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Advanced Tissue Sciences, Inc.
2001 Annual Report

The mission of Advanced Tissue Sciences is to redefine tissue repair and transplantation with products developed and derived from our tissue-engineering technology. Our achievements will enhance the quality of human life and create an environment that fosters innovation and employee satisfaction while delivering sustainable value to our shareholders.

strategic purpose

Investment Highlights

- Highly versatile core technology backed by strong patent portfolio
- Three products generating revenue
- Pipeline of attractive medium- and long-term products
- Strong strategic alliances and partners
- Self-pay and reimbursement markets
- Spectrum of regulatory environments
- High-volume manufacturing capability

Dear Shareholders:

At the start of 2001, Advanced Tissue Sciences had only one product approved and on the market in the United States – TransCyte® for burns. Since then, Dermagraft® has been approved by the Food and Drug Administration (FDA) for the treatment of hard-to-heal diabetic foot ulcers and is now being sold in this country. In addition, two marketing partners have begun selling skin care products containing our NouriCel™ cosmetic ingredient. And we're making progress toward a fourth product on the market: our strategic partner, INAMED Corporation, is pursuing approval of the company's tissue-engineered, human-based collagen for wrinkle injections.

Corporate Strategy

Leverage our technology and intellectual property

Invest in broad innovative research and development, internally and through collaborations, to drive our product pipeline to achieve our mission

Focus development and manufacturing efforts on commercializing off-the-shelf fibroblast-based products

Diversify the risks and the opportunities across a broad array of opportunities and products

Market, distribute and sell products through strategic partners or directly where the opportunity is compelling

Create new initiatives to unlock shareholder value

There were other major events during the year:

Dermagraft received a reimbursement pass-through code from the Centers for Medicare & Medicaid Services. We also began the pivotal clinical trial for Dermagraft in treating venous ulcers.

We signed a broad collaboration agreement with Medtronic, Inc. that included an investment by one of their subsidiaries of \$20 million in our company. Michael D. Ellwein, Medtronic's vice president and chief development officer, also joined our board of directors.

We completed a private placement of stock that raised net proceeds of approximately \$13.5 million.

In last year's annual report we outlined our revised corporate strategy, which can be boiled down to three key principles. The first is to focus development and manufacturing efforts on commercializing short- and medium-term, fibroblast-based products, since we have developed extensive internal expertise and know-how about dermal fibroblast cells.

The second is to market, distribute and sell products through strategic partners or directly where the opportunity is compelling.

The third is to create new strategic alliances and initiatives to unlock longer-term product opportunities.

The events of the past year are indicators of how we have been implementing that strategy to build shareholder value.

Advanced Tissue Sciences is developing products for health care that enhance the field of regenerative medicine. While the technology is based on tissue engineering, the ultimate goal is to develop products that rejuvenate, repair, regenerate, or replace what the body cannot heal itself.

What we're doing is guided by a strategic vision: a product portfolio that addresses various medical needs and builds from our core technology. As illustrated on page three, generating multiple, off-the-shelf products from a core technology can have a significant benefit on product development costs and leads to a value creation model that is a key differentiator between Advanced Tissue Sciences and other biotechnology companies.

We and our investors are not staking everything on just one product or a single approach to the marketplace. Instead, we are working to apply our technology to multiple applications with commercial potential that meet a variety of needs.

An example of this is the way we are broadening the potential applications of Dermagraft from foot ulcers to include venous ulcers, other wounds and skin conditions, and the possibility of periodontal and cardiovascular uses.

In addition, our products cover a spectrum of regulatory environments from the highly regulated biologics to cosmetic ingredients. That allows us to bring some new products to market much faster and with significantly lower regulatory costs.

The payment environment for our products also covers the full range from insurance

Value Creation Model

Leverage our technology and intellectual property

Invest in broad innovative research and development, internally and through collaborations, to drive our product pipeline to achieve our mission

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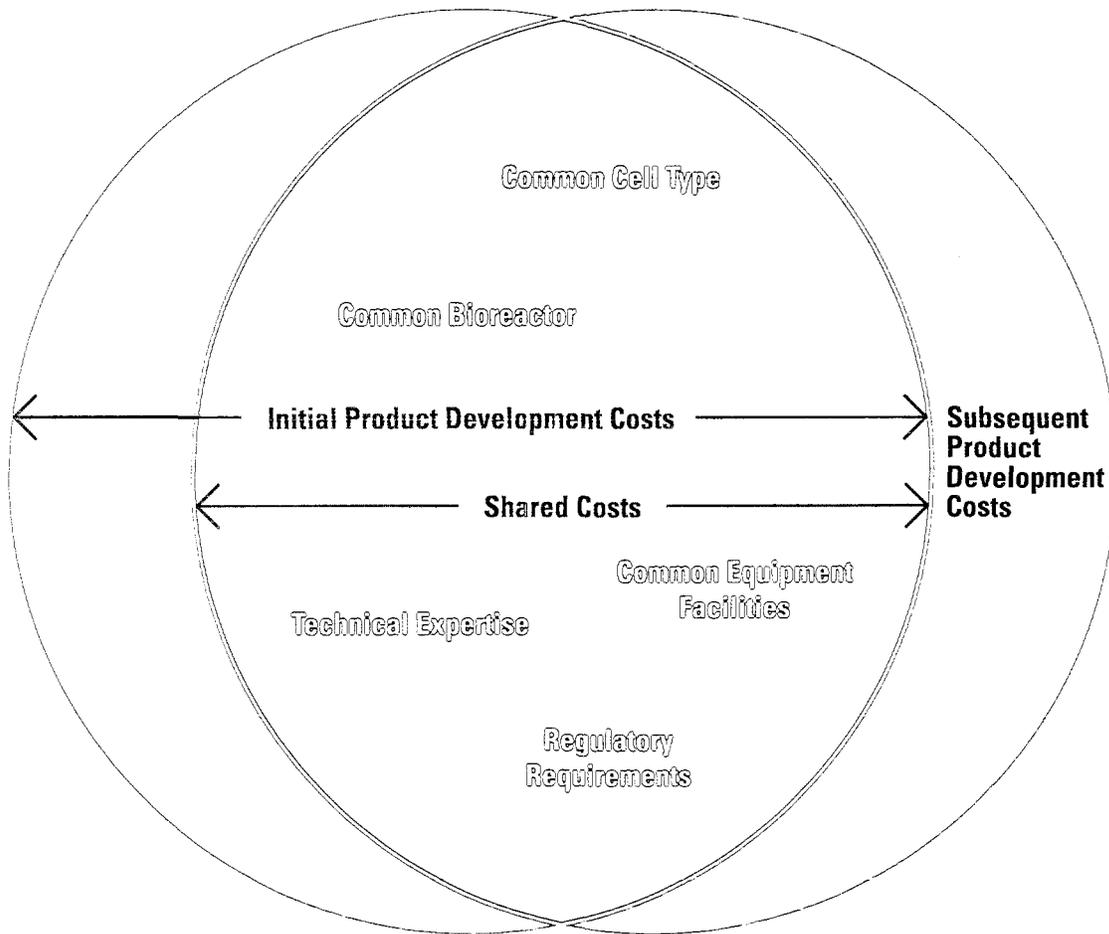
Market, distribute and sell products through strategic partners or directly where the opportunity is compelling

Create new initiatives to unlock shareholder value

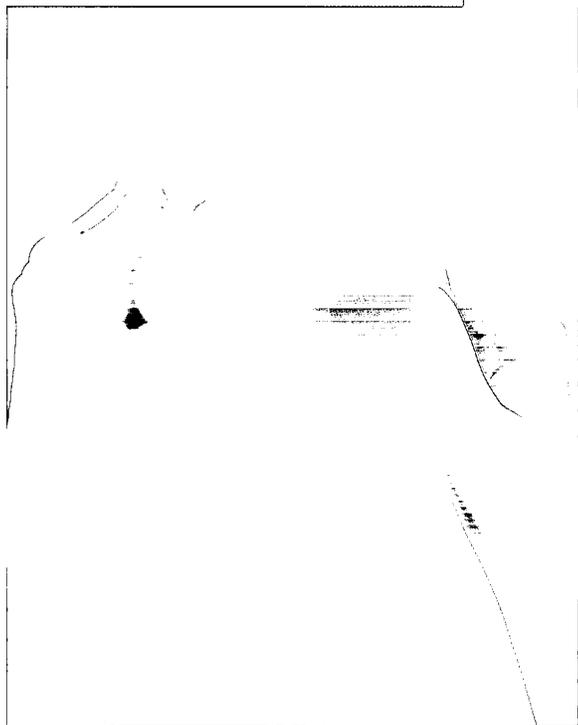
The company's strategic vision is to use our core technology to build a portfolio of off-the-shelf products that address a variety of medical needs. Most of the products in our pipeline share the same dermal fibroblast cell type, bioreactor technology, and facilities, and require related technical expertise. A major benefit of this approach is that development and other costs incurred for early products can be reduced or avoided with later products, as suggested by the diagram on this page.

For example, it took a significant investment to develop, get approval for, and begin production of TransCyte and Dermagraft. Subsequent applications of that same dermal fibroblast technology will not have to carry the development cost of learning how to work with the cells, designing and validating bioreactor technology to grow the tissue, or building a manufacturing facility. Information developed to meet regulatory requirements for earlier products can potentially be applied to future needs.

As a result, future products have the potential for higher margins to drive growing shareholder value. Current and future products that should benefit from this include NouriCel, collagen, the potential use of our dermal fibroblast technology for periodontal indications and possible future products such as Anginera™.



In October 2001, we entered into a collaboration with Medtronic, Inc. (NYSE: MDT) to explore the application of our technology in areas of therapeutic interest to Medtronic, including cardiovascular, neurological, endocrine and spinal. An affiliate of Medtronic invested \$20 million in shares of our common stock in return for specified rights including a right of first refusal to participate in the further development and commercialization of Anginera, our epicardial angiogenesis therapy. As a part of this collaboration, a Medtronic representative joined our board of directors.



Smith+Nephew

The company has two joint ventures with Smith & Nephew (NYSE: SNN). The first covers the application of Advanced Tissue Sciences' tissue-engineering technology for skin wounds. This includes Dermagraft, TransCyte and possible future developments for venous ulcers, pressure ulcers, burns and other non-aesthetic wound care treatments. The second joint venture covers tissue-engineered orthopedic cartilage, initially focusing on the repair of cartilage in knee joints.



INAMED

The company has a strategic alliance with INAMED Corporation (NASDAQ: IMDC) through which Advanced Tissue Sciences and INAMED have been collaborating in the development of human-based collagen for wrinkle treatment. In the future, the companies expect that the use of human-based collagen could expand to other aesthetic and reconstructive applications.

Strategic Alliances

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reimbursement to self-pay. That means we have current and future products whose market potential is not limited by insurance reimbursement issues.

This balanced approach allows us to manage the risks more effectively through all stages of the process, from development through regulatory, scale-up, manufacturing and marketing. All of this improves the probability of positive outcomes for these products and for our shareholders.

Strategic alliances, with partners who are industry leaders, play an important role in our strategy. Our joint ventures with Smith & Nephew, alliance with INAMED and new collaboration with Medtronic help us to further manage the risks across the entire product cycle.

We continue to look for various creative vehicles to unlock shareholder value as we develop additional products and uses from the multiple applications of our technology. Depending on the opportunity, some of these will be in the form of new subsidiaries.

With the accomplishments made during 2001, here are the milestones to watch for during 2002:

Anginera – We plan to begin the pivotal animal trial using our dermal fibroblast technology to treat hearts compromised by insufficient blood flow. These trials could become the basis for future clinical trials.

Collagen – Our partner, INAMED, had hoped to have approval for use of our human-based collagen in wrinkle injections – without requiring patients to take a skin test – before the end of 2001. They now expect to submit additional data to the FDA by mid-year. We will be working to develop additional uses for this product.

Dermagraft – With Dermagraft approved in the United States, Smith & Nephew is working

deliberately and systematically to educate doctors about its benefits and use. Now that we have the reimbursement code, we, along with Smith & Nephew, will be working to secure actual reimbursement coverage. However, growth in sales will depend in part on how quickly that progresses. Our goal is to have coverage in the hospital out-patient setting in most of the United States by the end of the year.

At the same time, we are continuing to explore the use of Dermagraft for other medical indications. It is currently being evaluated for the treatment of venous ulcers in a pivotal clinical trial.

Periodontal – We expect to initiate pivotal clinical trials for use of our dermal fibroblast technology in certain periodontal indications.

Underlying everything we do is the commitment to bring this company to profitability. That's why the determined execution of our strategic vision is so important. It helps us generate and pursue both near- and long-term opportunities which we believe will lead the market compared to our competitors.

One of the realities of the marketplace is that the adoption of new medical technologies by doctors and hospitals can be slow, especially with new products that are revolutionary and require a fundamental change in the treatment regimen. We've seen this in the adoption rate of TransCyte.

Unexpected delays in the regulatory review process can disrupt plans for a product launch as we saw in 2001 with collagen.

These are among the reasons that, in the near term, we believe our best revenue-generating opportunities should come from applying our products and technology to the cosmetic and aesthetics markets. They tend to be less regulated, insurance reimbursement is not a factor, and adoption of new products is typically faster than in wound care.

Product Pipeline

Leverage our technology and intellectual property

Invest in broad innovative research and development, internally and through collaborations, to drive our product pipeline to achieve our mission

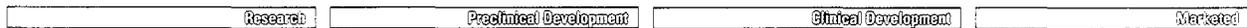
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TransCyte®



TransCyte is a human fibroblast-derived temporary skin substitute, designed as a temporary wound covering for the treatment of burns. It is the first human fibroblast-derived temporary skin substitute for the treatment of burns to be approved by the FDA for use on third-degree and second-degree burns. TransCyte is available in the United States, Canada and several other countries.



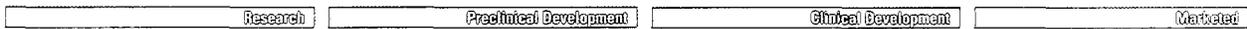
Dermagraft®



Dermagraft, a human fibroblast-derived dermal substitute, is designed for the treatment of conditions where skin has been injured or destroyed. It is cryopreserved, giving it an extended shelf life. In September 2001, the company received a Pre-Market Approval from the U.S. Food and Drug Administration for the use of Dermagraft in the treatment of chronic foot ulcers in patients with diabetes. In Canada and Australia, Dermagraft has been approved for the treatment of all chronic wounds.



NouriCel™



NouriCel is derived from the company's patented process for growing bioengineered human tissue products. As they grow, they produce an array of natural growth factors and other compounds produced by healthy new skin. After the tissue is collected, a nutrient solution enriched with these compounds remains. This solution, which does not contain any cells or tissue, is NouriCel. It has been clinically shown to reduce the appearance and depth of fine lines and wrinkles while improving skin texture and elasticity. The company believes NouriCel has market potential as a cosmetic ingredient for rejuvenating aging and sun-damaged skin. We are also exploring other health and beauty-related applications for NouriCel.

