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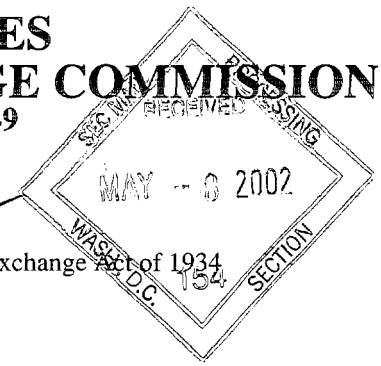
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549



~~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, 2001**

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.)**

One Innovation Drive, 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. ☐

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 on March 15, 2002, was approximately $143.7 million.

The number of shares of Common Stock outstanding as of March 15, 2002, was 21,937,876.

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 2002 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
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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," 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.

Item 1. BUSINESS.

Company Overview

Regeneration Technologies, Inc., or RTI, is a leader in the use of natural tissues and innovative technologies to repair and promote the natural healing of human bone and other human tissues. Using core human physiology—the basic biology of natural tissues as they function in the body—our human tissue implants are improving surgical outcomes. We are a provider of comprehensive healing and natural tissue products in a broad range of markets. In addition, we are the largest processor and distributor in the United States of allografts that are precisely tooled for specific surgical uses, in terms of revenues, for the year ended December 31, 2001. Our distributors distribute our allografts in all 50 states and in eleven countries internationally. We are also a processor of "conventional allografts," which are allografts that are not tooled by the processor for a specific surgical use.

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, urinary incontinence and heart valve disorders. Our current grafts range from conventional allografts to grafting material which is precisely tooled for specific surgical uses, including bone dowels, wedges, pastes and pins, urological allografts and heart valves.

The following table outlines the markets we serve and the amount and percentage of our revenues, net of management services fees, from core operations for the years ended December 31, 2001, 2000 and 1999:

	Year Ended December 31,					
	2001		2000		1999	
Market						
Spinal allografts	$36,003	54.9%	$30,069	53.4%	$17,079	55.5%
Other precision tooled allografts	13,832	21.1	10,532	18.7	4,683	15.2
Other processed tissue	15,751	24.0	15,732	27.9	9,027	29.3
Total	$65,586	100.0%	$56,333	100.0%	$30,789	100.0%

We distribute our allografts both within and outside the United States. Foreign distribution, primarily in Europe, accounted for 2.4% of our net revenues during the year ended December 31, 2001 and 2.6% during the years ended December 31, 2000 and 1999.

We pursue a market-by-market approach to distribution of our allografts, including strategic arrangements in order to increase our penetration in selected markets. We have an alliance with Medtronic Sofamor Danek in the spinal market, with Exactech, Inc. in portions of the bone paste market, and with C.R. Bard, Inc. in the urological market.

The BioCleanse™ process is a patent-pending tissue sterilization process that is designed to add an extra measure of safety to RTI's allografts by sterilizing the tissue, providing surgeons and patients an allograft free of any bacteria or virus. 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. Tissue is sterilized in batches through the BioCleanse™ process only after tissue 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.

Industry Overview

Defects in bone and other human tissue can be caused by a variety of sources including trauma, congenital defect, infectious disease, cancer and other disease 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, "autograft" tissue, "allograft" tissue and "xenograft" tissue. An autograft procedure is one in which the surgeon harvests tissue from one part of a patient's body for transplant to another part of the body to make the needed repair. In contrast to autograft, allograft tissues are recovered from deceased human donors, processed for biologic safety and certain mechanical characteristics and then transplanted by a surgeon into the patient's body to make the needed repair. Procedures using xenograft tissue, while not widely used in the United States other than for heart valves, involve recovering animal tissue, typically from cattle or pigs, and then transplanting that recovered tissue into the patient's body.

Market Segments

We process human musculoskeletal and other tissue, including bone, cartilage, tendon, ligament, dermal and cardiovascular tissue, in producing our line of proprietary allografts. Our current tissues range from conventionally processed bone and soft tissue to bone implants that are precisely tooled for specific surgical uses, urological allografts and heart valves. The service fees we charge for our allografts vary extensively, ranging from a list service fee of less than $200 to in excess of $7,000 per allograft. Our most commonly used precision tooled spinal allografts have listed services fees ranging from approximately $750 to $2,600. The following table summarizes our current allograft offerings in each of the market segments we serve and current distribution of these allografts.

Market Segment	Current Allografts	Current Distribution
Spinal Allografts	—MD™ Series Threaded Bone Dowels	Medtronic Sofamor Danek
	—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	
Other Precision Tooled Allografts	—CorIS™ Cortical Bone Interference Screws	Network of independent distributors
	—Pre-shaped bone-tendon-bone, Quad & Achilles tendons	
	—Soft tissue tendons (gracilis, semitendinosus, tibialis)	
	—Tendons with bone blocks	
	—Meniscus and instrumentation set	
	—Fresh osteochondral allografts	
	—Cortical Bone Pins	
	—Mini screws	
	—HTO Wedges	
	—AlloAnchor™ RC Allograft	
	—OSTEOFIL® Allograft Paste (frozen)	
	—OSTEOFIL® RT Allograft Paste (room temperature)	
	—OSTEOFIL® ICM Formed Allograft Paste	
	—OSTEOFIL® IC Moldable Allograft Paste	
	—Regenafil® Injectable Bone Paste	Direct distribution
	—Regenaform® Moldable Bone Paste	
	—Pericardium membrane	
	—Opteform® Moldable Bone Paste	Exactech, Inc.
Other Processed Tissue	—Femoral heads	Network of independent distributors
	—ImPack™ preground femoral heads	
	—Ilium blocks and strips	
	—Fibula rings	
	—Femoral wedges	
	—Cancellous/Cortical cancellous chips	
	—Cancellous cubes and blocks	
	—Cortical/Cortical cancellous strips	
	—Heart valves, veins	
	—FasLata™ fascia lata allograft	C.R. Bard
	—Dermal allograft	C.R. Bard

Tissue Recovery

Tissue recovery is the actual removal of tissue from a donor. Tissue recovery personnel aseptically recover tissue within 24 hours following a donor's death using surgical instruments and sterilization techniques similar to those used in hospitals for routine surgery. Recovered tissue is placed on wet or dry ice and then transported by the recovery personnel to the tissue bank.

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 for the advancement of tissue processing technologies, the 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. We screen recovered tissue in numerous ways to guard against transmittable diseases. This screening process includes evaluation of risk on the basis of donor lifestyle, interviews with the donor's family and physical examination of the donor. We also perform biomedical testing at various stages during the processing of tissue, using U.S. Food and Drug Administration, or FDA, licensed tests and other tests for known viruses and pathogens.

The limited supply of human tissue has at times limited our growth, and may not be sufficient to meet our future needs. Other factors, some of which are unpredictable, such as negative publicity, regulatory actions or national events like those of September 11, also can unexpectedly reduce the available supply of tissue. Southeast Tissue Alliance, or SETA (formerly the University of Florida Tissue Bank, Inc., or UFTB) our largest recovery group, supplied us with approximately 45% of our total tissue during 2001. Our three largest recovery groups together recovered approximately 75% of our total tissue. If we were to lose any one of these three sources of tissue, the impact on our results would be material.

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 eleven 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.

In the spinal market, during 2001 we continued our strategic alliance with Medtronic Sofamor Danek, or MSD. We have two management services agreements with that company under which they provide management services to assist in the distribution and marketing of our non-paste spinal allografts and our Osteofil® bone paste for spinal uses. MSD's sales representatives interact directly with surgeons, providing the necessary instrumentation, customer support, surgeon education and training, and marketing for our current non-paste spinal allografts and our Osteofil® bone paste. In exchange for its management services, we pay MSD service fees. Under the agreement for management services on our current line of non-paste spinal allografts, we currently pay MSD a service fee equal to 70% of the amount charged to each customer for all grafts except for our assembled allograft, on which we pay a service fee equal to 50% of the amount charged to each customer. We have not yet achieved significant distribution nor incurred significant management fees on our assembled allograft. Under this agreement, MSD also has a 60 day right of first refusal for the exclusive rights to provide management services related to distribution of any new allografts or other developments relating to spinal and cranial medical procedures. Following this 60-day period, we are free to distribute these grafts by other means generally at the management fees and under other terms offered by RTI to MSD. The agreement expires in July 2021. Under the agreement for management services on our bone pastes, the amount of this service fee is 54% of the amount charged to each customer. This service fee is paid for distribution of Osteofil® for uses both in and

outside of the spine. This agreement expires in May 2018 or the expiration of our bone paste patent, whichever occurs later. Under these agreements, MSD also has the exclusive right, subject to certain exceptions, to provide management services to assist in the distribution of the allografts covered by these agreements outside of the United States. MSD has not exercised this right to date. We currently are in discussions with MSD regarding possible overpayments and underpayments by both parties, resulting from a variety of issues. We also are discussing some possible revisions to our agreements with them, as well as changes in the terms of our relationship. We cannot predict the results from these discussions or whether they will be material to our business.

In the United States, we have 20 independent distributors specializing in general orthopedics, which distribute our allografts through approximately 260 sales representatives, complemented by our internal sales and marketing staff of 35 people. Internationally, we have four distributors that distribute our allografts through approximately 320 sales representatives. This network distributes conventional and sports medicine allografts and non-spinal Osteofil® directly to hospitals and surgeons in their exclusive territory. Distributors and sales representatives receive commissions and bonuses for the revenues they generate and have the right to maintain their status as the exclusive distributor in their territory if they reach a specified annual quota.

Also in the general orthopedics market, we have an agreement with Exactech, Inc., or Exactech, for the distribution of certain bone pastes in the United States. Exactech distributes these bone pastes through its network of sales agencies. Under this agreement, we receive a distribution fee from Exactech equal to 32.5% of the amount charged by Exactech to its customers. Exactech has the right to distribute improvements to certain of the bone pastes they currently distribute, or that we may develop in the future, subject to the terms of this agreement. This agreement automatically terminates if we do not receive distribution fees for any period of time longer than six months. Additionally, we have the right to terminate this agreement if the amount paid to us under the agreement during any calendar year falls below a minimum specified amount. We have been involved in an arbitration proceeding with Exactech, which is discussed under "Item 3, Legal Proceedings."

We use direct distribution for the oral-maxillofacial market, with an emphasis on the periodontal market. We use direct mail product information sheets and we attend trade shows to increase the exposure of our allografts. Our marketing staff supports these marketing efforts by speaking at various clinics and universities.

In the urological market, we have an exclusive distribution agreement with C.R. Bard providing for the marketing and distribution of 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 equal to 40% 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, blood vessel and bone paste allografts through 10 cardiovascular distributors, using approximately 50 sales representatives within the United States.

Research and Development

We plan to continue to develop new allografts and technologies within the orthopedics, urological and cardiovascular markets and to develop additional tissue-related technologies for other markets. As of December 31, 2001, our research and development staff consisted of 25 professional and technical personnel. Our research and development staff works closely with surgeons in the development of new techniques and procedures related to tissue healing.

Medical Advisory Board

The Medical Advisory Boards of RTI and Alabama Tissue Center, or ATC, are made up of doctors, surgeons and medical experts who meet periodically as a group to provide us with advice on industry trends in product development and surgical techniques. The RTI and ATC Medical Advisory Boards also work with members of our research and development staff in the development of new allografts and tissue technologies. Currently, the RTI Medical Advisory Board has eleven members and the ATC Medical Advisory Board has four members, representing a broad range of experience in fields relevant to our technologies and technologies under development.

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.

We presently hold four patents covering our MD–Series cortical bone dowel, a patent on the use of the interference screw technology, a patent covering our segmentally demineralized graft, and a patent with claims directed toward our segmentally demineralized stent or conduit technology in the United States. We also presently have one foreign patent covering our MD–Series cortical bone dowel 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 78 patent applications pending in the U.S. (including continuation and divisional applications), and 79 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 techniques and processes in tissue recovery, research and development, tissue processing and quality assurance.

Competition

Competition in the bone and tissue healing industry is intense and subject to rapid technological change and evolving industry requirements and standards. Generally, competitors 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. For the foreseeable future, we believe a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation on the patient in order to obtain the autograft tissue. In addition, many members of the medical community will continue to prefer to use metals and synthetics due in part to their familiarity with the products and the procedures required for their use. While synthetics do not stimulate the growth of new tissue, we believe that researchers will eventually develop methods for permitting the combination of synthetic tissue with recombinant growth stimulating materials in order to create a synthetic tissue that stimulates bone growth. We and a number of other companies are conducting research intended to develop this technology.

Our principal competitors in the conventional allograft market include the Musculoskeletal Transplant Foundation, the American Red Cross Tissue Services, AlloSource and LifeNet. Among our competitors in precision tooled allograft are Osteotech, LifeNet, Musculoskeletal Transplant Foundation, and Tutogen. Other companies who process bone pastes include Osteotech, AlloSource, GenSci Regeneration Sciences, Wright Medical Technologies, and Musculoskeletal Transplant Foundation. 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 is our principal competitor distributing human heart valves, blood vessels, conduits and patch materials. LifeNet, American Red Cross and Northwest Tissue Service also compete in this market, but to a lesser degree.

Government Regulation

Government regulation plays a significant role in the processing and distribution of allografts. The production, testing, labeling, storage, record keeping, approval, advertising and promotion of allografts are governed or influenced by the 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 ensuring proper 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 premarket approval or clearance from the FDA for products 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 in the budgetary review period with implementation estimated for late 2002 or early 2003. We are currently an FDA registered tissue processor in compliance with this rule. See below in "Risk Factors" for a more comprehensive discussion of this proposed regulation.

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. Guidelines 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 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 "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 Good Manufacturing Practices. Depending on the nature and extent of any FDA decision applicable to our allografts, further distribution of the affected grafts 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) premarketing process. In the letter, the FDA states that it will issue guidance on the required submissions for this process "in the near future." We are currently preparing the anticipated documentation for submission to the FDA. We and the other processors are permitted to continue distributing these allografts while going through this process.

Typically under the 510(k) premarket notification process, we would submit an application containing data which demonstrates the "substantial equivalence" of our product 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.

However, in this case the FDA guidance is likely to indicate an alternative basis for filing premarket approval data under the 510(k) process. We do not anticipate that the preparation for our submission will have a material effect on our results. However, because we have not yet been provided official guidance by the FDA, we cannot assure that significant expense will not occur. 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.

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 premarket 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. We segregate the material and properly dispose of it in compliance with applicable environmental regulations.

For a discussion of recent matters relating to FDA and state regulators applicable to us, see below in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

Employees

As of December 31, 2001, we had a total of 360 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	201
Tissue Recovery	21
Sales and Marketing	35
Research and Development	25
General and Administrative	78

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 have a limited operating history, are at an early stage of development and may not succeed or continue to be profitable.

We incorporated in 1997 and commenced operations as an independent entity in 1998, and are at an early stage of development. Accordingly, we have a limited operating history on which to base an evaluation of our business and prospects. We expect our operating expenses to increase and we will need to generate significant revenues to return to profitability. We may not be able to achieve growth in our revenues at levels which will return us to or sustain profitability on a quarterly or annual basis.

Many of the risks inherent in the development of a new enterprise will affect our business, including:

- market acceptance of our existing and future allografts and technologies;
- our ability to continue to develop markets for our allografts and technologies;
- our ability to raise sufficient capital to support the cost of commercializing our current allografts and technologies and developing new allografts and technologies to remain competitive;

- management of our growth and issues associated with a longer operating history; and
- our ability to attract and retain qualified management, sales, technical and scientific staff.

It is difficult for us to predict our future results of operations due to our limited operating history and the uncertain nature of our markets. As we increase our operating expenses to continue our research and development, expand manufacturing and add to our tissue recovery and distribution programs, these expenditures may not result in increased revenues and we may incur sizable losses.

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, regulatory actions or national events like those of September 11, also can unexpectedly reduce the available supply of tissue.

Donor recovery groups are part of relatively complex relationships. They deal with 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 these other groups. 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 contracts with recovery groups which are favorable to RTI.

SETA, our largest recovery group, supplied us with approximately 45% of our total tissue during 2001. Our three largest recovery groups together recovered approximately 75% of our total tissue. If we were to lose any one of these three sources of tissue, the impact on our 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 these sources sufficient to meet our needs, we may not be able to locate 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, which could cause the market price of our common stock to decline. We expect our revenues would continue to suffer for at least as long as needed tissue is in short supply.

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:

- 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
- our ability to train 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 a small portion of the medical community has 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.

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

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

- we could be forced to recall or withdraw 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 production costs could increase.

Further, to be successful, we will need to manage our production capacity related to tissue recovery and processing facilities in relation to demand. It may be difficult for us to match our production 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 production, it will reduce our revenues and increase our cost per allograft processed.

For example, during the three months ended December 31, 2001, we were not as successful as we had planned in managing the medical release of donor tissue into processing. During that period, the amount and type of tissue which was released and processed resulted in a change in the mix of allografts processed and a lower number of allografts processed than were processed in prior quarters. Due to many relatively fixed costs of our manufacturing operations, this resulted in a much higher cost per allograft processed and a higher cost of inventory. The effect of this increased cost of inventory will be experienced as inventory is distributed or otherwise depleted in future periods as an increase to costs of processing and distribution, unless efficiencies are gained which lower our cost of inventory distributed. At this time, we cannot estimate the effect or timing of this increased cost on our future results.

There are many factors which affect the level and timing of donor medical releases, such as effectiveness of donor screening performed by our 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 recovery groups are also processors who provide us with partially processed tissues which they have already determined as medically suitable for processing. Therefore, these sources provide a higher level of documentation than those who perform 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 manufacturing efficiency and minimize our cost per allograft processed.

Valuation allowances that we take against our supply of unprocessed and processed tissue may turn out to be inadequate, potentially resulting in inventory losses greater than estimated losses and requiring us to take larger allowances in the future, which would have a negative effect on our results of operations.

