on the campus of the University of Alabama in Birmingham, Alabama comprising 3,200 square feet, with four clean rooms for tissue processing and packaging, and freezers for tissue storage. We had a two-year term lease which expired in August 2002 and we are currently paying $4,000 on a month to month basis. On August 11, 2003, we have entered into a new long-term lease agreement for Alabama Tissue Center. The new lease, comprising 9,745 square feet, commenced in December 2003 and will run for 65 months. The monthly rent will be approximately $11,000.

We also lease space at seven of our recovery group locations throughout the United States.

Item 3. LEGAL PROCEEDINGS.

We are, from time to time, involved in litigation relating to claims arising out of our operations in the ordinary course of business. We believe that none of these claims that were outstanding as of December 31, 2003 will have a material adverse impact on our financial position or results of operations.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None.

PART II

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

Market Information and Holders

Our common stock is quoted on the Nasdaq Stock Market under the symbol "RTIX." The following table sets forth the range of high and low sales prices for our common stock for each quarterly period in the last two fiscal years.

2002	High	Low
First Quarter	$11.15	$4.44
Second Quarter	$ 7.86	$4.76
Third Quarter	$ 8.00	$5.47
Fourth Quarter	$10.11	$7.33

2003	High	Low
First Quarter	$ 9.90	$7.48
Second Quarter	$14.05	$8.69
Third Quarter	$17.25	$8.77
Fourth Quarter	$12.20	$8.02

As of March 5, 2004, we had 154 stockholders of record of our common stock. The closing sale price of our common stock on March 5, 2004 was $12.07 per share.

Dividend Policy

We have never paid cash dividends. We do not expect to declare or pay any dividends on our common stock in the foreseeable future, but instead intend to retain all earnings, if any, to invest in our operations. In addition, our bank credit facility restricts our ability to pay dividends. The payment of future dividends is within the discretion of our board of directors and will depend upon our future earnings, if any, our capital requirements, financial condition, debt covenant terms, and other relevant factors.

Recent Issuances of Unregistered Securities

On November 26, 2002, we completed a private placement of our common stock resulting in net proceeds to us of approximately $25,683. We sold 3.8 million shares of common stock at $7.25 per share pursuant to a purchase agreement between us and the investors party thereto, a copy of which was filed with the Securities and Exchange Commission. Based on representations contained in the purchase agreement, all of the investors were "accredited investors" within the meaning of the Securities Act of 1933. We sold these shares in reliance on the exemption provided by Section 4(d) of the Securities Act and Rule 506 promulgated thereunder. As part of this financing, we also entered into a registration rights agreement with the investors requiring us to file a registration statement covering the resale of the shares we sold, which we filed and which was declared effective by the SEC.

Item 6. SELECTED FINANCIAL DATA.

The statement of operations data set forth below for the years ended December 31, 1999 and 2000, as well as the data as of December 31, 2001, have been derived from our audited consolidated financial statements and accompanying notes which are not included elsewhere in this Form 10-K.

The statement of operations data set forth below for the years ended December 31, 2001, 2002, and 2003, and selected balance sheet data as of December 31, 2002 and 2003 have been derived from our audited

consolidated financial statements and accompanying notes of which, the financial statements as of December 31, 2003 and 2002 and for the three years in the period ended December 31, 2003 are included elsewhere in this Form 10-K. The selected consolidated financial data set forth below should be read along with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and accompanying notes included elsewhere in this document.

	Year Ended December 31,				
	1999	2000	2001	2002	2003
	(In thousands, except share and per share data)				
Statement of Operations Data:					
Revenues:					
Fees from tissue distribution	$ 70,783	$ 120,905	$ 138,762	$ 116,974	$ 73,531
Other revenues	2,237	1,598	1,964	1,516	1,979
Total revenues	73,020	122,503	140,726	118,490	75,510
Management services fees	39,994	64,572	73,176	49,430	—
Net revenues	33,026	57,931	67,550	69,060	75,510
Costs of processing and distribution	21,096	31,063	39,455	44,879	42,766
Gross profit	11,930	26,868	28,095	24,181	32,744
Expenses:					
Marketing, general and administrative	7,816	17,674	35,962	29,236	23,515
Research and development	1,675	2,392	2,631	2,460	2,441
Litigation settlement	—	—	—	2,000	—
Asset abandonments	—	—	—	3,098	169
Restructuring	—	—	—	1,352	—
Total expenses	9,491	20,066	38,593	38,146	26,125
Operating income (loss)	2,439	6,802	(10,498)	(13,965)	6,619
Equity in income of unconsolidated subsidiary	—	1	—	—	—
Other (expense) income:					
Interest expense	(285)	(434)	(106)	(2,758)	(981)
Interest income	187	1,207	1,313	186	235
Total other (expense) income—net	(98)	773	1,207	(2,572)	(746)
Income (loss) before income tax benefit (expense)	2,341	7,576	(9,291)	(16,537)	5,873
Income tax benefit (expense)	619	(3,117)	3,786	3,032	483
Net income (loss)	2,960	4,459	(5,505)	(13,505)	6,356
Other comprehensive (loss) income, net of tax:					
Unrealized derivative (loss) income	—	—	(344)	443	—
Comprehensive income (loss)	$ 2,960	$ 4,459	$ (5,849)	$ (13,062)	$ 6,356
Net income (loss) per common share—basic	$ 0.81	$ 0.42	$ (0.25)	$ (0.60)	$ 0.24
Net income (loss) per common share—diluted	$ 0.18	$ 0.22	$ (0.25)	$ (0.60)	$ 0.24
Weighted average shares outstanding—basic	3,669,970	10,639,884	21,760,596	22,434,436	26,365,348
Weighted average shares outstanding—diluted	16,636,791	20,343,214	21,760,596	22,434,436	26,999,175

	As of December 31,		
	2001	2002	2003
Balance Sheet Data:			
Cash and cash equivalents	$ 13,504	$ 9,811	$ 10,051
Working capital	27,688	25,752	39,696
Total assets	118,700	141,190	136,416
Long-term debt—less current portion	658	2,266	621
Total stockholders' equity	67,784	82,622	92,397

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

You should read the following discussion of our financial condition and results of operations together with the financial statements and the notes to these statements included elsewhere in this filing. This discussion contains forward-looking statements based on our current expectations, assumptions, estimates and projections about us and our industry. Our actual results could differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

Management Overview

In 2003, we achieved net revenues of $75.5 million and net income of $6.4 million. Our net income included the reversal of deferred tax valuation allowances of $2.7 million. Our net revenues were impacted in our sports medicine and general orthopedic product lines by the change from our previous distribution network to exclusive distribution primarily through Stryker Endoscopy and Exactech, Inc. In addition, during the three months ended December 31, 2003, we experienced a decrease in our net revenues from the first three quarters of 2003 as a result of our largest distributor, Medtronic Sofamor Danek, or MSD, executing programs to reduce its level of allograft inventory.

Our goals for 2004 are to continue to build on the Company's strengths as we turn our focus to the future. There are several challenges we face heading into 2004 that we will focus on in order to meet our goals. The key challenges are:

- Work with MSD to implement improvements to our distribution agreement;
- Expand our distribution into new markets;
- Continue to advance our operational and procurement programs, raising the bar for safety standards in the industry;
- Increase the financial resources allocated to our research and development initiatives; and
- Secure a new long-term financing arrangement.

Our primary goal in 2004 is to improve our relationship with MSD. MSD has historically accounted for between 50% and 60% of our net revenues and our relationship with MSD is a key component to our success in 2004. We are currently working on improvements to our agreement, which will resolve certain distribution issues and will strengthen our relationship with our largest distributor.

We are committed to maximizing distribution growth in all product categories for 2004 and beyond. Key initiatives for 2004 include developing our own biologics distribution group, forming new non-exclusive distribution arrangements and strengthening relationships with existing exclusive distributors.

The efforts of 2003 put forth in our tissue recovery and operational effectiveness initiatives have enabled us to consistently meet the needs of our current distributors. Our national network of tissue procurement agencies provides services to donor families and education to their communities about the benefits of tissue donation. Our state-of-the-art, pharmaceutical-grade processing facility allows us to improve the quality of our implants and increase our effectiveness in meeting surgeon demand. We will continue to advance our operational and procurement programs, which raise the bar for safety standards in the industry.

During the second half of 2003, we developed a long-term product development plan to steadily introduce new products, which we expect will become an ever-increasing component of our revenue. In 2004, we expect to almost double the financial resources in our research and development efforts to support our product

development plan. Our scientists are focusing their studies on delivering optimal regenerative medicine, by achieving higher levels of osteoinductivity and osteoconductivity through allograft, as well as expanding the uses of the BioCleanse technology to infuse healing pharmaceutical components into allograft implants. In addition, in 2004, we will be ready to launch the BioCleanse process for musculosketal soft tissue. Clinical trials have been advancing steadily, and preliminary findings show the implants are performing extremely well. We are geared to develop sophisticated processing technology to accelerate the introduction of new tissue implants and to continuously raise the bar for tissue safety.

We have already met our challenge of securing a new long-term financing arrangement. On February 20, 2004, we entered into a new long-term financing agreement with a major financial institution. The new agreement consists of a $9.0 million five-year term loan and a $16.0 million revolving credit loan. This agreement gives us more financial freedom, as we are no longer required to maintain a large portion of our cash balance in a restricted account. All of our cash can now be utilized for operating purposes, so we can focus our attention on how to best utilize our cash to meet our business needs.

Critical Accounting Policies

Although our financial statements have been prepared in accordance with accounting principles generally accepted in the United States, we must often make estimates and judgments that affect reported amounts. These estimates and judgments are based on historical experience and assumptions that we believe to be reasonable under the circumstances. Assumptions and judgments based on historical experience may provide reported results which differ from actual results.

We often introduce new technologies and processes and therefore we may be at risk of using estimates based on assumptions that later become invalid.

The accounting policies which we feel are "critical," or require the most use of estimates and judgment, relate to the following items presented in our financial statements: 1) Tissue Inventory Valuation; 2) Accounts Receivable Allowances; 3) Valuation of Long-Lived Assets; and 4) Revenue Recognition.

Tissue Inventory Valuation. Accounting principles generally accepted in the United States require that inventory be stated at the lower of cost or market value. Due to various reasons, some tissue within our inventory will never become distributed allograft, the source of our revenue. Therefore we must make estimates of future distribution from existing inventory in order to write-off inventory which will not be distributed and which therefore has reduced or no market value.

Our management reviews available information regarding processing costs, inventory distribution rates, industry supply and demand, medical releases and processed tissue rejections, in order to determine write-offs of cost above market value. For a variety of reasons, we may from time to time be required to adjust our assumptions as processes change and as we gain better information. For example, during 2002, we determined, through our inventory valuation analysis, that the write-off requirements were higher than previously estimated, resulting in a $1.0 million increase in write-offs during that year. Although we continue to refine the information on which we base our estimates, we cannot be sure that our estimates are accurate indicators of future events.

Accounts Receivable Allowances. We maintain allowances for doubtful accounts based on our review and assessment of historical payment history and our estimate of the ability of each client to make payments on amounts invoiced. If the financial condition of any of our clients were to deteriorate, additional allowances might be required. From time to time we must adjust our estimates. For example, during 2002, we determined that our accounts receivable allowance was lower than previously estimated, which resulted in a $1.0 million decrease in our bad debt allowance during that year. Also, during 2001, we determined that our accounts receivable allowance was not sufficient and we therefore recorded an additional $5.8 million of bad debt allowance during that year. Changes in estimates of the collection risk related to accounts receivable can result in decreases and

increases to current period net income. Changes in estimates of the collection risk related to accounts receivable can result in decreases and increases to current period net income.