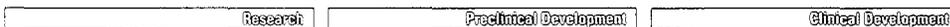


Human-Based Collagen



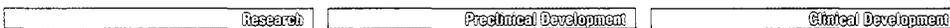
Collagen is a family of naturally occurring proteins that serve as the basic structural building blocks of many tissues of the body. We have applied our existing technology to manufacture human-based collagen. The objective has been to develop a product which, after its purification, can be sterilized and easily injected or implanted into the human body. Injections of collagen are already used in the marketplace to help eliminate wrinkles, enhance lips and for reconstructive purposes. We plan to commercialize our human-based collagen for soft tissue augmentation, such as wrinkle revision, subject to regulatory approval, through our strategic alliance with INAMED Corporation. Other possible applications may include medical device coatings, as an additive to cosmetics, or use as a natural vehicle for drug delivery.

Dermagraft® Venous Ulcers



The company continues to explore the use of Dermagraft for other medical indications. The product is currently in a pivotal clinical trial for the treatment of venous ulcers.

Periodontal



Assuring that there is adequate hard and soft tissue around teeth is critical to periodontal health. Periodontal surgeries often require the harvesting of donor tissue from another location in the patient's mouth. Significant morbidity is often associated with both the harvesting of donor tissue as well as the healing of the donor site. In addition, there is often insufficient donor tissue available to cover all sites requiring treatment at the same time, thus necessitating repeated surgeries. The company is evaluating a fibroblast-based tissue to determine if it can be used as a substitute for an autologous connective tissue graft. Pivotal clinical trials evaluating periodontal indications are expected to begin this year.

Anginera™



Improving circulation to regions of the heart that have insufficient blood flow is critical to the treatment of coronary artery disease. The company is currently evaluating the ability of a tissue-engineered, fibroblast-based tissue, Anginera, to stimulate blood vessel formation in the heart. This human-based tissue secretes multiple angiogenic growth factors which may present an advantage over other products that are based on only a single growth factor. Research has demonstrated that Anginera can induce microvessel formation with maturation into arterioles and venules. Additional preclinical studies are underway to determine if these vascular changes lead to improved ventricular function.

Other Development Work



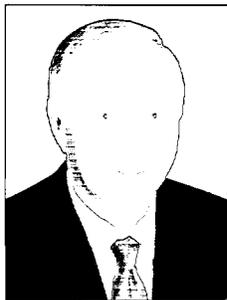
The company is doing additional development work in the following areas:

- Small diameter vascular grafts. These could ultimately be used for peripheral bypass, coronary bypass, A-V fistula and other clinical situations that require vascular grafts. This potential product is in the preclinical stage of development. Other coronary work includes efforts to develop an ischemic repair device and heart muscle.
- Tissue-engineered human cartilage for orthopedic applications such as repair of damaged joints. This potential product is in the preclinical stage of development. We are also working on cartilage for craniofacial applications.
- We also hope to develop other applications for human-based collagen and extracellular matrix in soft tissue augmentation.

Because of this, we will be working to develop the revenue and profit potential of NouriCel. Just before this annual report was printed, we announced the formation of BioNuvia, Inc., a science-driven subsidiary, to give better focus to this effort. Its mission is to develop and market bioengineered products for enhancing appearance and rejuvenating the body. Milestones to look for during 2002 include the national launch by our existing partners of their skin care products containing NouriCel. We hope to sign agreements with additional partners to sell other products containing this ingredient.

In presentations we give at investor conferences, the company overview contains a summary we call "Investment Highlights," which you will find printed inside the front cover of this annual report. It is a snapshot of where the company is right now. As you read this year's report, we hope you'll readily see our accomplishments and how those investment highlights are a base from which the company can grow and continue to build shareholder value.

We thank you for your support.



A handwritten signature of Arthur J. Benvenuto in black ink.

Arthur J. Benvenuto
Chairman, President and Chief Executive Officer



A handwritten signature of Gail K. Naughton in black ink.

Gail K. Naughton, Ph.D.
Vice Chairman

OFFICERS

Arthur J. Benvenuto
Chairman, President and
Chief Executive Officer

Gail K. Naughton, Ph.D.
Vice Chairman

Joseph R. Kietzel
Executive Vice President and
Chief Operating Officer

Mark J. Gergen
Senior Vice President,
Chief Financial and
Development Officer

Charles E. Anderson
Vice President, Quality

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Vice President, Research

Don Rinde!!
Vice President, Corporate Development
and Strategic Planning

Kerry Vail
Vice President, General Manager
BioNuvia, Inc.

CORPORATE HEADQUARTERS

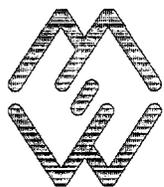
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SEC FORM 10-K

A copy of the company's Annual Report to the Securities and Exchange Commission on Form 10-K is available without charge upon request to:

Investor Relations
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ADVANCED TISSUE S C I E N C E S®

FINANCIAL STATEMENTS

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SELECTED FINANCIAL DATA

See Note 1 to the accompanying consolidated financial statements for a discussion of the basis of presentation. The selected financial data should be read in conjunction with the consolidated financial statements and related notes thereto included elsewhere in this document. The information is not necessarily indicative of future operating results.

	Years Ended December 31,				
	2001	2000	1999	1998	1997
	(In thousands, except per share amounts)				
Revenues:					
Joint venture contract (1)	\$ 16,778	\$ 20,647	\$ 25,767	\$ 18,862	\$ 12,165
Product sales (2)	5,328	87	--	1,035	976
Milestones, contracts & fees (3)	6,834	4,537	17,036	584	10
Research and development					
Expenses	7,784	7,428	6,746	10,750	10,054
Equity in losses of joint					
ventures (1)	(12,391)	(13,278)	(21,558)	(17,628)	(11,990)
Net loss	(28,373)	(24,571)	(21,306)	(43,285)	(36,089)
Net loss applicable to common					
Stock	(28,373)	(24,619)	(21,864)	(43,863)	(36,089)
Basic and diluted loss per					
common share	\$ (.43)	\$ (.41)	\$ (.45)	\$ (1.11)	\$ (.96)
Weighted average shares used in					
the calculation of basic and					
diluted loss per common share	66,069	60,575	48,507	39,373	37,548
	December 31,				
	2001	2000	1999	1998	1997
	(In thousands)				
Cash, cash equivalents and short-					
term investments	\$ 29,973	\$ 31,051	\$ 26,079	\$ 23,054	\$ 17,086
Working capital	30,508	25,082	10,651	20,442	13,216
Total assets	61,922	59,106	59,386	53,985	50,460
Long-term debt, capital lease					
obligations and redeemable					
preferred stock (4)	11,812	14,399	24,139	34,949	28,096
Accumulated deficit	(292,706)	(264,333)	(239,762)	(218,456)	(175,171)
Stockholders' equity	42,023	35,802	21,423	12,527	13,966

- (1) In April 1996, we formed the Dermagraft Joint Venture with Smith & Nephew plc for the commercialization of Dermagraft for the treatment of diabetic foot ulcers, having formed a separate joint venture for the commercialization of tissue engineered cartilage for orthopedic applications with Smith & Nephew in April 1994. We and Smith & Nephew began sharing in the revenues and expenses of the joint ventures in January 1997. Joint venture contract revenues include:
- (a) Sales of TransCyte and Dermagraft to the Dermagraft Joint Venture at cost, of \$12,767,000, \$12,771,000, \$13,717,000, \$10,927,000 and \$1,190,000 for the years ended December 31, 2001, 2000, 1999, 1998 and 1997.
 - (b) Revenues for research and development, marketing and other activities performed for the Dermagraft and NeoCyte Joint Ventures.
- (2) Includes sales of our products to unrelated customers, including sales of collagen to Inamed Corporation in the years ended December 31, 2001 and 2000; and sales of TransCyte made by our sales force in the years ended December 31, 1998 and 1997.
- (3) Includes (a) recognition of milestones and license fees from strategic partners, (b) royalties, and (c) revenues for research, development and other activities performed for unrelated parties under collaborative agreements and government grants. Milestones and license fees of \$5,000,000, \$3,595,000 and \$16,405,000 were recognized in the years ended December 31, 2001, 2000 and 1999 respectively.
- (4) Includes both current and long-term portions of debt.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read with "Selected Financial Data" and our financial statements and notes thereto included elsewhere in this annual report on Form 10-K. The discussion and analysis in this annual report on Form 10-K may contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. The cautionary statements made in this annual report on Form 10-K should be read as applying to all related forward-looking statements wherever they appear in this annual report on Form 10-K. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to these differences include those discussed in "Factors Affecting Operating Results" included in Part I, Item 1 – Business above as well as those discussed elsewhere. Such risks and uncertainties could cause actual results to differ materially from any future performance suggested below. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date of this report.

Advanced Tissue Sciences, Inc. is engaged in the development and manufacture of human-based tissue products for tissue repair and transplantation using our proprietary tissue engineering technology. Our leading products are skin products, TransCyte for the temporary covering of severe and partial-thickness burns, and Dermagraft for the treatment of severe skin ulcers. In addition, we are focusing our resources on the development of tissue engineered products for other wound care, aesthetic and reconstructive, cardiovascular and orthopedic applications. These other applications include collagen and our nutrient solution, NouriCel, for aesthetic and reconstructive applications.

Since 1996 we have participated in a joint venture, the Dermagraft Joint Venture, with Smith & Nephew plc for the worldwide commercialization of Dermagraft in the treatment of diabetic foot ulcers.

In 1998, we expanded the Dermagraft Joint Venture to include additional technology for the treatment of skin tissue wounds and applications such as venous ulcers, pressure ulcers, and TransCyte for full and partial-thickness burns. We received marketing approval for TransCyte in the United States from the FDA, in 1997, as a temporary covering for severe, full-thickness, or third degree burns and for partial-thickness, or second degree burns. Until September 1998, we marketed TransCyte for burns through a direct sales force in the United States, however subsequent to the expansion of the Dermagraft Joint Venture in 1998, TransCyte was and will be marketed in the United States and throughout the rest of the world for burn and other wound care applications under the Dermagraft Joint Venture.

Dermagraft for the treatment of diabetic foot ulcers was approved for sale in Canada and was introduced by the Dermagraft Joint Venture in the United Kingdom and several other European countries, on a limited basis, in 1997. In that year we also submitted a PMA application to the FDA for approval to market Dermagraft for the treatment of diabetic foot ulcers in the United States. In 1998 the FDA decided the PMA application was not approvable without supportive data from an additional controlled clinical trial. The additional clinical trial began in late 1998, and by August 2000 statistical significance was reached for the primary endpoint and a new PMA application was submitted to the FDA. In September 2001, we received approval from the FDA to market Dermagraft as a human fibroblast-derived dermal substitute in the treatment of chronic foot ulcers in patients with diabetes. We are currently also marketing Dermagraft for the treatment of diabetic foot ulcers, through the Dermagraft Joint Venture, in Australia, New Zealand and South Africa. We have been seeking approval of Dermagraft in Sweden as a pharmaceutical through the Mutual Recognition process, however in 2001 we withdrew the application while we assess the need for further clinical and process information requested by the regulatory authority. Pharmaceutical guidelines generally require much more extensive and rigorous clinical and process information than is customarily provided for products that are regulated as devices.

In 2001, Dermagraft was granted extended indications in both Canada and Australia for the treatment of lower limb ulcers, partial and full-thickness chronic wounds, the promotion of granulation tissue and the preparation of wounds for skin grafting.

In connection with the expansion of the Dermagraft Joint Venture, in January 1999 we received a \$15,000,000 up front payment from Smith & Nephew that was recognized in contract revenues during 1999, as related financial commitments were met. See Note 3 to the consolidated financial statements for more information on the financial transactions associated with the Dermagraft Joint Venture.

In February 2000, with a delay in the commercial introduction of Dermagraft in the United States and a requirement for an additional clinical trial by the FDA substantially increasing the partners' required investment, we

agreed in principle with Smith & Nephew to restructure the Dermagraft Joint Venture. The restructuring agreement was amended and implemented in September 2000. See Note 3 to the consolidated financial statements for more information on the financial transactions associated with the Dermagraft Joint Venture.

The objective of the restructuring was to defer the potential payment of certain milestones by Smith & Nephew while providing us a royalty stream and an opportunity to increase our long-term return from the venture. Specifically, except for \$10,000,000 in regulatory approval and reimbursement milestones related to Dermagraft in the treatment of diabetic foot ulcers, we agreed to make all other approval, reimbursement and sales milestones subject to, and payable from, joint venture earnings exceeding certain minimum levels. In return, the Dermagraft Joint Venture will pay us royalties on joint venture product sales. As part of the agreement we also sold the Dermagraft manufacturing assets that we owned to DermEquip, but retained all raw material inventory. DermEquip is a limited liability company owned jointly with Smith & Nephew, and is consolidated in our financial statements. The proceeds of this sale were used in September 2000 to pay down a portion of the outstanding balance of the NeoCyte Loan, with the remaining outstanding principal and interest being paid in our common stock based on a specified average market price. Subsequent to this transaction, the Dermagraft Joint Venture in September 2000 made us a new long-term loan, with raw material inventory being pledged as collateral security. See Notes 3, 7 and 10 to the consolidated financial statements for a discussion of transactions under the Dermagraft Joint Venture.

Under the restructured joint venture, we are sharing equally with Smith & Nephew in the expenses and revenues of the Dermagraft Joint Venture, except that we funded the first \$6 million of expenses for conducting clinical trials and regulatory support of Dermagraft and TransCyte in the treatment of venous ulcers and pressure ulcers. In addition, we funded a proportion of manufacturing and distribution costs and costs related to post-market studies for TransCyte through 1999. See Note 3 to the consolidated financial statements for a discussion of transactions under the Dermagraft Joint Venture.

In addition to Smith & Nephew's share of the ongoing investments in the Dermagraft Joint Venture they have paid \$30 million to us in fees and milestone payments since 1996, including \$5 million in 2001 on the approval by the FDA of the PMA for Dermagraft in the treatment of diabetic foot ulcers. Other payments of up to \$131 million will be due to us from Smith & Nephew subject to the achievement of various regulatory, sales and profitability milestones, over the term of the agreement which terminates in the year 2046 unless extended by mutual agreement of the partners. This amount includes a milestone payment of \$5 million related to the reimbursement status of Dermagraft and coverage by regional insurance carriers in the United States under Medicare. In December 2001, Dermagraft received an Ambulatory Payment Classification (or APC) pass-through code under the Hospital Outpatient Prospective Payment System from the Centers for Medicare & Medicaid Services (or CMS). The pass-through payment code for Dermagraft covers Medicare patients with diabetic foot ulcers treated in a hospital outpatient setting. The original notice indicated that the code would become effective on January 1, 2002, however the CMS subsequently postponed the implementation of all new outpatient codes, pending a review by the CMS. The CMS announced on February 28, 2002 that the new codes would become effective on April 1, 2002. Once the code becomes effective, each Medicare local carrier or fiscal intermediary can begin developing coverage guidelines to determine when, how often, and under what conditions they will pay for the use of Dermagraft for patients with chronic diabetic foot ulcers. The pass-through payment code is the first step toward receipt of the \$5 million milestone payment, subject to other conditions in our agreements with Smith & Nephew.

In addition to the Dermagraft Joint Venture, since 1994 we have shared in a separate joint venture with Smith & Nephew, the NeoCyte Joint Venture, for the worldwide development, manufacture and marketing of human tissue engineered cartilage for orthopedic applications. We are sharing equally with Smith & Nephew in the expenses of the joint venture. During 2000, an IDE was submitted to the FDA requesting approval to begin pilot human clinical studies of human tissue engineered cartilage. The FDA raised agency jurisdictional issues as to whether or not this product should be regulated as a medical device or biologic, as well as questions about the pre-clinical studies. We continue to work closely with the FDA to address these issues. The efforts of the joint venture in this area currently center around articular cartilage, in which we commenced a pivotal large animal pre-clinical study in 2001.