We classify our tissue inventory into three major categories: Unprocessed Donor Tissue (UDT), Tissue in Process (TIP), and Implantable Donor Tissue (IDT). At each stage of storage and processing, for a variety of reasons, the tissue is at risk of not becoming distributed allograft, which is the source of our revenue.

- We establish a valuation allowance for a portion of UDT tissue that is likely, based on historical data, to fail to be medically released into processing. In addition, if any UDT tissue has not been released into processing within one year of receipt, the cost is fully recorded to the valuation allowance.
- We establish a valuation allowance on TIP inventory based on estimates of future rejection rates, and also for the full cost of all TIP inventory which has not met all quality requirements for transfer into IDT for more than twelve months.
- For IDT inventory, we establish a valuation allowance for the difference between carrying cost and market value for allograft types which we determine are distributable but have incurred a cost of processing and distribution greater than the related carrying cost. In addition, we record an allowance for the full cost of allografts types which we consider to be undistributable. These items may be undistributable due to oversupply or due to obsolescence, which may result if we have introduced a new allograft type which displaces demand for a previously used allograft type. Finally, if we fail to make a determination of oversupply or obsolescence prior to the time any allograft has remained in IDT inventory for longer than two years, or within one year prior to expiration, we will record an allowance for the full cost of the allograft.

In establishing these valuation allowances, we rely largely on our experience in operating our business and the data that we have accumulated since our inception. It is possible the allowances we record by these means may be inadequate and we could experience actual inventory loss greater than anticipated, and be required to establish higher allowances in the future based on additional experience gained to that time. Since any valuation allowance has the effect of reducing our profitability during the period in which the allowance is recorded, this could have a material adverse effect on our results of operations for the relevant period.

Rapid technological change 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, including the use of recombinant 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, chemical and other companies such as Johnson & Johnson, Cryolife, Osteotech and the Musculoskeletal Transplant Foundation;

- academic and scientific institutions; and
- public and private research organizations.

Many of our competitors have much greater financial, technical, research, marketing, sales, 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.

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

While we market a portion of our current technologies directly to our customers, we currently derive the majority of our revenues through our relationships with two companies, Medtronic Sofamor Danek and C.R. Bard. In the year ended December 31, 2001, we derived approximately 53% of our net revenues from distribution assisted by management services provided by one company, Medtronic Sofamor Danek. This company provides nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for our line of spinal allografts. If our relationship with this distributor were terminated for any reason and we were unable to replace the relationship with other means of distribution, our revenues could be materially and adversely affected. We currently are in discussions with Medtronic Sofamor Danek regarding possible overpayments and underpayments by both parties, resulting from a variety of issues. We also are discussing some possible revisions to our agreements with them, as well as changes in the terms of our relationship. We cannot predict the results from these discussions or whether they will be material to our business.

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 or renew our current distribution arrangements on favorable terms, our revenues may decline, which could cause the market price of our shares to decline.

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

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

For example, in mid-2001, the FDA reviewed our BioCleanse™ system after the FDA raised concerns about the process in a letter to us dated May 3, 2001. While the FDA stated in January 2002 that it had concluded the compliance portion of its review of our BioCleanse™ process and determined we were in compliance with existing regulations and that no regulatory action was warranted, the possibility always exists that the FDA could raise concerns with other aspects of our business. Moreover, while the FDA's review was made in the context of our current procedures, including the BioCleansing of tissue from multiple donors, their decision does not constitute a formal approval of our process and they are free to raise the same or similar concerns in the future.

If any of our allografts fall under the FDA's definitions as "more than minimally manipulated or indicated for nonhomologous use," we would be required to obtain medical device 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 premarket approval may result. The FDA may require post-market testing and surveillance to monitor the effects of such allografts, may restrict the commercial applications of these allografts, and may conduct periodic inspections of our facility and our suppliers' facilities. Delays encountered during the FDA approval process may shorten the patent protection period during which we have the exclusive right to commercialize such 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) premarketing process. In its letter, the FDA stated that it will issue guidance on the required submissions for this process "in the near future." We are currently preparing the anticipated documentation for submission to the FDA. We and the other processors are permitted to continue distributing these allografts while going through this process.

Typically under the 510(k) premarket notification process, we would submit an application containing data which demonstrates the "substantial equivalence" of our product 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. However, in this case we believe the FDA guidance is likely to indicate an alternative basis for filing data under the 510(k) process. We do not anticipate that the preparation for our submission will have a material effect on our results. However, because we have not yet been provided official guidance by the FDA, we cannot assure that significant expense will not occur. 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.

Proposed FDA regulations of human cellular and tissue-based products, titled "Good Tissue Practices," would regulate all stages of allograft manufacture, from procurement of tissue to distribution of final products. 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. As currently written, the proposed rules conflict with the manner in which we currently operate, namely pooling, or batching, of tissue from multiple donors in the BioCleanse™ process. While the regulation does provide for a petition process for a variance from this rule if supported by a scientific justification, the FDA could nonetheless find this practice unacceptable for the manufacture of human tissue products. A final finding of this nature would require us to expend significant resources to bring our process into compliance and would adversely affect 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 premarket review by the FDA.

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. For example, on June 21, 2001, we changed our BioCleanse™ procedures to comply with the State of Florida's regulation requiring donated tissue processed for transplantation to be traceable from individual donor to individual recipient. State agencies could also adversely impact our profitability by finding the practice of batching tissue from multiple donors in the BioCleanse™ process unacceptable even when we are able to trace individual donor tissue, thus requiring us to expend significant resources to bring our process into compliance.

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 us or our industry in general. These actions or any negative publicity could cause the market price of our shares to decline.

Our industry is subject to additional 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 production of our allografts. While at present we believe we comply with these laws and regulations, if we fail to conduct our business in compliance with these laws and regulations, it could subject us to significant liabilities. We carry insurance that would cover some liabilities arising from hazardous biological materials, however liabilities could arise in the future for which our insurance will 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 would harm our financial condition.

We are required to refinance or otherwise repay amounts we owe under our loan facilities within the next six months.

We were advised by the Bank of America in February 2002 that we were not in compliance with certain financial ratio covenants required to be met under our line of credit and construction loan facilities. Our lender advised us that, though it was not exercising its right to declare outstanding amounts that we owe immediately due and payable, we would not be permitted to borrow new funds. On April 8, 2002, we entered into an agreement with our lender that terminates our line of credit facility and, subject to the satisfaction of certain conditions, provides for a waiver of these covenants in exchange for our commitment to repay amounts that we owe within the next six months. In order to do this, we would either need to refinance all or some of the indebtedness, or repay it from funds generated by our continuing operations. We cannot be sure whether we will be able to accomplish this and, if we do not, it could have a material and adverse effect on our financial condition.

As of December 31, 2001, we had $13.5 million of available cash and cash equivalents. As of March 29, 2002, our available cash and cash equivalents was $7.1 million. Since we presently are unable to borrow funds under our loan facilities, absent an infusion of additional capital or other strategic transaction, we likely will be required to fund our cash needs through continuing operations. At present, this would not be sufficient to fund the completion of the new facilities we presently are constructing and equipping, which in turn could result in the interruption of our business plan and result in additional expense.

We may need to raise additional funds to operate and grow our business, and if we are unable to raise these funds, our ability to execute our business strategy could be disrupted.

Pursuing our business strategy may require us to raise additional funds. However, the extent of our future capital requirements and the adequacy of available funds will depend on numerous factors, including:

- our success in implementing cost reductions in order to generate sufficient working capital through operations;
- our ability to refinance or otherwise repay amounts we owe under our loan facilities within the next six months as required under agreement with our lender;
- market acceptance of our existing and future allografts and tissue-based technologies;
- progress in our efforts to develop new allografts and tissue-based technologies;
- our success in commercializing technologies we have in development; and
- the development of strategic distribution alliances.

To the extent we are successful in raising additional funds, we likely would do so through equity or debt financings, strategic alliances or other sources. The terms of any future equity financings may be dilutive to our stockholders and the terms of any debt financings likely will contain restrictive covenants that limit our ability to pursue particular courses of action, including paying dividends. Our ability to obtain financing depends upon the status of our future business prospects, as well as conditions prevailing in the capital markets.

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. Recent publicity concerning prions and the potential transmission of Transmissible Spongiform Encephalopathy, or TSE, through human musculoskeletal tissue and tissue-based products may adversely affect tissue recovery, as well as the demand for our allografts. Unfavorable reports of 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 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.

There have been recent changes to our senior management that could make more difficult the management of our business and the execution of our strategy.

We have made a number of changes to our senior management in recent months, including the hiring of our new President and Chief Executive Officer, Brian Hutchison, and the departure of our Chief Financial Officer and Vice President of Sales. As the members of our management adjust to their positions and responsibilities, it could make more difficult the effective management of our business and the execution of our business strategy.

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 products 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 and compete more effectively against us.

Because patent applications are secret until patents are actually issued and the publication of discoveries in the scientific or patent literature lags behind actual discoveries, we cannot be certain if 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 do 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 product 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 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 our technologies or distribute our allografts. This could hurt our revenues and the market price of our shares.

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. Although we have not received any material product liability claims to date and have obtained insurance to cover these claims should they arise, claims could arise in the future for which our insurance will not be adequate. 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. 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.

We are party to lawsuits and other proceedings that could result in financial consequences or have other adverse effects.

We are party to a number of legal proceedings, including a proceeding with one of our distributors relating to distribution and patent rights with respect to some of our allografts. In this proceeding, an arbitration with Exactech, Inc., we likely will be required to pay damages, though the amount is not known. We also are party to several recently filed securities class action lawsuits which allege that statements we made in the past concerning our net income and earnings were false and misleading. While we intend to defend these class action lawsuits vigorously, we cannot predict their outcome. We also recently were advised by the Securities and Exchange Commission that they have opened an informal inquiry with respect to the facts relating to the class action lawsuits. At present, we do not know the amounts, if any, that we may be required to pay with respect to the above legal proceedings. It is possible, however, that such amounts could have a material adverse effect on our financial condition. We also cannot say whether there will be any adverse consequences to us arising from the SEC's inquiry.

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 are subjecting 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.

Item 2. PROPERTIES.

Our physical facilities, located in Alachua, Florida, include two company-owned buildings comprising 45,000 square feet, as well as leased space in nearby buildings. These facilities include 20 clean-rooms for tissue processing and packaging, freezers for storage of tissue and laboratory facilities. We currently house our BioCleanse™ processing and laboratory operations in approximately 10,000 square feet of space which we lease for $13,227 per month. We plan to reduce the amount of space covered by this lease through August 2002, retaining approximately 2,500 square feet for BioCleanse™ operations related to xenograft research. We expect the monthly rent at that time to be $3,516 per month. This lease expires on January 31, 2004. We also currently lease approximately 8,800 square feet of warehouse space at a rate of $4,500 per month under a lease expiring in June 2002. We currently plan to vacate this space upon the expiration of the lease and move our warehouse inventories to our new buildings.

We are constructing three new buildings on approximately 21 acres of property we own adjacent to our existing facilities, including a 65,000 square foot manufacturing facility, a 50,000 square foot office building and a 20,000 square foot commons building. The commons building is substantially completed, while the manufacturing and office buildings are expected to be completed and placed into service between June and September 2002. We believe the 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.

We were advised by the Bank of America in February 2002 that we were not in compliance with certain financial ratio covenants required to be met under our construction loan facility. Our lender advised us that, though it was not exercising its right to declare outstanding amounts that we owe immediately due and payable, we would not be permitted to borrow new funds. On April 8, 2002, we entered into an agreement with our lender that terminates our line of credit facility and, subject to the satisfaction of certain conditions, provides for a waiver of these covenants in exchange for our commitment to repay amounts that we owe within the next six months. Since we are unable to borrow funds under this loan facility at present, we would not be able to fund the completion of the new facilities without additional sources of financing, which in turn could result in the interruption of our business plan and result in additional expense. We cannot be sure whether we will be able to accomplish this and, if we do not, it would have a material and adverse effect on our financial condition.

Our wholly owned subsidiary, Georgia Tissue Bank, operates from a leased building in Atlanta, Georgia comprising 9,300 square feet, with three clean-rooms for tissue processing and packaging, and freezers for tissue storage. This lease has a three-year term, expiring in October 2002. We cannot assure that negotiations to renew this lease or to locate and lease alternative space will result in renewal or lease on terms favorable to us. The current rent under this lease is $13,374 per month.

Our wholly owned subsidiary, Alabama Tissue Center, operates from a leased space on the campus of 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. This lease has a two-year term, expiring in August 2002. We cannot assure that negotiations to renew this lease or to locate and lease alternative space will result in renewal or lease on terms favorable to us. The current rent under this lease is $4,097 per month.

Item 3. LEGAL PROCEEDINGS.

Exactech Litigation

On June 22, 1999, Exactech, Inc. filed a complaint in the Circuit Court of the Eighth Judicial Circuit in Alachua County, Florida against RTI, the Southeast Tissue Alliance, or SETA, and 19 medical distributors and sales agents of RTI. The complaint alleged that we breached a license agreement under which Exactech has certain rights to distribute our bone paste products. SETA assigned this agreement to us as part of our formation and separation from SETA. The court granted our motion to enforce an arbitration provision in the agreement,

and the matter is now in arbitration. Only RTI, Exactech and SETA remain as parties in the arbitration.

The dispute relates to the scope of rights transferred under the license agreement. We maintain that the scope of rights we transferred to Exactech was narrow, while Exactech asserts that it has broader rights. Specifically, Exactech contends that under the agreement, it has the right to distribute eight specific forms of moldable bone paste being distributed by us and any other shapes and sizes of bone paste for use outside of the spine. RTI and Exactech each conducted discovery, including the exchange of documents and the taking of depositions, and in July 2001, a multi-day hearing, including the testimony of witnesses, was held before the arbitration panel.

Upon our motion, the arbitration panel bifurcated the proceeding and focused on the scope of Exactech's rights under the license agreement in the initial phase of the arbitration. On December 21, 2001, the panel ruled that we had the right to distribute the two most widely distributed bone paste products, but not to distribute the other six forms of moldable bone paste (which contain cortical cancellous chips) for non-spinal applications. The panel ruled in our favor on the other claims of breach asserted by Exactech.

Exactech alleges it has suffered monetary damages. The amount of damages, if any, that Exactech is entitled to recover and Exactech's request for injunctive relief will be determined in the second phase of the arbitration proceeding. We are having settlement discussions. We anticipate that the hearing to determine damages, if necessary, will be held in mid-2002. Because the final ruling of the second phase of the arbitration proceeding has not been completed we cannot estimate the amount or range of potential loss.

Osteotech Litigation

On February 25, 1999, RTI, SETA and Medtronic Sofamor Danek, or MSD, brought suit in U.S. District Court for the Northern District of Florida against Osteotech, Inc. The initial complaint alleged that Osteotech is infringing two patents for Diaphysical Cortical Bone Dowels. On October 6, 2000, the court allowed the plaintiffs to amend the complaint to add an additional count that Osteotech also is infringing a third, recently-issued patent for the Diaphysical Cortical Bone Dowels. SETA licenses these patents to us on an exclusive basis and we then sublicense these patents to MSD. Plaintiffs are seeking injunctive relief against Osteotech, preventing it from continuing to distribute products that infringe any of the three patents. Plaintiffs also are seeking monetary damages in an amount based on the profit they believe they would have made if the patents never were infringed by Osteotech. All legal expenses in this action are being paid by MSD. The parties are concluding discovery and trial is anticipated to begin in this case on September 16, 2002.

Musculoskeletal Transplant Foundation Litigation

On June 13, 2001, we filed a complaint against the Musculoskeletal Transplant Foundation, or MTF, in the United States District Court for the Northern District of Florida, alleging that MTF engaged in an intentional, targeted campaign of falsehoods and innuendo designed to undermine our company and our tissue. Specifically, we believe MTF has published advertisements and otherwise has disseminated materials containing misleading and disparaging statements about us and our tissue in an effort to diminish our revenue and to increase MTF's revenue.

Our complaint included causes of action for (1) false advertising and unfair competition in violation of the Lanham Act; (2) intentional interference with existing and prospective business relationships; and (3) unfair competition in violation of the Florida Deceptive and Unfair Trade Practices Act. In its answer to our complaint, MTF made similar claims against us.

The parties entered into a settlement agreement in January 2002 and agreed to withdraw all claims and counterclaims against each other. As part of the settlement, neither party admitted liability and no damages were paid by either party.

Securities Class Action Litigation and Related Regulatory Inquiries

On February 1, 2002, we announced, among other things, that we were delaying the release of our financial results for the fourth quarter of 2001 and the year then ended while our management completed its evaluation of certain inventory issues it identified in the process of preparing our annual financial statements.

Following this announcement, the Nasdaq Stock Market suspended trading in our common stock pending release of our financial results and its receipt of certain requested information. After providing the Nasdaq Stock Market with the information it requested and releasing our financial results for 2001 to the public on February 19, 2002, trading in our shares was allowed to resume the following day. We also were advised by the staff of the Securities and Exchange Commission on February 1, 2002 that it was opening an informal inquiry with respect to these matters. We have cooperated with the staff in connection with its inquiry into these matters.

Also following our announcement, on February 4, 2002, a securities class action lawsuit entitled Michael Keskinen v. Regeneration Technologies, Inc. et al., No. 1:02-CV9 MMP-WW was filed in the United States District Court, Northern District of Florida Gainesville Division, against us and certain of our current and former officers and directors. Since the Keskinen lawsuit was filed, a number of additional securities class action lawsuits have been filed in the U.S. District Court for the Northern District of Florida based upon the same alleged facts. The class actions purport to be brought on behalf of all persons who purchased our common stock between July 25, 2001 and January 31, 2002. We expect that the series of class action lawsuits will be consolidated into a single action. The class actions generally allege that our inventory was overvalued and, as a result, public statements made by us during the class time period about our net income and earnings per share were false and misleading. The plaintiffs assert that the defendants' conduct violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 10b-5 thereunder. The class actions do not specify an amount of damages. Since these lawsuits were filed recently, we have not yet filed our responses and no discovery has occurred. While we intend to defend these actions vigorously, we are not able to predict their outcome. An unfavorable outcome in the litigation could have a material adverse effect on our financial condition and results of operations.