Valuation of Long-Lived Assets and Investments. Accounting principles generally accepted in the United States require that long-lived assets on our balance sheet be stated at the lower of cost, net of depreciation and amortization, or fair value. The factors in this valuation which require significant estimates and judgments are: 1) determination of the estimated useful life of each asset, which determines expense per period, number of periods of expense, and the carrying value of each asset at any time; and 2) determination of the fair value of assets, which may result in impairment charges when fair value is lower than the carrying value of assets, which we would recognize as a charge to earnings during the period we made the determination.

These determinations require complex calculations based on estimated future benefit and fair value. We have often made investments for which the expected future benefit has not been easily estimated. Examples of such investments include, but are not limited to, our acquisition of GTB; our acquisition of ATC; our investment in Organ Recovery Systems, Inc., or ORS; our investment in equipment; our investment in development of software; and our investment in obtaining patents.

If we overestimate the useful life of an asset, or overestimate the fair value of an asset, and at some time in the future we dispose of that asset for a lower amount than its carrying value, our reported total assets and net income will be higher than they would have been during periods prior to our recognition of the loss on disposal of assets, and lower during the period when we recognize the loss.

Long-lived assets include certain long-term investments, such as our investment in ORS and the goodwill associated with our acquisition of ATC. The fair value of these long-term investments are dependent on their performance, as well as volatility inherent in the external markets for this investment. In assessing potential impairment for these investments, we consider these factors as well as forecasted financial performance. If forecasts are not met, impairment charges may be required.

Revenue Recognition. We recognize revenue upon shipping, or receipt by our customers of the processed tissue for implantation, depending on our distribution agreements with our customers. For consignment inventory, we recognize revenue when the tissue is transferred from our consignment inventory locations to our customers for implantation. Effective November 1, 2002, our revenues no longer reflect a management service fee as management service fees are no longer included in our distribution agreements. However, revenues will continue to be reported on a gross basis, which includes any management services fees incurred by us related to the distribution of our allografts. We recognize our other revenues when all significant contractual obligations have been satisfied.

We permit returns of tissue in accordance with the terms of contractual agreements with customers if the tissue is returned in a timely manner, in unopened packaging and from the normal channels of distribution. We provide allowances for returns based upon analysis of our historical patterns of returns, matched against the fees from which they originated. Historical returns have been within the amounts we reserved.

Off Balance-Sheet Arrangements

As of December 31, 2003, we did not have any significant off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Regulatory Actions

In a letter released January 25, 2002, the FDA stated that it had concluded the compliance portion of its review of our BioCleanse process and determined that based on validation data submitted by us and under current FDA requirements, we were in compliance with existing FDA requirements and that no regulatory action was

warranted. The FDA's letter was the result of its review of our BioCleanse process undertaken during mid-2001 after the FDA raised concerns about the process in a letter to us dated May 3, 2001. The BioCleanse validation studies submitted by us to the FDA represented a combination of previously conducted studies, modifications of previous studies and novel methodologies suggested by the FDA for demonstrating sterilization of tissue-based products with respect to conventional infectious disease agents. During the year ended December 31, 2001, we devoted considerable personnel and financial resources to addressing the FDA's concerns.

On June 21, 2001, in response to concerns raised by regulators in the State of Florida, we changed our BioCleanse procedures to comply with that state's regulation requiring donated tissue processed for transplantation to be traceable from individual donor to individual recipient.

On March 12, 2002, we and other tissue processors were advised by the FDA that our bone paste allografts would be subject to regulation as medical devices under the 510(k) pre-marketing process. We submitted the required documentation to the FDA in August 2002 and are awaiting clearance . We, as well as other processors, are permitted to continue distributing these allografts while going through this process. While we are confident that we will obtain necessary approval to continue marketing these allografts, if we do not it would have a material and adverse effect on our revenues and our profitability.

In December 2003, our Menasha, Wisconsin site for RTI Donor Services, Inc. was inspected by the FDA. The inspection resulted in no FD483 being issued.

On June 24, 2003 we renewed our ISO 9001 and EN 46001 certifications with the International Organization for Standardization and received an ISO 13485 certification.

ISO 9001 standards, a standard intended for quality management system assessment, have been adopted around the world and many companies require their suppliers to have ISO 9001 certification.

The ISO 13485 certification is based on the same framework as the ISO 9001 certification, but contains requirements specific to medical device manufacturers. The certification process covers all aspects of a company's business, from design, procurement, and production, to distribution and customer satisfaction. The EN 46001 certification is the European equivalent of the ISO 13485 certification.

On July 17, 2003, we were approved for accreditation by the American Association of Tissue Banks. The accreditation covers the processing, storage and distribution of musculoskeletal tissue for transplantation and research. Accreditation is awarded for a three-year term, after which we will apply for renewal.

Results of Operations

The following table sets forth, in both dollars and as a percentage of net revenues, the results of our operations for the years indicated:

	Year Ended December 31,					
	2003		2002		2001	
			(In thousands)			
Statement of Operations Data:						
Revenues:						
Fees from tissue distribution	$73,531		$116,974		$138,762	
Other revenues	1,979		1,516		1,964	
Total revenues	75,510		118,490		140,726	
Management services fees	—		49,430		73,176	
Net revenues	75,510	100.0%	69,060	100.0%	67,550	100.0%
Costs of processing and distribution	42,766	56.6	44,879	65.0	39,455	58.4
Gross profit	32,744	43.4	24,181	35.0	28,095	41.6
Expenses:						
Marketing, general and administrative	23,515	31.1	29,236	42.2	35,962	53.2
Research and development	2,441	3.2	2,460	3.6	2,631	3.9
Litigation settlement	—	—	2,000	2.9	—	—
Asset abandonments	169	0.2	3,098	4.5	—	—
Restructuring	—	—	1,352	2.0	—	—
Total expenses	26,125	34.5	38,146	55.2	38,593	57.1
Operating income (loss)	6,619	8.9	(13,965)	(20.2)	(10,498)	(15.5)
Other (expense) income:						
Interest expense	(981)	(1.3)	(2,758)	(4.0)	(106)	(0.2)
Interest income	235	0.3	186	0.3	1,313	1.9
Total other (expense) income—net	(746)	(1.0)	(2,572)	(3.7)	1,207	1.7
Income (loss) before income tax benefit	5,873	7.9	(16,537)	(23.9)	(9,291)	(13.8)
Income tax benefit	483	0.6	3,032	4.3	3,786	5.6
Net income (loss)	6,356	8.5	(13,505)	(19.6)	(5,505)	(8.2)
Other comprehensive income (loss), net of tax:						
Unrealized derivative income (loss)	—	—	443	0.6	(344)	(0.5)
Comprehensive income (loss)	$ 6,356	8.5%	$ (13,062)	(19.0)%	$ (5,849)	(8.7)%

2003 Compared to 2002

Total Revenues. Our total revenues decreased by $43.0 million or 36.3%, to $75.5 million for the year ended December 31, 2003 from $118.5 million for the year ended December 31, 2002. As described in more detail above, effective November 1, 2002, we entered into a new distribution agreement with MSD, our largest distributor. Under our new agreement with MSD, we are no longer responsible for the collection of total distribution fees but instead receive a fee based on our listed average net distribution fee from MSD. Consequently, subsequent to November 1, 2002, our total revenues will be the same as our net revenues. Accordingly, we believe that analysis of our revenues on a net revenues basis is more meaningful than any comparison on a total revenues basis.

Management Services Fees. Management services fees, which consisted of amounts paid to MSD for management services it provided to assist in the distribution of our allografts, decreased by $49.4 million, or 100%, to $0 million for the year ended December 31, 2003 from $49.4 million for the year ended December 31, 2002. This decrease was due to the change to our distribution agreement with MSD as described above.

Net Revenues. Our net revenues, which consist primarily of fees from tissue distributions, increased by $6.4 million, or 9.3%, to $75.5 million for the year ended December 31, 2003 from $69.1 million for the year ended December 31, 2002. The increase was due to an increase of $7.3 million in revenues from the distribution of our spinal allografts and an increase of $1.7 million from the distribution of our cardiovascular tissues, offset by a decrease of $1.2 million from the distribution of our sports medicine allografts and a $1.9 million decrease from the distribution of our general orthopedic allografts. The increased revenues from the distribution of our spinal allografts primarily relates to increases in tissue transfer fees, which were implemented in mid-2002 as part of the new distribution agreement with MSD, noted above. The increase in cardiovascular revenues was the result of the continued high demand for these allografts, together with our success in entering into new recovery agreements. The decrease in the distribution of sports medicine allografts was due to our transition of the distribution of these allografts to Stryker Endoscopy from our previous distribution network. The decrease from the distribution of general orthopedic allografts was primarily due to our transition of the distribution of these allografts to MSD and Exactech from our previous distribution network. Unit volume distributions of our sports medicine line of products increased nine percent in 2003 compared to 2002. Unit volume distributions of general orthopedic products remained constant in 2003, as compared to 2002 levels, as we focused more of our attention on spine and sports medicine products during the year. The lower net revenues from distributions for both our sports medicine and general orthopedic product lines were offset by lower commission expense in 2003. Under our new distribution agreements with Exactech and Stryker, we do not pay commissions, but instead they pay us license and service fees based on a percent of the average net distribution fee for the products they distribute. Other revenues, which consist of tissue processing fees, tissue recovery fees, biomedical laboratory fees, manufacturing royalties, grant revenues, distribution of reproductions of our allografts to distributors for demonstration purposes, and restocking fees, increased by $463,000 to $2.0 million for the year ended December 31, 2003 compared to $1.5 million for the year ended December 31, 2002. During the three months ended December 31, 2003, we experienced a decrease in our net revenues as a result of our largest distributor executing programs to reduce their levels of inventory.

Costs of Processing and Distribution. Costs of processing and distribution decreased by $2.1 million, or 4.7%, to $42.8 million for the year ended December 31, 2003 from $44.9 million for the year ended December 31, 2002. As a percentage of net revenues, these costs decreased from 65% for the year ended December 31, 2002 to 56.6% for the year ended December 31, 2003. This decrease was primarily attributable to lower provisions for product obsolescence in 2003. Also, under our new distribution agreements, gross margins have increased resulting in lower costs of processing and distribution as a percentage of net revenues.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses decreased by $5.7 million, or 19.6%, to $23.5 million for the year ended December 31, 2003 from $29.2 million for the year ended December 31, 2002. This decrease was primarily due to $2.6 million of one-time charges and restructuring expenses recognized in 2002 and a decrease in commission expense of $5.5 million for the year ended December 31, 2003 as a result of a change in our distribution structure. Under our new distribution agreements with Exactech and Stryker, we do not pay commissions, but instead they pay us license and service fees based on a percent of the average net distribution fee for the products they distribute.

Research and Development Expenses. Research and development expenses decreased by $19,000, or 0.8%, to $2.4 million for the year ended December 31, 2003 from $2.5 million for the year ended December 31, 2002. As a percentage of net revenues, research and development expenses decreased from 3.6% for the year ended December 31, 2002 to 3.2% for the year ended December 31, 2003. The decrease was primarily due to reduced personnel costs in 2003 as a result of our restructuring efforts in 2002, along with reduced costs associated with outside studies, and an increase in our net revenues, without a commensurate increase in research and development expenses.

Asset Abandonments. We recognized a loss on asset abandonments of $169,000 during the year ended December 31, 2003. The assets abandonded consisted of a software project of $111,000, and loss on the sale of our former administrative and manufacturing buildings of $58,000.

Other Expense and Income—Net. Other expense, net for the year ended December 31, 2003 was of $746,000 compared to $2.6 million for the year ended December 31, 2002. This decrease in net expense was the result of a derivative gain of $444,000 for the year ended December 31, 2003 compared to a derivative loss of $2.3 million for the year ended December 31, 2002. The gain on the derivative position was due to the change in fair value of an interest rate swap that we entered into to hedge our previously existing credit facilities

Income Taxes. Income tax benefit for the year ended December 31, 2003 was $483,000, compared to $3.0 million for the year ended December 31, 2002. As a percentage of income (loss) before income taxes, the benefit was 8.2% for the year ended December 31, 2003 compared to 18.3% for the year ended December 31, 2002. The percentage for the year ended December 31, 2003 was lower than the statutory rate due to the reversal of valuation allowances, of $2.7 million, previously recorded against our future realization of certain deferred tax assets. With our continued profitability, a determination was made that it is now more likely than not that the deferred tax assets associated with the valuation allowance will be realized. This determination resulted in the reversal of the valuation allowances.