In May 1999, we entered into a strategic alliance with Inamed Corporation for the development and marketing of several of our human-based, tissue engineered products for aesthetic and certain reconstructive applications. Under the related agreements, Inamed licensed rights to further develop, manufacture and sell certain of our tissue engineered products such as human-based collagen for use in wrinkle correction and as a bulking agent for the treatment of urinary incontinence, cartilage for plastic and reconstructive surgery, and extracellular matrix for use in breast reconstruction and other soft tissue augmentation. We are responsible for the development of the products and the related manufacturing processes while Inamed is responsible for clinical, regulatory and marketing activities. We, or an affiliate, have the right to manufacture the products developed for Inamed. In total, under the agreements between the parties, in exchange for worldwide licensing rights, Inamed has paid us a series of payments totaling \$10 million, including \$5 million to purchase our common stock. Inamed also received five-year warrants

to purchase up to 500,000 shares of common stock. In addition to a price for our product and royalties on Inamed's sales in the market place, we may potentially receive up to a total of \$10 million in milestones based on product approvals in the United States, subject to our success in developing products under the agreement and Inamed's success in obtaining such approvals.

During 2001, a subsidiary of Inamed, McGhan Medical, filed a PMA supplement with the FDA seeking approval to add our human-based collagen to McGhan's existing injectable collagen products for wrinkle treatments. Inamed announced in October 2001 that the FDA had requested additional pre-clinical data and had asked them to perform skin-test studies, which are currently being conducted. During 2001 we shipped our human-based collagen to Inamed for the purposes of clinical studies, evaluation and testing, however pre-launch sales of collagen to Inamed are expected to cease, pending receipt of FDA approval and the subsequent launch of the product in the wrinkle treatment market. See Note 3 to the consolidated financial statements for a discussion of transactions under our alliance with Inamed.

In September 2000, we signed a license and supply agreement with Biozhem Cosmeceuticals, Inc. Under the agreement, we granted a license to use and are selling NouriCel to Biozhem. NouriCel is a patent-pending by-product of our tissue engineering processes, to be used in Biozhem's branded skin care products. As well as a selling price for sales of NouriCel to Biozhem, we are entitled to specified milestone payments and royalties on sales of Biozhem's products in the skin care marketplace. Additionally, we were granted warrants to purchase Biozhem common stock at specified prices in future time periods. In January 2002, with the launch Biozhem's product having been delayed from the expected date in the agreement, we amended our agreement with Biozhem to defer the payment to us of an initial milestone of \$1 million, from December 2001 to November 2002. In addition, the amended agreement provides for a new schedule of minimum royalty payments by Biozhem to us in 2002, including the payment of minimum royalties originally scheduled in 2001. Our decision to defer the milestone and minimum royalties was based primarily upon Biozhem's ability to make the payments as a result of the delay in Biozhem's receipt of income from sales of our product. Terms of the original agreement with Biozhem relating to payments and other obligations after 2003 remain unchanged. See Note 3 to the consolidated financial statements for a discussion of transactions under our alliance with Biozhem.

In October 2000, we signed a license and supply agreement with SkinMedica, Inc. Under this agreement, we granted a license to use and are selling NouriCel to SkinMedica, to be used in SkinMedica's branded skin care products sold through a network of dermatologists and plastic surgeons. We are entitled to a selling price for sales of NouriCel to SkinMedica and to specified milestone payments and royalties on sales of SkinMedica's products in the skin care marketplace. We were also granted warrants to purchase SkinMedica common stock at specified prices in future time periods. In May 2001, the agreement was amended to change specified commencement and termination provisions. See Note 3 to the consolidated financial statements for a discussion of transactions under our alliance with SkinMedica.

In October 2001, we entered into a broad strategic collaboration with Medtronic, Inc. to explore the application of our technology in the areas of cardiovascular, neurological, endocrine and spinal. An affiliate of Medtronic simultaneously purchased \$20 million of our common stock at \$3.72 per share, in return for specified rights including a right of first refusal to collaborate in the further development and commercialization of Anginera, our epicardial angiogenesis therapy, a product that stimulates new blood vessel growth and therefore increased blood flow, a right of first offer/first negotiation to collaborate in other programs within the cardiovascular, neurological, endocrine and spinal areas where we elect not to pursue those programs internally, and a limited non-exclusive license to our intellectual property in the four therapeutic areas identified to facilitate Medtronic's exploration of cell and tissue engineered technology in combination with Medtronic's medical devices. Net proceeds of the equity investment were approximately \$19.9 million.

In May 2000, researchers at the University of Washington announced that they would be partnering with us and others in a project, funded by a \$10 million grant from NIH to grow functional human heart tissue. The proportion of the grant for which we would be eligible is approximately \$1.8 million. The grant is expected to cover the first five years of an anticipated 10 year project.

In September 2000, we were awarded a \$2 million Advanced Technology Program grant from NIST, for development of a tissue engineered Ischemic Repair Device to induce vascularization of, and restore function to, tissues and organs with reduced blood supplies, or ischemia. The grant commenced in 2000 and is payable over three years. This grant follows a \$2 million award in October 1997 from NIST to fund collaborative cardiovascular research with the University of California, San Diego, that was completed in the second quarter of 2001.

Also in September 2000, we were awarded a grant in excess of \$800,000 from NIH and the National Institute of Dental and Craniofacial Research to develop tissue engineered cartilage for the treatment of temporomandibular disorders. Payments under the grant are payable over four years.

In October 2001, we signed a 10-year lease on 29,000 square feet of additional office and research laboratory space in a facility approximately three miles from our La Jolla location, and expect to move the majority of our research activities into the new facility in May 2002. The lease term will commence in May 2002, subject to the completion of improvements. We have options to extend the term of the lease for two five-year periods. As a condition of signing the lease, we were required to purchase a standby letter of credit in the amount of \$1.7 million. This facility replaces a laboratory facility of approximately 7,000 square feet, on which our lease expired in January 2002.

To date, we have experienced significant operating losses in funding the research, development, testing and marketing of our products and expect to continue to incur substantial operating losses. Through December 30, 2001, we had incurred cumulative net operating losses of \$292.7 million. Our ability to achieve profitability depends in part upon our ability to successfully manufacture Dermagraft and TransCyte for skin ulcers and burns, for our partner, Inamed, to obtain regulatory approval for their human-based collagen product, for us to cost-effectively manufacture collagen and our nutrient solution for aesthetic applications, and for each of these products to be successfully marketed by our partners. We may never achieve a profitable level of operations or even if we achieve profitability, we may not be able to sustain it on an ongoing basis.

We have incurred and expect to continue to incur, either directly or through the Dermagraft Joint Venture, substantial expenditures in support of the commercialization, development, clinical trials and post-market studies of TransCyte and Dermagraft for burn and skin ulcer applications, for manufacturing systems and in advancing other applications of our core technology. We also expect to incur additional costs for the development of products and manufacturing processes under our strategic alliance with Inamed, additional costs for the development and clinical trials of tissue engineered cartilage products through the NeoCyte Joint Venture, costs for products we may develop for cardiovascular applications, and costs which may be associated with other products which we may undertake from time to time. Our agreements with our current strategic alliance partners are structured to share some or all of these costs as well as to provide us with income from milestone payments, royalties and licensing fees for the respective products. See Note 3 to the consolidated financial statements for details regarding financial transactions under our strategic alliance agreements.

Critical Accounting Policies

Our financial statements are prepared in conformity with generally accepted accounting principles. We believe the following accounting policies, in particular, are critical to our results of operations and to the understanding of our consolidated financial statements. Our consolidated financial statements include the accounts of Advanced Tissue Sciences, its wholly owned subsidiaries, and DermEquip L.L.C., a limited liability company owned jointly with Smith & Nephew. DermEquip is a special purpose entity which was established to finance an expansion of our manufacturing facility, and which holds the assets used in the facility. All intercompany accounts and transactions are eliminated. Our other interests in joint ventures with Smith & Nephew are accounted for under the equity method.

Revenues from product sales are recognized when products are shipped and title has passed, and we have no further specified performance obligations. Revenues from product sales to related parties, such as our joint ventures with Smith & Nephew, are recognized at such time as ownership of the product is transferred to the related party, generally upon the completion of manufacturing. Such product sales to related parties are equal to our cost.

As a result of the delay in Dermagraft approval by the FDA until September 2001, we continue to incur significant costs associated with excess production capacity within our manufacturing facility. The Dermagraft Joint Venture purchases Dermagraft and TransCyte from us as they are manufactured, at cost, including period costs, and immediately writes the inventory down to estimated market value at the date of purchase. The estimated market value is the net realizable value at which the Joint Venture believes it will be able to sell the products to its customers. In the year ended December 31, 2001 inventory write-downs by the Dermagraft Joint Venture totaled \$9,089,000, down from \$9,821,000 in 2000. We incur our share of the write-downs, currently 50%, through our equity in the joint venture. To the extent that we do not sell such products to the Dermagraft Joint Venture, we would be required to write such inventories down to net realizable value.

We own and have patents pending in the United States and abroad to protect the processes and products we are developing. Direct patent application costs related to patents issued are amortized over the estimated useful life of the patent, approximately 20 years from the date of application. Such costs related to pending applications are deferred until the patent is issued or charged to operations at the time a determination is made not to pursue an application. Patent application and maintenance costs related to licensing agreements are expensed as incurred.

Results of Operations

The presentation of the statement of operations in the attached financial statements has been reformatted from prior presentations to more clearly reflect revenue and cost transactions between us and our joint ventures with Smith & Nephew. These transactions are separately presented from transactions with other parties.

Year Ended December 31, 2001 as Compared to the Year Ended December 31, 2000

Joint venture contract revenues were \$16,778,000 in 2001, compared to \$20,647,000 in 2000. Joint venture contract revenues include sales of Dermagraft and TransCyte to the Dermagraft Joint Venture at cost, and revenues for research and development, administration, and other services performed for the Dermagraft and NeoCyte Joint Ventures under collaborative agreements. See Notes 3 and 15 to the consolidated financial statements for further discussion of transactions under the Dermagraft and NeoCyte Joint Ventures. Sales of Dermagraft and TransCyte to the Dermagraft Joint Venture were \$12,767,000 in 2001, and \$12,771,000 in 2000. Growth in sales of Dermagraft and TransCyte in 2002 and beyond will be primarily dependent on the Dermagraft Joint Venture partners' success in obtaining product reimbursement from both national healthcare systems and private insurers, and on the success of Smith & Nephew in marketing the products.

Revenue for services performed for the joint ventures was \$4,011,000 in 2001, compared to \$7,876,000 in 2000. The primary causes of this decrease are a reduction of \$2,077,000 in revenue for services performed for the NeoCyte Joint Venture, and \$1,647,000 due to the completion in 2000 of the clinical trial of Dermagraft for the treatment of diabetic foot ulcers.

Product sales to third parties were \$5,328,000 in 2001, compared to \$87,000 in 2000. These revenues primarily represent sales of our human-based collagen to Inamed Corporation, which we have been shipping to Inamed for the purposes of clinical studies, evaluation and testing. Prior to the launch of Inamed's human-based collagen product, our sales of collagen to Inamed are expected to cease, pending receipt of FDA approval and Inamed's subsequent launch of the product in the wrinkle treatment market.

Milestone revenue in 2001 was \$5,000,000, compared to \$3,595,000 in 2000. In September 2001 we recognized the \$5,000,000 milestone from Smith & Nephew that resulted from the approval of the PMA for Dermagraft in the treatment of diabetic foot ulcers in the United States. In 2000 we recognized the final \$3,595,000 of a \$5,000,000 licensing payment received from Inamed Corporation in 1999.

Other contract and fee revenue was \$1,834,000 in 2001, compared to \$942,000 in 2000, primarily reflecting an increase in government grant revenue.

Joint venture contract expense was \$16,564,000 in 2001, compared to \$20,420,000 in 2000. Joint venture contract expenses include (in thousands):

	<u>2001</u>	<u>2000</u>
Manufacturing and distribution costs – Dermagraft & TransCyte	\$ 12,645	\$ 12,699
Research and development costs	2,299	5,673
Administration and other expenses	<u>1,620</u>	<u>1,962</u>
Total joint venture contract expenses	\$ 16,564	\$ 20,334

As a result of the delay in Dermagraft approval by the FDA until September 2001, we continue to incur significant costs associated with excess production capacity within our manufacturing facility. We expect to continue to have excess production capacity in future years. The Dermagraft Joint Venture purchases Dermagraft and TransCyte from us as they are manufactured at cost, including period costs, and immediately writes the inventory down to estimated market value at the date of purchase. The estimated market value is the net realizable value at which the Joint Venture believes it will be able to sell the products to its customers. In the year ending December 31, 2001 inventory write-downs by the Dermagraft Joint Venture totaled \$9,089,000, down from \$9,821,000 in 2000. We incur our share of the write-downs, currently 50%, through our equity in the joint venture. To the extent that we do not sell such products to the Dermagraft Joint Venture, we would be required to write such inventories down to net realizable value.

The decrease in joint venture research and development contract expenses resulted primarily from the reduced spending in 2001 by the NeoCyte Joint Venture, and the completion during 2000 of the clinical trial of Dermagraft in the treatment of diabetic foot ulcers.

Cost of goods sold for products sold to third parties increased from \$153,000 in 2000, to \$8,340,000 in 2001. This increase primarily reflects production costs for the human-based collagen sold to Inamed in 2001, which included costs associated with the implementation of collagen manufacturing.

Research and development expense for projects, other than those performed for our joint ventures with Smith & Nephew, increased by \$356,000 to \$7,784,000, from \$7,428,000 in 2000. Year over year, development costs related to the development of NouriCel increased by \$792,000, and research costs under grant projects increased by \$525,000. These increases were offset by a reduction of \$1,073,000 in collagen product development costs included in research and development, as our collagen product was moved from product development into manufacturing. Our research and development costs, under both our joint ventures and for other projects, will continue to be significant due to continuing and anticipated clinical trials and post-market studies during 2002 and beyond. In addition, in 2002 we will incur increased costs related to our new research facility. A discussion of our current research and development projects appears below :

Research and Development Expenses

(In thousands, except dates)

Expenditure includes overheads and support services such as quality assurance and information technology

	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>Expenditure to Date</u>
Projects :				
Dermagraft & TransCyte R&D (Dermagraft Joint Venture)	\$ 1,932.2	\$ 3,351.8	\$ 6,986.5	**
Articular cartilage pre-clinical research (NeoCyte Joint Venture)	367.2	2,321.0	2,817.6	**
NIST grant - vascular grafts (see Cardiovascular page 6)	34.1	1,298.8	1,718.7	4,365.5
Development of Aesthetic & Reconstructive manufacturing processes	1,146.7	1,427.8	--	2,574.5
NIST grant – ischemic repair devices (see Cardiovascular page 7)	841.7	75.2	--	916.9
Anginera pre-clinical research	518.2	170.9	--	689.1
Initial 5 year phase of NIH grant to grow heart tissue (University of Washington) (see Cardiovascular page 7)	512.1	62.3	--	574.4
NIH grant – tempromandibular disorders (see Other Therapeutic Tissues page 10)	243.2	48.5	--	291.7
Periodontal pre-clinical research	272.7	--	--	272.7
Other active grants	423.9	226.8	120.6	463.4
Other research & development expenditure, including management & administration	3,791.2	4,117.4	4,656.5	**
Total Research and Development	\$ 10,083.2	\$ 13,100.5	\$ 16,299.9	

** Total expenditure to date not available or estimable, due to historical changes in reporting methodologies or business re-organization.