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

There were no matters submitted to a vote of our security holders during the fourth quarter of our year ended December 31, 2001.

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 the periods indicated since our common stock began trading on the Nasdaq Stock Market on August 10, 2000:

2000	High	Low
Third Quarter (August 10, 2000 to September 30, 2000)	$14.63	$8.25
Fourth Quarter	$15.00	$8.69

2001	High	Low
First Quarter	$14.88	$8.69
Second Quarter	$14.95	$8.80
Third Quarter	$12.82	$7.85
Fourth Quarter	$12.20	$9.00

As of March 15, 2002, we had 171 stockholders of record of our common stock. The closing sale price of our common stock on March 15, 2002 was $7.30 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 existing 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 and other relevant factors.

Use of Proceeds

On August 9, 2000 the Securities and Exchange Commission declared effective our Registration Statement on Form S-1 (File No. 333-35756). The offering date was August 10, 2000. The offering has terminated and all of the securities registered have been sold. The managing underwriters were Bank of America Securities, LLC, Lehman Brothers, and Stephens, Inc. Our registration was for 5,700,000 shares of common stock, par value $.001 per share. We sold 3,800,000 shares and the selling stockholder in the offering sold 1,900,000 shares, in both cases for $14.00 per share, generating $53.2 million in gross proceeds for us and $26.6 million in gross proceeds for the selling stockholder. After deducting approximately $3.7 million in underwriting discounts and commissions and $1.5 million in other transaction expenses, our net proceeds were $48.0 million. None of the payments for underwriting discounts and commissions and other transaction expenses represented direct or indirect payment to any of our directors, officers, persons owning 10% or more of any class of our equity securities or other affiliates.

From the effective date of the registration statement through December 31, 2001, the following table identifies the approximate amounts of the net proceeds paid directly or indirectly to others:

	(in thousands)
Working capital	$17,210
Construction of a new manufacturing facility	8,861
Continued research and development	2,500
Expansion of tissue supply and distribution programs	2,500
Purchase of additional manufacturing automation equipment	2,000
Investment in Organ Recovery Systems, Inc.	5,250
Investment in interest bearing cash and cash equivalent funds	9,704
Total use of net proceeds	$48,025

In addition, we may also use a portion of the net proceeds from the offering to acquire businesses, assets, technologies or product lines that complement our existing business if we could make these acquisitions on terms which we deem to be favorable.

Our management will have significant flexibility in applying the net proceeds of the offering. Pending any use as described above, we intend to invest the net proceeds in short-term, interest-bearing investment-grade instruments.

Recent Issuances of Unregistered Securities

On April 26, 2001, Dr. Charles P. Garrison exercised his warrant to purchase 5,534 shares of our common stock for a total consideration amount of $31,245. Dr. Garrison received this warrant in connection with the conversion of a $500,000 note, due November 2002, into shares of our common stock which he had received in connection with the purchase of certain assets of the National Tissue Bank Network, Georgia Tissue Bank, Inc. and equipment owned by Dr. Garrison by GTB during 1999. As this was a private transaction and did not involve a public offering of securities, we relied on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, for this transaction.

On April 18, 2001, Medtronic Asset Management, Inc. exercised its warrant pursuant to a cashless exercise provision to purchase 67,325 shares of our common stock. Medtronic Asset Management, Inc. received this warrant in connection with the purchase of certain of our equity securities in October 1999. As this was a private transaction and did not involve a public offering of securities, we relied on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, for this transaction.

On October 10, 2001, Stephens-Regeneration LLC exercised its warrant pursuant to a cashless exercise provision to purchase 54,238 shares of our common stock. Stephens-Regeneration LLC received this warrant in connection with the purchase of certain of our equity securities in October 1999. As this was a private transaction and did not involve a public offering of securities, we relied on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, for this transaction.

Item 6. SELECTED FINANCIAL DATA.

The statement of operations data set forth below for the year ended December 31, 1997 and the period from January 1, 1998 to February 11, 1998 for our predecessor business have been derived from the audited statements of revenues and direct costs and accompanying notes. In addition, the statement of operations data set forth below for the period from February 12, 1998, when we began operations, to December 31, 1998, and for the years ended December 31, 1999, 2000 and 2001, and selected balance sheet data as of December 31, 1999, 2000 and 2001 have been derived from our consolidated financial statements and accompanying notes included elsewhere in this Form 10-K. The following items should be considered when comparing the selected consolidated financial information from period to period: During the year ended December 31, 1997, the period from January 1, 1998 to February 11, 1998 and the period from February 12, 1998 to December 31, 1998, revenues from core operations and cost of processing and distribution consisted of revenues from and costs of conventional tissue processing and distribution of precision tooled allografts. Beginning in April 1999, revenues from core operations included revenues for direct distribution of conventional tissue into Florida and Georgia as well as revenues for distribution of allografts that are precisely tooled for specific surgical uses. 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, 1997	Period from January 1, 1998 to February 11, 1998	Period from February 12, 1998 to December 31, 1998	Year Ended December 31, 1999	Year Ended December 31, 2000	Year Ended December 31, 2001
			(In thousands, except for share and per share data)			
Statement of Operations Data:						
Revenues from core operations:						
Fees from tissue distribution	$11,074	$2,416	$ 31,892	$ 70,783	$ 120,905	$ 138,762
Other revenues from core operations	2,435	410	3,365	2,237	1,598	1,964
Total revenues	13,509	2,826	35,257	73,020	122,503	140,726
Management services fees	8,875	1,932	24,129	39,994	64,572	73,176
Net revenues	4,634	894	11,128	33,026	57,931	67,550
Costs of processing and distribution	3,344	590	10,621	21,096	31,063	39,455
Gross profit	1,290	304	507	11,930	26,868	28,095
Expenses:						
Marketing, general and administrative	1,357	208	3,211	7,816	17,674	35,962
Research and development	479	68	1,472	1,675	2,392	2,631
Total expenses	1,836	276	4,683	9,491	20,066	38,593
Operating (loss) income			(4,176)	2,439	6,802	(10,498)
Equity in income of unconsolidated subsidiary			—	—	1	—
Interest (expense) income:						
Interest expense			(153)	(285)	(434)	(106)
Interest income			187	187	1,207	1,313
Total interest income (expense)—net			34	(98)	773	1,207
(Loss) income before income tax benefit (expense)			(4,142)	2,341	7,576	(9,291)
Income tax benefit (expense)			—	619	(3,117)	3,786
Net (loss) income			(4,142)	2,960	4,459	(5,505)
Other comprehensive income (loss), net of tax— Unrealized derivative loss			—	—	—	(344)
Comprehensive (loss) income			$ (4,142)	$ 2,960	$ 4,459	$ (5,849)
Net (loss) income per common share—basic			$ (1.12)	$ 0.81	$ 0.42	$ (0.25)
Net (loss) income per common share—diluted			$ (1.12)	$ 0.18	$ 0.22	$ (0.25)
Weighted average shares outstanding—basic			3,686,770	3,669,970	10,639,884	21,760,596
Weighted average shares outstanding—diluted			3,686,770	16,636,791	20,343,214	21,760,596

	As of December 31,		
	1999	2000	2001
Balance Sheet Data:			
Cash and cash equivalents	$ 7,536	$ 34,944	$ 13,504
Working capital (including cash and cash equivalents)	14,052	60,336	27,688
Total assets	48,539	108,552	118,700
Long-term obligations—less current portion	2,027	3,684	658
Total stockholders' equity	15,438	72,476	67,784

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.

Overview

We were incorporated in 1997 as a wholly owned subsidiary of Southeast Tissue Alliance, or SETA (formerly the University of Florida Tissue Bank, Inc., or UFTB). 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 in exchange for shares of preferred stock. We also assumed various liabilities of SETA that were related to the transferred business. At approximately the same time, we sold shares of our preferred stock to a number of unrelated investors.

In addition, SETA assigned to us various agreements to which it was party at the time of the separation, including an agreement with Medtronic Sofamor Danek, or MSD, under which that company was given the right to be the exclusive provider of management services for our current line of precision tooled allografts for use in spinal and cranial medical procedures, including our bone dowels. Under this agreement, we are required to pay MSD 70% of the amount charged for non-paste spinal allografts, excluding our assembled allografts, for which we are required to pay MSD 50% of the amount charged.

At approximately the time of our separation from SETA, James M. Grooms, our current Chairman of the Board, former Chief Executive Officer, and officer of SETA prior to our separation from that entity, contributed his royalty rights in certain intellectual property to us in exchange for shares of our preferred stock. We recorded the assets acquired from SETA and Mr. Grooms and the liabilities assumed from SETA at their historical cost basis since these were deemed to be transactions between entities under common control.

In May 1998 we entered into a second agreement with MSD under which it was given the right to be the exclusive provider of management services for our current line of bone paste allografts for use in spinal and cranial medical procedures. Originally, the agreement required us to pay 60% of the amount charged on our Osteofil® line of bone paste allografts which were used in spinal applications. The agreement was amended in September 2000 to require payment on distribution of all Osteofil® distributed, regardless of surgical use, at a rate of 54% of the amount charged.

On April 15, 1999, we changed our business strategy to distribute both conventional allografts and allografts that are precisely tooled for specific surgical uses. Prior to that time, we processed both conventional and precision tooled allografts, but we only directly distributed the precision tooled allograft, allowing SETA to distribute the conventional tissue processed by us. On April 15, 1999, as part of this change in business strategy, we entered into a Programs Transfer Agreement with SETA under which SETA transferred to us its recovery operations outside of Florida and Georgia, conventional allograft distribution services, and its interests in agreements with various tissue recovery programs in exchange for the offset of amounts owed to us by SETA. Also on that date, we entered into a Tissue Recovery Agreement with SETA under which SETA functions as one of our tissue recovery agencies, supplying us with the majority of the tissue it recovers. As of April 15, 1999, the total amount owed to us by SETA was approximately $5.0 million. Under the terms of the agreements, UFTB transferred to us its unprocessed donor tissue and conventional tissue with a fair value of approximately $3.0 million and equipment and fixtures with a fair value of approximately $100,000 as a partial offset against the

existing amounts owed to us by SETA. SETA agreed to repay the remaining amounts it owed to us by offsetting recovery fees from April 15, 1999 through June 30, 1999 against the outstanding balance, which fees, net of administrative costs, were approximately $700,000, and making monthly payments through the end of 1999 to repay the remaining balance of approximately $1.2 million.

On November 1, 1999, we acquired the net assets of Georgia Tissue Bank, Inc. along with certain equipment owned by a director of Georgia Tissue Bank. We financed this acquisition with a cash payment of $500,000 and promissory notes totaling $1.3 million. We recorded our acquisition of the net assets of Georgia Tissue Bank under the purchase method of accounting.

On August 21, 2000, we acquired substantially all of the existing assets and liabilities of a division of the University of Alabama Health Services Foundation, which had been doing business as the Alabama Tissue Center in Birmingham, Alabama. The acquisition was financed by a cash payment of $300,000 and the issuance of $3.5 million in shares of our common stock, valued at the initial public offering price of $14.00 per share. We may be required to make an additional cash payment of $300,000 if certain milestones are achieved prior to December 31, 2004. These milestones have not been achieved to date. We recorded our acquisition of the net assets Alabama Tissue Center under the purchase method of accounting.

All of our operations are located in the United States, although we distribute our allografts to customers both within and outside the United States.

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 Allowances; 2) Accounts Receivable Allowances; 3) Valuation of Long-Lived Assets; and 4) Revenue Recognition.

Tissue Inventory Valuation Allowances. 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 reserve against inventory which will not be distributed and which therefore have 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 reserves for 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 the year ending December 31, 2001, we determined that our inventory valuation allowance requirement was higher than our previous estimates and we therefore reserved an additional $2.3 million.

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. During December 2001, we determined that existing allowances were not sufficient. Accordingly, we recorded $5.8 million of additional bad debt allowances. 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. 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 would be recognized as a charge to earnings during the period the determination is made.

These determinations require complex calculations based on estimated future benefit. 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 have overestimated the useful life of an asset, or overestimated the fair value of an asset, and at some time in the future that asset is disposed of or sold for a lower amount than the carrying value of that asset, our reported total assets and net income will be higher than they would have been during periods prior to the recognition of the loss on disposal of assets, and lower during the period when we recognize the loss.

Revenue Recognition. Revenue is recognized at the time we ship processed tissue for implant or the tissue is transferred from our consignment inventory locations for implant. Revenues are reported gross of any management services fees we incur related to the distribution of our allografts. We recognize any other revenues directly related to our core operations 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 reserved.

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 regulations and that no regulatory action was warranted. The FDA's letter was the result of its review of our BioCleanse™ system 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. It is possible that state agencies could further adversely impact our profitability by finding the practice of batching tissues from multiple donors in the BioCleanse™ process unacceptable even when we are able to trace individual donor tissue. This would require significant additional resources to bring our process into compliance.

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) premarketing process. In the letter, the FDA states that it will issue guidance on the required submissions for this process "in the near future." We are currently preparing the anticipated documentation for submission to the FDA. We and the other processors are permitted to continue distributing these allografts while going through this process.

Typically under the 510(k) premarket notification process, we would submit an application containing data which demonstrates the "substantial equivalence" of our product 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. However, in this case the FDA guidance is likely to indicate an alternative basis for filing premarket approval data under the 510(k) process. We do not anticipate that the preparation for our submission will have a material effect on our results. However, because we have not yet been provided official guidance by the FDA, we cannot assure that significant expense will not occur. 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.

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,					
	2001		2000		1999	
			(In thousands)			
Statement of Operations Data:						
Revenues from core operations:						
Fees from tissue distribution	$138,762		$120,905		$70,783	
Other revenues from core operations	1,964		1,598		2,237	
Total revenues	140,726		122,503		73,020	
Management services fees	73,176		64,572		39,994	
Net revenues	67,550	100.0%	57,931	100.0%	33,026	100.0%
Costs of processing and distribution	39,455	58.4	31,063	53.6	21,096	63.9
Gross profit	28,095	41.6	26,868	46.4	11,930	36.1
Expenses:						
Marketing, general and administrative	35,962	53.2	17,674	30.5	7,816	23.7
Research and development	2,631	3.9	2,392	4.1	1,675	5.1
Total expenses	38,593	57.1	20,066	34.6	9,491	28.7
Operating (loss) income	(10,498)	(15.5)	6,802	11.8	2,439	7.3
Equity in income of unconsolidated subsidiary	—	—	1	—	—	—
Interest (expense) income:						
Interest expense	(106)	(0.2)	(434)	(0.7)	(285)	(0.9)
Interest income	1,313	1.9	1,207	2.1	187	0.6
Total interest income (expense)—net	1,207	1.7	773	1.4	(98)	(0.3)
(Loss) income before income tax benefit (expense)	(9,291)	(13.8)	7,576	13.2	2,341	7.0
Income tax benefit (expense)	3,786	5.6	(3,117)	(5.4)	619	1.9
Net (loss) income	(5,505)	(8.2)	4,459	7.8	2,960	8.9
Other comprehensive loss, net of tax—						
Unrealized derivative loss	(344)	(0.5)	—	—	—	—
Comprehensive loss	$ (5,849)	(8.7)%	$ 4,459	7.8%	$ 2,960	8.9%

2001 Compared to 2000

Total Revenues. Our total revenues increased by $18.2 million, or 14.9%, to $140.7 million for the year ended December 31, 2001 from $122.5 million for the year ended December 31, 2000.

Fees from tissue distribution increased by $17.9 million, or 14.8%, to $138.8 million for the year ended December 31, 2001 from $120.9 million for the year ended December 31, 2000. The increase in fees from tissue distribution was due largely to an increase of $10.5 million in revenues from the distribution of our spinal allografts and an increase of $7.3 million from the distribution of other precision tooled allografts. Fees from the distribution of other processed tissue was relatively unchanged for the year ended December 31, 2001. Other revenues from core operations, which consist primarily of tissue processing fees, tissue recovery fees, biomedical laboratory fees, manufacturing royalties, distribution of reproductions of our allografts to distributors for demonstration purposes, and restocking fees, increased by $366,000 to $2.0 million for the year ended December 31, 2001 compared to $1.6 million for the year ended December 31, 2000.

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, increased by $8.6 million, or 13.3%, to $73.2 million for the year ended December 31, 2001 from $64.6 million for the year ended December 31, 2000. This increase was due to the greater revenues generated through the management services of MSD. Management fees are payable to MSD on revenue from the distribution of spinal allografts and Osteofil® bone paste allograft used in non-spinal applications. As a percentage of total revenue, management service fees decreased slightly from 52.7% to 52.0%.

Net Revenues. Our net revenues increased by $9.6 million, or 16.6%, to $67.6 million for the year ended December 31, 2001 from $57.9 million for the year ended December 31, 2000. As a percentage of total revenues, our net revenues increased slightly from 47.3% for the year ended December 31, 2000 to 48.0% for the year ended December 31, 2001. This increase in net revenues as a percentage of total revenues was due primarily to allograft distribution on which management fees are payable to MSD comprising a smaller percentage of our total revenues during the year ended December 31, 2001.