2002 Compared to 2001

Total Revenues. Our total revenues decreased by $22.2 million or 15.8%, to $118.5 million for the year ended December 31, 2002 from $140.7 million for the year ended December 31, 2001. As described in more detail above, effective November 1, 2002, we entered into a new distribution agreement with MSD, our largest distributor. Under our new agreement with MSD, we are no longer responsible for the collection of total distribution fees but instead receive a fee based on our listed average net distribution fee from MSD. Consequently, subsequent to November 1, 2002, our total revenues will be the same as our net revenues. Accordingly, we believe that analysis of our revenues on a net revenues basis is more meaningful than any comparison on a total revenues basis. In addition, because we operated under the new agreement for the last two months of 2002, we believe that a comparison of our 2002 total revenues to our 2001 total revenues may not be meaningful.

Management Services Fees. Management services fees, which consist of amounts paid to MSD for the management services it provides to assist in the distribution of our allografts, decreased by $23.7 million, or 32.5%, to $49.4 million for the year ended December 31, 2002 from $73.2 million for the year ended December 31, 2001. This decrease was due to the decrease of revenues from the distribution of our spinal allografts and the change to our distribution agreement with MSD as described above.

Net Revenues. Our net revenues, which consist primarily of fees from tissue distributions, increased by $1.5 million, or 2.2%, to $69.1 million for the year ended December 31, 2002 from $67.6 million for the year ended December 31, 2001. The increase was due to an increase of $2.0 million in revenues from the distribution of our spinal allografts, an increase of $952,000 from the distribution of sports medicine allografts, an increase of $2.6 million from the distribution of cardiovascular tissues, offset in part by a decrease of $3.6 million from the distribution of general orthopedic allografts. The decrease from the distribution of general orthopedic allografts was the result of us focusing more of our processing efforts primarily on spinal allografts in the second half of the year. Other revenues, which consist of tissue processing fees, tissue recovery fees, biomedical laboratory fees, manufacturing royalties, grant revenues, distribution of reproductions of our allografts to distributors for demonstration purposes, and restocking fees, decreased by $448,000 to $1.5 million for the year ended December 31, 2002 compared to $2.0 million for the year ended December 31, 2001.

Costs of Processing and Distribution. Costs of processing and distribution increased by $5.4 million, or 13.7%, to $44.9 million for the year ended December 31, 2002 from $39.5 million for the year ended December 31, 2001. As a percentage of net revenues, these costs increased from 58.4% for the year ended December 31, 2001 to 65% for the year ended December 31, 2002. The increase in costs of processing and distribution as a percentage of revenues was primarily attributable to an increase in the costs of donor tissue recovery.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses decreased by $6.7 million, or 18.7%, to $29.2 million for the year ended December 31, 2002 from $36.0 million

for the year ended December 31, 2001. This decrease was primarily the result of bad debt expense of $6.2 million during the 2001 period relating to certain disputed invoices with several customers, compared to a net credit of $652,000 for bad debt expense during the 2002 period.

Research and Development Expenses. Research and development expenses decreased by $171,000, or 6.5%, to $2.5 million for the year ended December 31, 2002 from $2.6 million for the year ended December 31, 2001. As a percentage of net revenues, research and development expenses decreased slightly from 3.9% for the year ended December 31, 2001 to 3.6% for the year ended December 31, 2002. This decrease was due to an increase in net revenues without a commensurate increase in research and development expenses.

Litigation Settlement. In June 2002, we reached an agreement in settlement of a dispute with one of our distributors under which we were required to, among other things, pay $1.5 million in quarterly cash installments of $250,000 beginning September 30, 2002. We recognized a charge of $2.0 million during the second quarter of 2002 for the settlement and related expenses of this dispute.

Asset Abandonments. We recognized a loss on asset abandonments of $3.1 million during the year ended December 31, 2002. The assets consisted of capitalized patent expense of $418,000, abandoned processing equipment of $148,000 and an abandoned software project of $2.5 million.

Restructuring Expenses. During the year ended December 31, 2002, we implemented a formal restructuring plan which resulted in $1.4 million of expenses. Included in these expenses were severance benefits, costs of closing a processing facility in Atlanta and consulting expenses relating to the development of the restructuring plan.

Other Expense and Income—Net. Net other expense and income for the year ended December 31, 2002 was an expense of $2.6 million compared to income of $1.2 million for the year ended December 31, 2001. This increase in net expense was primarily due to a derivative loss of $2.3 million and interest expense on capital leases. The loss on the derivative position was due to the change in fair value of certain interest rate swaps that we entered into to hedge our previously existing credit facilities. As a result of the restructuring of our credit facility described below and elsewhere in our public filings, these swaps no longer qualified as effective hedges under applicable accounting rules. Of the $2.3 million derivative loss, $260,000 represents the amount we paid to terminate one of these interest rate swaps.

Income Taxes. Income tax benefit for the year ended December 31, 2002 was $3.0 million, compared to $3.8 million for the year ended December 31, 2001. As a percentage of loss before income taxes, income tax benefit was 18.3% for the year ended December 31, 2002 compared to 40.7% for the year ended December 31, 2001. The percentage for the year ended December 31, 2002 was lower than the statutory rate due to our recognition of a valuation allowance recorded against our future realization of deferred tax assets.

Liquidity and Capital Resources

Certain Commitments.

On December 19, 2002, we entered into a credit agreement with Bank of America, N.A. pursuant to which the bank advanced $15.1 million to us, which we used to repay $15.1 million of loans from the bank that were due on December 31, 2002 and were collateralized by a lien on substantially all of our assets, including real estate. The credit agreement called for quarterly interest payments at the daily floating LIBOR rate plus 2% (3.46% at December 31, 2003). At the end of the one-year agreement, or December 18, 2003, all outstanding principal and unpaid interest was due in full. We received an extension on the credit agreement, until March 17, 2004. Amounts owed under the credit agreement were collateralized by certain restricted deposits. We had the right to direct the investment of the restricted deposits in certain permitted investments, as defined in the credit

agreement, but we did not have the right to otherwise use the restricted deposits while the loan remained outstanding. The credit agreement contained various restrictive covenants which limited, among other things, indebtedness, liens and business combination transactions. In addition, we were required to maintain a consolidated leverage financial ratio of no greater than 2.5 to 1.0 as of the end of each quarter subsequent to December 31, 2003. We were in compliance with the consolidated leverage financial ratio at December 31, 2003.

On February 20, 2004, we fully repaid the outstanding balance on the credit agreement, or $12.1 million, and terminated the agreement. The cash collateral account was applied to the outstanding balance and the remaining amount of the cash collateral account, or $1.2 million, no longer serves as collateral under this agreement.

On February 20, 2004, the Company entered into a new long-term financing agreement with a financial institution. The new agreement consists of a $9.0 million five-year term loan and a $16.0 million revolving credit loan. The $9.0 million term loan calls for monthly principal and interest payments. Interest on the new loan agreement is at the LIBOR rate plus 4.25%. Under the $16.0 million revolving credit loan, the Company can borrow up to the maximum eligible amount, based on certain outstanding receivables and inventories. Interest on outstanding amounts under the revolving credit loan is at the LIBOR rate plus 3.75%. Principal and interest on the revolving credit loan are payable upon maturity, unless otherwise called for in the agreement. The term loan and revolving credit loan are fully collateralized by the assets of the Company, including accounts receivable, inventories and certain property and equipment.

As described in "Risk Factors" above, at December 31, 2003, we had a recorded liability to MSD of $10.7 million, for management service fee obligations which were recognized under the terms of the prior distribution agreement. We are disputing certain components of the recorded liability to MSD, which has primarily focused on the contractual terms and, among other things, responsibilities of the parties relative to losses on consignment inventories and uncollected accounts receivable. We, along with MSD, have attempted for over a year, to resolve these issues in a manner that addressed the needs of the two companies. The parties have been unable to reach an agreement with respect to the amount owed. The current distribution agreement calls for the two parties to enter into arbitration to settle the dispute if a settlement cannot otherwise be reached. We are in discussions with MSD to resolve these matters and to improve our current distribution agreement. Management believes that the ultimate settlement of these matters will not exceed the liability provided for in the Company's consolidated financial statements.

The following table provides a summary of our debt obligations, capital lease obligations, operating lease payments, estimated future expenditures and other purchase obligations as of December 31, 2003.

	Contractual Payments Due by Period					
	Total	2004	2005	2006	2007	After 2007
Debt[1]	$12,068	$12,068	$ —	$—	$—	$—
Swap agreement	1,552	1,552	—	—	—	—
Capital lease obligations[2]	2,228	1,607	608	8	5	—
Operating lease payments[3]	1,887	704	467	365	154	197
Estimated future expenditures	—	—	—	—	—	—
Other purchase obligations[4]	1,777	1,777	—	—	—	—
Total	$19,512	$17,708	$1,075	$373	$159	$197

(1) These amounts are included on our Consolidated Balance Sheets.

(2) The present value of these obligations, excluding interest, is included on our Consolidated Balance Sheets. See Note 10 of the Consolidated Financial Statements for additional information about our capital lease obligations.

(3) Our operating lease obligations are described in Note 17 of the Notes to the Consolidated Financial Statements.

(4) Our other purchase obligations consisted of our issued and outstanding purchase orders as of December 31, 2003.

On February 20, 2004, the Company entered into a new long-term financing agreement with a financial institution. The new agreement consists of a $9.0 million five-year term loan and a $16.0 million revolving credit loan. The $9.0 million term loan calls for monthly principal payments of $125,000 beginning April 1, 2004 through February 1, 2009, with a final payment of $1.6 million on February 20, 2009. Principal amounts outstanding on the $16.0 million revolving credit loan are due on the maturity date of the agreement, February 20, 2009, unless otherwise called for in the agreement.

Cash Flows.

Our net cash used in operating activities was $1.9 million for the twelve months ended December 31, 2003 compared to net cash provided by operating activities of $6.5 million for the twelve months ended December 31, 2002, a decrease of $8.4 million. During the twelve months ended December 31, 2003, cash was provided by net income of $6.4 million, a decrease in accounts receivable of $8.2 million and a decrease in income taxes receivable of $1.5 million. The decrease in accounts receivable was primarily the result of our new contract with MSD. As described in more detail above, under our new agreement with MSD, which was entered into in late 2002, we no longer receive gross revenues with respect to allografts distributed by MSD (with a corresponding charge for distribution fees payable to MSD). We are now paid a license fee by MSD with respect to distribution activities. The decrease in income taxes receivable resulted from a federal tax refund generated from net operating losses, for tax purposes, experienced in prior years.

During the twelve months ended December 31, 2003, primary uses of cash were an increase in inventories of $14.3 million and a decrease in accounts payable of $7.6 million. The increase in our inventories is the result of our ability to produce more allograft product and our major distributor decreasing their inventory levels during late 2003. The decrease in our accounts payable is the result of paying MSD a portion of the outstanding amount we owe them. Significant non-cash adjustments to operating activities for the twelve months ended December 31, 2003 included depreciation and amortization expense of $4.8 million and a provision for inventory write-downs of $1.3 million. The increase in our deferred income tax benefit is the result of a reversal of tax valuation allowances as a result of our continued profitability and a determination that it is now more likely than not that the deferred tax assets associated with the valuation allowance will be realized.