We generally do not provide forward-looking estimates of costs and time to complete current projects, as such estimates involve a high degree of uncertainty. Uncertainties include, but are not limited to, our ability to predict the outcome of complex research, regulatory requirements placed upon us by regulatory authorities such as the FDA, our ability to raise capital to finance research activities, competition from other entities of which we may become aware in future periods, predictions of market potential from products that may be derived from our research projects, and our ability to recruit and retain personnel with the necessary knowledge and skills to perform the research. We have made certain commitments to third parties in order to receive funds under our research grants. Such commitments involve estimates of time needed and activities required to complete projects. However significant uncertainty exists in our ability to accurately forecast the costs of performing the activities, such as the cost of recruiting and retaining the necessary personnel with the knowledge and skills to perform the research, the cost of required materials, and the overhead required to support the specific projects.

Selling, general and administrative expenses in 2001 increased by \$2,727,000 over 2000, to \$12,515,000. Salary and benefits expense increased by \$1,163,000, including \$449,000 of recruitment related costs, primarily as a result of senior management additions made in the fourth quarter of 2000 and the first quarter of 2001, and the

building of infrastructure to support anticipated product launches. Outside services expense for consultants and professional services increased by \$728,000 as a result of planning and business development initiatives undertaken during 2001. The increase in 2001 compared to 2000 also reflects a non-cash charge of \$677,000 in 2001 related to compensation expense for a variable stock option. Expense related to the variable stock option was zero for the full year 2000. See Note 10 to the consolidated financial statements for a discussion of transactions associated with our capital stock.

Our equity in losses of joint ventures was \$12,391,000 in 2001, compared to \$13,278,000 million in 2000. These amounts represent our share of the losses of the Dermagraft and NeoCyte Joint Ventures. Joint venture losses were reduced in 2001 primarily as a result of the NeoCyte Joint Venture's decrease in research and development spending, and the completion of the clinical trial of Dermagraft in the treatment of diabetic foot ulcers in 2000.

Joint venture product sales to third parties for the year 2001 were \$4,212,000, compared to \$4,280,000 in 2000. Of these sales, TransCyte accounted for \$3,792,000 in 2001 and \$3,940,000 in 2000. The reduction in sales resulted primarily from the Joint Venture's ability to meet market demand being constrained by declines in manufacturing yields.

Interest income and other was \$525,000 in 2001, compared to \$1,925,000 in 2000. Interest income in 2001 was \$1,083,000 below interest income received in 2000, due to a combination of lower interest rates and lower average cash balances. Total interest expense was \$643,000 in 2001, compared to \$1,513,000 in 2000. Excluding interest expense incurred on behalf of our joint ventures with Smith & Nephew, which appears in joint venture contract expense in our statement of operations, interest expense was \$244,000 in 2001, compared to \$786,000 in 2000. The decrease in interest expense reflects lower interest rates, the repayment of a \$10,000,000 loan from Smith & Nephew in September 2000, and a declining balance in the Chase loan. These decreases were partially offset by interest on approximately \$5,412,000 in borrowings from the Dermagraft Joint Venture associated with the restructuring of the Joint Venture in September 2000. See Notes 3 and 7 to the consolidated financial statements for a discussion of transactions associated with our joint ventures.

We paid dividends on preferred stock of approximately \$48,000 in 2000. All remaining shares of our Convertible Series B Preferred Stock were converted to common stock in March 2000. See Note 11 to the consolidated financial statements for details regarding our Convertible Series B Preferred Stock.

Year Ended December 31, 2000 as Compared to the Year Ended December 31, 1999

Joint venture contract revenues were \$20,647,000 in 2000, compared to \$25,767,000 in 1999. Joint venture contract revenues include sales of Dermagraft and TransCyte to the Dermagraft Joint Venture at cost, and revenues for research and development, administration, and other services performed for the Dermagraft and NeoCyte Joint Ventures under collaborative agreements. See Notes 3 and 15 to the consolidated financial statements for further discussion of transactions under the Dermagraft and NeoCyte Joint Ventures. Sales of Dermagraft and TransCyte to the Dermagraft Joint Venture were \$12,771,000 in 2000, compared to \$13,717,000 in 1999. The reduction in sales reflects primarily the timing of products moving from work in process to inventory and therefore being recorded as sales to the Dermagraft Joint Venture, as well as reductions in manufacturing costs arising from process improvements. Inventory held by the Dermagraft Joint Venture was reduced by approximately \$450,000 from December 31, 1999 to December 31, 2000.

Revenue for services performed for the joint ventures was \$7,876,000 in 2000, compared to \$12,050,000 in 1999. This is primarily due to the completion in 2000 of the clinical trial of Dermagraft for the treatment of diabetic foot ulcers. The costs of the trial, which were significantly higher for the full year of 1999 than the partial year's expense in 2000, were charged to the Dermagraft Joint Venture under our collaborative agreement.

Product sales of \$87,000 in 2000 represent our first sales of human-based collagen to Inamed Corporation. There were no product sales to third parties in 1999.

Milestone revenue was \$3,595,000 in 2000, compared to \$16,405,000 in 1999. Milestone revenue in 2000 relates to the recognition of \$3,595,000 of a \$5 million licensing payment received from Inamed Corporation in 1999, the first \$1,405,000 having been recognized into revenues in 1999. The \$5 million milestone payment from Inamed in 1999 was recognized over 18 months, representing the performance period. Additionally, revenue in 1999 included the recognition of a \$15,000,000 up front payment from Smith & Nephew associated with the expansion of the Dermagraft Joint Venture. See Note 3 to the consolidated financial statements regarding these milestone and up front payments.

Other contract and fee revenue was \$942,000 in 2000, compared to \$631,000 in 1999, primarily reflecting an increase in government grant income.

Joint venture contract expenses were \$20,334,000 in 2000 compared to \$25,593,000 in 1999. Joint venture contract expenses include (in thousands):

	<u>2000</u>	<u>1999</u>
Manufacturing and distribution costs – Dermagraft & TransCyte	\$ 12,699	\$ 13,717
Research and development costs	5,673	9,554
Administration and other expenses	<u>1,962</u>	<u>2,322</u>
Total joint venture contract expenses	\$ 20,334	\$ 25,593

The cost to manufacture and distribute Dermagraft and TransCyte decreased from \$13,717,000 in 1999 to \$12,699,000 in 2000. As a result of the delay in Dermagraft approval by the FDA, we continued to incur significant costs associated with excess production capacity within our manufacturing facility in 2000 and 1999. The Dermagraft Joint Venture purchases Dermagraft and TransCyte from us as they are manufactured, at cost including period costs, and immediately writes the inventory down to estimated market value at the date of purchase. Period costs reflect overhead costs related to excess production capacity and include rent, depreciation, and quality control, facilities, supplies and other such costs to support, or related to excess production capacity. The estimated market value is the net realizable value at which the Joint Venture believes it will be able to sell the products to its customers. In the year ending December 31, 2000 inventory write-downs by the Dermagraft Joint Venture totaled \$9,821,000, down from \$11,982,000 in 1999. To the extent that we do not sell such products to the Dermagraft Joint Venture, we would be required to write such inventories down to net realizable value.

The decrease in joint venture research and development contract expenses primarily relates to the costs of the additional clinical trial of Dermagraft for the treatment of diabetic foot ulcers, which began in late 1998 and was completed in the first half of 2000.

Cost of goods sold for products sold to third parties was \$153,000 in 2000, reflecting production costs for human-based collagen sold to Inamed. As shipments commenced in 2000, there was no related cost of goods sold in 1999.

Research and development expense for projects other than those performed for our joint ventures with Smith & Nephew increased in 2000 by \$682,000 to \$7,428,000, from \$6,746,000 in 1999. The increase primarily relates to our investment in the development of human-based collagen and NouriCel.

Selling, general and administrative expenses were \$9,788,000 in 2000, compared to \$9,527,000 in 1999. A decrease in facilities costs of approximately \$900,000, primarily related to the consolidation of our facilities into two buildings in 1999, was offset by an increase in compensation, benefit and recruitment related costs.

Equity in losses of Joint Ventures was \$13,278,000 in 2000, compared to \$21,558,000 in 1999. These amounts represent our share of the losses of the Dermagraft and NeoCyte Joint Ventures. During 1999, we funded certain manufacturing and distribution costs associated with the transfer of sales and marketing of TransCyte in the United States to the Dermagraft Joint Venture, and included such costs as a loss in equity in Joint Ventures. No such costs were included as a loss in equity in 2000, compared to approximately \$3,200,000 in 1999. Other factors affecting the reduction include the completion of the clinical trial of Dermagraft for diabetic foot ulcers in 2000, increased sales to third parties, and reductions in the Dermagraft Joint Venture's cost structure.

Interest income and other was \$1,925,000 million in 2000, compared to \$362,000 in 1999. Interest income in 2000 was largely unchanged from 1999, however we incurred other expenses of approximately \$1,300,000 in 1999 related to the consolidation of our operations into two facilities. Specifically, this included a \$417,000 fee paid in terminating a long-term facility lease, and asset disposals and write-downs of approximately \$900,000.

Total interest expense was \$1,513,000 in 2000, compared to \$1,801,000 in 1999. Excluding interest expense incurred on behalf of our joint ventures with Smith & Nephew, which appears in joint venture contract expense in our statement of operations, interest expense was \$786,000 in 2000, compared to \$1,047,000 in 1999. The decrease in interest expense primarily reflects the repayment of a \$10,000,000 loan from Smith & Nephew in June 1999, partially offset in 2000 by additional borrowing from Smith & Nephew related to the NeoCyte Joint Venture, that were repaid in September. See Notes 3 and 7 to the consolidated financial statements for details regarding these transactions.

We paid dividends on preferred stock of approximately \$48,000 in 2000 and \$558,000 in 1999. All remaining shares of our Convertible Series B Preferred Stock were converted to common stock in March 2000. See Note 11 to the consolidated financial statements for details regarding our Convertible Series B Preferred Stock.

Liquidity and Capital Resources

To date, we have funded our operating and capital expenditures primarily through the sale of equities, contract revenues, funding from strategic partners, bank loans, government grants, product sales and lease financing transactions.

In addition to investments in money market funds, our cash equivalents consist primarily of investments in commercial paper, which are unsecured obligations, and obligations issued or guaranteed by the United States Government with maturities of three months or less at the date of acquisition. Short-term investments are valued on the basis of quoted market value and consist primarily of investments in commercial paper and obligations issued or guaranteed by the United States Government with maturities of one year or less but more than three months at the date of acquisition. Cash equivalents and short-term investments are stated at amortized cost, which approximates market value. As of December 31, 2001 and 2000, our cash equivalents and short-term investments were classified as available-for-sale. These investments all mature in less than one year. There were no significant unrealized or realized gains or losses related to such securities during the years ended December 31, 2001 or 2000. When making investments in commercial paper, we use ratings supplied by recognized debt-rating agencies to assess potential risks.

Cash and cash equivalents at December 31, 2001 increased by approximately \$5,776,000 from December 31, 2000. Major inflows included \$19,943,000 in net proceeds from the sale of common stock to an affiliate of Medtronic, Inc. in October 2001, \$13,548,000 in net proceeds from the sale of common stock to a private group of investors led by the State of Wisconsin Investment Board in November 2001, the receipt of \$5,000,000 from Smith & Nephew on the approval of the PMA for Dermagraft, see Note 3, and \$6,854,000 in net proceeds from sales of short-term investments. These inflows were partially offset by the use of \$22,846,000 to fund operations, a net investment of \$11,148,000 to support the Dermagraft and NeoCyte Joint Ventures, \$1,700,000 in restricted cash (see Note 9 to the consolidated financial statements), \$971,000 for capital expenditures and \$2,673 for payment of debt (see Note 7 to the consolidated financial statements). Cash flows were as follows (in thousands):

	<u>2001</u>
CASH FLOWS :	
Sale of common stock to an affiliate of Medtronic in October 2001	\$ 19,943
Sale of common stock to a private group in November 2001	13,548
Dermagraft milestone payment received from Smith & Nephew	5,000
Net proceeds from short-term investments	6,854
Cash used to support operations, excluding milestone income	(22,846)
Investment in joint ventures with Smith & Nephew, net	(11,148)
Debt payment	(2,673)
Restricted cash to support letter of credit	(1,700)
Capital expenditures	(971)
Other cash disbursements, net	(231)
	<hr/>
NET CHANGE IN CASH AND EQUIVALENTS December 31, 2001 to 2000	<u>\$ 5,776</u>

Receivables from joint ventures from December 31, 2001 to December 31, 2000 increased by \$378,000, in line with product sales. Receivables from Inamed increased by \$3,459,000 from December 31, 2000 to December 31, 2001, primarily relating to receivables from Inamed for sales of collagen. Inventory increased by \$832,000, primarily relating to collagen. During 2001, a subsidiary of Inamed, McGhan Medical, filed a PMA supplement with the FDA seeking approval to add our human-based collagen to McGhan's existing injectable collagen products for wrinkle treatments. Inamed announced in October 2001 that the FDA had requested additional pre-clinical data and had asked them to perform skin-test studies, which are currently being conducted. During the fourth quarter of 2001, we continued to ship our human-based collagen to Inamed for the purposes of clinical studies, evaluation and testing, however pre-launch sales of collagen to Inamed are expected to cease, pending receipt of FDA approval and the subsequent launch of the product in the wrinkle treatment market.

Current and long-term debt at December 31, 2001 decreased by \$2,413,000 from December 31, 2000, primarily reflecting the reduction in the DermEquip Chase loan. See Note 7 to the consolidated financial statements for a discussion of long-term debt. Accrued expenses decreased primarily as the result of a decrease in accrued wages and benefits.

There were no deferred revenues at December 31, 2001 or 2000.

Maturities of long-term debt and capital lease obligations over the next five years are approximately \$7,972,000 in 2002, \$2,560,000 in 2003 and \$1,280,000 in 2004. Of the \$7,972,000 in 2002, \$5,412,000 relates to a

loan from the Dermagraft Joint Venture currently payable on December 31, 2002. See Note 7 to the consolidated financial statements for further detail regarding the Dermagraft Joint Venture Loan.

Under an agreement with Ethicon, Inc., for the supply of the mesh framework used by us in the manufacture of Dermagraft, we are committed to purchasing minimum quantities. Based upon current market prices the commitment is estimated to be approximately \$2.5 million in 2002, with the current agreement expiring in January 2003.