Costs of Processing and Distribution. Costs of processing and distribution increased by $8.4 million, or 27.0%, to $39.5 million for the year ended December 31, 2001 from $31.1 million for the year ended December 31, 2000. As a percentage of net revenues, these costs increased from 53.6% for the year ended December 31, 2000 to 58.4% for the year ended December 31, 2001. This increase was attributable primarily to fourth quarter adjustments we made to increase our inventory valuation allowance by $2.3 million in 2001.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses increased by $18.3 million, or 103.5%, to $36.0 million for the year ended December 31, 2001 from $17.7 million for the year ended December 31, 2000. A significant portion of this increase was due to an increase in bad debt expense for 2001 of $6.2 million, $5.8 million of which was taken in the fourth quarter specifically related to disputed invoices with several customers, compared to $566,000 for 2000. Other increases in 2001 compared to 2000 included an increase in distributor commissions of $3.4 million, primarily for the distribution of other processed tissue; consulting expense related to governmental and public relations of $2.4 million, including expenses relating to the FDA's review of our BioCleanse™ process and to regulatory actions taken by the State of Florida; expense related to the hiring of additional marketing and administrative staff to support our growing business of $1.8 million; legal expense related to ongoing and new legal proceedings of $1.3 million; and depreciation expense of $783,000 for building and equipment placed into service during the year. In addition, ATC, acquired in August 2000, contributed $987,000 to the above increases. As a percentage of net revenues, marketing, general and administrative expenses increased from 30.5% for the year ended December 31, 2000 to 53.2% for the year ended December 31, 2001. Management is currently in the process of evaluating alternative actions to reduce the amount of marketing, general and administrative expenses incurred in the future.

Research and Development Expenses. Research and development expenses increased by $239,000, or 10.0%, to $2.6 million for the year ended December 31, 2001 from $2.4 million for the year ended December 31, 2000. This increase was due primarily to an increase in staffing and in consulting fees. We expense all research and development costs as incurred. As a percentage of net revenues, research and development expenses decreased from 4.1% for the year ended December 31, 2000 to 3.9% for the year ended December 31, 2001. This decrease was due to an increase in net revenues without a commensurate increase in research and development expenses.

Interest Income and Expense—Net. Net interest income for the year ended December 31, 2001 was $1.2 million compared to $773,000 for the year ended December 31, 2000. This increase was due to proceeds from our initial public offering, which occurred in August of 2000, being invested in interest-bearing accounts for a longer time period during the year ended December 31, 2001 than during the year ended December 31, 2000.

Income Taxes. Income tax benefit for the year ended December 31, 2001 was $3.8 million, compared to income tax expense of $3.1 million for the year ended December 31, 2000. As a percentage of loss before income taxes, income tax benefit was 40.7% for the year ended December 31, 2001; as a percentage of income before income taxes, income taxes were 41.1% for the year ended December 31, 2000. These percentages are higher than the statutory rate due to a combination of our research and development income tax credit, and deferred compensation expense, which is not an allowable deduction for income tax purposes.

2000 Compared to 1999

Total Revenues. Our total revenues increased by $49.5 million, or 67.8%, to $122.5 million for the year ended December 31, 2000 from $73.0 million for the year ended December 31, 1999.

Fees from tissue distribution increased by $50.1 million, or 70.8%, to $120.9 million for the year ended December 31, 2000 from $70.8 million for the year ended December 31, 1999. The increase in fees from tissue distribution was due largely to an increase of $37.6 million in revenues from the distribution of our spinal allografts. Additional increases in tissue revenue were due to an increase of $5.8 million from the distribution of other precision tooled allografts, and an increase of $6.7 million from the distribution of other processed tissue. Other processed tissue revenues increased due to our not having assumed UFTB's conventional tissue distribution business until April 1999, the acquisition of Georgia Tissue Bank in November 1999, the acquisition of Alabama Tissue Center in August 2000, and the expansion of our conventional tissue business to a broader geographic range during 2000. We also expanded our conventional tissue business internationally, by adding new international distributors in Europe and Asia during the year 2000. Other revenues from core operations, which consist of tissue processing fees, biomedical laboratory fees, soft tissue recovery fees and manufacturing royalties, decreased by $600,000 to $1.6 million for the year ended December 31, 2000 from $2.2 million for the year ended December 31, 1999. This decrease was due primarily to our not receiving any processing fees from UFTB as a result of our assumption of their conventional tissue distribution business in April 1999, rather than continuing to process UFTB's conventional tissue for a fee.

Management Services Fees. Management services fees increased by $24.6 million, or 61.5%, to $64.6 million for the year ended December 31, 2000 from $40.0 million for the year ended December 31, 1999. The increase in the absolute amount of these fees was due to the greater revenues generated through the management services of MSD. As a percentage of total revenues, however, these fees decreased from 54.8% for the year ended December 31, 1999 to 52.7% for the year ended December 31, 2000. This decrease in management services fees as a percentage of total revenues was attributable to the management services fees payable by us on certain of our allografts being 70% of revenues derived from distribution of allografts for which MSD provides management services for the full year of 2000 compared to 80% during a portion of 1999. In addition, an increase in distribution of our non-spinal, non-Osteofil® allografts, for which we do not pay management services fees, contributed to the reduction in management services fees as a percentage of total fees.

Net Revenues. Our net revenues increased by $24.9 million, or 75.5%, to $57.9 million for the year ended December 31, 2000 from $33.0 million for the year ended December 31, 1999. As a percentage of total revenues, our net revenues increased from 45.2% for the year ended December 31, 1999 to 47.3% for the year ended December 31, 2000. This increase in net revenues as a percentage of total revenues was due mainly to the impact of distribution of our non-spinal allografts, for which we do not pay management services fees, and the impact of our paying 80% of spinal revenues to Medtronic Sofamor Danek during a portion of 1999 while paying 70% of spinal revenues for the full year of 2000.

Costs of Processing and Distribution. Costs of processing and distribution increased by $10.0 million, or 47.2%, to $31.1 million for the year ended December 31, 2000 from $21.1 million for the year ended December 31, 1999. As a percentage of net revenues, however, these costs decreased from 63.9% for the year ended December 31, 1999 to 53.6% for the year ended December 31, 2000. This reduction was attributable primarily to improvements in processing efficiencies achieved through our introduction of automated processing machinery, as well as efficiencies associated with increased volume. In addition, the increase in our net revenues due to reduced management services fees payable by us also resulted in a reduction of the percentage of our net revenues attributable to costs of processing and distribution.

Marketing, General and Administrative Expenses. Marketing, general and administrative expenses increased by $9.9 million, or 126.1%, to $17.7 million for the year ended December 31, 2000 from $7.8 million for the year ended December 31, 1999. Contributing to this increase was an increase of $3.1 million in administrative payroll expenses to support the growth of our business, as well as an increase of $1.4 million in marketing and direct distribution payroll expense. Other cost increases included an increase in distributor commissions, primarily on conventional tissue, of $2.2 million, and increased depreciation expense of $800,000 for new equipment and the corporate buildings purchased on March 30, 2000. The acquisition of Georgia Tissue Bank in November 1999 contributed $600,000 and the acquisition of Alabama Tissue Center in August 2000 contributed $400,000 to the overall increase in marketing, general and administrative expenses. As a percentage of net revenues, marketing, general and administrative expenses increased from 23.7% for the year ended December 31, 1999 to 30.5% for the year ended December 31, 2000.

Research and Development Expenses. Research and development expenses increased by $0.7 million, or 41.2%, to $2.4 million for the year ended December 31, 2000 from $1.7 million for the year ended December 31, 1999. This increase was due largely to our hiring additional personnel to develop new allografts and technologies. As a percentage of net revenues, research and development expenses decreased from 5.2% for the year ended December 31, 1999 to 4.1% for the year ended December 31, 2000. This decrease was due to our net revenues rising without a commensurate increase in research and development expenses.

Interest Income and Expense—Net. Net interest income for the year ended December 31, 2000 was $800,000 compared to net interest expense of $100,000 for the year ended December 31, 1999. Interest expense of $400,000 incurred due to usage of our line of credit and payments on capital leases during the year 2000 was offset by $1.2 million in interest income due to the investment of cash in excess of immediate requirements after our public offering.

Income Tax Benefit (Expense). Income tax expense for the year ended December 31, 2000 was $3.1 million versus an income tax benefit of $600,000 for the year ended December 31, 1999. In 1998 we recorded a valuation allowance with respect to a deferred tax asset since we believed at the time that it was unlikely to be realized. In 1999, as a result of achieving positive net income for that year, this valuation allowance was reversed, resulting in the income tax benefit reported for 1999. As a result of having positive net income for the year ended December 31, 2000, we recorded an income tax expense.

Liquidity and Capital Resources

Our net cash used in operating activities was $4.4 million for the twelve months ended December 31, 2001 compared to net cash used in operating activities of $9.2 million for the twelve months ended December 31, 2000, a decrease of $4.8 million. During the twelve months ended December 31, 2001, primary uses of cash were an increase of product and supply inventories of $5.8 million, net loss of $5.5 million, and deferred income taxes of $2.6 million. Non-cash expenses for the year included bad debt expense of $6.2 million, depreciation and amortization of $2.6 million, and accrued expenses of $1.3 million. The additional bad debt reserves we recorded for the year ending December 31, 2001 resulted from several of our outstanding invoices becoming the subject of dispute during December 2001.

Our net cash used in investing activities increased by $18.1 from $10.3 million for the twelve months ended December 31, 2000 to $28.4 million for the twelve months ended December 31, 2001. On June 7, 2000, we started construction of new manufacturing and administrative buildings on land purchased on March 30, 2000. Costs of constructing and equipping the new facilities, along with continued equipment purchases to support our staff and automation efforts, contributed to this increased use of cash. Cash used for construction in process for the twelve months ended December 31, 2001 was $19.2 million, compared to $2.2 million for the twelve months ended December 31, 2000. During the twelve months ended December 31, 2001, $5.3 million was used for an investment in preferred stock and warrants to purchase common stock issued by Organ Recovery Systems, Inc., or ORS, a privately held company organized for the purpose of advancing organ transplantation technology.

Net cash provided by financing activities for the twelve months ended December 31, 2001 was $11.4 million, compared to $47.0 million for the twelve months ended December 31, 2000, a decrease of $35.6 million. Net proceeds from the public offering or our stock in August 2000 totaled $48.0 million. Advances under our construction loan facility described below totaled $12.8 million during 2001. We did not borrow any funds under this facility in 2000. We did not borrow any funds under our line of credit facility during 2001, compared to $2.8 million borrowed under this facility during 2000.

On April 13, 2001, our line of credit facility with the Bank was increased to $10.0 million. Until recently, this line of credit facility permitted us to borrow funds on a revolving basis, collateralized by revenues and current and intangible assets. The facility was due to expire in May 2002. As of December 31, 2001, no balance was outstanding under this facility. We also have a $16.0 million construction loan facility with the Bank of which $12.8 million presently is outstanding.

During the fourth quarter of 2001, our gross profit declined to $4.1 million compared to $8.6 million for the prior quarter, while at the same time our expenses for the quarter increased. We were not in compliance at December 31, 2001 with certain covenants including financial ratio covenants required by the line of credit facility, the construction loan agreement and the term loan agreement with the Bank. In February 2002, the Bank notified us that we could no longer borrow funds under the line of cedit facility and that the bank would not make further advances under the construction loan agreement. Effective April 8, 2002, at our request, the bank cancelled the line of credit facility. At the same time, the bank waived compliance with the loan covenants including the financial ratio covenants for the three loans through September 30, 2002. At that time, the outstanding principal and interest, presently $15.3 million, under the construction loan and the term loan will be due and payable. In addition, if the construction loan and the term loan have not been repaid by July 31, 2002, the interest rates on these loans will increase by an additional 1.5%.

We are pursuing alternative sources of financing and intend to refinance this indebtedness. However, if such refinancing does not occur prior to September 30, 2002, we intend to repay the loans from funds available from operations and from our working capital. As of December 31, 2001, our current assets consisting of cash, accounts receivable and inventories exceeded our current liabilities, including the $15.3 million of indebtedness described above, by $17.6 million. As of March 29, 2002, this figure was $13.2 million (unaudited). In addition, we have initiated targeted cost reductions in implementing our operating plan for 2002. As part of these efforts, we are in the process of renegotiating our management services agreement services agreement with Medtronic Sofamor Danek. It is our intention to renegotiate terms that are more favorable to us than the current terms. We believe our current working capital, our current working capital, our refinancing plans, and the cash we generate through our planned cost reductions and our continuing operations will be sufficient to meet our liquidity and capital needs for the next twelve months, including the repayment of the amounts we owe under our current credit facilities. However. there can be no assurance that we will succeed in accomplishing these plans. If a refinancing cannot be arranged, if we are not able to negotiate more favorable terms under our agreements with Medronic Sofamor Danek, or if our operating performance is lower than we project, the availability of cash could be strained by the end of the third quarter. For a more complete discussion of the risks to us if these events do not occur, please see "Business—Risk Factors—We are required to refinance or otherwise repay amounts we owe under our loan facilities within the next six months."

We have revised our previously reported estimates of the total cost of constructing and equipping the new facilities described above from $31.0 million to $35.1 million due to an increase in the scope of the project, as well as design changes to specialized operating equipment which require facility modifications. Of the estimated cost, $21.5 million has been incurred to date, of which $12.8 million was obtained under a construction loan facility from the Bank of America. We intend to finance the remaining costs with $11.7 million of the proceeds from our initial public offering, and $10.6 million through a combination of additional bank financing, capital leases and funds from continuing operations. As discussed above, we were advised by our current lender that we will not be permitted to borrow new funds under our construction facility and that we are required to repay amounts that we owe lender within the next six months. These circumstances could make it difficult to obtain the funds we need to complete this construction project, particularly if we are not able to refinance our existing indebtedness or repay it with funds from continuing operations. Any inability to complete this project could result in the interruption of our business plan and result in additional expense. For a more complete discussion of the risks to us relating to this repayment obligation, please see "Business—Risk Factors—We are required to refinance or otherwise repay amounts we owe under our loan facilities within the next six months."

We have revised our previously reported estimates of the total cost of constructing and equipping the new facilities described above from $31.0 million to $35.1 million due to an increase in the scope of the project, as well as design changes to specialized operating equipment which require facility modifications. Of the estimated cost, $21.5 million has been incurred to date, of which $12.8 million was obtained under a construction loan facility from the Bank of America. We intend to finance the remaining costs with $11.7 million of the proceeds from our initial public offering, and $10.6 million through a combination of additional bank financing, capital leases and funds from continuing operations.

As part of our purchase of shares of preferred stock and warrants issued by ORS described above, we entered into a strategic business agreement with ORS under which we and ORS have agreed to jointly establish three organ perfusion service centers in markets to be designated by us. As part of this agreement, we have agreed to pay all reasonable costs to establish and equip the three organ perfusion centers to specifications provided by ORS. As of December 31, 2001, we had not funded any part of this commitment.

As of December 31, 2001, we had $13.5 million of available cash and cash equivalents. As of March 29, 2002, our available cash and cash equivalents was $7.1 million. We are in the process of identifying and implementing various cost reduction opportunities. We believe that working capital as of December 31, 2001 along with working capital we anticipate for 2002 will be adequate to fund operations over the next 12 months. If we are not successful in doing so, it would disrupt our business and have a material adverse effect on our financial condition.

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 balanced mix of debt maturities along with fixed-rate debt, variable-rate debt and derivative financial instruments (interest rate swaps) 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 2002. However, we cannot assure that interest rates will not significantly change in 2002. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Our interest rate swap arrangements involve the exchange of variable interest rate payments, based on the 30-day LIBOR plus 1.5%, without exchanging the notional principal amount. Payments or receipts on the agreement are recorded as adjustments to interest expense.

At December 31, 2001, we had an outstanding swap agreement, maturing March 30, 2005, with a notional amount of $2.6 million. Under the agreement we receive a fixed interest rate of 8.35%. The interest will remain fixed until the 30-day LIBOR is determined to be greater than or equal to 8%, at which time the interest rate will revert to the 30 day LIBOR plus 1.5%. The counter party to this swap arrangement is a major financial institution.

The fair value of this interest rate swap agreement represents the estimated receipt or payment that would be made to terminate the agreement. At December 31, 2001, we would have paid approximately $189,000 to terminate the agreement. An increase of 1.0% in the yield curve would not result in an increased penalty to us as LIBOR would still be less than 8% and our interest rate would still be equal to 8.35%.

At December 31, 2001, we had an outstanding swap agreement maturing April 2, 2007, with a notional amount of $16 million. Under the agreement, we receive a fixed interest rate of 7.49%. The interest will remain fixed until the 30-day LIBOR is determined to be greater than or equal to 8%, at which time the interest rate will revert to the 30 day LIBOR plus 1.5%. The counter party to this swap arrangement is a major financial institution. At December 31, 2001, we would have paid approximately $574,000 to terminate this agreement. An increase of 1.0% in the yield curve would not result in an increased penalty to us as LIBOR would still be less than 8% and our interest rate would still be equal to 7.49%.

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 14(a)(1).

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

Not applicable.

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 2002 Annual Meeting of Stockholders is incorporated by reference.

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 2002 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 2002 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 2002 Annual Meeting of Stockholders is incorporated by reference.

PART IV

Item 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULE AND REPORTS ON FORM 8-K.

(a) (1) *Financial Statements*:

See "Index to Consolidated Financial Statements and Financial Statement Schedule" on page F-1, the Independent Auditors' Report on page F-2 and the Consolidated Financial Statements on pages F-3 to F-28, all of which are incorporated herein by reference.

(2) *Financial Statement Schedule*:

The Independent Auditors' Report and consolidated financial statement schedule is filed as part of this Report:

Schedule II, Valuation and Qualifying Accounts for the years ended December 31, 2001, 2000 and 1999.