Our net cash provided by investing activities for the twelve months ended December 31, 2003 was $1.4 million compared to net cash used in investing activities of $15.7 million for the twelve months ended December 31, 2002, an increase of $17.1 million. During the twelve months ended December 31, 2003, primary uses of cash were capital expenditures of $1.4 million and a payment of $250,000 made in connection with the Company's purchase of certain assets of Alabama Tissue Center, originally consummated in August 2000. We were required to make a contingent payment of $250,000 pursuant to the terms of the purchase agreement because we reached a certain level of profitability within the period of time specified in the agreement. In October 2003, cash was provided from proceeds of the sale of our two former buildings for $3.0 million.

Net cash provided by financing activities for the twelve months ended December 31, 2003 was $800,000, compared to $5.5 million for the twelve months ended December 31, 2002, a decrease of $4.7 million. Our primary sources of cash were $2.0 million of proceeds we received from exercises of stock option awards and $3.8 million of cash from deposits which are no longer restricted pursuant to our $15.1 million term agreement with Bank of America, N.A. These deposits are no longer restricted as we made repayments of $3.0 million on our $15.1 million term agreement during the year. The agreement required a certain level of restricted deposits, which were based on the outstanding loan amount. When we repaid $3.0 million, $3.3 million of cash was released from the restricted deposit account and made available for operating purposes. Other primary uses of cash for financing activities included repayments of $1.9 million on capital lease obligations and the $3.0 million repayment of our term loan noted above.

As of December 31, 2003, we had $10.1 million of cash and cash equivalents and $14.8 million of cash which was restricted as collateral under our credit agreement described above. As of March 5, 2004, our cash

and cash equivalents were $17.5 million. We believe that our working capital as of December 31, 2003, together with working capital we anticipate generating during 2004, will be adequate to fund our operations for at least the next 12 months.

As of December 31, 2003, we had federal and state net operating loss carryforwards (net of tax) of $3.3 million and research and development tax credit carryforwards of $1.3 million. We anticipate a portion of these amounts will be utilized to offset our tax liability in 2004, with any remainder used in ensuing years. When these carryforwards are fully utilized, they will increase our cash flows by $4.6 million due to the reduction in taxes payable.

Impact of Inflation

Inflation generally affects us by increasing our cost of labor, equipment and processing tools and supplies. We do not believe that the relatively low rates of inflation experienced in the United States since the time we began operations have had any material effect on our business.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are subject to market risk from exposure to changes in interest rates based upon our financing, investing and cash management activities. We use a mix of debt maturities along with variable-rate debt and derivative financial instruments (an interest rate swap) to manage our exposure to changes in interest rates. We do not expect changes in interest rates to have a material adverse effect on our income or our cash flows in 2004. However, we cannot assure that interest rates will not significantly change in 2004. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Our interest rate swap arrangement involves the exchange of variable interest rate payments, based on LIBOR, without exchanging the notional principal amount. Payments or receipts on the agreement are recorded as adjustments to interest expense because our derivative instrument does not qualify as an effective hedge under relevant accounting rules. An increase of 1% in the LIBOR index rate would have resulted in an estimated $500 decrease to the fair value of our investment in the swap arrangement as of the end of December 31, 2003.

At December 31, 2003, we had an outstanding swap agreement maturing April 2, 2007, with a notional amount of $15.4 million. Under the agreement, we receive LIBOR and pay a fixed interest rate of 5.99%. The counter party to this swap arrangement is a major financial institution. At December 31, 2003, we would have paid $1.6 million to terminate this agreement. An increase of 1.0% in the yield curve would not result in an increased penalty to us and our interest rate would still be equal to 5.99%. On February 20, 2004, we terminated the swap agreement by paying off the fair value of the swap, or $1.6 million.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and supplementary data required in this item are set forth at the pages indicated in Item 15(a)(1).

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES.

As of the end of the period covered by this report, an evaluation was performed on the effectiveness of the design and operation of our disclosure controls and procedures under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective as of the end of the period covered by this report. In addition, no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) occurred during the fourth quarter of our fiscal year ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information set forth under the caption "Directors and Executive Officers" in our definitive proxy statement to be used in connection with our 2004 Annual Meeting of Stockholders is incorporated by reference. Information relating to our Code of Ethics that applies to our senior financial professionals is included on page 2 of this Annual Report on Form 10-K.

Item 11. EXECUTIVE COMPENSATION.

The information set forth under the caption "Executive Compensation" in our definitive proxy statement to be used in connection with our 2004 Annual Meeting of Stockholders is incorporated by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The information set forth under the caption "Beneficial Ownership of Common Stock by Certain Stockholders and Management" in our definitive proxy statement to be used in connection with our 2004 Annual Meeting of Stockholders is incorporated by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information set forth under the caption "Certain Relationships and Related Transactions" in our definitive proxy statement to be used in connection with our 2004 Annual Meeting of Stockholders is incorporated by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information set forth under the caption "Audit Matters—Audit Fees" in our definitive proxy statement to be used in connection with our 2004 Annual Meeting of Stockholders is incorporated by reference.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) (1) *Financial Statements:*

See "Index to Consolidated Financial Statements and Consolidated Financial Statement Schedule" on page 36, the Independent Auditors' Report on page 37 and the Consolidated Financial Statements on pages 38 to 58, all of which are incorporated herein by reference.

(2) *Financial Statement Schedule:*

The following consolidated financial statement schedule is filed as part of this Report:

Schedule II, Valuation and Qualifying Accounts for the years ended December 31, 2003, 2002 and 2001.

(3) *Exhibits:*

The following exhibits are filed as part of this report or incorporated herein by reference.

2.1	Asset Purchase Agreement by and among University of Alabama Health Services Foundation, P.C., Alabama Tissue Center, Inc. and Regeneration Technologies, Inc., dated April 27, 2000.[1]†
3.1	Certificate of Incorporation of Regeneration Technologies, Inc.[1]
3.2	Bylaws.[1]
3.3	Certificate of Designation of Rights and Preferences of Class A Preferred Stock, Class B Preferred Stock and Class C Preferred Stock of Regeneration Technologies, Inc.[1]
4.1	Amended and Restated Registration Rights Agreement dated as of October 11, 1999, by and among Regeneration Technologies, Inc., the investors set forth on Exhibit A to the Class C Preferred Stock and Warrant Purchase Agreement dated as of October 11, 1999 and the Stockholders listed on Exhibits A and B thereto.[1]
4.2	Stockholder's Agreement dated as of October 11, 1999, by and among Regeneration Technologies, Inc., the investors set forth on Exhibit A to the Class C Preferred Stock and Warrant Purchase Agreement dated as of October 11, 1999 and the Stockholders listed on Exhibits A, B and C thereto.[1]
4.3	Specimen Stock Certificate.[1]
4.4	Purchase Agreement, dated November 26, 2002, among the Regeneration Technologies, Inc. and the Investors listed on the signature page thereto.[5]
4.5	Registration Rights Agreement, dated November 26, 2002, among Regeneration Technologies, Inc. and the Investors listed on the signature page thereto.[5]
10.1	Program Transfer Agreement between Regeneration Technologies, Inc. and the University of Florida Tissue Bank, Inc. dated April 15, 1999.[1]†
10.2	Tissue Recovery Agreement between Regeneration Technologies, Inc. and the University of Florida Tissue Bank, Inc. dated April 15, 1999.[1]†
10.3	Exclusive Distributorship Agreement between Regeneration Technologies, Inc. and C.R. Bard, Inc., dated June 6, 1998.[1]†
10.4	Exclusive License Agreement between Regeneration Technologies, Inc., as successor in interest to the University of Florida Tissue Bank, Inc. and Exactech, Inc., dated April 22, 1997, as amended.[1]†
10.5	Exclusive Distribution and License Agreement, effective as of June 1, 2002, between Regeneration Technologies, Inc. and Medtronic Sofamor Danek USA, Inc.[4]†

10.6	Master Lease Agreement between Regeneration Technologies, Inc., as successor in interest to the University of Florida Tissue Bank, Inc., and American Equipment Leasing, dated January 23, 1998.[1]
10.7	Purchase Contract between Regeneration Technologies, Inc. and Echelon International Corp., dated January 31, 2000, as amended.[1]
10.8	Lease between Echelon International Corp. and Regeneration Technologies, Inc., dated February 4, 2000.[1]
10.9	Lease between Regeneration Technologies, Inc. and First Street Group L.C., dated June 14, 1999.[1]
10.10	Omnibus Stock Option Plan.[1]
10.11	Year 2000 Compensation Plan.[1]
10.12	Form of Indemnification Agreement between Regeneration Technologies, Inc. and its directors and executive officers.[1]
10.13	Employment Agreement between Regeneration Technologies, Inc. and Brian K. Hutchison, dated November 30, 2001.[2]
10.14	Employment Agreement between Regeneration Technologies, Inc. and Thomas F. Rose, dated May 1, 2002.
10.15	Incentive Stock Option Grant Agreement between Regeneration Technologies, Inc. and Brian K. Hutchison, dated December 3, 2001.[2]
10.16	Separation Agreement and Release between Regeneration Technologies, Inc. and Jamie M. Grooms, dated June 17, 2002.[3]
10.17	$15,100,000 Credit Agreement, dated December 19, 2002, between Regeneration Technologies, Inc. and Bank of America, N.A.[6]
10.18	$25,000,000 Loan Agreement, dated as of February 20, 2004, by and among Regeneration Technologies, Inc. and certain of its subsidiaries and Merrill Lynch Business Financial Services, Inc.
21	Subsidiaries of the Registrant.[2]
23.1	Independent Auditors' Consent.
31.1	Certification of Brian K. Hutchison, Chairman, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Thomas F. Rose, Vice President and Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Brian K. Hutchison, Chairman, President and Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, regarding the information contained in Regeneration Technologies, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2003.
32.2	Certification of Thomas F. Rose, Vice President and Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, regarding the information contained in Regeneration Technologies, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2003.

1 Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-35756).
2 Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2001.
3 Incorporated by reference our Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
4 Incorporated by reference our Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

5 Incorporated by reference to our Current Report on Form 8-K filed on December 2, 2002.

6 Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2002.

† Confidentiality requested, confidential portions have been omitted and filed separately with the Commission, as required by Rule 406(B) of the Securities Act of 1933.

(b) *Reports on Form 8-K:*

None.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of Regeneration Technologies, Inc.:

We have audited the accompanying consolidated balance sheets of Regeneration Technologies, Inc. and subsidiaries (the "Company") as of December 31, 2003 and 2002, and the related consolidated statements of operations and comprehensive income (loss), of stockholders' equity, and of cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the United States of America. 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, such consolidated financial statements present fairly, in all material respects, the financial position of Regeneration Technologies, Inc. and subsidiaries as of December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants

Orlando, Florida
March 5, 2004

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Consolidated Balance Sheets
(In thousands, except share data)

	December 31, 2003	December 31, 2002
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,051	$ 9,811
Restricted deposits	14,757	18,510
Accounts receivable—less allowances of $4,456 in 2003 and $4,748 in 2002	5,942	14,082
Inventories	41,655	28,626
Prepaid and other current assets	940	2,649
Deferred tax assets—current	5,237	3,134
Total current assets	78,582	76,812
Property, plant and equipment—net	43,689	50,575
Deferred tax assets	2,466	2,789
Goodwill	2,863	2,613
Other assets—net	8,816	8,401
	$136,416	$141,190
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 18,919	$ 26,526
Accrued expenses	5,928	7,137
Current portion of deferred revenue	364	447
Note payable	12,068	15,100
Current portion of long-term debt	1,607	1,850
Total current liabilities	38,886	51,060
Long-term debt—less current portion	621	2,266
Derivative liabilities	1,552	1,996
Deferred revenue	2,960	3,246
Total liabilities	44,019	58,568
Commitments and contingencies		
Stockholders' equity:		
Common stock, $.001 par value: 50,000,000 shares authorized; 26,517,865 and 26,209,378 shares issued and outstanding, respectively	26	26
Additional paid-in capital	102,018	99,235
Accumulated deficit	(9,377)	(15,733)
Deferred compensation	(256)	(892)
Less treasury stock, 133,296 shares	(14)	(14)
Total stockholders' equity	92,397	82,622
	$136,416	$141,190

See notes to consolidated financial statements.