We expect to continue to expend cash as we incur substantial research and development expenses, additional costs in support of clinical trials, general and administrative costs in support of product commercialization, and expenditures for capital equipment and patents. In addition, under the terms of our agreements with Smith & Nephew, we have agreed to fund our share of the costs of the Dermagraft and NeoCyte Joint Ventures. To the extent that such costs can be forecast, they are mutually agreed by us and Smith & Nephew as partners in the joint ventures. We have also agreed to fund specified costs to develop products, and related manufacturing processes, which will be marketed by Inamed under the terms of our licensing agreement. These uses of cash are expected to be only partially offset by revenues received from the Dermagraft and NeoCyte Joint Ventures with Smith & Nephew, from the Inamed alliance, from sale or royalties under our alliance agreements for the marketing of NouriCel-based products, or from other potential revenue sources. If, for any reason, Smith & Nephew were to terminate the Dermagraft Joint Venture, we would experience a substantial increase in the need for and use of our cash to support the commercialization and manufacture of Dermagraft and TransCyte. If Smith & Nephew were to terminate the NeoCyte Joint Venture, we would experience an increase in the need for and use of our working capital to support the development of our orthopedic cartilage products, or we would need to reduce or terminate our investment in such development if funding from other sources were not available to us.

Our cash requirements are dependent upon a number of factors, including the achievement and timing of regulatory approvals and third-party reimbursement, sales and marketing efforts by our partners, market acceptance of our products and potential products, the establishment of new strategic alliances, the timing and expense of pre-clinical and clinical studies, and new technological innovations. We currently believe we have sufficient funds to support our planned operations into the fiscal year 2003.

The further development of our technology and commercialization of our products, as well as any further development of manufacturing capabilities or the establishment of any additional sales, marketing and distribution capabilities, will require the commitment of substantial funds. Sources of funds may include payments from alliances with Smith & Nephew, Inamed, Biozhem or SkinMedica. We may also pursue additional public or private offerings of equity or debt securities. Additional funding could potentially be obtained through new strategic alliances or other collaborative arrangements, or through the extension of existing strategic alliances. However, funds from the sources outlined above may not be available when needed or on terms favorable to us, under existing arrangements or otherwise, and we may not be successful in entering into any other strategic alliances or collaborative arrangements.

We continually review our product development activities in an effort to allocate available resources to those products we believe have the greatest commercial potential. Factors considered by us in determining the products to pursue include projected market demand, potential for regulatory approval and reimbursement, if required, under the existing healthcare system, as well as anticipated healthcare reforms, technical feasibility, expected and known product attributes and estimated costs to bring the product to market. Based on these and other factors that we consider relevant, we may from time to time reallocate resources among product development activities. Additions to products under development or changes in products being pursued can substantially and rapidly change our funding requirements.

Market Risk

We are exposed to changes in interest rates primarily from our long-term debt arrangements and, secondarily, our investments in certain securities. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We believe that a hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments at December 31, 2001.

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Advanced Tissue Sciences, Inc.

We have audited the accompanying consolidated balance sheets of Advanced Tissue Sciences, Inc. as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity 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. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Advanced Tissue Sciences, Inc. at December 31, 2001 and 2000, and the consolidated results of its operations and its 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.



ERNST & YOUNG LLP

San Diego, California
January 29, 2002

ADVANCED TISSUE SCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(Dollars In Thousands, Except Per Share Amounts)

	December 31,	
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 29,973	\$ 24,197
Short-term investments	--	6,854
Receivable from joint ventures	1,852	1,474
Receivables from third parties	3,546	87
Inventory	6,605	5,773
Other current assets	2,669	1,727
Total current assets	44,645	40,112
Property - net	11,067	13,681
Patent costs - net	2,527	2,320
Restricted cash (Note 9)	1,700	--
Other assets	1,983	2,993
Total assets	\$ 61,922	\$ 59,106
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,050	\$ 1,075
Payable to joint ventures (Notes 3 and 7)	6,039	5,977
Accrued expenses	4,314	5,391
Short-term debt, and current portion of long-term debt (Note 7)	2,734	2,587
Total current liabilities	14,137	15,030
Long-term debt	3,840	6,400
Other long-term liabilities	1,922	1,874
Total liabilities	19,899	23,304
Commitments and contingencies (Notes 8 and 9)		
Stockholders' equity:		
Common Stock, \$.01 par value; 125,000,000 shares authorized; 73,148,553 and 64,200,941 shares issued and outstanding at December 31, 2001 and 2000, respectively	731	642
Additional paid-in capital	335,368	301,168
Note received in connection with the sale of Common Stock and deferred compensation applicable to Common Stock	(1,370)	(1,672)
Accumulated deficit	(292,706)	(264,333)
Accumulated other comprehensive income (loss) – loss on securities	--	(3)
Total stockholders' equity	42,023	35,802
Total liabilities and stockholders' equity	\$ 61,922	\$ 59,106

See accompanying notes to the consolidated financial statements.

ADVANCED TISSUE SCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Per Share Amounts)

	Years Ended December 31,		
	2001	2000	1999
Revenues:			
Joint venture contract	\$ 16,778	\$ 20,647	\$ 25,767
Product sales to third parties	5,328	87	--
Contracts and fees -			
Milestones	5,000	3,595	16,405
Others	<u>1,834</u>	<u>942</u>	<u>631</u>
Total revenues	<u>28,940</u>	<u>25,271</u>	<u>42,803</u>
Costs and expenses:			
Joint venture contract	16,564	20,334	25,593
Cost of goods sold	8,340	153	--
Research and development	7,784	7,428	6,746
Selling, general and administrative	<u>12,515</u>	<u>9,788</u>	<u>9,527</u>
Total costs and expenses	<u>45,203</u>	<u>37,703</u>	<u>41,866</u>
Income (loss) from operations before equity			
in losses of joint ventures	(16,263)	(12,432)	937
Equity in losses of joint ventures	<u>(12,391)</u>	<u>(13,278)</u>	<u>(21,558)</u>
Loss from operations	(28,654)	(25,710)	(20,621)
Other income (expense):			
Interest income and other	525	1,925	362
Interest expense	<u>(244)</u>	<u>(786)</u>	<u>(1,047)</u>
Net loss	(28,373)	(24,571)	(21,306)
Dividends on preferred stock	<u>--</u>	<u>(48)</u>	<u>(558)</u>
Net loss applicable to common stock	\$ <u>(28,373)</u>	\$ <u>(24,619)</u>	\$ <u>(21,864)</u>
Basic and diluted loss per common share	\$ <u>(.43)</u>	\$ <u>(.41)</u>	\$ <u>(.45)</u>
Weighted average number of common shares used in the computation of basic and diluted loss per common share	<u>66,069</u>	<u>60,575</u>	<u>48,507</u>

See accompanying notes to the consolidated financial statements.

ADVANCED TISSUE SCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Years Ended December 31,		
	2001	2000	1999
Operating activities:			
Net loss	\$ (28,373)	\$ (24,571)	\$ (21,306)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	3,660	3,903	4,772
Compensation for services paid in stock, options or warrants	1,044	450	344
Equity in losses of joint ventures	12,391	13,278	21,558
Other adjustments to net loss	83	(18)	1,575
Deferred revenue	--	(3,595)	3,595
Changes in assets and liabilities:			
Receivables from joint ventures	(378)	711	(1,023)
Receivable from Inamed	(3,459)	(87)	--
Inventory	(832)	(1,478)	(931)
Other current assets	(942)	(57)	(414)
Accounts payable	(25)	320	(139)
Payable to joint ventures	62	(2,985)	2,234
Accrued expenses	(1,077)	(157)	2,071
Net cash provided by (used in) operating activities	<u>(17,846)</u>	<u>(14,286)</u>	<u>12,336</u>
Investing activities:			
Purchases of short-term investments	(3,462)	(9,778)	(15,995)
Maturities and sales of short-term investments	10,316	12,909	12,510
Acquisition of property	(971)	(873)	(972)
Investment in joint ventures	(12,698)	(19,635)	(24,700)
Distributions from joint ventures	1,550	4,343	3,440
Patent application costs	(298)	(367)	(483)
Other long-term assets	(361)	496	(264)
Net cash used in investing Activities	<u>(5,924)</u>	<u>(12,905)</u>	<u>(26,464)</u>
Financing activities:			
Proceeds from borrowings	260	7,612	1,840
Payments of borrowings	(2,673)	(6,636)	(2,690)
Net proceeds from sale of Common Stock	33,491	20,000	19,877
Restricted cash	(1,700)	5,000	(5,000)
Repurchase of Common Stock	--	--	(457)
Options and warrants exercised	120	7,942	10
Payment of note receivable and accrued interest from related party – common stock	--	1,265	--
Note receivable from related party – common stock	--	(1,332)	--
Other long-term obligations	48	1,446	88
Net cash provided by financing Activities	<u>29,546</u>	<u>35,297</u>	<u>13,668</u>
Net increase (decrease) in cash and cash equivalents	5,776	8,106	(460)
Cash and cash equivalents at beginning of year	<u>24,197</u>	<u>16,091</u>	<u>16,551</u>
Cash and cash equivalents at end of year	<u>\$ 29,973</u>	<u>\$ 24,197</u>	<u>\$ 16,091</u>

See accompanying notes to the consolidated financial statements.

ADVANCED TISSUE SCIENCES, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(Dollars In Thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income / (Loss)	Accrued Dividends/ Note Receivable/ Deferred Compensation	Total Stock holders' Equity
	Shares	Amount	Shares	Amount					
Balance, December 31, 1998	350	--	40,353,524	403	230,963	(218,456)	(383)	12,527	
Sale of Common Stock			4,533,039	45	19,829			19,874	
Issuance of Common Stock for debt and accrued interest			2,800,595	28	10,776			10,804	
Conversion of Preferred Stock	(309)	--	7,865,798	79	1,926			2,005	
Transfer of Preferred Stock to Redeemable Preferred Stock	(41)		(463,154)	(5)	(2,045)			(2,045)	
Repurchase of Common Stock			432,808	4	(1,762)		(472)	(1,767)	
Preferred Stock dividends			300,000	3	468		(813)	312	
Restricted Common Stock awarded for services			777,934	9	1,122		(301)	1,320	
Options exercised					1,311			(301)	
Interest on note receivable						(21,306)		(21,306)	
Net loss and comprehensive loss									
Balance, December 31, 1999	--	--	56,600,544	566	262,588	(239,762)	(1,969)	21,423	
Sale of Common Stock			3,494,365	35	19,965			20,000	
Issuance of Common Stock for debt and accrued interest			770,453	8	5,668			5,676	
Conversion of Preferred Stock	--	--	1,354,539	14	5,026			5,040	
Preferred Stock dividends	--	--	37,926	--	63		(63)	--	
Warrants and Options exercised			1,943,114	19	7,923		360	7,942	
Other					(65)			295	
Comprehensive loss:						(24,571)		(24,571)	
Net loss								(3)	
Unrealized loss on securities								(3)	
Total comprehensive loss						(24,571)		(24,574)	
Balance December 31, 2000	--	--	64,200,941	642	301,168	(264,333)	(3)	35,802	
Sale of Common Stock			8,910,679	89	33,402			33,491	
Options exercised			36,933		120			120	
Other					678		302	980	
Comprehensive loss:						(28,373)		(28,373)	
Net loss								3	
Unrealized loss on securities								(3)	
Total comprehensive loss						(28,373)		(28,370)	
Balance, December 31, 2001	--	\$ --	73,148,553	\$ 731	\$ 335,368	\$ (292,706)	\$ --	\$ 42,023	

See accompanying notes to the consolidated financial statements.

ADVANCED TISSUE SCIENCES, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Basis of Presentation

Organization - Advanced Tissue Sciences, Inc. is a leader in the field of tissue engineering, using its proprietary technology to develop and manufacture human-based products for tissue repair and transplantation. We are focusing on the worldwide commercialization of tissue engineered products for wound care, aesthetic and reconstructive, cardiovascular and orthopedic applications. We currently have two leading therapeutic products, both of which are being commercialized through a joint venture, the Dermagraft Joint Venture, with Smith & Nephew plc. The first, TransCyte is available for sale in the United States, the United Kingdom and other European countries, Canada, Australia, New Zealand and South Africa, for the treatment of full and partial-thickness burns. The second product, Dermagraft, for the treatment of foot ulcers in patients with diabetes, is available in Canada, Australia, New Zealand and South Africa, and on a limited basis in the United Kingdom and other European countries. In September 2001, we received approval from the FDA to market Dermagraft in the treatment of chronic foot ulcers in patients with diabetes in the United States. In addition to the Dermagraft Joint Venture, we also have a strategic alliance with Inamed Corporation for the development of tissue engineered products for aesthetic and reconstructive markets.

Principles of Consolidation - The consolidated financial statements include the accounts of Advanced Tissue Sciences, its wholly owned subsidiaries, and DermEquip, L.L.C., a limited liability company owned jointly with Smith & Nephew. DermEquip is a special purpose entity which was established to finance an expansion of our manufacturing facility, and which holds the assets used in the facility. All intercompany accounts and transactions have been eliminated. Our other interests in joint ventures with Smith & Nephew are accounted for under the equity method. See Note 3 for more information on the financial transactions associated with the Dermagraft Joint Venture.

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

Dependence on Certain Suppliers - Certain materials, such as the mesh frameworks we use in our therapeutic products, are sourced from single manufacturers. Any significant supply interruption would adversely affect our product manufacturing. In addition, an uncorrected impurity or supplier's variation in a raw material, either unknown to us or incompatible with our manufacturing process, could have a material adverse effect on our ability to manufacture our products.

Reclassification - Certain reclassifications have been made to prior year amounts to conform to the presentation for the year ended December 31, 2001. In particular, the presentation of the statement of operations has been reformatted from prior presentations to more clearly reflect revenue and cost transactions between us and our joint ventures with Smith & Nephew. These transactions are separately presented from transactions with other parties.

Note 2 - Summary of Significant Accounting Policies

Cash Equivalents and Short-term Investments - In addition to investments in money market funds, cash equivalents consist primarily of investments in commercial paper and obligations issued or guaranteed by the United States Government with maturities of three months or less at the date of acquisition. Cash equivalents were approximately \$28,649,000 as of December 31, 2001 and \$24,278,000 as of December 31, 2000. Short-term investments are valued on the basis of quoted market value and consist primarily of investments in commercial paper and obligations issued or guaranteed by the United States Government with maturities of one year or less but more than three months at the date of acquisition. Cash equivalents and short-term investments are stated at amortized cost, which approximates market value. As of December 31, 2001 and 2000, our cash equivalents and short-term investments were classified as available-for-sale and consisted of (in thousands):

	<u>2001</u>	<u>2000</u>
Debt securities of U.S. Government agencies	\$ 2,000	\$ --
Commercial paper	3,994	26,110
Money market funds	<u>22,655</u>	<u>5,009</u>
Total cash equivalents and short-term investments	<u>\$ 28,649</u>	<u>\$ 31,119</u>

These investments all mature in less than one year. There were no significant unrealized or realized gains or losses related to such securities during the years ended December 31, 2001 or 2000.

Our cash and cash equivalents included approximately \$301,000 at December 31, 2001 and \$167,000 at December 31, 2000 held by DermEquip. These amounts are fully consolidated in our balance sheet.