(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]
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	Management Services Agreement between Regeneration Technologies, Inc., as successor in interest to the University of Florida Tissue Bank, Inc. and Sofamor Danek Group, dated July 23, 1996.[1]†
10.6	Management Services Agreement between Regeneration Technologies, Inc., as successor in interest to the University of Florida Tissue Bank, Inc., and Sofamor Danek Group, dated May 11, 1998.[1]†
10.7	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]
10.8	Purchase Contract between Regeneration Technologies, Inc. and Echelon International Corp., dated January 31, 2000, as amended.[1]

10.9 Lease between Echelon International Corp. and Regeneration Technologies, Inc., dated February 4, 2000.[1]

10.10 Sublease between Regeneration Technologies, Inc. and the University of Florida Tissue Bank, Inc., dated February 12, 1998.[1]

10.11 Lease between Regeneration Technologies, Inc. and First Street Group L.C., dated June 14, 1999.[1]

10.12 Lease agreement between Georgia Tissue Bank Inc. and Charles P. Garrison, dated November 1, 1999.[1]

10.13 Employment Agreements between Regeneration Technologies, Inc. and James M. Grooms, dated February 9, 1998.[1] *

10.14 Employment Agreements between Regeneration Technologies, Inc. and Richard R. Allen, dated February 13, 1998.[1] *

10.15 Employment Agreements between Regeneration Technologies, Inc. and Frederick C. Preiss, dated November 25, 1998.[1] *

10.16 Employment Agreements between Regeneration Technologies, Inc. and Thomas Brewer, dated June 15, 1998.[1] *

10.17 Employment Agreements between Regeneration Technologies, Inc. and James P. Abraham, dated November 28, 1998.[1] *

10.18 Employment Agreements between Regeneration Technologies, Inc. and Nancy R. Holland, dated February 13, 1998.[1] *

10.19 Omnibus Stock Option Plan.[1] *

10.20 Year 2000 Compensation Plan.[1] *

10.21 Form of Indemnification Agreement between Regeneration Technologies, Inc. and its directors and executive officers.[1]

10.22 Line of Credit Agreement, dated September 1999.[1]

10.23 Mortgage between Regeneration Technologies, Inc. and Bank of America, N.A., dated March 30, 2000.[1]

10.24 Promissory Note between Regeneration Technologies, Inc. and Bank of America, N.A., dated March 30, 2000.[1]

10.25 Management Services Agreement between Regeneration Technologies, Inc. and Allograft Resources of Wisconsin, Inc., dated June 15, 1998.[1]†

10.26 Shaft Recovery and Service Reimbursement Agreement between Regeneration Technologies, Inc. and Tutogen Medical, Inc., dated September 29, 1998.[1]†

10.27 Employment Agreement between Regeneration Technologies, Inc. and David R. Bilyeu, dated September 19, 2000.[2] *

10.28 Amendment to Exhibit 10.6, Second Amendment to Management Services Agreement, Bone Paste, between Regeneration Technologies, Inc., as successor in interest to the University of Florida Tissue Bank, Inc., and Sofamor Danek Group, dated September 15, 2000.[2]

10.29 Construction Loan Agreement by and between Regeneration Technologies, Inc. and Bank of America, N.A., dated April 2, 2001.[3]

10.30	Promissory Note between Regeneration Technologies, Inc. and Bank of America, N.A., dated April 2, 2001.[3]
10.31	Loan Agreement by and between Regeneration Technologies, Inc. and Bank of America, N.A., dated as of April 17, 2001.[3]
10.32	Security Agreement by and between Regeneration Technologies, Inc. and Bank of America, N.A., dated April 17, 2001.[3]
10.33	Renewal Promissory Note between Regeneration Technologies, Inc. and Bank of America, N.A., dated April 17, 2001.[3]
10.34	Tax Indemnity Agreement by and between Regeneration Technologies, Inc. and Bank of America, N.A., dated April 17, 2001.[3]
10.35	Amendment to Exhibit 10.5, Amendment to Management Services Agreement by and between Regeneration Technologies, Inc. and Medtronic Sofamor Danek, dated September 18, 2001.[4]
10.36	Employment Agreement between Regeneration Technologies, Inc. and Brian K. Hutchison, dated November 30, 2001. *
10.37	Incentive Stock Option Grant Agreement between Regeneration Technologies, Inc. and Brian K. Hutchison, dated December 3, 2001. *
10.38	Forbearance Agreement by and between Regeneration Technologies, Inc. and Bank of America N.A., dated April 8, 2002.
21	Subsidiaries of the Registrant.
23.1	Independent Auditors' Consent.

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1 Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-35756).

2 Incorporated by reference to our Company's Annual Report on Form 10-K for the year ended December 31, 2000.

3 Incorporated by reference our Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

4 Incorporated by reference our Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.

† 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.

* Employment contract or compensatory plan or arrangement

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

No reports on Form 8-K have been filed during the last quarter of the period covered by this report.

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying consolidated balance sheets of Regeneration Technologies, Inc. and subsidiaries (the "Company") as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity (deficiency), and cash flows for each of the three years in the period ended December 31, 2001. 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, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP
Certified Public Accountants

Orlando, Florida
April 8, 2002

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Consolidated Balance Sheets
(In thousands, except share data)

	December 31, 2001	December 31, 2000
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,504	$ 34,944
Accounts receivable—less allowances of $6,890 in 2001 and $1,114 in 2000	21,695	27,272
Product inventories	28,150	22,036
Supply inventories	1,133	1,406
Prepaid and other current assets	3,523	2,077
Deferred tax asset	5,416	1,290
Total current assets	73,421	89,025
Property, plant and equipment—net	36,122	14,787
Goodwill—net	2,613	2,810
Deferred tax assets	—	1,177
Investment in ORS	5,250	—
Other assets—net	1,294	753
	$118,700	$108,552
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 22,038	$ 22,436
Accrued expenses	7,365	4,767
Current portion of deferred revenue	297	265
Construction loan	12,790	—
Current portion of long-term debt	3,243	1,217
Due to SETA	—	4
Total current liabilities	45,733	28,689
Long-term debt—less current portion	658	3,684
Deferred tax liabilities	27	—
Derivative liabilities	763	—
Deferred revenue	3,735	3,703
Total liabilities	50,916	36,076
Commitments and contingencies (Notes 17, 19 and 23)		
Stockholders' equity:		
Common stock, $.001 par value: 50,000,000 shares authorized; 22,058,695 and 21,686,962 shares issued, respectively; and 21,927,319 and 21,556,066 shares outstanding, respectively	22	22
Additional paid-in capital	72,166	71,552
(Accumulated deficit) retained earnings	(2,228)	3,277
Accumulated other comprehensive loss	(443)	—
Deferred stock-based compensation	(1,719)	(2,363)
Less treasury stock, 131,376 and 130,896 shares, respectively	(14)	(14)
Total stockholders' equity	67,784	72,476
	$118,700	$108,552

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,		
	2001	2000	1999
Revenues from core operations:			
Fees from tissue distribution	$ 138,762	$ 120,905	$ 70,783
Other revenues from core operations	1,964	1,598	2,237
Total revenues	140,726	122,503	73,020
Management services fees	73,176	64,572	39,994
Net revenues	67,550	57,931	33,026
Costs of processing and distribution	39,455	31,063	21,096
Gross profit	28,095	26,868	11,930
Expenses:			
Marketing, general and administrative	35,962	17,674	7,816
Research and development	2,631	2,392	1,675
Total expenses	38,593	20,066	9,491
Operating (loss) income	(10,498)	6,802	2,439
Equity in income of unconsolidated subsidiary	—	1	—
Interest (expense) income:			
Interest expense	(106)	(434)	(285)
Interest income	1,313	1,207	187
Total interest income (expense)—net	1,207	773	(98)
(Loss) income before income tax benefit (expense)	(9,291)	7,576	2,341
Income tax benefit (expense)	3,786	(3,117)	619
Net (loss) income	(5,505)	4,459	2,960
Other comprehensive loss, net of tax—			
Unrealized derivative loss	(344)	—	—
Comprehensive (loss) income	$ (5,849)	$ 4,459	$ 2,960
Net (loss) income per common share—basic	$ (0.25)	$ 0.42	$ 0.81
Net (loss) income per common share—diluted	$ (0.25)	$ 0.22	$ 0.18
Weighted average shares outstanding—basic	21,760,596	10,639,884	3,669,970
Weighted average shares outstanding—diluted	21,760,596	20,343,214	16,636,791

See notes to consolidated financial statements.

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity (Deficiency)
(In thousands)

	Preferred Stock A	Preferred Stock B	Preferred Stock C	Common Stock	Additional Paid-in Capital	(Accumulated Deficit) Retained Earnings	Deferred Stock-based Compensation	Note Receivable from Stockholder	Due from Stockholder-net of due to Stockholder	Accumulated Other Comprehensive Loss	Treasury Stock	Total
Balance, December 31, 1998	$ 2	$6,580	$ —	$ 4	$ 457	$(4,142)	$ (531)	$(2,137)	$(1,659)	$ —	$ (5)	$(1,431)
Purchased and forfeited treasury stock	—	—	—	—	—	—	1	—	—	—	(1)	—
Stock options granted in lieu of director and consulting fees	—	—	—	—	20	—	—	—	—	—	—	20
Settlement of amounts due from SETA by transfer of assets	—	—	—	—	—	—	—	2,137	983	—	—	3,120
Amounts advanced to SETA	—	—	—	—	—	—	—	—	(7,404)	—	—	(7,404)
Payments received from SETA	—	—	—	—	—	—	—	—	8,076	—	—	8,076
Sale of Series C Preferred stock	—	—	10,000	—	—	—	—	—	—	—	—	10,000
Stock issuance costs	—	—	—	—	(33)	—	—	—	—	—	—	(33)
Vested deferred compensation	—	—	—	—	—	—	130	—	—	—	—	130
Net income	—	—	—	—	—	2,960	—	—	—	—	—	2,960
Balance, December 31, 1999	2	6,580	10,000	4	444	(1,182)	(400)	—	(4)	—	(6)	15,438
Issuance of common stock options	—	—	—	—	2,774	—	(2,774)	—	—	—	—	—
Issuance of common stock in initial public offering	—	—	—	4	49,471	—	—	—	—	—	—	49,475
Issuance of common stock for the purchase of Alabama Tissue Center	—	—	—	—	3,500	—	—	—	—	—	—	3,500
Conversion of preferred stock to common stock	(2)	(6,580)	(10,000)	14	16,568	—	—	—	—	—	—	—
Purchased and forfeited treasury stock	—	—	—	—	(3)	—	8	—	—	—	(8)	(3)
Conversion of note payable to common stock (Note 18)	—	—	—	—	250	—	—	—	—	—	—	250
Amounts advanced to stockholder	—	—	—	—	—	—	—	—	(5,837)	—	—	(5,837)
Payments received from stockholder	—	—	—	—	—	—	—	—	5,841	—	—	5,841
Stock issuance costs	—	—	—	—	(1,450)	—	—	—	—	—	—	(1,450)
Vested deferred compensation	—	—	—	—	—	—	803	—	—	—	—	803
Net income	—	—	—	—	—	4,459	—	—	—	—	—	4,459
Balance, December 31, 2000	—	—	—	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 loss	—	—	—	—	—	—	—	—	—	(443)	—	(443)
Net loss	—	—	—	—	—	(5,505)	—	—	—	—	—	(5,505)
Balance, December 31, 2001	$—	$ —	$ —	$ 22	$72,166	$(2,228)	$(1,719)	$ —	$ —	$(443)	$(14)	$67,784

See notes to consolidated financial statements.

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2001	2000	1999
Cash flows from operating activities:			
Net (loss) income	$ (5,505)	$ 4,459	$ 2,960
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization expense	2,630	1,674	801
Bad debt expense	6,221	566	171
Provision for inventory obsolescence	2,394	891	527
Provision for product returns	357	411	353
Amortization of deferred revenue	(286)	(225)	(225)
Deferred income tax benefit	(2,602)	(489)	(1,760)
Deferred stock-based compensation and nonqualified option expense	1,123	815	152
Loss on disposal of property, plant and equipment	—	—	5
Changes in assets and liabilities—cash provided by (used in):			
Accounts receivable	(1,001)	(12,690)	(9,417)
Product and supply inventories	(8,235)	(7,407)	(7,243)
Prepaid and other current assets	(510)	(472)	(240)
Other assets	(593)	(466)	(230)
Accounts payable	(398)	968	7,038
Accrued expenses	1,661	2,712	673
Deferred revenue	350	40	—
Other liabilities	—	—	(40)
Net cash used in operating activities	(4,394)	(9,213)	(6,475)
Cash flows from investing activities:			
Cash paid for purchase of assets, net of cash received	—	(267)	(485)
Purchase of property, plant and equipment	(23,183)	(10,078)	(2,381)
Investment in Organ Recovery Systems, Inc.	(5,250)	—	—
Net cash used in investing activities	(28,433)	(10,345)	(2,866)
Cash flows from financing activities:			
Proceeds from stock offering, net of offering costs	—	48,025	—
Stock issuance costs	(22)	—	—
Proceeds from exercise of stock options	155	—	—
Proceeds from mortgage obligation	—	2,800	—
Advances under construction loan	12,790	—	—
Payments on capital lease and note obligations	(1,532)	(1,062)	(473)
Amounts advanced to stockholder	(4)	(5,837)	(7,404)
Payments received from stockholder	—	5,845	8,076
Line of credit borrowings (payments)—net	—	(2,787)	2,787
Purchase of treasury stock	—	(18)	(2)
Proceeds from sales of Preferred C stock—net of issuance costs	—	—	9,967
Net cash provided by financing activities	11,387	46,966	12,951
Net (decrease) increase in cash and cash equivalents	(21,440)	27,408	3,610
Cash and cash equivalents, beginning of period	34,944	7,536	3,926
Cash and cash equivalents, end of period	$ 13,504	$ 34,944	$ 7,536

See notes to consolidated financial statements.

(In thousands, except share and per share data)

1. Organization

Regeneration Technologies, Inc. ("RTI"), was incorporated in Florida on August 22, 1997, and began operations on February 12, 1998, following a contribution of assets to RTI by the University of Florida Tissue Bank, Inc. ("UFTB"). At the time of the separation, UFTB contributed certain assets (including certain intellectual property) to RTI and RTI assumed certain related liabilities in exchange for 1,200,000 shares of Series A Preferred stock (see Note 14). In addition, an officer of UFTB contributed his royalty rights in certain intellectual property to RTI in exchange for 577,348 shares of Series A Preferred stock. RTI recorded the assets acquired and the liabilities assumed from UFTB and the assets acquired from the officer of UFTB at their historical cost basis as these were deemed to be transactions between entities under common control. As such, the $39 of net liabilities assumed resulted in a charge to additional paid-in capital. The historical costs of the individual assets acquired and liabilities assumed by RTI at the date of the separation from UFTB are presented below:

Accounts receivable	$ 3,536
Inventories and supplies	1,274
Prepaid expenses	106
Property, plant and equipment	1,733
Intangible assets	50
Accounts payable	(5,529)
Capital lease obligations	(1,209)
Net liabilities assumed	$ (39)

Simultaneous with the separation of RTI from UFTB, certain third parties invested $6,580 in exchange for 748,152 shares of Series B Preferred stock.

During 1999, RTI's wholly owned subsidiary, Georgia Tissue Bank ("GTB"), acquired the net assets of the National Tissue Bank Network, Georgia Tissue Bank, Inc. ("NTBN") along with certain equipment owned by a director of NTBN (see Note 8).

On August 21, 2000, RTI acquired substantially all of the existing assets and liabilities of a division of the University of Alabama Health Services Foundation ("UAHSF"), which had been doing business as the Alabama Tissue Center ("ATC") in Birmingham, Alabama (see Note 8).

On February 6, 2001 RTI formed Biological Recovery Group ("BRG"). BRG functions as a wholly owned subsidiary of RTI, focusing on bringing advances in technology to the recovery of tissues nationwide.

On February 15, 2001, the University of Florida Tissue Bank ("UFTB") changed its name to Southeast Tissue Alliance ("SETA").

RTI has established RTI Devices, Inc. ("RTIDI") for the development and commercialization of products which may be regulated as devices by the FDA. To date, RTIDI has not been active in generating income or expense and holds no assets or liabilities.

RTI, GTB, BRG, ATC, and RTIDI (collectively, the "Company") process human musculoskeletal 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, and bone paste grafts.

2. Business Operations and Liquidity

As described in Notes 9, 10 and 11, the Company was not in compliance at December 31, 2001 with certain covenants including financial ratio covenants required by the line of credit facility, the construction loan agreement and the term loan agreement with Bank of America, N.A. (the "Bank"). In February 2002, the Bank notified the Company that it could no longer borrow funds under the line of credit facility and that the Bank has no obligation to make further advances under the construction loan agreement. Effective April 8, 2002, the Bank cancelled the line of credit facility. However, the Bank did waive compliance with the loan covenants including the financial ratio covenants for the three loans through September 30, 2002, at which date the outstanding principal and interest under the construction loan and the term loan, which as of December 31, 2001 was $15,345, will be due and payable. If the construction loan and the term loan have not been repaid by July 31, 2002, the Bank will be entitled to an increase in the interest rates of 1.5%.

The Company is pursuing alternative sources of financing and intends to refinance this indebtedness. However, if such refinancing does not occur prior to September 30, 2002 the Company intends to repay the loans from funds available from operations and from the Company's working capital. As of December 31, 2001, the Company's current assets consisting of cash, accounts receivable and inventories exceeded the Company's current liabilities (including the loans of $15,345 above) by $17,616. As of March 29, 2002, the Company's comparable excess current assets totaled $13,213 (unaudited). In addition, management has initiated targeted cost reductions in implementing its operating plan for 2002. As part of these efforts, management is in the process of renegotiating its management services agreement with Medtronic Sofamor Danek. It is management's intent to renegotiate terms which are more favorable to the Company than the currently stated terms. Management believes its current working capital, its refinancing plans, and the cash generated through our planned cost reductions and our continuing operations will be sufficient to meet the Company's liquidity and capital needs for the next twelve months. However, there can be no assurance that management will succeed in accomplishing such plans. If refinancing cannot be arranged and if the Company's operating performance is lower than projected, the availability of cash could be strained by the third quarter of 2002.

3. Summary of Significant Accounting Policies

Principles of Consolidation—The consolidated financial statements include the accounts of RTI and its wholly owned subsidiaries GTB, BRG, ATC, and RTIDI (see Note 8). All intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents—The Company considers all funds in banks and overnight sweep accounts with an original maturity of three months or less to be cash and cash equivalents.