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Income (Loss)
(In thousands, except share and per share data)

	Year Ended December 31,		
	2003	2002	2001
Revenues:			
Fees from tissue distribution	$ 73,531	$ 116,974	$ 138,762
Other revenues	1,979	1,516	1,964
Total revenues	75,510	118,490	140,726
Management services fees	—	49,430	73,176
Net revenues	75,510	69,060	67,550
Costs of processing and distribution	42,766	44,879	39,455
Gross profit	32,744	24,181	28,095
Expenses:			
Marketing, general and administrative	23,515	29,236	35,962
Research and development	2,441	2,460	2,631
Litigation settlement	—	2,000	—
Asset abandonments	169	3,098	—
Restructuring	—	1,352	—
Total expenses	26,125	38,146	38,593
Operating income (loss)	6,619	(13,965)	(10,498)
Other (expense) income:			
Interest expense	(981)	(2,758)	(106)
Interest income	235	186	1,313
Total other (expense) income—net	(746)	(2,572)	1,207
Income (loss) before income tax benefit (expense)	5,873	(16,537)	(9,291)
Income tax benefit	483	3,032	3,786
Net income (loss)	6,356	(13,505)	(5,505)
Other comprehensive income (loss), net of tax:			
Unrealized derivative income (loss)	—	443	(344)
Comprehensive income (loss)	$ 6,356	$ (13,062)	$ (5,849)
Net income (loss) per common share—basic	$ 0.24	$ (0.60)	$ (0.25)
Net income (loss) per common share—diluted	$ 0.24	$ (0.60)	$ (0.25)
Weighted average shares outstanding—basic	26,365,348	22,434,436	21,760,596
Weighted average shares outstanding—diluted	26,999,175	22,434,436	21,760,596

See notes to consolidated financial statements.

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity
(In thousands)

	Common Stock	Additional Paid-in Capital	(Accumulated Deficit) Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Deferred Compensation	Treasury Stock	Total
Balance, January 1, 2001	$ 22	$ 71,554	$ 3,277	$ —	$(2,363)	$ (14)	$ 72,476
Stock issuance costs	—	(22)	—	—	—	—	(22)
Issuance of common stock options	—	478	—	—	(478)	—	—
Exercise of common stock options	—	394	—	—	—	—	394
Exercise of warrants	—	31	—	—	—	—	31
Purchased and forfeited treasury stock	—	1	—	—	(1)	—	—
Vested deferred compensation	—	(270)	—	—	1,123	—	853
Accumulated other comprehensive income	—	—	—	(443)	—	—	(443)
Net loss	—	—	(5,505)	—	—	—	(5,505)
Balance, December 31, 2001	22	72,166	(2,228)	(443)	(1,719)	(14)	67,784
Issuance of common stock	4	27,546	—	—	—	—	27,550
Stock issuance costs	—	(1,867)	—	—	—	—	(1,867)
Issuance of common stock options	—	51	—	—	(51)	—	—
Exercise of common stock options	—	710	—	—	—	—	710
Vested deferred compensation	—	(12)	—	—	878	—	866
Income tax benefit of nonqualified stock option exercises	—	641	—	—	—	—	641
Accumulated other comprehensive income	—	—	—	443	—	—	443
Net loss	—	—	(13,505)	—	—	—	(13,505)
Balance, December 31, 2002	26	99,235	(15,733)	—	(892)	(14)	82,622
Stock issuance costs	—	(29)	—	—	—	—	(29)
Exercise of common stock options	—	1,979	—	—	—	—	1,979
Vested deferred compensation	—	(396)	—	—	636	—	240
Income tax benefit of nonqualified stock option exercises	—	1,229	—	—	—	—	1,229
Net income	—	—	6,356	—	—	—	6,356
Balance, December 31, 2003	$ 26	$102,018	$ (9,377)	$ —	$ (256)	$ (14)	$ 92,397

See notes to consolidated financial statements.

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net income (loss)	$ 6,356	$(13,505)	$ (5,505)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation and amortization expense	4,782	3,226	2,630
Provision for (reduction of) bad debts	182	(652)	6,221
Provision for inventory writedowns	1,299	4,021	4,347
(Reduction of) provision for product returns	(225)	(236)	357
Amortization of deferred revenue	(369)	(339)	(286)
Deferred income tax (benefit) expense	(551)	69	(2,602)
Deferred stock-based compensation and nonqualified option expense	240	866	1,123
Deferred revenue	—	—	350
Derivative (gain) loss	(444)	2,029	—
Litigation settlement	—	2,000	—
Loss on asset abandonment	169	2,680	—
Write-off of capitalized patent and trademark expenses	—	418	—
Changes in assets and liabilities:			
Accounts receivable	8,183	8,501	(1,001)
Inventories	(14,328)	(3,365)	(10,188)
Income taxes receivable	1,475	1,406	—
Prepaid and other current assets	674	(531)	(510)
Other assets	(445)	(2,383)	(593)
Accounts payable	(7,607)	4,488	(398)
Accrued expenses	(1,289)	(2,227)	1,661
Net cash (used in) provided by operating activities	(1,898)	6,466	(4,394)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(1,427)	(15,658)	(23,183)
Additional cash paid for purchases of assets	(250)	—	—
Proceeds from sale of property, plant and equipment	3,032	—	—
Investment in Organ Recovery Systems, Inc.	—	—	(5,250)
Net cash provided by (used in) investing activities	1,355	(15,658)	(28,433)
Cash flows from financing activities:			
Proceeds from stock offering	—	27,550	—
Stock issuance costs	(29)	(1,867)	(22)
Proceeds from exercise of stock options	1,979	710	155
Payment made to terminate swap agreement	—	(260)	—
Advances under construction loan	—	—	12,790
Payments on capital lease and note obligations	(1,888)	(17,224)	(1,532)
Payment on term loan	(3,032)	—	—
Amounts advanced to stockholder	—	—	(4)
Proceeds of issuance of term loan	—	15,100	—
Restricted deposits	—	(18,510)	—
Decrease in restricted deposits	3,753	—	—
Net cash provided by financing activities	783	5,499	11,387
Net increase (decrease) in cash and cash equivalents	240	(3,693)	(21,440)
Cash and cash equivalents, beginning of year	9,811	13,504	34,944
Cash and cash equivalents, end of year	$ 10,051	$ 9,811	$ 13,504

See notes to consolidated financial statements.

1. Business

Regeneration Technologies, Inc. ("RTI"), and its subsidiaries (collectively, the "Company") process human tissue received from various tissue recovery agencies. The processing transforms the tissue into either conventional or precision tooled allografts, some of which are patented. These allografts are distributed domestically and internationally, for use in spinal vertebrae repair, musculoskeletal reconstruction and fracture repair. The processed tissue includes cortical dowels, cervical implants, cortical bone interference screws, bone paste grafts and cardiovascular tissue of heart valves, veins, and arteries.

2. Summary of Significant Accounting Policies

Principles of Consolidation—The consolidated financial statements include the accounts of RTI and its wholly owned subsidiaries, Georgia Tissue Bank (inactive), Alabama Tissue Center, Biological Recovery Group (inactive), and RTI Services, Inc. The consolidated financial statements also include the accounts of RTI Donor Services, Inc., which is a controlled entity. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. All intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents—The Company considers all funds in banks and short-term investments with an original maturity of three months or less to be cash and cash equivalents.

Restricted Deposits—At December 31, 2003, the Company had $14,757 on deposit with a commercial bank in satisfaction of the collateral requirement contained in a credit agreement. In accordance with the credit agreement, the Company has the right to direct the investment of the restricted funds in certain permitted investments, as defined in the credit agreement, but has no right to the restricted deposits while the loan remains outstanding. The deposits consisted of cash and a certificate of deposit at December 31, 2003. The restricted deposits serve as collateral under the credit agreement, which matures in less than one-year, and therefore have been classified as current assets in the consolidated balance sheets.

Inventories—Implantable donor tissue inventories are stated at the lower of cost or market, with cost determined using the first-in, first-out method. Inventory writedowns are recorded for unprocessed donor tissue based on the estimated amount of inventory that will not pass the quality control process based on historical data, and the amount of inventory that is not readily saleable, unusable or slow moving. In addition, inventory writedowns are estimated for tissue in process inventory that is not readily saleable or unusable. Any inventory deemed to be obsolete are included in the writedown at the time the determination is made.

Property, Plant and Equipment—Property, plant, and equipment are stated at cost less accumulated depreciation and amortization. The cost of equipment under capital leases and leasehold improvements is amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset. Depreciation is computed on the straight-line method over the following estimated useful lives of the assets:

Buildings	25 years
Building improvements and leasehold improvements	8 to 10 years
Processing equipment	8 to 10 years
Office equipment, furniture and fixtures	5 to 7 years
Computer hardware and software	3 years

Software Development Costs—Included in property, plant and equipment are costs related to internally-developed and purchased software that are capitalized. Capitalized costs include direct costs of materials and services incurred in developing or obtaining internal-use software and payroll and payroll-related costs for employees directly involved in the development of internal-use software.

Investment in Organ Recovery System, Inc.—The Company accounts for its investment in preferred shares of stock issued by Organ Recovery Systems, Inc. ("ORS") under the cost method as the Company does not exhibit control over ORS. At December 31, 2003, the cost of this investment approximated fair value.

Research and Development Costs—Research and development costs are expensed as incurred. Research and development costs for the years ended December 31, 2003, 2002 and 2001 were $2,441, $2,460 and $2,631, respectively.

Revenue Recognition—Revenue is recognized at the time the Company ships the processed tissue for implant or upon receipt by the customer in accordance with the Company's distribution agreements. Revenue for consignment inventory is recognized when the tissue is transferred from the Company's consignment inventory locations for implant. Effective November 1, 2002, revenues no longer reflect a management service fee as these fees are no longer included in the Company's distribution agreements. However, prior year revenues will still be reported gross of any management services fees the Company incurred related to the distribution of its products designated for spinal vertebrae repair through its exclusive distribution agreement with Medtronic Sofamor Danek. Other revenues are recognized when all significant contractual obligations have been satisfied.

The Company permits returns of tissue in accordance with the terms of contractual agreements with customers if the tissue is returned in a timely manner, in unopened packaging and from the normal channels of distribution. Allowances for returns are provided based upon analysis of the Company's historical patterns of returns matched against the sales from which they originated.

A $4,500 nonrefundable, up-front fee received from Medtronic Sofamor Danek ("MSD") in the period ended December 31, 1998 was deferred and is being recognized as revenue on a straight-line basis over the 12 year life (originally 20 year life) of the exclusive management services agreement with MSD. This revenue is recorded in other revenues which is shown in the consolidated statements of operations.

Income Taxes—The Company uses the asset and liability method of accounting for income taxes. Deferred income taxes are recorded to reflect the tax consequences on future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts which are more likely than not to be realized.

Stock-Based Compensation Plans—The Company accounts for stock-based compensation under the intrinsic value method as permitted by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and has disclosed pro forma net income and earnings per share amounts using the fair value based method, as required by Statement of Financial Accounting Standard ("SFAS") No. 123, *Accounting for Stock Based Compensation*.

Had compensation cost for grants after March 31, 2000 been determined on the basis of fair value pursuant to SFAS No. 123, net income (loss) and net income (loss) per common share would have been affected as follows for the years ended December 31, 2003, 2002 and 2001.