Impairment of Long-Lived Assets - We account for impairment of long-lived assets in accordance with SFAS No. 121, "Accounting for the Impairment of Long-lived Assets and for Long-lived Assets to be Disposed of". SFAS No. 121 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances suggest that the carrying amount of the asset may not be recoverable. In accordance with SFAS No. 121, we use an estimate of the future undiscounted net cash flows of the related asset or asset grouping over the remaining life in measuring whether the asset's carrying amount is recoverable. Assets are grouped at the lowest level for which there are identifiable cash flows. While our current and past operating history could be indicative of an impairment, we believe the future cash flows to be received from the majority of long-lived assets will exceed the assets' carrying value. We believe that no impairment adjustments need be made at December 31, 2001.

Inventory - Inventories manufactured for sale are stated at cost. Such costs are principally standard costs which approximate actual costs on a first-in, first-out basis reflecting the price at which such goods will be sold to the respective customer.

Property - Property is recorded at cost and is depreciated using estimated useful lives ranging from 2 to 11 years. For financial statement purposes, depreciation is generally computed using the straight-line method. For tax purposes, depreciation is generally computed by accelerated methods on allowable useful lives. Amortization of capitalized leases is included with depreciation expense. Depreciation expense for the years ended December 31, 2001, 2000 and 1999 amounted to approximately (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Depreciation expense	\$ 3,569	\$ 3,817	\$ 4,712

Patents - We own and have patents pending in the United States and abroad to protect the processes and products we are developing. Direct patent application costs related to patents issued are amortized over the estimated useful life of the patent, approximately 20 years from the date of application. Such costs related to pending applications are deferred until the patent is issued or charged to operations at the time a determination is made not to pursue an application. Patents are presented net of accumulated amortization of approximately \$496,000 at December 31, 2001 and \$405,000 at December 31, 2000. Patent application and maintenance costs related to licensing agreements are expensed as incurred.

Industry Segment and Geographic Information – We operate in a single industry segment, the development and commercialization of human-based tissue products for tissue repair and transplantation. During the years ended December 31, 2001, 2000 and 1999, international sales have been through a related party. We have no foreign operations.

Revenue Recognition - Revenues from product sales are recognized when products are shipped and title has passed, and we have no further specified performance obligations. Revenues from product sales to related parties are recognized at such time as ownership of the product is transferred to the related party, generally upon the completion of manufacturing. Such product sales to related parties are equal to our cost. See Note 3 for more information on the financial transactions associated with the Dermagraft Joint Venture. We perform research and certain administrative functions for our joint ventures with Smith & Nephew, for which we are reimbursed as expenditure is incurred. Under license agreements such as the one that we have with Inamed, up front fees, as applicable, are deferred and recognized over the exclusivity period, term of the license or ongoing research period, in accordance with Staff Accounting Bulletin No. 101. At December 31, 2001 and 2000 we had no such deferred revenue. In 1999 we received a \$5 million milestone payment from Inamed, which was recognized over eighteen months, representing the performance period. See Note 3 for more information on the financial transactions associated with the Dermagraft Joint Venture. Deferred revenue at December 31, 1999 associated with this milestone payment was \$3.6 million. Milestone payments, if any, are recognized when earned, provided that the event is substantive, its achievability was not assured at the inception of the respective agreement, and that our performance obligations have been met. If these criteria are not met, any milestone payment would be recognized over the remaining minimum period of the performance obligation. Revenues from government grants are recognized based on the performance requirements of the grant, or as the grant expenditures are incurred.

Research and Development Costs – Research and development costs are expensed as incurred. Such costs include proprietary research and development activities and expenses associated with collaborative research agreements. Total research and development expenses were \$10.1 million in the year ended December 31, 2001, \$13.1 million in the year ended December 31, 2000, and \$16.3 million in the year ended December 31, 1999. Of these amounts, in the year ended December 31, 2001, we incurred \$4.4 million of expense related to research conducted for our joint ventures with Smith & Nephew, or for research reimbursable under grants, compared to \$7.4 million of such expense in the year ended December 31, 2000, and \$11.4 million in the year ended December 31, 1999.

Basic and Diluted Loss Per Common Share - Basic earnings per share are determined based on the weighted average number of shares outstanding during the period. Diluted earnings per share include the weighted average number of shares outstanding and give effect to potentially dilutive common share equivalents such as options and warrants outstanding, in periods in which they are dilutive. Both the basic and diluted loss per common share for the years ended December 31, 2001, 2000 and 1999 are based on the weighted average number of shares of our common stock outstanding during the periods. The net loss applicable to common stock used in the calculation of basic and diluted loss per common share includes dividends of \$48,000 for the year ended December 31, 2000 and \$558,000 for the year ended December 31, 1999 accrued on our Convertible Series B Preferred Stock outstanding during such periods. There were no such dividends included in the net loss applicable common stock for the year ended December 31, 2001, as all remaining shares of our Convertible Series B Preferred Stock were converted to common stock in March 2000.

Stock-Based Compensation - As permitted under SFAS No. 123, "Accounting for Stock-Based Compensation", we follow APB Opinion No. 25, "Accounting for Stock Issued to Employees," in accounting for outstanding stock options and warrants issued to employees. Under APB Opinion No. 25, compensation expense relating to employee stock options is determined based on the excess of the market price of our stock over the exercise price on the date of grant and does not require the recognition of compensation expense for stock issued under plans defined as non-compensatory. Adoption of SFAS No. 123 for options issued to employees would require recognition of employee compensation expense based on their computed "fair value" on the date of grant. In accordance with SFAS No. 123 and EITF 96-18, stock options and warrants issued to consultants and other non-employees as compensation for services provided to us are accounted for based upon the fair value of the services provided or the estimated fair market value of the option or warrant, whichever can be more clearly determined. We recognize this

expense over the period the services are provided. See Note 12 regarding transactions under our employee benefit plans.

New Accounting Standards – In June 2001, the Financial Accounting Standards Board (or FASB), issued SFAS No. 141, “Business Combinations” and SFAS No. 142, “Goodwill and Other Intangible Assets”. Under these rules, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually for impairment. As we have no existing goodwill in our balance sheet, we do not expect the adoption of SFAS No. 141 and SFAS No. 142 to have a material impact on our financial statements.

Note 3 - Strategic Alliances

Smith & Nephew Joint Ventures

In 1994, we entered into a joint venture with Smith & Nephew plc for the development of tissue engineered cartilage for orthopedic applications, the NeoCyte Joint Venture. Smith & Nephew is a global medical device company employing over 7,000 people, with operations in 34 countries, that markets technically innovative products principally in the areas of wound management, orthopedics and endoscopy.

Under the NeoCyte Joint Venture, Smith & Nephew contributed the first \$10 million in funding and we contributed certain technology licenses. The NeoCyte Joint Venture’s total funding since inception reached \$10 million in January 1997 and, as provided in the joint venture agreement, we began sharing equally in NeoCyte Joint Venture revenues and expenditures. See Note 15 with respect to related party transactions with the NeoCyte Joint Venture.

In April 1996, we entered into a separate agreement with Smith & Nephew to form the Dermagraft Joint Venture for the worldwide commercialization of Dermagraft for the treatment of diabetic foot ulcers. In January 1998, we agreed with Smith & Nephew to expand the Dermagraft Joint Venture to include venous ulcers, pressure ulcers, burns and other skin tissue wounds. At that time, we retained the exclusive right to market TransCyte, a temporary covering for full and partial-thickness burns, in the United States, while the Dermagraft Joint Venture was granted the right to market TransCyte for other skin wounds in the United States. In 1998, we agreed with Smith & Nephew to further expand the Dermagraft Joint Venture to include exclusive rights to market TransCyte for full and partial-thickness burns in the United States, effective in October of that year.

As consideration for entering into the Dermagraft Joint Venture, we received a \$10 million up front fee in 1996. In addition, as a part of the agreement to expand the joint venture, Smith & Nephew purchased \$20 million, or 1,533,115 newly-issued shares of our common stock at approximately \$13.05 per share in January 1998 (see Note 10) and we also received an additional \$15 million as consideration for expanding the joint venture in January 1999, which was recognized into revenue in 1999 as the related financial commitments were met. Additionally, we received a milestone payment of \$5 million in 2001 on the approval by the FDA of the PMA for Dermagraft in the treatment of diabetic foot ulcers, and could receive, subject to the achievement of certain milestones related to regulatory approvals, reimbursement and sales levels, further payments of up to \$131 million.

In February 2000, we agreed in principle with Smith & Nephew to restructure certain payments associated with the Dermagraft Joint Venture as a result of delays in the commercial introduction of Dermagraft in the United States. The requirement for an additional clinical trial by the FDA substantially increased the partners’ investments, necessitating the restructuring. The restructuring deferred the potential payment of certain milestones by Smith & Nephew, while providing Advanced Tissue Sciences a royalty stream and an opportunity to increase our long-term return from the venture. Specifically, except for \$10 million in regulatory approval and reimbursement milestones related to Dermagraft in the treatment of diabetic foot ulcers, the first \$5 million of which we received in 2001 on the approval by the FDA of our PMA, we agreed to make all other approval, reimbursement and sales milestones subject to, and payable from, joint venture earnings exceeding certain minimum levels. In return, the Dermagraft Joint Venture pays us royalties on joint venture product sales. In addition, as a part of the agreement, as amended in September 2000, we sold the Dermagraft manufacturing plant assets that we owned to DermEquip, see Note 1 with regard to the DermEquip entity, but retained the raw material inventory.

We share equally with Smith & Nephew in the expenses and revenues of the expanded Dermagraft Joint Venture, except that we funded the first \$6 million of expenses for conducting clinical trials and for

regulatory support of Dermagraft and TransCyte in the treatment of venous and pressure ulcers. In addition, we funded certain manufacturing and distribution costs and certain costs related to post-market studies of TransCyte through December 1999. However, such manufacturing and distribution costs will be returned to us out of future gross margin or net profits, if any, from sales of TransCyte for burns in the United States. See Note 15 with respect to related party transactions with the Dermagraft Joint Venture. Under the expanded Dermagraft Joint Venture, we will continue to manufacture, and Smith & Nephew will continue to market and sell the Dermagraft Joint Venture's products.

Per the agreement, as amended in September 2000, we and Smith & Nephew also agreed that certain of the proceeds from the sale of the manufacturing plant assets discussed above would be used to pay down a portion of the outstanding balance of the loan from Smith & Nephew related to the NeoCyte Joint Venture, the NeoCyte Loan. This transaction was completed in September 2000, at which time the outstanding balance of principal and interest due on the loan was \$10 million. The cash portion we paid down amounted to \$4.3 million, the balance of \$5.7 million being paid by means of issuing 770,453 shares of our common stock to Smith & Nephew.

In a subsequent transaction in September 2000, the Dermagraft Joint Venture made a new loan to us of \$5.4 million, with raw material inventory being pledged as collateral security. This loan, which is payable on December 31, 2002 unless extended by mutual agreement of the partners, is included in "Payable to joint ventures" in the consolidated balance sheet at December 31, 2001 and 2000.

The results of operations of the joint ventures for the years ended December 31, 2001, 2000 and 1999 are as follows (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
<u>Dermagraft Joint Venture</u>			
Net sales	\$ 4,211	\$ 4,301	\$ 2,571
Contract revenue	603	--	--
Cost of goods sold	13,776	13,710	13,958
Other costs and expenses	18,511	12,298	35,135
Net loss	(27,472)	(21,707)	(46,522)
Current assets	8,140	7,780	4,852
Non-current assets	151	201	278
Current liabilities	5,891	3,427	4,450
Partners' capital (deficit)	2,400	4,554	680
<u>NeoCyte Joint Venture</u>			
Costs and expenses	\$ 1,138	\$ 3,822	\$ 5,533
Net loss	(1,138)	(3,822)	(5,533)
Current assets	193	94	142
Non-current assets	77	167	274
Current liabilities	146	298	832
Partners' capital (deficit)	124	(37)	(416)

Inamed Agreements

In May 1999, we entered into a strategic alliance with Inamed for the development and marketing of a number of our potential products for certain aesthetic and reconstructive applications. Specifically, Inamed licensed rights to further develop, manufacture and sell tissue engineered products for use in cosmetic surgery as a temporary covering after laser resurfacing or chemical peels, cartilage for plastic and reconstructive surgery, and extracellular matrix for use in breast reconstruction. In addition, in September 1999, Inamed also received license rights to use our extracellular matrix, including human-based collagen, from our three-dimensional tissue engineering process, for wrinkle correction and other soft tissue augmentation, and as a bulking agent for the treatment of urinary incontinence. Inamed is a global surgical and medical device company engaged in the development, manufacturing and marketing of medical products for aesthetic medicine, plastic and reconstructive surgery and the treatment of obesity.

In total, under the agreements between the parties, in exchange for worldwide licensing rights, Inamed has paid us a series of payments totaling \$10 million, including \$5 million to purchase our common stock. Inamed also received five-year warrants to purchase up to 500,000 shares of our common stock. In addition to a price for our product and royalties on Inamed's sales in the market place, we may potentially receive up to a total of \$10 million in milestones based on product approvals in the United States, subject to our success in developing products under the agreement and Inamed's success in obtaining such approvals.

Under our agreement, we are responsible for the funding and development of the products and the related manufacturing processes, while Inamed is responsible for funding clinical, regulatory and marketing activities. We, or an affiliate, may elect to manufacture the products developed under the agreement. See Note 2 regarding revenue recognition for up front fees and milestones under this agreement.

Medtronic Agreement

In October 2001, we entered into a collaboration with Medtronic, Inc. to explore the application of our technology in areas of therapeutic interest to Medtronic. Under the terms of the collaboration, we will explore the application of our technology in four therapeutic areas: cardiovascular, neurological, endocrine and spinal.

An affiliate of Medtronic invested \$20 million in shares of our common stock at \$3.72 per share in return for specified rights including a right of first refusal to participate in the further development and commercialization of Anginera, our epicardial angiogenesis therapy, a product that stimulates new blood vessel growth and therefore increased blood flow; a right of first offer/first negotiation to participate in other programs within the cardiovascular, neurological, endocrine and spinal areas where we elect not to pursue those programs internally; and a limited non-exclusive license to our intellectual property in the four therapeutic areas identified, to facilitate Medtronic's exploration of cell and tissue engineered technology in combination with Medtronic's medical devices. Net proceeds of the equity investment were approximately \$19.9 million.

Note 4 - Inventories

Inventories consist of the following components as of December 31, 2001 and 2000 (in thousands):

	<u>2001</u>	<u>2000</u>
Raw materials and supplies	\$ 5,277	\$ 5,021
Work-in-process	1,221	683
Finished goods	<u>107</u>	<u>69</u>
	<u>\$ 6,605</u>	<u>\$ 5,773</u>

Note 5 - Property

The major classes of property as of December 31, 2001 and 2000 are as follows (in thousands):

	<u>2001</u>	<u>2000</u>
Equipment	\$ 21,257	\$ 20,496
Furniture and fixtures	727	746
Leasehold improvements	12,032	11,989
Equipment under capital leases	<u>110</u>	<u>110</u>
	34,126	33,341
Less accumulated depreciation and amortization	<u>(23,059)</u>	<u>(19,660)</u>
Net property	<u>\$ 11,067</u>	<u>\$ 13,681</u>

Note 6 - Accrued Expenses

Accrued expenses as of December 31, 2001 and 2000 consisted of (in thousands):

	<u>2001</u>	<u>2000</u>
Salaries and benefits	\$ 3,605	\$ 4,371
Clinical studies	--	175
Other	<u>709</u>	<u>845</u>
	<u>\$ 4,314</u>	<u>\$ 5,391</u>

Note 7 - Long-Term Debt

In August 1997, DermEquip entered into a term loan agreement with The Chase Manhattan Bank to borrow up to \$16 million. During the first half of 1998, DermEquip completed drawdowns under the loan agreement to a total of \$16 million. Principal is payable in equal quarterly installments from June 1998 through June 2004. The Chase loan bears interest payable quarterly at the 90-day London Interbank Offered Rate, or LIBOR, plus ¼ percent, which was 2.91% at December 31, 2001. Smith & Nephew and ourselves jointly and severally guarantee DermEquip's obligations with respect to the Chase loan. The guarantees are secured by DermEquip's assets, having a carrying value of \$9.8 million as of December 31, 2001, and by each company's interest in DermEquip. The outstanding balance of the Chase loan at December 31, 2001 was \$6.4 million.