Product and Supply Inventories—Product and supply inventories are stated at the lower of cost or market, with cost determined by the first-in, first-out method. The Company estimates the amount of inventory that will not pass the quality control process based upon the Company's historical rejection percentages and, accordingly, records a valuation allowance against the cost of inventory. In addition, the cost of tissue in process which has not become implantable donor tissue within one year of processing is fully charged to the valuation allowance. Any inventory deemed to be obsolete is charged to the valuation allowance at the time the determination is made. In addition, the cost of items which have existed in implantable donor tissue inventory for a period longer than two years, or which are within one year of expiration, is charged to the valuation allowance.

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:

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

Software Development Costs—In March 1998, the AICPA issued Statement of Position No. 98-1, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use ("SOP 98-1"). SOP 98-1 states that for software obtained or developed for internal use, computer software costs that are incurred in the preliminary project stage should be expensed as incurred. Costs to develop internal use computer software during the application development stage should be capitalized under a fixed-asset model, as long as those costs meet certain predefined characteristics. SOP 98-1 also provides that these capitalized development costs should be amortized in a systematic and rational manner over the estimated useful life of the software. Training and maintenance costs incurred during the post-implementation operating stage should be expensed as incurred. The Company accounts for software development costs in accordance with SOP 98-1.

Goodwill—Goodwill is amortized on a straight-line basis over 15 years. Goodwill is reported net of accumulated amortization of $262 and $65 at December 31, 2001 and 2000, respectively.

Other Assets—Other assets primarily consist of patents and trademarks. 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 $85 and $40 at December 31, 2001 and 2000, respectively.

Research and Development Costs—Research and development costs are expensed as incurred. Research and development costs for the years ended December 31, 2001, 2000 and 1999 were $2,631, $2,392 and $1,675, respectively.

Revenue Recognition—On December 3, 1999, the staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements ("SAB 101"), that summarizes the staff's views in applying accounting principles generally accepted in the United States of America to revenue recognition in financial statements. The accounting and disclosure requirements that are described in SAB 101 apply to all registrants. The Company has conformed its revenue recognition policy to the requirements of SAB 101.

Revenue is recognized at the time the Company ships the processed tissue for implant or the tissue is transferred from the Company's consignment inventory locations for implant. Revenues are reported gross of any management services fees the Company incurs related to the distribution of its products. Any other revenues directly related to the Company's core operations 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. Historical product returns have been within the amounts reserved.

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

Income Taxes—The Company accounts for income taxes under the asset and liability approach specified by Statement of Financial Accounting Standards ("SFAS") No. 109, Accounting for Income Taxes. SFAS No. 109 requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns by applying enacted statutory rates applicable to future years to differences between financial statement carrying amounts and the tax basis of existing assets and liabilities.

Stock-Based Compensation Plans—In October 1995, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123, Accounting for Stock-Based Compensation, which is effective for fiscal years beginning after December 15, 1995. Under SFAS No. 123, the Company may elect to recognize stock-based compensation expense based on the fair value of the awards or to account for stock-based compensation under Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees, and disclose in the consolidated financial statements the effects of SFAS No. 123 as if the recognition provisions were adopted. The Company has adopted the recognition provisions of APB Opinion No. 25.

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 calculation of basic and diluted EPS is presented below:

	Year Ended December 31,		
	2001	2000	1999
Basic shares	21,760,596	10,639,884	3,669,970
Effect of dilutive securities:			
Stock options	—	1,253,005	475,522
Conversion of preferred stock	—	8,450,325	12,491,299
Diluted shares	21,760,596	20,343,214	16,636,791

Options to purchase approximately 3,354,600 shares of common stock at prices ranging from $1.30 to $14.95 per share were outstanding as of December 31, 2001 but were not included in the computation of diluted EPS for the year ended December 31, 2001 because SFAS No. 128, Earnings per Share, prohibits adjusting the denominator of diluted EPS for additional potential common shares when a loss from continuing operations is reported. Options to purchase approximately 820,752 shares of common stock at prices ranging from $11.75 to $14.00 per share were outstanding as of December 31, 2000 but were not included in the computation of diluted EPS for the year ended December 31, 2000 because the options' exercise prices were greater than the average market price of the common shares. Options to purchase approximately 576,283 shares of common stock at prices ranging from $3.80 to $5.65 per share were outstanding as of December 31, 1999 but were not included in the computation of diluted EPS for the year ended December 31, 1999 because the options' exercise prices were greater than the average market price of the common shares.

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 value of its property, plant and equipment and its intangible assets by comparing the carrying values to the estimated future undiscounted cash flows. A deficiency in these cash flows relative to the carrying amounts is an indication of the need for a write-down due to impairment. The impairment write-down would be the difference between the carrying amounts and the fair value of these assets. A loss on impairment would be recognized by a charge to earnings.

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.

New Accounting Standards—SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, is effective for all fiscal years beginning after June 15, 2000. SFAS No. 133, as amended, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. Under SFAS No. 133, certain contracts that were not formerly considered derivatives may now meet the definition of a derivative. The Company adopted SFAS No. 133 effective January 1, 2001. The Company uses certain derivatives and financial instruments in managing certain risks, including interest rate risks. The Company does not enter into derivatives or other financial instruments for trading or speculative purposes. Instruments include interest rate swaps that qualify for the "short cut" method of accounting under SFAS No. 133. Under the "short cut" method, the Company assumes no ineffectiveness in a hedging relationship. Since the structure of the interest rate swap will allow the use of the "short cut" method, there will be no need to measure effectiveness and there will be no charge to earnings for changes in fair value. All changes in fair value will be recorded as unrealized derivative income (loss) through other comprehensive income (loss). The Company did not incur any significant adverse impact on its interest rate risk management activities at December 31, 2001 in applying the "short cut" method.

On June 29, 2001, SFAS No. 141, Business Combinations, was approved by the FASB. SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. Goodwill and certain intangible assets will remain on the balance sheet and will not be amortized. 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. 141 on July 1, 2001 and has determined that there is no impact on its consolidated financial position or results of operations.

On June 29, 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 applicable intangible assets, including those recorded in past business combinations, will cease upon adoption of this statement. The Company is required to implement SFAS No. 142 on January 1, 2002. The Company expects that the effect of ceasing amortization of goodwill will increase net income by approximately $109 after tax, or $.01 per diluted share in 2002. The Company has not completed its assessment of the additional impact, if any, of adopting SFAS No. 142.

Early adoption and retroactive application of SFAS No. 141 or SFAS No. 142 is not permitted. However, any goodwill and any other intangible asset determined to have an indefinite useful life that is acquired in a business combination completed after June 30, 2001 will not be amortized. Goodwill and intangible assets acquired in business combinations completed before July 1, 2001 have continued to be amortized through December 31, 2001.

On October 3, 2001, SFAS No. 144, Accounting for the Impairment or Disposal of Long-lived Assets was approved by the FASB. SFAS No. 144 addresses the financial accounting and reporting of the impairment or

disposal of long-lived assets. This statement supercedes SFAS No. 121, Accounting for the Impairment of Long-lived Assets and will be effective January 1, 2002. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001. The Company does not expect the adoption of SFAS No. 144 to have a material effect on its consolidated financial statements.

Reclassifications—Certain amounts in the 2000 and 1999 consolidated financial statements, as previously reported, have been reclassified to conform to the 2001 presentation. In particular, the Company began reclassifying depreciation, insurance, rent, utilities and royalty expenses previously reported at marketing, general and administrative expenses to costs of processing and distribution in the fourth quarter of 2001.

4. Product Inventories

Product inventories by stage of completion are as follows:

	December 31,	
	2001	2000
Unprocessed donor tissue	$ 4,867	$ 2,743
Tissue in process	13,117	8,657
Implantable donor tissue	10,067	10,509
Non-tissue inventory for resale	99	127
	$28,150	$22,036

5. Property, Plant and Equipment

Property, plant and equipment are as follows:

	December 31,	
	2001	2000
Land	$ 850	$ 850
Building and improvements	3,613	3,613
Construction in process	21,452	2,210
Production equipment	6,007	4,870
Leasehold improvements	827	784
Office equipment, furniture and fixtures	744	649
Computer hardware and software	5,001	2,366
Equipment under capital leases	2,644	2,112
	41,138	17,454
Less accumulated depreciation and amortization	5,016	2,667
	$36,122	$14,787

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. Total interest cost for the years ended December 31, 2001, 2000 and 1999 was $662, $507 and $285, and of that $556, $73 and $0 was capitalized to construction in process, respectively. Construction in process includes $629 and $73 in capitalized interest costs at December 31, 2001 and 2000, respectively.

As of December 31, 2001, authorized expenditures on the remaining construction of the new manufacturing facilities totaled approximately $13.6 million. That total has been contractually committed.

6. Investment in ORS

On November 2, 2001 the Company purchased 1,285,347 shares of 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 purchase was paid for in cash and recorded at a total cost of $5,250.

The Company entered into a strategic business agreement with ORS on November 2, 2001 whereby the Company and ORS have agreed to jointly establish three organ perfusion service centers in markets to be designated by the Company. As part of this agreement, the Company has agreed to pay all reasonable costs to establish and equip the three organ perfusion centers to specifications provided by ORS and to lease any equipment used to ORS for $1.00 (one dollar) per year. As of December 31, 2001, the Company had not funded any part of this commitment. As part of this strategic business agreement, ORS issued a warrant to the Company to acquire 390,000 shares of ORS's common stock. The warrant is exercisable for 10 years at an exercise price per share of $3.89, subject to adjustments as provided for in the warrant.

7. Other Assets

Other assets are as follows:

	December 31,	
	2001	2000
Patents and trademarks	$1,028	$632
Construction loan costs	199	—
Other	152	161
	1,379	793
Less accumulated amortization	85	40
	$1,294	$753

Patents and trademarks are amortized on the straight-line method over the shorter of the remaining protection period or estimated useful life.

8. Asset Purchases

On November 1, 1999, GTB acquired the assets and existing liabilities of NTBN and certain equipment owned by Dr. Charles Garrison, a director of NTBN. The purpose of the transaction was to expand the Company's ability to produce conventional tissue grafts and expand donor recovery and tissue distribution in areas outside of the Company's existing network for donor recovery and tissue distribution.

The acquisition was recorded under the purchase method of accounting and, accordingly, the purchase price was allocated to the assets and liabilities on the basis of estimated fair market value on the date of purchase. The fair value of the assets and liabilities at the date of acquisition recorded in conjunction with the transaction is as follows:

Accounts receivable	$ 359
Inventories	2,130
Property, plant and equipment	3
Accounts payable	(375)
Accrued liabilities	(382)
Net assets acquired, excluding cash	1,735
Cash	15
Net assets acquired	$1,750
Purchase financed by:	
Cash payment	$ 500
Notes payable—stated rate of 6.50% due November 2002 (effective rate of 9.25%)	681
Note payable—9.25% due November 2002 convertible to common stock (see Note 14)	500
Note payable—9.25% due November 2002	69
Total financing	$1,750

On August 21, 2000, RTI acquired substantially all of the existing assets and liabilities of a division of the University of Alabama Health Services Foundation ("UAHSF"), which had been doing business as the Alabama Tissue Center ("ATC") in Birmingham, Alabama. The acquisition was financed by a cash payment of $250 and the issuance of $3,500 in shares of the Company's common stock, valued at the Company's initial public offering price of $14.00 per share. The Company may be required to make an additional cash payment of $250 upon the achievement of certain milestones prior to December 31, 2004. The total initial consideration of $3,750 plus legal fees associated with the transaction amounted to a total initial investment of $3,767. The purpose of the transaction was to expand the business of RTI into the use of cryopreservation technology for cardiovascular tissue.

The acquisition was recorded under the purchase method of accounting and, accordingly, the purchase price was allocated to the assets and liabilities on the basis of estimated fair market value on the date of purchase. The acquisition resulted in an excess of cost over the fair value of net assets acquired equal to $2,875 which has been accounted for as goodwill.

The fair value of the assets and liabilities at the date of acquisition recorded in conjunction with the transaction is as follows:

Inventories	$ 695
Property, plant and equipment	228
Goodwill	2,875
Accrued liabilities	(31)
Net assets acquired	$3,767
Purchase financed by:	
250,000 shares of RTI common stock at public offering price of $14.00 per share	$3,500
Cash payment to UAHSF	250
Cash paid for legal fees	17
Total financing	$3,767

The unaudited pro forma results assuming GTB and ATC had been acquired on January 1, 1999, including pro forma adjustments for amortization of goodwill and income taxes, are approximately as follows:

	Year Ended December 31,	
	2000	1999
Total revenues	$123,800	$78,800
Net income	4,300	2,900
Net income per share—diluted	$ 0.21	$ 0.17

9. Line of Credit

In March 1999, the Company entered into a revolving line of credit facility with the Bank for an amount not to exceed $2,000 expiring in March 2000. This line of credit was subsequently replaced in September 1999 with a new line not to exceed $6,000 expiring in September 2000. On April 13, 2001 the line of credit facility was increased to $10.0 million. The line of credit facility permits the Company to borrow on a revolving basis. This facility is secured by the Company's accounts receivable, inventories, cash and cash equivalents, certain general intangibles (excluding copyrights, trademarks, trade names and service marks) and goodwill, revenues, income and receipts. This facility is scheduled to expire in May 2002. As of December 31, 2001, the Company had available borrowing capacity of $10.0 million and carried no balance under this facility. The line of credit is to be utilized for the purpose of supporting accounts receivable. The interest rate associated with this line of credit is the 30-day LIBOR rate plus 1.5%. At December 31, 2001, the interest rate of the line of credit was 3.93%. No balance was outstanding on this line of credit on December 31, 2001 or 2000.

The line of credit agreement contains various restrictive covenants, which limit among other things, the Company's ability to incur indebtedness, make loans, make acquisitions, pay dividends and make stock purchases. In addition, the Company must satisfy certain financial ratios, including a debt service coverage ratio

greater than or equal to 1.35 to 1.00, and funded debt to earnings before interest, taxes, depreciation and amortization ratio of not greater than 3.00 to 1.00. The Company was not in compliance at December 31, 2001 with certain covenants and financial ratios contained in the line of credit facility. Accordingly, in February 2002 the Bank notified the Company that that the Company's right to borrow under the line of credit facility is terminated. The Bank waived compliance with these covenants, subject to certain conditions set forth in the Forbearance Agreement dated April 8, 2002, through September 30, 2002. At that time, if the Company has not paid off all of its debt to the Bank, the Bank will have the right to foreclose on all assets securing the debt. Effective April 8, 2002, the Bank cancelled the line of credit facility.

10. Construction Loan

On April 2, 2001, the Company entered into a $16,000 long term construction loan agreement with the Bank for the construction of new manufacturing and administrative buildings. Under the promissory note related to the construction loan agreement, monthly interest only payments, at a rate of LIBOR plus 2.0%, are due through April 2002. Beginning in May 2002, monthly principal payments (ranging from $30 to $40) plus interest are due through March 2007, at which time the outstanding principle and accrued and unpaid interest is payable in full. The Company has entered into an interest rate swap agreement (see Note 12) which fixes the interest rate at 7.49% per year if the Company's debt ratio is maintained from April 2002 through March 2007, at which time the outstanding principal and unpaid interest is payable in full. The promissory note contains provisions that the applicable margin in excess of LIBOR will vary from 1.5% to 2.5% based on the level of the debt ratio. The debt ratio is defined as funded debt divided by earnings before interest, taxes, depreciation and amortization.

The construction loan agreement is collateralized by the land and buildings, as well as fixtures, leases and rents. This agreement contains various restrictive covenants which limit, among other things, mergers, liens, indebtedness and dispositions. In addition, the Company must satisfy certain financial ratios, including a debt service coverage ratio greater than or equal to 1.35 to 1.00, and a funded debt to earnings before interest, taxes, depreciation and amortization ratio of not greater than 3.00 to 1.00. As of December 31, 2001, the Company was not in compliance with certain of these covenants. Accordingly, in February 2002 the Bank notified the Company that the Bank has no obligation to make further advances under the construction loan agreement. Effective April 8, 2002, the Bank has waived compliance with these covenants and any cross-default available to the Bank under the Company's other loan agreements with the Bank through September 30, 2002, subject to certain conditions. Effective April 8, 2002, the interest rate on the construction loan agreement is prime plus 0.5%. In the event the construction loan agreement is not paid off by July 31, 2002, the applicable interest rate shall increase to prime plus 2%. In accordance with the waiver, the Company's assets pledged as security under the line of credit (see Note 9) and the term loan agreement (see Note 11) have been cross-collateralized to secure the construction loan agreement. The balance of the construction loan at December 31, 2001 is $12,790.

These borrowings have been classified as current due to the Company's non-compliance with its most restrictive financial covenants as of December 31, 2001. Management is currently evaluating financing alternatives for the remaining construction period and is currently funding construction through its cash reserves.

11. Long-term Debt

Long-term debt is as follows:

	December 31,	
	2001	2000
Mortgage payable	$2,555	$2,695
Notes payable, 6.5%	—	450
Note payable, 9.25%	—	46
Note payable, 9.25%	—	63
Capital leases	1,346	1,647
Total	3,901	4,901
Less current portion	3,243	1,217
Long–term portion	$ 658	$3,684

Contractual maturities of long-term debt are as follows:

2002	$3,243
2003	482
2004	176
2005	—
2006	—
	$3,901

On March 30, 2000, the Company purchased the buildings and land (6.19 acres) the Company had occupied under lease, plus an additional 20.82 acres of land for future expansion. The purchase price for the two buildings and 6.19 acres was $3,600 with the Bank, a mortgage payable in the amount of $2,800 to finance the purchase of the buildings and the 6.19 acres of land. Interest on the loan is at 30 day LIBOR plus 1.5%.