	Year Ended December 31,		
	2003	2002	2001
Net income (loss):			
As reported	$ 6,356	$(13,505)	$(5,505)
Add: stock-based employee compensation expense included in reported net income (loss), net of related tax effects	46	78	79
Deduct: total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(1,747)	(1,681)	(743)
Pro forma net income (loss)	$ 4,655	$(15,108)	$(6,169)
Net income (loss) per common share:			
Basic, as reported	$ 0.24	$ (0.60)	$ (0.25)
Basic, pro forma	$ 0.18	$ (0.67)	$ (0.28)
Diluted, as reported	$ 0.24	$ (0.60)	$ (0.25)
Diluted, pro forma	$ 0.17	$ (0.67)	$ (0.28)

Earnings Per Share—Basic earnings per share ("EPS") is computed by dividing earnings attributable to common shareholders by the weighted average number of common shares outstanding for the periods. Diluted EPS reflects the potential dilution of securities that could share in the earnings. A reconciliation of the number of common shares used in the calculation of basic and diluted EPS is presented below:

	Year Ended December 31,		
	2003	2002	2001
Basic shares	26,365,348	22,434,436	21,760,596
Effect of dilutive securities:			
Stock options	633,827	—	—
Diluted shares	26,999,175	22,434,436	21,760,596

Options to purchase approximately 3,137,157 shares of common stock at prices ranging from $1.30 to $14.95 per share were outstanding as of December 31, 2003. Options to purchase approximately 3,495,881 and 3,350,541 shares of common stock at prices ranging from $1.30 and $14.95 per share were outstanding as of December 31, 2002 and 2001, respectively, but were not included in the computation of diluted EPS for the years ended December 31, 2002 or 2001 because dilutive shares are not factored into the calculation of EPS when a loss from continuing operations is reported.

Use of Estimates—The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Impairment of Long-Lived Assets—Periodically, the Company evaluates the recoverability of the net carrying amount of its property, plant and equipment and its intangible assets by comparing the carrying amounts to the estimated future undiscounted cash flows. If the sum of the estimated future undiscounted cash flows were less than the carrying amount of the asset, a loss would be recognized for the difference between the fair value and the carrying amount.

Fair Value of Financial Instruments—The estimated fair value of amounts reported in the consolidated financial statements has been determined by using available market information and appropriate valuation methodologies. The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature. The fair value of capital lease obligations approximates the carrying value, based on current market prices.

Financial Instruments—The Company uses derivative financial instruments in the management of its interest rate exposure. The Company records all derivatives on the balance sheet at fair value. Changes in the derivative fair values that are designated as cash flow hedges are deferred and recorded as a component of accumulated other comprehensive income (OCI) until the hedged transactions occur and are recognized in earnings. The ineffective portion of a hedging derivative's change in fair value is immediately recognized in earnings as interest expense. The Company does not use derivative financial instruments for trading or speculative purposes.

Reclassifications—Certain amounts in the 2002 and 2001 consolidated financial statements, as previously reported, have been reclassified to conform to the 2003 presentation.

3. Stock Based Compensation

Stock Option Plans—In July 1998, the Company adopted a stock option plan (the "Plan") which provides for the grant of incentive and nonqualified stock options to key employees, including officers and directors of the Company, and consultants and advisors. The option price per share may not be less than 100% of the fair market value of such shares on the date such option is granted. The Plan allows for up to 4,406,400 shares of common stock to be issued with respect to awards granted. Awards or shares which are forfeited, surrendered or otherwise terminated are available for further awards; provided, however, that any such shares that are surrendered in connection with any award or that are otherwise forfeited after issuance shall not be available for purchase pursuant to incentive stock options intended to qualify under Code Section 422.

Stock option activity is summarized as follows for the years ended December 31, 2003, 2002 and 2001:

	2003		2002		2001	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1,	3,495,881	$ 7.60	3,350,541	$ 8.51	2,277,518	$ 6.37
Granted	416,500	10.34	1,245,000	5.22	1,485,425	10.80
Exercised	(303,815)	6.62	(351,924)	2.03	(241,468)	1.62
Canceled	(471,409)	9.58	(747,736)	10.34	(170,934)	9.84
Outstanding at December 31,	3,137,157	$ 7.75	3,495,881	$ 7.60	3,350,541	$ 8.51
Exercisable at December 31,	1,087,755	$ 7.31	831,696	$ 7.56	656,900	$ 4.78
Available for grant at December 31,	372,084		317,127		814,391	

Outstanding options under the Plan vest over a three to five year period. Options expire ten years from the date of grant.

Stock options outstanding and exercisable at December 31, 2003 are summarized as follows:

	Options Outstanding			Options Outstanding	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at December 31, 2003	Weighted Average Exercise Price
$1.30 to $2.66	121,744	12.11	$ 1.35	118,235	$ 1.34
$2.67 to $4.02	247,013	8.47	3.76	212,141	3.75
$4.03 to $5.39	1,050,000	8.86	4.80	222,000	4.80
$5.40 to $6.75	6,000	6.17	5.65	6,000	5.65
$6.76 to $8.12	116,800	8.57	7.90	38,300	7.89
$8.13 to $9.48	372,500	9.70	9.15	21,600	8.69
$9.49 to $10.85	735,880	8.24	10.05	259,600	10.10
$10.86 to $12.21	86,330	13.32	11.77	38,611	11.78
$12.22 to $13.58	357,398	12.73	13.37	148,008	13.47
$13.59 to $14.95	43,492	20.51	14.43	23,260	14.40
$1.30 to $14.95	3,137,157	9.62	$ 7.75	1,087,755	$ 7.31

The Company applies APB Opinion No. 25 in accounting for its stock options. No compensation expense has been recognized for options granted to employees after March 31, 2000 because the exercise price equaled the fair market value on the date of the grant. In accordance with APB Opinion No. 25, the Company has $105 of deferred compensation costs remaining to be amortized at December 31, 2003, related to the issuance of non-qualified stock options.

The Company recorded deferred compensation expense for options granted during the period October 1, 1999 through March 31, 2000. The total compensation cost related to these options of $2,499, net of subsequent cancellations, is being amortized over the life of the option grants, or 5 years. At December 31, 2003, $151 of this cost remained to be amortized through 2005.

The fair value of each grant prior to October 31, 1999 was estimated using the minimum value method with the following weighted-average assumptions:

Dividend Yield	—
Risk free interest rate	4.6% – 5.92%
Option term	4.77 Years

The fair value of each grant subsequent to October 31, 1999 was estimated using the Black-Scholes Option Pricing model with the following weighted-average assumptions used:

	Year Ended December 31,		
	2003	2002	2001
Expected life (years)	4.53	4.94	4.92
Risk free interest rate	4.25%	4.25%	4.45%
Volatility factor	60.63%	92.10%	67.79%
Dividend yield	—	—	—

Stock Awards—The Company awarded 3,699,130 shares of common stock to various key employees at the beginning of the Company's operations in 1998. These shares of common stock, which were valued at $0.18 per share, vested over a five-year period through August 2002. At the date of issuance, $655 in deferred compensation was recorded by the Company. Compensation expense of approximately $86 and $173 was recognized for these stock awards for the years ended December 31, 2002 and 2001, respectively.

4. Goodwill and Other Intangible Assets

In June 2001, SFAS No. 142, *Goodwill and Other Intangible Assets*, was approved by the FASB. SFAS No. 142 changes the accounting for goodwill and other intangible assets determined to have an indefinite useful life from an amortization method to an impairment-only approach. Amortization of indefinite-lived intangible assets, including goodwill, ceased upon adoption of this statement. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. The Company implemented SFAS No. 142 on January 1, 2002. In accordance with SFAS No. 142, the Company discontinued the amortization of goodwill effective January 1, 2002. The provisions of this accounting standard also require the completion of a transitional impairment test within six months of adoption, with any impairments identified treated as a cumulative effect of a change in accounting principle. Upon adoption, the Company performed the transitional impairment test and determined that no impairment of goodwill existed. The Company has one reporting unit, and therefore, utilized the fair value of its common stock for estimating the fair value of its reporting unit. A reconciliation of previously reported net income (loss) and earnings (loss) per share to the amounts adjusted for the exclusion of goodwill amortization net of the related income tax effect follows:

	Year Ended December 31,		
	2003	2002	2001
Reported net income (loss)	$6,356	$(13,505)	$(5,505)
Add: Goodwill amortization net of income tax	—	—	197
Pro forma net income (loss)	$6,356	$(13,505)	$(5,308)
Net income (loss) per common share—basic:			
Reported net income (loss)	$ 0.24	$ (0.60)	$ (0.25)
Goodwill amortization, net of income tax	—	—	0.01
Pro forma net income (loss)	$ 0.24	$ (0.60)	$ (0.24)
Net income (loss) per common share—diluted:			
Reported net income (loss)	$ 0.24	$ (0.60)	$ (0.25)
Goodwill amortization, net of income tax	—	—	0.01
Pro forma net income (loss)	$ 0.24	$ (0.60)	$ (0.24)

The carrying value of goodwill, net of accumulated amortization, increased by $250 for the year ended December 31, 2003. The increase was a result of a contingent payment made in connection with the Company's purchase of certain assets of Alabama Tissue Center ("ATC"), originally consummated in August 2000. Under the purchase agreement, if the business the Company acquired achieved a specified operating income within a defined period of time, an additional purchase price of $250 was required to be paid. As a result of the milestone being achieved, the Company paid $250 which has been recorded as additional goodwill. The carrying value of goodwill was $2,863 at December 31, 2003.

The following table reflects the components of other intangible assets which are recorded as a component of noncurrent other assets—net in the consolidated balance sheets:

	December 31,			
	2003		2002	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortizable intangible assets:				
Patents	$1,278	$150	$834	$125
Trademarks	84	10	80	6
Total	$1,362	$160	$914	$131

Amortization expense for the years ended December 31, 2003, 2002 and 2001 was $29, $54 and $249, respectively. Management estimates amortization expense of $56 for the next five years.

5. Inventories

Inventories by stage of completion are as follows:

	December 31, 2003	December 31, 2002
Unprocessed donor tissue	$ 6,246	$ 6,225
Tissue in process	20,065	13,556
Implantable donor tissue	14,176	7,537
Supplies	1,168	1,308
	$41,655	$28,626

6. Property, Plant and Equipment

Property, plant and equipment are as follows:

	December 31, 2003	December 31, 2002
Land	$ 625	$ 850
Buildings and improvements	35,622	39,431
Processing equipment	8,235	7,259
Leasehold improvements	816	812
Office equipment, furniture and fixtures	773	839
Computer hardware and software	3,152	2,986
Equipment under capital leases	6,322	6,294
	55,545	58,471
Less accumulated depreciation and amortization	(11,856)	(7,896)
	$ 43,689	$50,575

The Company capitalizes interest on borrowings during the active construction period of major capital projects. Capitalized interest is added to the cost of the underlying assets and is amortized over the useful lives of the assets once they are placed in service. Total interest costs, including interest on capital leases and derivative investments, for the years ended December 31, 2003, 2002 and 2001 were $981, $2,066 and $662, and of that $1,597 and $556 was capitalized to construction in process in 2002 and 2001 respectively.

7. Other Assets

Other assets are as follows:

	December 31, 2003	December 31, 2002
Patents and trademarks	$1,362	$ 914
Deposits	2,339	2,340
Investment in Organ Recovery Systems, Inc.	5,250	5,250
Other	25	28
	8,976	8,532
Less accumulated amortization of patents and trademarks	(160)	(131)
	$8,816	$8,401

Patents and trademarks are amortized on the straight-line method over the shorter of the remaining protection period or estimated useful life. Patents and trademarks are recorded net of accumulated amortization of $160 and $131 at December 31, 2003 and 2002, respectively.

8. Investment in Organ Recovery Systems, Inc.

On November 2, 2001 the Company purchased 1,285,347 shares of convertible preferred stock issued by Organ Recovery Systems, Inc. ("ORS"), a privately held company, at a price of $3.89 per share. ORS is organized for the purpose of advancing organ transplantation technology. The Company invested in ORS to continue its commitment to the promotion of effective use and distribution of human tissue. The purchase was paid for in cash and recorded at a total cost of $5,250.