In September 2000, the Dermagraft Joint Venture made a loan to us, the Dermagraft Joint Venture Loan, of approximately \$5.4 million payable on December 31, 2001 with raw material inventory being pledged as collateral security. The loan was subsequently renewed and is payable on December 31, 2002. See Notes 3 and 7 for further information on this loan. The loan is included in "Payable to joint ventures" on the face of the Consolidated Balance Sheet at December 31, 2001 and 2000.

Total interest expense for the years ended December 31, 2001, 2000 and 1999 was \$643,000, \$1,513,000, and \$1,801,000 respectively, including interest expense incurred on behalf of our joint ventures with Smith & Nephew, which appears in joint venture contract expense in our statement of operations.

Debt and capital lease obligations as of December 31, 2001 and 2000 were as follows (in thousands):

	<u>2001</u>	<u>2000</u>
Chase Loan	\$ 6,400	\$ 8,960
Dermagraft Joint Venture Loan	5,412	5,412
Obligations under capital leases	--	27
Less current portion	<u>(7,972)</u>	<u>(7,999)</u>
Long-term debt	<u>\$ 3,840</u>	<u>\$ 6,400</u>

Maturities of long-term debt over the next five years are approximately \$7,972,000 in 2002, \$2,560,000 in 2003, and \$1,280,000 in 2004. Of the \$7,972,000 in 2002, \$5,412,000 relates to a loan from the Dermagraft Joint Venture payable on December 31, 2002, which may be extended by agreement of the Joint Venture partners. As substantially all of our debt carries interest at variable rates, the fair market value of such instruments is estimated to approximate their carrying value.

Note 8 - Lease Commitments

Operating lease commitments relate primarily to our facilities. The leases for our primary location, 85,000 square feet of space at our headquarters in La Jolla, San Diego, which includes manufacturing, research and administrative operations, expire in December 2005. These leases include the cost of a proportion of utilities charges and certain services, and provide for annual rental increases ranging from a minimum of 3% to a maximum of 7% based on changes in the Consumer Price Index.

In October 2001, we signed a 10-year lease on 29,000 square feet of additional office and research laboratory space in a facility approximately three miles from our La Jolla location, and expect to move the majority of our research activities into the new facility in May 2002. The lease term will commence in May 2002, subject to the completion of improvements. The lease provides for a 3% annual rent increase. We have options to extend the term of the lease for two five-year periods. As a condition of signing the lease, we were required to purchase a standby letter of credit in the amount of \$1.7 million. See Note 9 for a discussion of our commitments and contingencies. This facility replaces a laboratory facility of approximately 7,000 square feet, on which our lease expired in January 2002.

We have also financed approximately \$1.4 million of office furniture, communications and laboratory equipment under an operating lease with a term of four years, that expires in 2002.

The following is a summary of the annual future minimum operating lease commitments as of December 31, 2001, in thousands; there are no future capital lease commitments:

	<u>Operating Leases</u>
Year Ending December 31:	
2002	\$ 3,410
2003	3,291
2004	3,381
2005	3,472
2006	1,030
Thereafter	<u>5,943</u>
Total minimum lease payments	<u>\$20,527</u>

Rental expense charged to operations under operating leases for facilities and equipment for the years ended December 31, 2001, 2000 and 1999 amounted to approximately (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Rental expense under operating leases	\$ 2,652	\$ 2,347	\$ 4,251

Note 9 - Commitments and Contingencies

Under the terms of our agreements with Smith & Nephew, we have agreed to fund our share of the costs of the Dermagraft and NeoCyte Joint Ventures. To the extent that such costs can be forecast, they are mutually agreed by us and Smith & Nephew as partners in the joint ventures. We have also agreed to fund certain costs to develop products, and related manufacturing processes, which will be marketed by Inamed under the terms of our licensing agreement.

In October 2001, we purchased a \$1.7 million letter of credit as security for the lease of our new research facility. The letter of credit will expire in May of 2010, and as security we are required to maintain \$1.7 million in restricted cash balances with the issuing institution. The amount of the letter of credit and required restricted cash balances will decrease to \$850,000 in 2007, \$595,000 in 2008 and \$240,000 in 2009.

Under an agreement with Ethicon, Inc., for the supply of the mesh framework used by us in the manufacture of Dermagraft, we are committed to purchasing minimum quantities. Based upon current market prices the commitment is estimated to be approximately \$2.5 million in 2002, with the current agreement expiring in January 2003.

In 2000, we were awarded a \$2 million grant from NIST, to be distributed over a three-year period. Also in 2000, researchers at the University of Washington announced that they would be partnering with us and others in a project, funded by a \$10 million grant from NIH, to grow functional human heart tissue. The proportion of the grant for which we would be eligible is approximately \$1.8 million. The grant is expected to cover the first five years of an anticipated 10 year project. In the same year we were awarded a grant in excess of \$800,000 from NIH and the National Institute of Dental and Craniofacial Research to develop tissue engineered cartilage for the treatment of temporomandibular disorders. Payments under this grant are payable over four years. In October 2001, we were awarded a \$1.4 million Small Business Innovation Research grant from NIH and the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The grant, which is payable over three years, is to develop tissue engineered articular cartilage designed to better withstand the extreme forces experienced in the human body. Under each of these, and other smaller grants we have been awarded, we are committed to continuing our investment in the specified research, and meeting specified performance requirements, in order for us to receive the grant funding.

We are also responsible for patent application costs and associated maintenance fees related to inventions under certain licensing agreements. We seek to protect our proprietary technology through the use of various aspects of United States and foreign patent law and contractual arrangements. However, our patents or patent applications may not protect us against competitors with similar technology, or others may infringe upon or design around our present patents. We could incur substantial costs to defend or protect our patents and licensed patents against infringement.

Note 10 - Capital Stock

Common Stock

As of December 31, 2001, we had 5,856,345 shares of common stock reserved for issuance under outstanding options and warrants. In February 1999, our common stockholders approved an amendment to our Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 100,000,000 shares to 125,000,000 shares.

In October 2001, an affiliate of Medtronic, Inc. purchased 5,376,334 shares of our common stock at \$3.72 per share, equal to the average closing price for the 12 days prior to purchase. Net proceeds from this transaction were approximately \$19,942,000. In November 2001, we completed a private placement of 3,534,335 shares of our common stock at \$4.15 per share to a group of institutional investors. Net proceeds from this transaction were approximately \$13,548,000.

In September 2000, we completed a private placement of 3,494,365 shares of our common stock at \$5.7235 per share, resulting in net proceeds of approximately \$19.9 million. We also issued 770,453 shares of common stock to Smith & Nephew in September 2000 as payment for the remaining balance of a loan, the NeoCyte Loan. The loan balance paid by means of issuing these shares was approximately \$5.7 million.

In March 2000, 100.8 shares, representing all of our Convertible Series B Preferred were converted into 1,354,539 shares of common stock at \$3.72 per share.

In November 1999, we completed a public offering of 3,750,000 units at \$4.00 per unit, resulting in proceeds of \$15 million. Once issued, the units separated into 3,750,000 shares of our common stock and warrants to purchase an additional 1,750,000 shares of common stock at \$4.00 per share. In January 2000, we received an additional \$7.0 million from the exercise of warrants to purchase all 1,750,000 shares of common stock. As part of the November 1999 public offering, we agreed to reserve \$5 million of the proceeds for the redemption of our Series B Preferred Stock submitted for conversion, and to terminate an equity line agreement with a separate group of investors.

As part of our licensing agreement with Inamed, 783,039 shares of our common stock were purchased by Inamed, during 1999, for \$5 million, an average price of approximately at \$6.39 per share.

Inamed also received five-year warrants to purchase a total of 500,000 shares of common stock at an average exercise price of \$12.80 per share. Inamed has agreed to hold any investment in our common stock until at least October 2002.

In June 1999, a \$10 million loan and accrued interest of \$804,000, payable to Smith & Nephew and related to the formation of the Dermagraft Joint Venture, was converted into 2,800,595 shares of our common stock, as allowed under the loan agreement. See Note 3 for more information on the financial transactions associated with the Dermagraft Joint Venture.

In May 1995, our Chairman and Chief Executive Officer exercised an employee stock option. The purchase price was paid through the issue of an interest-bearing, full recourse promissory note. In July 1999, we extended the repayment terms on the note. As a result of the extension, the stock options exercised through the issuance of the note were accounted for as variable stock options which could result in significant increases and decreases in compensation expense subject to variability in our stock price. In September 2000, the outstanding principal and interest of \$1,265,000 was repaid by our Chairman and Chief Executive Officer and we guaranteed a personal loan obtained by the Chairman and Chief Executive Officer from a third party, for a like amount. The third party loan was collateralized by the shares exercised through the stock options, and its maintenance was dependent upon our share price maintaining a certain value. Following a decline in our share price, in October 2000, we honored our guarantee to the third party and re-established a note from our Chairman and Chief Executive Officer. The note receivable and accrued interest of approximately \$1.4 million at December 31, 2001 and \$1.3 million at December 31, 2000, are included in stockholders' equity in the accompanying balance sheets.

Stockholders Rights Agreements

In January 1995, we adopted a Shareholder Rights Plan, or the Rights Plan, and issued one preferred share purchase right, or Right, on each outstanding share of common stock. The Rights are exercisable only if a person or group acquires, or makes a tender offer to acquire, 15% or more of our common stock. The Rights Plan was amended in November 1999 to permit the State of Wisconsin Investment Board to beneficially own up to 19.99% of our common stock and in December 1999 to eliminate the continuing director provisions of the plan. In connection with the adoption of the Rights Plan, our Board of Directors designated and reserved 500,000 shares of our authorized Preferred Stock as Series A Junior Participating Preferred Stock, par value \$.01 per share. The Rights have no voting privileges and expire on January 6, 2005.

When exercisable, each Right entitles its holder to buy one-hundredth of a share of the Series A Preferred Stock at an exercise price of \$55, subject to certain anti-dilution adjustments. In addition, if at any time after the Rights become exercisable, should (i) we be acquired in a merger or other business combination transaction, or sell 50% or more of our consolidated assets or earnings power, each Right will entitle its holder to purchase a number of the acquiring company's common shares having a market value at the time of twice the Right's exercise price or (ii) a person or group acquire 15% or more of our outstanding common stock, except as noted above, each Right will entitle its holder, other than the acquirer, to purchase, at the Right's then-current exercise price, a number of shares of our common stock having a market value of twice the Right's exercise price. The rights are redeemable for one cent per Right at any time up to and including ten days after the acquisition of 15% of the then outstanding common stock.

Note 11 - Redeemable Preferred Stock

In July 1998, we raised \$25 million through a private placement of Convertible Series B Preferred Stock to a group of investors. The Series B Preferred Stock accrued dividends at 5% per annum, payable quarterly in common stock or cash at our option. Twenty percent of the Series B Preferred Stock was redeemable at the option of the holders on the occurrence of certain events. Through December 1999, 399.2 shares of the Convertible Series B Preferred Stock had been converted into 8,878,192 shares of common stock at an average price of \$2.25 per share.

In conjunction with our November 1999 public offering we agreed that \$5 million of the proceeds would be reserved for the redemption of any of our Series B Preferred Stock submitted for conversion. As a result of this agreement the remaining 100.8 shares of our Series B Preferred Stock were classified as redeemable and \$5 million of cash was restricted for redemption of the Series B Preferred Stock as of

December 31, 1999. In March 2000, 100.8 shares, representing all of our outstanding Series B Preferred Stock, were converted into 1,354,539 shares of our common stock at \$3.72 per share. As of December 31, 2001 and 2000 there were no shares of our Series B Preferred Stock outstanding and the \$5 million of restricted cash has been used to support our operations. As of December 31, 1999, 2,624,810 shares of common stock would have been required at that time for the conversion of all outstanding Series B Preferred Stock.

Note 12 - Employee Benefit Plans

Our 1997 Stock Incentive Plan provides for the grant of incentive stock options, non-qualified stock options and stock issuances to employees and consultants and automatic 50,000-share grants to non-employee directors, currently to a maximum of 6,800,790 shares of common stock. At December 31, 2001, a total of 4,831,345 shares were outstanding under options or available for grant under the 1997 Plan.

Under the 1997 Plan, we generally grant all employees stock options on their date of employment and on promotion. The number of shares granted is based on the employee's position and responsibilities. The options granted generally become exercisable in equal annual amounts over five years and have a term of ten years as long as the employee remains in our service. We also began to make annual grants to employees in 1997. Non-employee directors receive an automatic grant of 50,000 shares upon joining the Board and generally every third year thereafter. These options generally are immediately exercisable, become vested in equal annual amounts over three years and have a term of ten years assuming continued service on our Board of Directors.

In addition to the 1997 Plan, we have issued options and warrants to directors, consultants, employees and others as compensation for services. These options and warrants vest and are exercisable over a variety of periods as determined by our Board of Directors.

The following table summarizes activity under the 1997 Plan and for other options and warrants for common stock for the years ended December 31, 2001, 2000 and 1999:

	<u>1997 Plan</u>		<u>Other Options and Warrants</u>	
	<u>Number of Shares</u>	<u>Weighted Average Price Per Share</u>	<u>Number of Shares</u>	<u>Weighted Average Price Per Share</u>
Outstanding, December 31, 1998	3,897,722	\$8.62	1,509,640	\$7.44
Granted	1,151,150	\$3.65	2,250,000	\$5.95
Exercised	(777,934)	\$1.70	--	--
Canceled	<u>(226,298)</u>	\$6.65	<u>--</u>	--
Outstanding, December 31, 1999	4,044,640	\$8.64	3,759,640	\$6.55
Granted	1,284,860	\$7.26	--	--
Exercised	(148,114)	\$3.78	(1,795,000)	\$4.11
Canceled	<u>(695,792)</u>	\$8.52	<u>(29,640)</u>	\$7.09
Outstanding, December 31, 2000	4,485,594	\$8.43	1,935,000	\$8.80
Granted	609,460	\$4.05	--	--
Exercised	(36,933)	\$3.25	--	--
Cancelled	<u>(266,813)</u>	\$9.30	<u>(910,000)</u>	\$8.39
Outstanding, December 31, 2001	<u>4,791,308</u>	\$7.86	<u>1,025,000</u>	\$9.18

At December 31 of 2001, 2000 and 1999, information related to the 1997 plan and to other options and warrants was as follows:

	2001	2000	1999
Weighted average fair value of options granted under the 1997 plan	\$ 4.05	\$ 5.55	\$ 2.46
Weighted average fair value of other options & warrants granted	\$ --	\$ --	\$ 1.87
Number of shares exercisable under the 1997 plan	3,029,989	2,429,024	2,080,372
Weighted average price per share	\$ 9.12	\$ 9.80	\$ 10.20
Number of other options and warrants exercisable	775,000	1,560,000	3,259,640
Weighted average price per share	\$ 8.01	\$ 7.85	\$ 5.59

In May 1999, our Chairman and Chief Executive Officer was awarded 300,000 shares of restricted common stock under the 1997 Plan. The value at grant date was \$3.75, as determined by the market price of the stock upon that date. Under the award, subject to meeting certain requirements including continued service, 50,000 shares would vest annually at the completion of each of the first three years of the award, and the remaining 150,000 shares would vest at the end of five years or, if earlier, upon approval of Dermagraft for the treatment of diabetic foot ulcers in the United States. The first 50,000 shares vested in May 2000 and another 50,000 vested in May 2001. In September 2001, 150,000 shares vested when the FDA approved a PMA application for Dermagraft in the treatment of diabetic foot ulcers in the United States. At December 3, 2001, 50,000 shares remain unvested under the award. The difference between the market price at the grant date and the purchase price of \$.01 per share has been, and will be, recognized as compensation expense evenly over the restricted periods.