Simultaneous with entering into the $2,800 term loan, the Company entered into a swap agreement with a commercial bank which fixes its interest rate at 8.35%. (see Note 12). The interest rate will remain fixed until the 30-day LIBOR is determined to be greater than or equal to 8%, at which time the interest rate will revert to the 30-day LIBOR plus 1.5%. Payments or receipts on the agreement are recorded as adjustments to interest expense. The term loan is collateralized by the land and buildings as well as rents, as defined. The term loan agreement (the "loan agreement") contains various restrictive covenants, which limit among other things, the Company's ability to enter into leases, incur indebtedness, make loans, and make acquisitions. In addition, the Company must satisfy certain financial ratios, including a fixed charge ratio of greater than or equal to 1.25 to 1.00, and funded debt to earnings before interest, taxes, depreciation and amortization ratio of not greater than 4.00 to 1.00. As of December 31, 2001, the Company was not in compliance with certain of these covenants. Effective April 8, 2002 the Bank has waived compliance with these covenants and any cross-default available to the Bank under the Company's other loan agreements with the Bank through September 30, 2002, subject to certain conditions. Effective April 8, 2002, the interest rate on the term loan agreement shall be prime plus 0.5%. In the event the term loan agreement is not paid off by July 31, 2002, the applicable interest rate shall increase to prime plus 2%. In accordance with the waiver obtained from the Bank on April 8, 2002, the Company's assets pledged as security under the line of credit (see Note 9) and the construction loan agreement (see Note 10) have been cross-collateralized to secure the term loan agreement.

The borrowings under the term loan have been classified as current due to the Company's non-compliance with its most restrictive financial covenants as of December 31, 2001. Management is currently evaluating financial alternatives for the mortgage payable.

The notes payable related to the assets purchased from NTBN were collateralized by the assets purchased. All notes were originally due November 2002 (see Note 8). In 2000, a portion of one of the notes payable was converted into common stock of the Company at the Series C Preferred stock price of $5.65 (see Note 14). During 2001, the remaining notes payable were paid in full.

The capital leases have interest rates ranging from 5.83% to 20.65%, are collateralized by the related equipment, and are due from 2001 through 2004 (see Note 17).

12. Derivatives

The Company's interest rate swap agreements involve the exchange of variable rate interest payments, based on the 30-day LIBOR plus 1.5% for fixed rate interest payments, without exchanging the notional principal amount.

At December 31, 2001, the Company had an outstanding swap agreement maturing March 30, 2005, with a notional amount of $2,567. Under this agreement, the Company receives a fixed interest rate of 8.35%. Payments or receipts on the agreement are recorded as adjustments to interest expense. Such adjustments have not been significant. At December 31, 2001, the Company would have paid $189 if it had terminated this agreement.

At December 31, 2001, the Company had an outstanding swap agreement maturing April 2, 2007, with a notional amount of $16,000. Under this agreement, the Company receives a fixed interest rate of 7.49%. At December 31, 2001, the Company would have paid $574 if it had terminated this agreement.

For the twelve months ended December 31, 2001, the amount of derivative loss, net of taxes, for the two swap transactions was $344, which represented the change in the fair value during that period. This amount was recorded as "unrealized derivative loss" for comprehensive income (loss) presented in the condensed consolidated statements of operations and comprehensive income (loss).

Accumulated other comprehensive loss of $443 at December 31, 2001 includes the $344 derivative loss, net of taxes, and a $99 transition adjustment based on the notional amount of $2,695 at December 31, 2000. This transition adjustment was recorded as a cumulative-effect-type adjustment to "accumulated other comprehensive loss" in the equity section of the balance sheet as of January 1, 2001.

13. Income Taxes

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

	Year Ended December 31,		
	2001	2000	1999
Current:			
Federal	$(1,070)	$3,091	$ 967
State	(114)	515	174
Total current	(1,184)	3,606	1,141
Deferred:			
Federal	(2,351)	(418)	(1,590)
State	(251)	(71)	(170)
Total deferred	(2,602)	(489)	(1,760)
Total (benefit) expense	$(3,786)	$3,117	$ (619)

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

	2001		2000	
	Deferred Income Tax		Deferred Income Tax	
	Asset	Liability	Asset	Liability
Current:				
Derivative unrealized loss	$ 321	$ —	$ —	$ —
Uniform capitalization of inventory cost	—	—	786	—
Allowance for bad debts	2,358	—	—	—
Inventory reserve	1,877	—	164	—
Accrued reserves	800	—	462	—
State taxes	60	—	—	(122)
Total current	5,416	—	1,412	(122)
Noncurrent:				
Depreciation	—	(1,415)	—	(546)
Amortization	—	(5)	1	—
Unearned revenue	1,393	—	1,552	—
Deferred compensation	—	—	170	—
Total noncurrent	1,393	(1,420)	1,723	(546)
Total	$6,809	$(1,420)	$3,135	$(668)

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

	Year Ended December 31,		
	2001	2000	1999
Statutory federal rate	(34.00)%	34.00%	34.00%
State income taxes—net of federal tax benefit	(2.37)	3.88	4.10
Meals and entertainment	0.80	0.47	1.00
Stock compensation expense	3.12	1.72	1.89
Research and experimentation credit	(8.37)	—	(2.30)
Change in valuation allowance	—	—	(65.55)
Miscellaneous	0.08	1.04	0.42
Effective tax rate	(40.74)%	41.11%	(26.44)%

14. Stockholders' Equity

Preferred Stock—Series A and B Preferred stocks were on parity with each other regarding dividends and liquidation, and were senior to the Company's common stock. The Series A Preferred stock was recorded at its par value rather than its face and liquidation value because the issuance of the Series A Preferred stock resulted from a transaction between entities under common control (see Note 1).

Series A and B Preferred stocks had voting rights equal to the number of whole shares of common stock into which the preferred stocks could be converted. Series A Preferred stock was convertible at any time into common shares at a price of $1.63 per share and Series B Preferred stock was convertible at any time into common shares at a price of $1.83 per share.

Series C Preferred stock was senior to the Series A and B Preferred stocks and common stock as to dividends and upon liquidation. Series C Preferred stock had voting rights equal to the number of whole shares of common stock into which the preferred stock could be converted. Series C Preferred stock was convertible at any time into common shares at a price of $5.65 per share. Holders of Series C Preferred stock were issued warrants to purchase up to 221,395 shares of common stock for a period of one year from the date of issuance at a purchase price of $5.65 per share. Under the Black Scholes model, the fair value of these warrants was determined to be approximately $400.

The Series A, B and C Preferred stocks automatically converted to common stock at their respective per share prices upon the closing of the initial public offering on August 10, 2000. The series A, B, and C Preferred stocks were converted to 8,531,270; 3,591,130, and 1,771,152 shares of common stock, respectively. As of December 31, 2001 and 2000, there were no preferred shares outstanding.

Common Stock—The common stock's voting, dividend, and liquidation rights are no longer subject to or qualified by the rights of the holders of the preferred stocks, as all then outstanding shares of preferred stock were converted to common stock on August 10, 2000. Common stockholders are entitled to one vote for each share held at all stockholder meetings. Common stock is not redeemable.

On June 16, 2000, the Company approved a stock split resulting in an exchange of 1 share for 4.8 shares of common stock issued and outstanding. All share and per share amounts have been retroactively adjusted for this split.

On August 10, 2000, the Company completed its initial public offering of common stock. The net proceeds to the Company from the sale of 3,800,000 shares of common stock offered by the Company were $48,025 after deducting underwriting discounts, commissions and offering expenses of $1,450.

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, 2001, 2000 and 1999:

	2001		2000		1999	
	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,	2,277,518	$ 6.37	1,300,848	$ 2.06	705,192	$1.30
Granted	1,485,425	10.80	1,053,792	11.51	618,768	2.85
Exercised	(241,468)	1.66	—	—	—	—
Canceled	(166,875)	9.50	(77,122)	3.75	(23,112)	1.30
Outstanding at December 31,	3,354,600	$ 8.51	2,277,518	$ 6.37	1,300,848	$2.06
Exercisable at December 31,	954,184	$ 5.94	450,276	$ 1.93	154,238	$1.30
Available for grant at December 31,	810,332		2,128,882		3,105,552	

The weighted average fair value per share of options granted during the years ended December 31, 2001, 2000 and 1999 was $6.41, $5.71 and $2.87, respectively.

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, 2001 are summarized as follows:

	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at December 31, 2001	Weighted Average Exercise Price
Range of Exercise Prices					
$1.30 to $1.88	605,033	1.8	$ 1.34	367,666	$ 1.33
$3.13 to $3.80	542,835	2.7	3.65	248,898	3.66
$5.65 to $10.13	968,860	4.6	9.76	59,051	9.03
$10.74 to $12.88	511,160	4.3	12.29	66,972	12.28
$13.54 to $14.95	726,712	3.3	13.79	211,598	13.75
$1.30 to $14.95	3,354,600	3.4	$ 8.51	954,185	$ 5.94

The Company applies APB Opinion No. 25 in accounting for its stock options. No compensation cost has been recognized for those 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 $478 of

deferred compensation costs remaining to be amortized at December 31, 2001, related to the issuance of non-qualified stock options.

The Company recorded deferred stock-based compensation expense for options granted during the period October 1, 1999 through March 31, 2000. The fair value of each grant was determined by the difference between the option exercise price and either (1) the $5.65 per share price from the sale of Series C preferred stock in October 1999 for grants from October 1, 1999 through December 31, 1999 or (2) the expected public offering price of $13.00 per share for grants from January 1, 2000 through March 31, 2000. The total stock-based 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, 2001, $1,100 of this cost remained to be amortized through 2005.

Had compensation cost for grants after March 31, 2000 been determined on the basis of fair value pursuant to SFAS No. 123, net (loss) income and net (loss) income per common share would have been affected as follows for the years ended December 31, 2001, 2000 and 1999.

	Year Ended December 31,		
	2001	2000	1999
Net (loss) income, as reported	$(5,505)	$4,459	$2,960
Net (loss) income, pro forma	$(6,774)	$3,088	$2,837
Net (loss) income per common share—basic, as reported	$ (0.25)	$ 0.42	$ 0.81
Net (loss) income per common share—basic, pro forma	$ (0.31)	$ 0.29	$ 0.77
Net (loss) income per common share—diluted, as reported	$ (0.25)	$ 0.22	$ 0.18
Net (loss) income per common share—diluted, pro forma	$ (0.31)	$ 0.15	$ 0.17

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,		
	2001	2000	1999
Expected life (years)	4.92	4.66	4.71
Risk free interest rate	4.45%	6.23%	5.72%
Volatility factor	67.79%	60.00%	60.00%
Dividend yield	0.00%	0.00%	0.00%

Stock Awards—The Company awarded 3,699,130 shares of common stock to various key employees at the beginning of the Company's operations. These shares of common stock, which were valued at $0.18 per share, vest over a five-year period. At the date of issuance, $655 in deferred stock-based compensation was recorded by the Company. Compensation expense of approximately $173, $127, and $131 was recognized for these stock awards for the years ended December 31, 2001, 2000 and 1999, respectively. Remaining amortization of $86, before accounting for forfeitures, will be recognized during 2002.

Issuances of Unregistered Securities—On April 26, 2001, Dr. Charles P. Garrison exercised his warrant to purchase 5,534 shares of common stock for a total consideration amount of $31. Dr. Garrison 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 of certain assets of the National Tissue Bank Network, Georgia Tissue Bank, Inc. and equipment owned by Dr. Garrison by GTB 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 to settle the transaction, and the remainder of the warrant was automatically deemed cancelled. Medtronic Asset Management, Inc. receive this warrant in connection with the purchase of certain the Company's equity securities in October 1999.

On April 10, 2001, Stephens-Regeneration LLC excercised a warrant to purchase 110,698 shares of common stock having an excercise price of $5.65 per shares. 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 to settle the transaction and the remainder of the warrant was automatically deemed cancelled. Medtronic Asset Management, Inc. received this warrant in connection with the purchase of certain of the Company's equity securities in October 1999.

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 the employee to contribute 20% of the employee's salary up to the 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, 2001, 2000 and 1999 the Company's contributions to the plan were $420, $475, and $156, respectively.

16. Concentrations of Risk

Distribution—The Company's principal concentration of risk is related to its limited distribution channels. The Company's revenues are related to the distribution efforts of four independent companies with the majority of its revenues coming from one of the distribution companies, Medtronic Sofamor Danek ("MSD") (see Note 18). In 1999, the Company expanded to include more revenue from direct distribution. The amount of revenue from direct distribution was approximately 15%, with 80% of the remaining revenue coming from MSD. In 2000, the amount of revenue from direct distribution was approximately 20%, with 78% of the remaining revenue coming from MSD. In 2001, the amount of revenue from direct distribution was approximately 22%, with 76% of the remaining revenue coming from MSD.

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 bone and related connective tissue from human donors. 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

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

Prepaid Inventory— During 2001 and 2000, the Company advanced to the tissue recovery agencies and recorded as prepaid inventory expense $5,227 and $4,453, respectively, and amortized $6,525 and $3,768 to cost of unprocessed donor tissue inventory, respectively. At December 31, 2001 and 2000, prepaid inventory balances related to recovery funding were $120 and $1,418, respectively. Prepaid inventory is classified in prepaid and other assets in the accompanying consolidated balance sheets.

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 provide the Company incentive to assist UFTB-Italia in their 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 had no operations as of December 31, 1998. As of December 31, 2001, UFTB-Italia 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, 2001, 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, 2001 and 2000, the Company had $354 and $393, respectively, of outstanding accounts receivable due from UFTB-Italia. Total tissue distributions to UFTB-Italia in 2001, 2000, and 1999 were $518, $722, and $202, respectively.

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, 2001 are as follows:

	Capital Leases	Operating Leases
2002	$ 776	$388
2003	524	73
2004	180	—
	1,480	$461
Less amounts representing interest	134	
Present value of net minimum lease payments	$1,346	

Rent expense for the periods ended December 31, 2001, 2000 and 1999 was $954, $839, and $748, respectively.

Employment Agreements—The Company has employment contracts with four officers of the Company, providing for total annual payments of approximately $1,368, $1,013, $657 and $321 from 2001 through 2004, respectively. The contracts provide for periodic adjustments to compensation and expire on various dates in 2003 and 2004.

18. Related Parties

The Company had certain related party transactions with SETA, formerly known as UFTB. Through April 15, 1999, SETA recovered whole donor tissue and distributed conventional tissue. The Company processed

this tissue for SETA for a fee and compensated SETA for the nonconventional tissue retained from the whole donor tissue. On April 15, 1999, the Company entered into two new agreements under which SETA transferred to the Company all rights to conventional tissue distribution and national recovery programs, permitting SETA to focus primarily on tissue recovery and SETA settled amounts due to the Company. As of April 15, 1999, the total due from SETA and the note receivable from SETA was $4,964. Under the terms of the agreements, SETA transferred its unprocessed donor tissue and conventional tissue with a fair value of $3,030 and equipment and fixtures with a fair value of $90 for a total non–cash asset transfer of $3,120 to the Company as an offset against the existing due from stockholder and note receivable from stockholder. Additionally, SETA agreed to repay the remaining balance by (a) offsetting recovery fees from April 15, 1999 through June 30, 1999 against the outstanding balance, which fees, net of administrative costs, were $657, and (b) making monthly payments through the end of 1999 to repay the remaining balance of $1,187. As of December 31, 1999, SETA had repaid all amounts owed to the Company in accordance with the terms of the two new agreements entered into on April 15, 1999.

The following is a summary of transactions and balances with SETA as of December 31, 2000 and 1999 and for the years ended December 31, 2000 and 1999:

	2000	1999
Due from (to) SETA, net	($4)	$4
Tissue recovery fees and support services charged by SETA to the Company	6,695	5,344
Processing fees, tissue fees, and support services charged to SETA by the Company	281	2,592

On February 15, 2001, the University of Florida Tissue Bank ("UFTB") changed its name to Southeast Tissue Alliance ("SETA"). In connection with the dissolution of their status as a direct support organization to the University of Florida, SETA transferred all shares of the Company to University of Florida Research Foundation on March 16, 2001. SETA no longer has a related party relationship with the Company.

In January 1999, Medtronic, Inc. acquired Sofamor Danek Group, the owner of 50% of RTI's then outstanding shares of Series C Preferred stock, and changed its name to MSD. MSD is currently the largest tissue distributor for the Company (see Note 16). The following is a summary of transactions with MSD for the years ended December 31, 2001, 2000 and 1999, and balances for MSD as of December 31, 2001 and 2000:

	Year Ended December 31,		
	2001	2000	1999
Tissue distribution revenue under management services agreement (included in fees from tissue distribution)	$112,607	$94,641	$57,228
Management services fees	73,176	64,572	39,994
Deferred revenue recognized (included in other revenues from core operations)	225	225	225
Administrative costs reimbursed by Medtronic Sofamor Danek (included in marketing, general and administrative expense)	483	374	436
Management services fees payable (included in accounts payable)	18,983	18,445	—
Deferred revenue	3,703	3,928	—

As part of the agreement to purchase the assets of NTBN (see Note 8), Dr. Garrison was given the option to convert a $500 note due November 2002, or any portion of the note, into common stock of the Company at $5.65 per share and a warrant to purchase additional shares at the ratio of one share for each eight shares of common stock purchased under the option. These were the same terms at which RTI originally issued its shares of Series C Preferred stock. The option to convert the $500 note was exercisable at any time before February 22, 2000. On February 15, 2000, Dr. Garrison partially exercised his option, and purchased 44,280 shares of common stock for an aggregate exercise price of $250, reducing the balance of the note payable by this amount, and receiving a warrant to purchase an additional 5,534 shares of common stock at an exercise price of $5.65 per share. The

balance of the note payable immediately prior to the exercise of the option was $462, and was $212 after the exercise. The remaining balance of the note was paid in May 2001, and the option to convert additional note payable amounts into common stock of the Company expired with that repayment.