Realization of the Company's investment in ORS is dependent upon ORS's successful execution of its operational strategies and the continued industry acceptance of its current and future product developments. In 2003, ORS raised additional equity at a price equal to what the Company paid for its shares of preferred stock. Accordingly, management of the Company believes there has been no impairment of the Company's investment.

9. Note Payable

Note payable is as follows:

	December 31,	
	2003	2002
Term loan	$12,068	$15,100

On December 19, 2002, the Company entered into a credit agreement with a commercial bank pursuant to which the bank advanced $15,100 to the Company which was used to repay $15,100 of loans from the bank that were due on December 31, 2002 and were collateralized by a lien on substantially all of the Company's assets, including real estate. The credit agreement calls for quarterly interest payments at the daily floating LIBOR rate plus 2% (3.46% at December 31, 2003). At the end of the one-year agreement, or December 18, 2003, all outstanding principal and accrued and unpaid interest was due in full. The Company received an extension on the credit agreement, until March 17, 2004. Amounts owed under the term loan agreement are collateralized by the restricted deposits. The Company has the right to direct the investment of these restricted deposits in certain permitted investments where fair value is substantially the same as cost, as defined in the credit agreement, but has no right to otherwise use the restricted deposits while the loan remains outstanding. The credit agreement contains various restrictive covenants which limit, among other things, indebtedness, liens and business combination transactions. In addition, the Company must have a consolidated leverage financial ratio no greater than 2.5 to 1.0 as of the end of each quarter subsequent to December 31, 2002. The Company was in compliance with the consolidated financial leverage ratio at December 31, 2003.

On February 20, 2004, the Company, with proceeds from a new long-term financing agreement, see Note 23, fully repaid the outstanding balance on the credit agreement, or $12,068, and terminated the agreement. The restricted deposits were applied to the outstanding balance and the remaining amount of the restricted deposits, or $1,200, no longer serves as collateral under this agreement.

10. Long-term Debt

Long-term debt is as follows:

	Year Ended December 31,	
	2003	2002
Capital leases	$2,228	$4,116
Less current portion	1,607	1,850
Long-term portion	$ 621	$2,266

Contractual maturities of long-term debt are as follows:

2004	$1,607
2005	608
2006	8
2007	5
	$2,228

The capital leases have interest rates ranging from 5.25% to 20.65%, are collateralized by the related equipment, and are due at various dates through 2007.

11. Derivatives

The following table summarizes the notional transaction amounts and fair values for outstanding derivatives at December 31, 2003 and 2002:

	December 31, 2003			December 31, 2002		
	Notional Amount	Fair Value	Maturity	Notional Amount	Fair Value	Maturity
Interest rate swap	$15,383	$(1,552)	2007	$15,760	$(1,996)	2007

The Company's interest rate swap does not qualify as an effective hedge under relevant accounting rules since (1) the maturity of the loan does not coincide with that of the swap and refinancing of the debt and related future cash flows are not certain; and (2) interest rates are not effectively hedged.

The net decrease in fair value for the derivative liabilities of the interest rate swap for the year ended December 31, 2003 was $444. The net increase in fair value for the derivative liabilities of interest rate swaps for the year ended December 31, 2002 was $1,233. From December 31, 2001 to April 7, 2002, the fair value of the derivative liabilities decreased $44, which was recorded as unrealized derivative income as part of comprehensive income (loss). From April 8, 2002 to December 31, 2002, the fair value of the derivative liabilities increased $1,309, which was charged to income, as part of interest expense, since as of April 8, 2002, the swaps no longer qualified as effective hedges under relevant accounting rules. Also, during the year ended December 31, 2002, the Company recognized $763, net of tax, of accumulated other comprehensive loss as a charge to income as part of interest expense, due to the accelerated amortization of the balance of the accumulated other comprehensive loss to correspond to the period covered by the extended Forbearance Agreement, which ended December 31, 2002. On February 20, 2004, the Company terminated the swap agreement by paying off the fair value of the swap, or $1,615.

12. Income Taxes

The income tax benefit consisted of the following components:

	Year Ended December 31,		
	2003	2002	2001
Current:			
Federal	$ 68	$(2,724)	$(1,070)
State	—	(377)	(114)
Total current	68	(3,101)	(1,184)
Deferred:			
Federal	(496)	61	(2,351)
State	(55)	8	(251)
Total deferred	(551)	69	(2,602)
Total income tax benefit	$(483)	$(3,032)	$(3,786)

The components of the deferred tax assets and liabilities consisted of the following at December 31:

	2003		2002	
	Deferred Income Tax		Deferred Income Tax	
	Asset	Liability	Asset	Liability
Current:				
Derivative unrealized loss	$ 586	$ —	$ 748	$ —
Allowance for bad debts	611	—	378	—
Inventory reserves	2,165	—	2,281	—
Accrued reserves	2,353	—	1,394	—
State taxes	22	—	19	—
Valuation allowance	(500)	—	(1,686)	—
Total current	5,237	—	3,134	—
Noncurrent:				
Depreciation	—	(3,510)	—	(656)
Amortization	—	(782)	—	(551)
Unearned revenue	1,256	—	1,430	—
Federal net operating loss	3,282	—	2,261	—
State net operating loss	801	—	851	—
Research and development credit	1,291	—	955	—
AMT credit	128	—	—	—
Valuation allowance	—	—	(1,501)	—
Total noncurrent	6,758	(4,292)	3,996	(1,207)
Total	$11,995	$(4,292)	$ 7,130	$(1,207)

The Company has recorded a valuation allowance to reduce the deferred tax assets reported. Based on the weight of the evidence, management has determined that it is more likely than not that some portion or all of the deferred tax assets will not be realized. As such, valuation allowances of $500 and $3,187 have been established at December 31, 2003 and December 31, 2002, respectively.

The Company recorded a non-cash tax benefit from the exercise of nonqualified stock options as an addition to its deferred income tax assets in the amount of $1,229 and $641 for the years ended December 31, 2003 and 2002, respectively.

As of December 31, 2003, the Company has federal net operating loss carryforwards of $9,653 that will expire in the year 2022, as well as state net operating loss carryforwards of $28,759 that will expire in the years 2021 and 2022.

As of December 31, 2003, the Company has research and development tax credit carryforwards of $1,291 that will expire in years 2018 through 2022, as well as alternative minimum tax credit carryforwards of $128 that are carried forward indefinitely.

The effective tax rate differs from the statutory federal income tax rate for the following reasons:

	Year Ended December 31,		
	2003	2002	2001
Statutory federal rate	34.00%	(34.00)%	(34.00)%
State income taxes—net of federal tax benefit	3.76%	(4.72)%	(2.37)%
Meals and entertainment	0.71%	0.25%	0.80%
Stock compensation expense	0.48%	0.82%	3.12%
Donated tissue contribution	(1.48)%	—	—
Research and experimentation credit	—	—	(8.37)%
Miscellaneous	0.06%	0.52%	0.08%
Valuation allowance	(45.75)%	18.80%	—
Effective tax rate	(8.22)%	(18.33)%	(40.74)%

13. Restructuring

The Company's formal restructuring plan announced on April 24, 2002 has resulted in the recognition of $869 in restructuring charges through December 31, 2003, including charges for severance benefits, costs of closing its Atlanta processing facility and consulting expenses relating to development of the restructuring plan. The following table presents restructuring charges recognized through December 31, 2003:

	Accruals	Reversals	Non-cash Charges	Total Charges
Employee separation benefits	$ 710	$230	$—	$480
Lease obligations	80	—	—	80
Consulting	200	—	—	200
Fixed asset write-offs	—	—	69	69
Facility closure	170	130	—	40
	1,160	$360	$ 69	$869
Cash payments	800			
Reversals	360			
Balance at December 31, 2003	$ —			

For the year ended December 31, 2003, the Company reversed $21 in restructuring accruals after reviewing the actual expenses incurred and revising its estimates for these expenditures. Prior to announcing its formal restructuring plan on April 24, 2002, the Company incurred restructuring charges of $462 related to consulting expenses.

14. Stockholders' Equity

Preferred Stock—The Company has 5,000,000 shares of preferred stock authorized under its Certificate of Incorporation, none of which currently is outstanding. These shares may be issued in one or more series having such terms as may be determined by the Company's Board of Directors.

Common Stock—The common stock's voting, dividend, and liquidation rights presently are not subject to or qualified by the rights of the holders of any outstanding shares of preferred stock, as the Company presently

does not have any shares of preferred stock outstanding. Holders of common stock are entitled to one vote for each share held at all stockholder meetings. Shares of common stock do not have redemption rights.

On November 26, 2002, the Company completed a private placement of 3,800,000 shares of common stock for approximately $27,550. Transaction costs totaled $1,867. As part of the private placement transaction, the Company entered into a registration rights agreement with the stockholders who purchased these shares. The registration rights agreement required the shares to be registered for resale and that the registration statement be declared effective by the SEC within a specified amount of time or the Company would have been required to pay liquidated damages to the purchasers. These requirements under the registration rights agreement have been met.

Issuances of Unregistered Securities—On April 26, 2001, a director of National Tissue Bank Network ("NTBN") exercised his warrant to purchase 5,534 shares of common stock for total consideration of $31. The director received this warrant in connection with the conversion of a $500 note, due November 2002, into shares of common stock which he had received in connection with the purchase by the Company of certain assets of NTBN and equipment owned by the director during 1999.

On April 18, 2001, Medtronic Asset Management, Inc. exercised a warrant to purchase 110,698 shares of common stock having an exercise price of $5.65 per share. Pursuant to a cashless exercise provision in the warrant, the Company issued 67,325 shares of common stock at par value on May 9, 2001, and the remainder of the warrant was automatically deemed cancelled.

On April 10, 2001, Stephens-Regeneration LLC exercised a warrant to purchase 110,698 shares of common stock having an exercise price of $5.65 per share. Pursuant to a cashless exercise provision in the warrant, the Company issued 54,238 shares of common stock at par value on May 9, 2001, and the remainder of the warrant was automatically deemed cancelled.

15. Retirement Benefits

The Company has a qualified 401(k) plan available to all employees who meet certain eligibility requirements. The 401(k) plan allows each employee to contribute 20% of the employee's salary up to the annual maximum allowed under the Internal Revenue Code. The Company has the discretion to make matching contributions up to 6% of the employee's earnings. For the years ended December 31, 2003, 2002 and 2001, the Company's contributions to the plan were $525, $445, and $420, respectively.

16. Concentrations of Risk

Distribution—The Company's principal concentration of risk is related to its limited distribution channels. The Company's net revenues are related to the distribution efforts of four independent companies with the majority of its net revenues coming from one of the distribution companies, Medtronic Sofamor Danek ("MSD"). For years ended December 31, 2003, 2002, and 2001, the amount of net revenues coming from MSD were approximately 60%, 55%, and 53%, respectively.

The Company's distribution agreements are subject to termination by either party for a variety of causes. No assurance can be given that such distribution agreements will be renewed beyond their expiration dates, continue in their current form or at similar rate structures. Any termination or interruption in the distribution of the Company's products through one of its major distributors could have a material adverse effect on the Company's operations.

Tissue Supply—The Company's operations are dependent on the availability of connective tissue from human donors. For the majority of the tissue recoveries, the Company relies on the efforts of independent procurement agencies to educate the public and increase the willingness to donate bone tissue. These

procurement agencies may not be able to obtain sufficient tissue to meet present or future demands. Any interruption in the supply of tissue from these procurement agencies could have a material adverse effect on the Company's operations.

17. Commitments and Contingencies

Commitment—At December 31, 2003, the Company had a recorded liability to MSD of $10,695, for management service fee obligations which were recognized under the terms of the prior distribution agreement. The Company is disputing certain components of the recorded liability to MSD, which has primarily focused on the contractual terms and, among other things, responsibilities of the parties relative to losses on consignment inventories and uncollected accounts receivable. The Company, along with MSD, have attempted for over a year, to resolve these issues in a manner that addressed the needs of the two companies. The Company has been unable to reach an agreement with MSD with respect to the amount owed. The current distribution agreement calls for the Company and MSD to enter into arbitration to settle the dispute if a settlement cannot otherwise be reached. We are in discussions with MSD to resolve these matters and to improve our current distribution agreement. Management believes that the ultimate settlement of these matters will not exceed the liability provided for in the Company's consolidated financial statements.