Other options and warrants granted include warrants issued to an investment group which are exercisable for a total of 225,000 shares of common stock at exercise prices ranging from \$10.50 to \$14.00 per share. These warrants were issued as commitment fees on an equity line no longer in place. During the year ended December 31, 1999, \$35,000 was charged to expense, reflecting the amortization of the fair market value of these warrants over the commitment period. In addition, we charged \$366,000 to expense in 2001, \$472,000 in 2000, and \$309,000 in 1999, in connection with options or warrants and restricted stock awards granted to employees.

The following table summarizes by price ranges the number of shares, weighted average exercise price and weighted average remaining life, in years, of options and warrants exercisable and outstanding as of December 31, 2001:

Price Range	Exercisable		Total Outstanding		
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Life
<i>1997 Plan:</i>					
\$1.96 - 3.93	944,843	\$3.60	1,559,503	\$3.55	7.2
\$3.94 - 5.89	172,525	\$4.90	469,135	\$4.70	8.4
\$5.90 - 7.85	211,788	\$7.12	842,408	\$7.13	8.1
\$7.86 - 9.81	257,051	\$8.63	384,355	\$8.47	4.7
\$9.82 - 11.78	147,020	\$10.67	231,200	\$10.61	6.5
\$11.79 - 13.74	1,085,372	\$13.42	1,089,982	\$13.42	4.0
\$13.75 - 15.70	59,340	\$14.74	62,675	\$14.72	4.9
\$15.71 - 17.66	<u>152,050</u>	\$17.49	<u>152,050</u>	\$17.49	4.4
Total 1997 Plan	<u>3,029,989</u>	\$9.12	<u>4,791,308</u>	\$7.86	6.4
<i>Other Options and Warrants:</i>					
\$1.47 - 1.67	300,000	\$1.57	300,000	\$1.57	1.5
\$9.82 - 11.78	175,000	\$10.50	175,000	\$10.50	1.1
\$11.79 - \$13.74	250,000	\$12.79	500,000	\$12.79	2.6
\$14.00	<u>50,000</u>	\$14.00	<u>50,000</u>	\$14.00	3.1
Total other	<u>775,000</u>	\$8.01	<u>1,025,000</u>	\$9.18	2.0

The following table reflects our pro forma net loss applicable to common stock and basic and diluted loss per common share for the years ended December 31, 2001, 2000 and 1999 had the expense provisions of FAS No. 123 been implemented (in thousands except per share amounts):

	2001	2000	1999
Net loss applicable to common stock:			
As reported	\$ (28,373)	\$ (24,619)	\$ (21,864)
Pro forma	(32,247)	(29,705)	(27,640)
Basic and diluted loss per share:			
As reported	\$ (.43)	\$ (.41)	\$ (.45)
Pro forma	(.49)	(.49)	(.57)

Because the FAS 123 method of accounting has not been applied to options granted prior to January 1, 1995, the above pro forma information may not be representative of that to be expected in future years.

The fair value of each option grant has been estimated on the date of grant using the Black-Scholes option pricing model. The following weighted average assumptions were used for grants made under the 1997 Plan in 2001, 2000 and 1999: (i) risk-free interest rates of 3.5% to 5.0% for 2001, 5.1% to 6.8% for 2000 and 4.5% to 6.2% for 1999; (ii) expected lives of six years for 2001 and five years for 2000 and 1999, and (iii) volatility of 109% for 2001, 96% for 2000 and 79% for 1999. It is assumed that no dividends are paid on the stock in all the Black-Scholes option pricing model estimates. The estimated value of warrants issued in 1998 for services were based on the value of the services rendered.

We have a 401(k) Plan under which employees meeting certain eligibility requirements may elect to participate and contribute. Under the 401(k) Plan, we may elect to match a discretionary percentage of contributions. At December 31, 2001, no such matching contributions had been made to the 401(k) Plan since its inception.

Note 13 - Income Taxes

At December 31, 2001, we had federal net operating loss carryforwards of approximately \$297.8 million and California net operating loss carryforwards of \$34.9 million. The difference between the federal and California operating tax loss carryforwards principally results from a fifty-five percent limitation on California loss carryforwards, as we did not have operations in California until late 1989, and the capitalization of certain research and development expenses for California purposes. As of December 31, 2001, we have federal and California research and development tax credit carryforwards of approximately \$7.3 million and \$3.6 million, respectively, and have California manufacturer's investment tax credit carryforwards of approximately \$507,000. Federal net operating loss carryforwards of approximately \$1.1 million expired in 2001. Approximately \$400,000 will expire in 2002, and \$3.6 million in 2003, if not previously utilized. California net operating loss carryforwards of approximately \$533,000 expired in 2001. Approximately \$6.8 million will expire in 2002 and \$6.2 million in 2003, if not previously utilized. Federal research and development tax credit carryforwards of approximately \$24,000 expired in 2001. Approximately \$2,000 will expire in 2002 and \$131,000 in 2003, if not previously utilized. The California research and development tax credit carryforwards and California manufacturer's investment tax credit carryforwards will begin expiring in 2004, unless previously utilized.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss carryforwards could be limited if a cumulative change in our ownership of more than 50% were to occur within a three-year period. Included in the federal net operating loss carryforwards, and subject to an annual limitation, are approximately \$5 million of losses related to an acquisition.

Net deferred tax assets have been completely offset by a valuation allowance, as realization of the deferred tax assets is uncertain. During the year ended December 31, 2001, a valuation allowance of \$121,412,000 has been established. Significant components of our net deferred tax assets as of December 31, 2001 and 2000 are as follows (in thousands):

	<u>2001</u>	<u>2000</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 106,257	\$ 86,248
Tax credit carryforwards	9,966	7,578
Capitalized research and development	4,039	4,360
Depreciation	322	4,171
Other	1,858	1,982
Total deferred tax assets	<u>122,442</u>	<u>104,339</u>
Deferred tax liabilities:		
Patent expense	(1,030)	(947)
Total deferred tax liabilities	<u>(1,030)</u>	<u>(947)</u>
Net deferred tax assets before valuation allowance	121,412	103,392
Valuation allowance	(121,412)	(103,392)
Net deferred tax assets	<u>\$ --</u>	<u>\$ --</u>

Note 14 - Supplemental Cash Flow Information

The following summarizes the significant non-cash investing and financing activities and provides other supplemental cash flow information.

During the year ended December 31, 2001, there were no significant non-cash investing and financing activities.

During the year ended December 31, 2000, non-cash financing activities included (i) the repayment of approximately \$5.7 million of principal and interest on a loan by issuing 770,453 shares of common stock to Smith & Nephew, based on a specified average market price and (ii) the conversion of \$5 million of our Series B Preferred Stock into 1,354,539 shares of common stock. See Notes 3 and 10 for more information on these transactions.

During the year ended December 31, 1999, non-cash financing activities included (i) the repayment of a \$10 million loan and accrued interest payable by issuing 2,800,595 shares of common stock and (ii) the exercise of stock options for 775,000 shares of common stock wherein the purchase price and withholding taxes of approximately \$1.8 million were paid by the delivery of 463,154 shares of common stock.

In addition, compensation expense of \$1,004,000 in 2001, \$450,000 in 2000 and \$344,000 in 1999 was recognized related to compensatory and variable stock options and a restricted stock award under the 1997 Plan. Other non-cash activities have involved the issuance of compensatory stock options to employees. See also Note 12 for details of transactions under our employee benefit plans.

Net cash from operating activities reflects cash payments for interest expense for the years ended December 31, 2001, 2000 and 1999 of approximately (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Cash payments for interest expense	\$ 701	\$ 1,132	\$ 1,510

Note 15 – Related Party Transactions

In the years 2001, 2000 and 1999, we performed services for the Dermagraft and NeoCyte Joint Ventures and manufactured products for the Dermagraft Joint Venture to sell to customers or for use in clinical trials as described below. We have a 50% interest in each of the Dermagraft and NeoCyte Joint Ventures and share equally with Smith & Nephew in the expenses and revenues, except we funded the first \$6 million of expenses for conducting clinical trials and for regulatory support of Dermagraft and TransCyte in the treatment of venous and pressure ulcers.

Dermagraft Joint Venture

Product sales to related parties includes products sold to the Dermagraft Joint Venture. In addition, we recognize amounts in contract revenues for research and development, marketing and other activities performed for the Joint Venture. During the years ended December 31, 2001, 2000 and 1999 such amounts were (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Products sold to the Dermagraft Joint Venture	\$ 12,767	\$ 12,771	\$ 13,717
Contract revenues for activities performed	3,510	5,298	9,165

As a purpose of the Dermagraft Joint Venture is to share the costs of manufacturing Dermagraft and TransCyte, product sales to the Dermagraft Joint Venture are equal to our cost of goods sold for such products including period costs, except for the period from January 1, 1997 to September 30, 1998 when we also sold TransCyte in the United States and, therefore, absorbed period costs related to TransCyte. Period costs reflect overhead costs related to excess production capacity and include rent, depreciation, and quality control, facilities, supplies and other such costs to support, or related to, the excess production capacity. Due to costs related to excess production capacity, the Dermagraft Joint Venture immediately writes the inventory down to estimated market value at the date of purchase, which is the net realizable value at which the joint venture believes it will be able to sell the products to its customers. We incur our share of the write-downs, currently 50%, through our equity in the joint venture. During the years ended December 31, 2001, 2000 and 1999, such write-downs by the Dermagraft Joint Venture totaled (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Dermagraft Joint Venture inventory write-downs	\$ 9,089	\$ 9,821	\$ 11,982

As a result of restructuring the Dermagraft Joint Venture Agreement with Smith & Nephew, we will also receive certain royalty payments from the joint venture on product sales made by the joint venture.

NeoCyte Joint Venture

We recognized amounts in contract revenues for research and development activities performed for the NeoCyte Joint Venture. During the years ended December 31, 2000, 1999 and 1998, such amounts were (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Contract revenues for activities performed for NeoCyte Joint Venture	\$ 501	\$ 2,578	\$ 2,885

Our share of the costs incurred by us and charged to the Dermagraft and NeoCyte Joint Ventures are reflected in the equity in losses of joint ventures in the accompanying statement of operations. For the years ended December 31, 2001, 2000 and 1999, such costs charged were (in thousands):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Charged to Dermagraft and NeoCyte Joint Ventures	\$ 9,134	\$ 10,603	\$ 15,934

In addition, in 2001 we paid management fees to the Dermagraft Joint Venture for services provided in relation to the manufacture of human-based collagen. Such fees in 2001 amounted to \$603,000, and are recorded as related party revenue in the accounts of the Dermagraft Joint Venture. No such fees were paid in years prior to 2001. Future fees are dependent upon levels of production of collagen and, potentially, other products.

Note 16 – Selected Quarterly Data (Unaudited)

The following tables present unaudited quarterly financial information for each of the four quarters of the fiscal years ended December 31, 2001 and December 31, 2000. We believe this information reflects a fair presentation of such information in accordance with generally accepted accounting principles. The results are not necessarily indicative of results for any future period. More detailed information can be found in our quarterly statements on Form 10-Q for the respective periods. Due to the nature of our business and the presentation of our financial statements, we are not able to segregate gross margin information in our statement of operations. Selected unaudited quarterly results were as follows (in thousands except per share amounts):

	Year Ended December 31, 2001			
	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter
Joint venture contract revenue (1)	\$ 4,320	\$ 4,642	\$ 4,174	\$ 3,642
Total revenues	4,981	5,384	10,385	8,190
Joint venture contract expenses (1)	4,280	4,413	3,525	4,346
Compensation charge / (gain) related to variable stock option (see Note 10)	444	584	(797)	446
Income (loss) from operations before equity in losses in joint ventures	(5,590)	(6,028)	1,230	(5,875)
Equity in losses in joint ventures	(2,959)	(3,370)	(2,883)	(3,179)
Loss from operations	(8,549)	(9,398)	(1,653)	(9,054)
Net loss	(8,261)	(9,349)	(1,688)	(9,075)
Basic and diluted loss per common share (2)	\$ (.13)	\$ (.15)	\$ (.03)	\$ (.13)

	Year Ended December 31, 2000			
	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter
Joint venture contract revenue (1)	\$ 6,376	\$ 5,130	\$ 4,583	\$ 4,558
Total revenues	7,410	6,263	5,780	5,818
Joint venture contract expenses (1)	6,358	5,171	3,825	5,066
Compensation charge / (gain) related to variable stock option (see Note 10)	1,991	704	(138)	(2,557)
Income (loss) from operations before equity in losses in joint ventures	(5,045)	(3,987)	(2,379)	(1,021)
Equity in losses in joint ventures	(3,713)	(3,542)	(3,137)	(2,886)
Loss from operations	(8,758)	(7,529)	(5,516)	(3,907)
Net loss	(8,299)	(7,428)	(5,513)	(3,331)
Basic and diluted loss per common share (2)	\$ (.14)	\$ (.12)	\$ (.09)	\$ (.05)

- (1) This presentation has been reformatted from prior presentations to more clearly reflect revenue and cost transactions between us and our joint ventures with Smith & Nephew. These transactions are separately presented from transactions with other parties.
- (2) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share will not necessarily equal the total for the year.

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Statements in this annual report that are not strictly historical may be "forward-looking" statements, which involve risks and uncertainties. No assurances can be given, for example, that the company will successfully implement its business strategy, retain key members of management, develop its current products or any new products it may pursue, complete clinical trials, or be able to manufacture or successfully commercialize such products. Risks and uncertainties exist in the company's operations, including, without limitation, uncertainties related to clinical trials, the ability to obtain the appropriate regulatory approvals, the ability to obtain additional milestones and financing to continue operations when needed, a history of operating losses and accumulated deficits, the company's reliance on collaborative relationships, market acceptance of products, the company's ability to obtain and retain patent protection, as well as other risks detailed from time to time in publicly available filings with the Securities and Exchange Commission including, without limitation, Advanced Tissue Sciences' Annual Report on Form 10-K for the year ended December 31, 2001. The company undertakes no obligation to release publicly the results of any revision to these forward-looking statements to reflect events or circumstances arising after the date hereof.