The following is a summary of transactions and balances with Dr. Garrison as of and for the years ended December 31, 2001, 2000, and 1999:

	Year Ended December 31,		
	2001	2000	1999
Payments on GTB leased premises	$155	$149	$ 37
Payments for Medical Director fees	104	101	17
Principal and interest payments on notes	571	410	31
Notes payable	—	559	1,219
Conversion of notes payable to common stock	—	250	—

19. Legal Actions

EXACTECH LITIGATION

On June 22, 1999, Exactech, Inc. ("Exactech") filed a complaint in the Circuit Court of the Eighth Judicial Circuit, in and for Alachua County, Florida against the Company, SETA, and 19 medical distributors and sales agents of the Company. The complaint alleged that the Company breached a license agreement under which Exactech has certain rights to distribute the Company's bone paste products. SETA assigned this agreement to the Company as part of the Company's formation and separation from SETA. The court granted the Company's motion to enforce an arbitration provision in the agreement, and the matter is now in arbitration. Only the Company, Exactech and SETA remain as parties in the arbitration.

The dispute relates to the scope of rights transferred under the license agreement. The Company maintains that the scope of rights transferred to Exactech was narrow, while Exactech asserts that it has broader rights. Specifically, Exactech contends that under the agreement, it has the right to distribute eight specific forms of moldable bone paste being distributed by the Company and any other shapes and sizes of bone paste for use outside of the spine. The Company and Exactech each conducted discovery, including the exchange of documents and the taking of depositions, and in July 2001, a multi-day hearing, including the testimony of witnesses, was held before the arbitration panel.

Upon the Company's motion, the arbitration panel bifurcated the proceeding and focused on the scope of Exactech's rights under the license agreement in the initial phase of the arbitration. On December 21, 2001, the panel ruled the Company had the right to distribute the two most widely distributed bone paste products, but not to distribute the other six forms of moldable bone paste (which contain cortical cancellous chips) for non-spinal applications. The panel ruled in the Company's favor on the other claims of breach asserted by Exactech.

Exactech alleges it has suffered monetary damages. The amount of damages, if any, that Exactech is entitled to recover and Exactech's request for injunctive relief will be determined in the second phase of the arbitration proceeding. The parties are having settlement discussions. The Company anticipates that the hearing to determine damages, if necessary, will be held in mid-2002. Because the final ruling of the second phase of the arbitration proceeding has not been completed, the Company cannot estimate the amount or range of potential loss.

OSTEOTECH LITIGATION

On February 25, 1999, the Company, SETA and MSD brought suit in U.S. District Court for the Northern District of Florida against Osteotech, Inc. ("Osteotech"). The initial complaint alleged that Osteotech is infringing two patents for Diaphysical Cortical Bone Dowels. On October 6, 2000, the court allowed the Company and other plaintiffs to amend the complaint to add an additional count that Osteotech also is infringing

a third, recently-issued patent for the Diaphysical Cortical Bone Dowels. SETA licenses these patents to the Company on an exclusive basis and the Company then sublicenses these patents to MSD. The Company and other plaintiffs are seeking injunctive relief against Osteotech, preventing it from continuing to distribute products that infringe any of the three patents. The Company and other plaintiffs also are seeking monetary damages in an amount based on the profit they believe they would have made if the patents never were infringed by Osteotech. All legal expenses in this action are being paid by MSD. The parties are concluding expert discovery and trial is anticipated to begin in this case on September 16, 2002.

MUSCULOSKELETAL TRANSPLANT FOUNDATION LITIGATION

On June 13, 2001, RTI filed a Complaint against Musculoskeletal Transplant Foundation ("MTF") in the United States District Court for the Northern District of Florida, alleging that MTF engaged in an intentional, targeted campaign of falsehoods and innuendo designed to undermine RTI and RTI's tissue. Specifically, RTI believes that MTF has published advertisements and otherwise has disseminated materials containing misleading and disparaging statements about RTI and RTI's tissue in an effort to diminish RTI's revenue and to increase MTF's revenue.

RTI's complaint included causes of action for (1) false advertising and unfair competition in violation of the Lanham Act; (2) intentional interference with existing and prospective business relationships; and (3) unfair competition in violation of the Florida Deceptive and Unfair Trade Practices Act. In its answer to RTI's complaint, MTF made similar claims against RTI.

The parties entered into a settlement agreement in January 2002 and agreed to withdraw all claims and counterclaims against each other. As part of the settlement, neither party admitted liability and no damages were paid by either party.

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 are outstanding as of December 31, 2001 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,		
	2001	2000	1999
Interest paid during the period	$ 661	$ 434	$ 285
Income taxes (received) paid	(128)	1,666	1,052
Noncash capital lease obligations	532	771	282
Noncash settlement of note receivable and amount due from stockholder	—	—	3,120
Notes payable issued to acquire GTB	—	—	1,250
Conversion of preferred stock to common stock	—	16,582	—
Conversion of notes payable to common stock	—	250	—
Cancellation of capital lease obligation upon purchase of building	—	283	—
Reduction of rental accrual upon acquisition of land/building	—	225	—
Noncash insurance financing	937	430	—
Acquisition of assets of Alabama Tissue Center for stock	—	3,500	—
Issuance of stock options	478	2,774	—

21. Segment Data

The Company processes human musculoskeletal tissue received from various tissue recovery agencies and distributes the tissue through various channels. This one line of business represents 100% of consolidated fees from tissue distribution and is comprised of three primary product lines: spinal allografts, other precision tooled allografts and conventional tissue. The following table presents fees from tissue distribution by each of the Company's three primary product lines:

	Year Ended December 31,		
	2001	2000	1999
Fees from tissue distribution:			
Spinal allografts	$105,154	$ 94,641	$57,073
Other precision tooled allografts	17,857	10,532	4,683
Other processed tissue	15,751	15,732	9,027
Total	$138,762	$120,905	$70,783

The Company distributes its products both within and outside the United States. During the years ended December 31, 2001, 2000 and 1999, 97.6%, 97.4% and 97.4%, respectively, of net revenues came from distribution within the United States. Foreign net revenues of 2.4% during the year ended December 31, 2001 and 2.6% during the years ended December 31, 2000 and 1999 came primarily from distribution within Europe.

22. Quarterly Results of Operations (Unaudited)

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

	March 31, 2001	June 30, 2001	September 30, 2001	December 31, 2001
Quarter Ended:				
Net revenues	$17,175	$16,890	$17,860	$15,625
Gross profit	8,156	7,245	8,619	4,075
Net income (loss)	1,043	17	386	(6,951)
Net income (loss) per common share:				
Basic	$ 0.05	$ 0.00	$ 0.02	$ (0.32)
Diluted	$ 0.05	$ 0.00	$ 0.02	$ (0.32)

During the three months ended June 30, 2001 the Company experienced increases in payments to recovery agencies for marketing, public relations and related costs, and in consulting expense related to governmental relations, resulting in lowered net income for that period.

During the three months ended December 31, 2001 the Company experienced a decrease in sales and $2,300 of additional inventory allowances which resulted in a decrease in gross profit for that period. Also during that period, the Company recorded $5,800 of bad debt expense related to disputed invoices with several customers, contributing to a net loss for the period.

	March 31, 2000	June 30, 2000	September 30, 2000	December 31, 2000
Quarter Ended:				
Net revenues	$11,804	$13,340	$15,308	$17,479
Gross profit	4,807	5,893	6,718	9,450
Net income	464	755	1,070	2,170
Net income per common share:				
Basic	$ 0.13	$ 0.21	$ 0.08	$ 0.10
Diluted	$ 0.03	$ 0.04	$ 0.05	$ 0.09

Certain amounts previously reported in 2000 have been reclassified to conform to the 2001 presentation as follows:

	March 31, 2001	June 30, 2001	September 30, 2001
Gross Profit, as previously reported	$9,081	$8,214	$9,592
Reclass of certain costs previously reported in marketing, general and administrative costs to the costs of processing and distribution	(925)	(969)	(973)
Gross profit, as reclassified	$8,156	$7,245	$8,619

	March 31, 2000	June 30, 2000	September 30, 2000	December 31, 2000
Gross Profit, as previously reported	$5,477	$6,548	$7,442	$10,305
Reclass of certain costs previously reported in marketing, general and administrative costs to the costs of processing and distribution	(670)	(655)	(724)	(855)
Gross profit, as reclassified	$4,807	$5,893	$6,718	$ 9,450

The expense reclassifications above principally relate to royalty fees, insurance on manufacturing equipment and prorated utilities and rent related to production.

23. Subsequent Events

On February 1, 2002, the Company announced, among other things, that it was delaying the release of its financial results for the fourth quarter of 2001 and the year then ended while Management completed its evaluation of certain inventory issues it had identified in the process of preparing the Company's annual consolidated financial statements.

Following this announcement, the Nasdaq Stock Market suspended trading in the common stock pending release of the Company's financial results and its receipt of certain requested information. After providing the Nasdaq Stock Market with the information it requested and releasing its financial results for 2001 to the public on February 19, 2002, trading in the common stock was allowed to resume the following day. The Company also was advised by the staff of the Securities and Exchange Commission on February 1, 2002 that it was opening an informal inquiry with respect to these matters and the Company has cooperated with the staff in connection with its inquiry into these matters.

Also following this announcement, on February 4, 2002, a securities class action lawsuit entitled Michael Keskinen v. Regeneration Technologies, Inc. et al., No. 1:02-CV9 MMP-WW was filed in the United States District Court, Northern District of Florida Gainesville Division, against the Company and certain of its current and former officers and directors (collectively, the "Defendants"). Since the Keskinen lawsuit was filed, a number of additional securities class action lawsuits have been filed in the U.S. District Court for the Northern District of Florida based upon the same alleged facts. The class actions purport to be brought on behalf of all persons who purchased the Company's common stock between July 25, 2001 and January 31, 2002. The Company expects that the series of class action lawsuits will be consolidated into a single action. The class actions generally allege that the Company's inventory was overvalued and, as a result, public statements made by the Company during the class time period about its net income and earnings per share were false and misleading. The plaintiffs assert that the Defendants' conduct violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 10b-5 thereunder. The class actions do not specify an amount of damages. Since these lawsuits were filed recently, the Company has not yet filed its responses and no discovery has occurred. No provision has been made in the accompanying consolidated financial statements for losses, if any, that may result from the outcome of these cases because such amount is not estimable.

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.

April 9, 2002

REGENERATION TECHNOLOGIES, INC.

By: /s/ BRIAN K. HUTCHISON

Brian K. Hutchison
President, Chief Executive Officer and Principal Financial 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**	President, Chief Executive Officer and Principal Financial Officer	April 9, 2002
/s/ JAMES M. GROOMS **James M. Grooms**	Chairman of the Board	April 9, 2002
/s/ JOHN M. CAMPBELL **John M. Campbell**	Controller	April 9, 2002
/s/ PHILIP R. CHAPMAN **Philip R. Chapman**	Director	April 9, 2002
/s/ PETER F. GEAREN **Peter F. Gearen**	Director	April 9, 2002
/s/ MICHAEL J. ODRICH **Michael J. Odrich**	Director	April 9, 2002
/s/ ANTHONY C. PHILLIPS **Anthony C. Phillips**	Director	April 9, 2002

INDEPENDENT AUDITORS' REPORT

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

We have audited the consolidated financial statements of Regeneration Technologies, Inc. and subsidiaries (the "Company") as of December 31, 2001 and 2000, and for each of the three years in the period ended December 31, 2001, and have issued our report thereon dated April 8, 2002; 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 14. 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
April 8, 2002

REGENERATION TECHNOLOGIES, INC. AND SUBSIDIARIES

Schedule II
Valuation and Qualifying Accounts
Years Ended December 31, 2001, 2000 and 1999
(Dollars in thousands)

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts	Deductions	Balance at End of Period
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	2,394	—	—	3,812
For the year ended December 31, 2000:					
Allowance for doubtful accounts	335	566	—	146	755
Allowance for product returns	211	411	—	263	359
Allowance for obsolescence	527	891	—	—	1,418
For the year ended December 31, 1999:					
Allowance for doubtful accounts	39	171	125(a)	—	335
Allowance for product returns	119	353	—	261	211
Allowance for obsolescence	—	527	—	—	527

(a) Represents allowance for doubtful accounts on accounts receivable acquired from National Tissue Bank Network, Georgia Tissue Bank, Inc.

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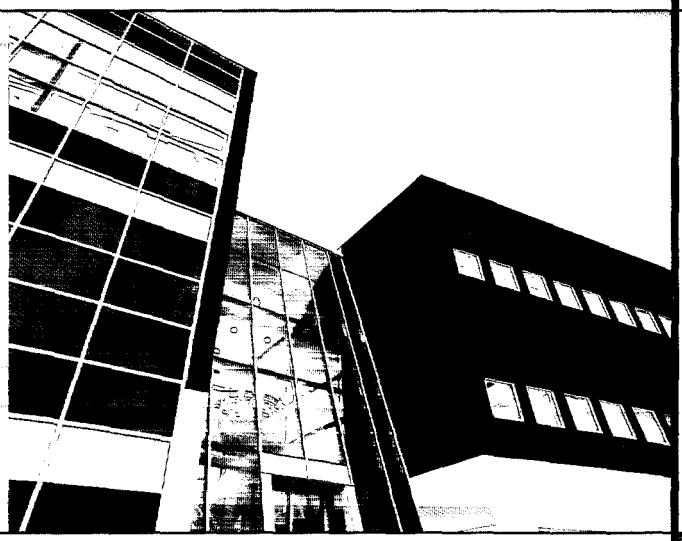
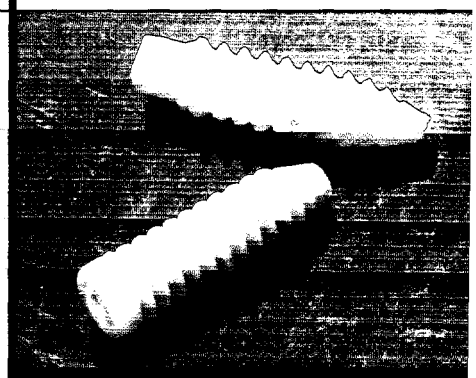


Regeneration Technologies Inc.



2001 Letter
To Shareholders

Brian K. Hutchison
President & CEO

The year 2001 was a challenging one for Regeneration Technologies. We faced several operational and financial issues during the year, which strained our resources and required management to shift its focus from long-term strategic objectives to near-term corporate survival. We experienced a decrease in overall revenues due to declines in tissue recovery, a change in the mix of the tissue recovered and delays in tissue processing. At the same time, legal and consulting fees and higher operating costs substantially increased our expenses. As a result, RTI reported a loss for the first time since 1998.

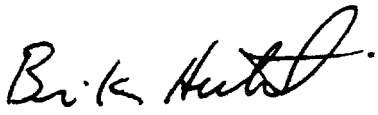
Our financial performance was disappointing, but we learned valuable lessons from this period in our corporate history. Today, RTI has emerged as a stronger company and our newly acquired knowledge provides the scaffolding on which we can build a better business that utilizes resources strategically, capitalizes on current market opportunities and sustains growth for the future.

Our hard work has already achieved some successes that will assist us in turning the company around for 2002 and beyond, as we reach a new inflection point. The positive outcome of the FDA's review of the BioCleanse™ tissue sterilization process will provide increased visibility and credibility within the industry. The BioCleanse™ tissue sterilization system gives RTI a strong advantage in the market. The FDA's determination that our scientific studies show that the BioCleanse™ process prevents contamination and cross-contamination of processed tissue by representative bacteria, viruses and spores signals the beginning of a significant trend. Surgeons, risk managers, purchasing agents and others involved in the tissue industry are starting to realize that without effective sterilization processes, bacteria and viruses can – and do – cause fatalities.

Our management team has been working diligently to improve our operations and we have also begun implementing cost reduction measures that will improve near-term profitability. Significant progress has also been made towards resolution of several legal matters. There are still some tough roads ahead, but we are confident that RTI is now better positioned to take advantage of market opportunities that will ensure our long-term success.

I was brought in as CEO of RTI in December 2001 to bring stability, direction and to drive this company forward. The strengths of this company – which attracted me to RTI in the first place – are still here. The basic fundamentals of the business are still here and our market is strong. There is a tremendous need for allograft in the spinal and orthopedic industries and RTI's technology and products are among the best available today. But this company would not exist without the extraordinary commitment of its employees and their dedication to the principles on which this company was founded: that innovative thinking brings about better options for surgery and better outcomes for patients.

Looking forward into 2002, we will focus our resources on our core business. RTI is committed to being an industry leader, providing the safest, highest quality products and the most innovative technology for surgeons and their patients. We will use our strength – years of knowledge and experience in the field – to improve the tissue industry, while continuing to provide our partners, customers and patients with leading edge products. We will renew and strengthen relationships with our partners and our recovery agencies that have made us successful in the past and we will concentrate on providing the highest level of service to our customers. We at RTI are driven to make the future bright for this company and for all those associated with it. I thank our customers, our shareholders and our employees for your continued support.



Brian K. Hutchison
President & CEO

Forward Looking Statement

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' Mission

Regeneration Technologies' mission is to advance life and revolutionize healing by:

- Expanding the gift of life given by donors and their families
- Pioneering innovations for tissue regeneration
- Dedicating ourselves to excellence, quality and customers
- Demonstrating integrity in everything we do

About Regeneration Technologies

Regeneration Technologies, Inc. is a leader in the use of natural tissues and innovative technologies to repair and promote the natural healing of human bone and other human tissues. Using core human physiology – the basic biology of natural tissues as they function in the body – our human tissue implants are improving surgical outcomes. We process human musculoskeletal and other tissue, including bone, cartilage, tendon, ligament, pericardial 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, urinary incontinence and heart valve disorders.

Board of Directors

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

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

Brian K. Hutchison
President & CEO

Michael J. Odrich
Managing Director
Lehman Brothers, Inc.

Anthony C. Phillips
President & CEO
Raymedica, Inc.

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Annual Shareholder's Meeting

Wednesday, May 29, 2002, 10 AM

University of Florida Hotel & Conference Center,
a Doubletree Facility

1714 SW 34th Street, Gainesville, Florida 32607

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TECHNOLOGIES, INC.

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