Manufacturing Rights—The Company has licensed manufacturing rights for some of its products. Under the agreement, the Company has agreed to accept and reimburse the processor for items that meet the Company's quality control guidelines.

Foreign Investment—In August 1998, the Company received a 30% ownership in UFTB-Italia for no consideration and, therefore, recorded a $0 investment in UFTB-Italia. The 30% ownership in UFTB-Italia was given to the Company to provide it with incentive to assist UFTB-Italia in its future efforts to develop a tissue bank business in Italy, which would include recovery, processing and distribution of tissue. UFTB-Italia is an entity created in late 1998 which, as of December 31, 2003, has only distributed tissue and has not begun to recover or process tissue. The Company is required to provide certain training to UFTB-Italia; however, UFTB-Italia must reimburse the Company for all costs of travel, housing, meals and related expenses. The Company bears the salary cost of Company personnel providing the training. As of December 31, 2003, salary costs incurred by the Company for training provided to UFTB-Italia are not significant. Additionally, the Company has not accrued salary costs for future training to be provided to UFTB-Italia as it is not probable that any additional training will be provided and the salary costs of such training cannot be reasonably estimated. The Company has recorded this investment on the equity basis. The Company records its share of the net income of UFTB-Italia and its share of net losses of UFTB-Italia only to the extent the net losses reduce the Company's investment to zero. Such net income or net loss is reflected as equity in income of unconsolidated subsidiary on the consolidated statement of operations. As of December 31, 2003 and 2002, the Company had $224 and $448, respectively, of outstanding accounts receivable due from UFTB-Italia. Total tissue distributions to UFTB-Italia in 2003, 2002, and 2001 were $88, $826, and $518, respectively. At December 31, 2003 and 2002, the Company's investment in UFTB-Italia was $0.

Leases—The Company leases various buildings, office equipment and fixtures under non-cancelable operating leases for various periods. The Company also leases various equipment under capital leases that are included in property, plant and equipment in the accompanying consolidated balance sheets.

Future minimum lease commitments under noncancelable leases as of December 31, 2003 are as follows:

	Capital Leases	Operating Leases
2004	$1,710	$ 704
2005	618	467
2006	9	365
2007	5	154
2008	—	147
2009	—	50
	2,342	$1,887
Less amounts representing interest	114	
Present value of net minimum lease payments	$2,228	

Rent expense for the periods ended December 31, 2003, 2002 and 2001 was $773, $1,383, and $954, respectively, and is included as a component of marketing, general and administrative expenses.

18. Related Parties

The following is a summary of transactions and balances with a director of NTBN as of and for the years ended December 31, 2003, 2002 and 2001:

	Year Ended December 31,		
	2003	2002	2001
Payments on leased premises	$—	$147	$155
Payments for Medical Director fees	—	45	104
Principal and interest payments on notes	—	—	571

19. Legal Actions

Exactech Litigation

In June 2002, the Company and Exactech, Inc. ("Exactech") reached an agreement in settlement of the arbitration resulting from the June 22, 1999 complaint filed by Exactech. In connection with the settlement, the Company recognized a charge of $2,000 in 2002, representing damages and legal fees relating to the dispute. Significant terms of the settlement include the following: 1) The payment by the Company to Exactech of $1,500 payable in quarterly cash installments of $250 beginning September 30, 2002 and continuing through December 31, 2003; 2) Exactech will be the exclusive distributor for the Company of produced moldable and flowable paste products for use in non-spinal musculoskeletal system procedures subject to certain limitations with respect to oral maxillofacial products; and 3) The Company will pay Exactech a royalty on the distribution of moldable paste products for use in spinal procedures. Royalty payments totaled $113 during 2003.

Other Litigation

The Company is, from time to time, involved in litigation relating to claims arising out of its operations in the ordinary course of business. The Company believes that none of these claims that were outstanding as of December 31, 2003 will have a material adverse impact on its financial position or results of operations.

20. Supplemental Cash Flow Information

Selected cash payments, receipts, and noncash activities are as follows:

	Year Ended December 31,		
	2003	2002	2001
Interest paid during the period	$ 1,438	$ 2,066	$ 662
Income taxes received	(1,510)	(2,445)	(128)
Noncash capital lease obligations	—	4,649	532
Noncash insurance financing	440	—	937
Issuance of stock options	—	48	478

21. Segment Data

The Company processes human tissue received from various tissue recovery agencies and distributes the tissue through various channels. This one line of business represents almost 100% of consolidated revenues and is comprised of four primary product lines: spinal, sports medicine, cardiovascular and general orthopedic. Effective November 1, 2002, the Company entered into a new distribution agreement with Medtronic Sofamor Danek ("MSD") under which the Company is no longer responsible for the collection of total distribution fees, but instead receives a fee from MSD based on the Company's average net distribution fee. Therefore, subsequent to November 1, 2002, the Company's total revenues are the same as its net revenues. The following table presents net revenues from tissue distribution and other non-tissue revenues:

	Year Ended December 31,		
	2003	2002	2001
Fees from tissue distribution:			
Spinal	$45,306	$37,971	$36,003
Sports medicine	8,855	10,028	9,076
Cardiovascular	5,141	3,426	811
General orthopedic	14,229	16,119	19,696
Other non-tissue	1,979	1,516	1,964
Total	$75,510	$69,060	$67,550

The Company distributes its products both within and outside the United States. Foreign distribution, primarily in Europe, accounted for 7.6%, 6.5% and 4.8% of the Company's net revenues during the years ended December 31, 2003, 2002 and 2001, respectively.

The following table presents total revenues from tissue distribution and for other non-tissue revenues:

	Year Ended December 31,		
	2003	2002	2001
Fees from tissue distribution:			
Spinal	$45,306	$ 85,153	$105,154
Sports medicine	8,855	10,028	9,076
Cardiovascular	5,141	3,426	811
General orthopedic	14,229	18,367	23,721
Other non-tissue	1,979	1,516	1,964
Total	$75,510	$118,490	$140,726

22. Quarterly Results of Operations (Unaudited)

The following table sets forth the results of operations for the periods indicated:

	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
Quarter Ended:				
Net revenues	$19,832	$23,081	$20,154	$12,443
Gross profit	8,890	10,457	9,298	4,099
Net income	1,399	1,881	1,619	1,457
Net income per common share:				
Basic	$ 0.05	$ 0.07	$ 0.06	$ 0.05
Diluted	$ 0.05	$ 0.07	$ 0.06	$ 0.05

During the three months ended December 31, 2003, the Company experienced a decrease in revenues as a result of its largest distributor executing programs to reduce their levels of allograft inventory. The Company also experienced higher costs of processing and distribution as a result of lower revenue volumes, which resulted in inefficiencies. The Company slowed down production during the quarter, however, the Company did not reduce its permanent operating personnel, as the Company viewed the slow down in orders as temporary. Also, during the three months ended December 31, 2003, the Company reduced the deferred income tax valuation allowance by $2,687 as a result of the Company's continued profitability and a determination that it is more likely than not that the associated deferred tax assets will be realized.

The following table sets forth the results of operations for the periods indicated:

	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002
Quarter Ended:				
Net revenues	$15,299	$ 14,520	$18,339	$20,902
Gross profit	6,096	2,201	8,554	7,330
Net (loss) income	(1,376)	(13,287)	226	932
Net (loss) income per common share:				
Basic	$ (0.06)	$ (0.61)	$ 0.01	$ 0.04
Diluted	$ (0.06)	$ (0.61)	$ 0.01	$ 0.04

During the three months ended March 31, 2002, the Company experienced a decrease in sales, an increase in marketing, general and administrative expenses and costs incurred as a result of a restructuring plan, resulting in lower net income for that period.

During the three months ended June 30, 2002, the Company experienced a decrease in revenues from the distribution of spinal allografts. This decrease was the result of a temporary shortage in inventory of certain allografts which are most often requested for spinal surgeries. In addition, in June 2002, the Company reached an agreement in settlement of a dispute with one of its distributors. As a result of the resolution, the Company recognized a charge of $2,000 during the three months ended June 30, 2002 for the settlement and related expenses of the dispute. The Company also recognized a loss on asset abandonment of $3,118 relating primarily to processing equipment and an abandoned software project.

23. Subsequent Events

On February 20, 2004, the Company entered into a new long-term financing agreement with a major financial institution. The new agreement consists of a $9,000 five-year term loan and a five-year $16,000

revolving line of credit. The $9,000 term loan calls for monthly principal and interest payments. Interest on the new loan agreement is at the LIBOR rate plus 4.25%. The new loan agreement has a term of five years. Under the $16,000 revolving credit loan, the Company can borrow up to the maximum eligible amount, based on certain outstanding receivables and inventories. Interest on outstanding amounts under the revolving credit loan is at the LIBOR rate plus 3.75%. Principal and interest on the revolving credit loan are payable upon maturity, unless otherwise called for in the agreement. The term loan and line of credit are fully collateralized by the assets of the Company, including accounts receivable, inventories and certain property and equipment. In conjunction with this new agreement, the Company repaid the remaining outstanding balance on the $15,100 term loan and terminated the outstanding swap agreement, of $1,615, noted earlier.

The credit agreement also contains various restrictive covenants which limit, among other things, indebtedness, liens and business combination transactions. In addition, the Company must maintain certain financial covenant ratios, including operating cash flows to fixed charges, senior debt to EBITDA, and total debt to EBITDA, as defined in the agreement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

March 10, 2004

REGENERATION TECHNOLOGIES, INC.

By: /s/ BRIAN K. HUTCHISON
Brian K. Hutchison
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ BRIAN K. HUTCHISON **Brian K. Hutchison**	Chairman, President and Chief Executive Officer (Principal Executive Officer)	March 10, 2004
/s/ THOMAS F. ROSE **Thomas F. Rose**	Vice President and Chief Financial Officer	March 10, 2004
/s/ PHILIP R. CHAPMAN **Philip R. Chapman**	Director	March 10, 2004
/s/ PETER F. GEAREN **Peter F. Gearen**	Director	March 10, 2004
/s/ MICHAEL J. ODRICH **Michael J. Odrich**	Director	March 10, 2004
/s/ DAVID J. SIMPSON **David J. Simpson**	Director	March 10, 2004

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of Regeneration Technologies, Inc.:

We have audited the consolidated financial statements of Regeneration Technologies, Inc. and subsidiaries (the "Company") as of December 31, 2003 and 2002, and for each of the three years in the period ended December 31, 2003, and have issued our report thereon dated March 5, 2004; such report is included elsewhere in this Form 10-K. Our audits also included the consolidated financial statement schedule of Regeneration Technologies, Inc. and subsidiaries, listed in Item 15(a)(2). This consolidated financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion based on our audits. In our opinion, such consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants

Orlando, Florida
March 5, 2004

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Schedule II
Valuation and Qualifying Accounts
Years Ended December 31, 2003, 2002 and 2001
(Dollars in thousands)

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Balance at End of Period
For the year ended December 31, 2003:				
Allowance for doubtful accounts	$4,448	$ 182	$ 249	$4,381
Allowance for product returns	300	60	285	75
Allowance for obsolescence	7,182	1,299	2,200	6,281
For the year ended December 31, 2002:				
Allowance for doubtful accounts	6,354	(652)	1,254	4,448
Allowance for product returns	536	292	528	300
Allowance for obsolescence	5,765	4,021	2,604	7,182
For the year ended December 31, 2001:				
Allowance for doubtful accounts	755	6,221	622	6,354
Allowance for product returns	359	357	180	536
Allowance for obsolescence	1,418	4,347	—	5,765