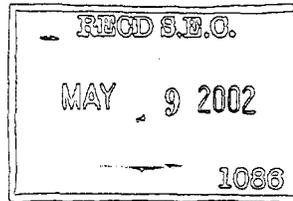




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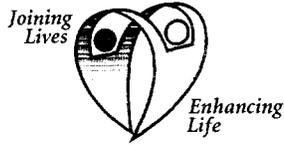


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*There is nothing more precious than the generous gift of donated tissue so that others may have an improved quality of life. Osteotech is dedicated to honoring the donor and generosity of their family by utilizing innovative technology and offering support to our tissue recovery partners, to ensure that the maximum number of patients benefit from this generous gift.*

f i n a n c i a l  
h i g h l i g h t s

*(dollars in thousands, except per share data)*

For the Year	<b>2001</b>	2000	1999
Net revenues	<b>\$ 77,846</b>	\$75,683	\$75,610
Net income (loss)	<b>(4,410)</b>	4,828	12,351
Net income (loss) per share			
Basic	<b>(.31)</b>	.34	.88
Diluted	<b>(.31)</b>	.34	.84
Total assets	<b>107,244</b>	104,438	89,730
Stockholders' equity	<b>67,786</b>	71,851	69,406
Cash flow from operations	<b>(2,019)</b>	10,175	14,459



Dear Fellow Shareholder:

In 2001, we faced a number of significant issues, which when taken together, caused marginal revenue growth and a net loss for the year. The net loss was the first yearly loss experienced since 1996. On a brighter note, we believe we turned the corner in mid-2001 as evidenced by our first quarter 2002 results where we posted a 26% increase in revenues over previous year's first quarter and returned to profitability. This performance represented the fourth consecutive quarterly revenue growth for the Company and you would have to go back seven quarters to find a better bottom line performance.

The primary negative impact to revenue in 2001 was the reduction in processing fees resulting from processing 33% fewer donors than in 2000. This decline constrained our ability to meet the market demand for our bio-implant tissue forms, although revenues of bio-implants grew 225% for the year. Revenue was also negatively impacted by the slight decline in Grafton® DBM revenues brought about primarily by the intense competition in this market segment. However, in addition to being offset by the 225% growth of our bio-implants, this decline was countered by a 127% growth in our rapidly expanding metal spinal implant line, a 29% increase in our overseas OsteoPure™ Femoral head processing revenue and a 36% increase in our overseas ceramic coatings and products revenue. The net result of all these changes in our revenue portfolio was an overall 3% increase in 2001 revenues to \$77,846,000.

As with revenue, the Company's profitability was negatively impacted by several factors, including the significant investment we have made to expand into bio-implant and metal systems and to bring these products to the market and grow market share. Putting further strain on the bottom line was a provision taken of \$1,845,000 primarily related to reserves for excess inventory and instrument sets for our spinal implant systems, a provision of \$2,287,000 for the writeoff of certain assets which will no longer be utilized in the processing of allograft tissue, and a \$700,000 provision for severance costs. Additionally, in the GenSci litigation, in which the Company prevailed, legal fees amounted to \$4,158,000. Excluding these four items, we would have reported net income of \$984,000 or \$.07 diluted earnings per share.

As mentioned before, we believe the Company turned the corner in mid-2001 and we also believe that we're positioned for success in 2002 and beyond. We believe this for six overriding reasons: 1) we are a fully integrated orthobiologics company with a focus in spinal orthopedics, 2) we provide a full line of complementary and competitive products to surgeons performing spinal fusion procedures, 3) we have built a large, well trained sales force to take our message to, and provide full service to, the surgeon, 4) we have taken significant steps to increase our tissue supply, 5) we have an

innovative research and development pipeline for the future, and 6) we have a growing global presence that will allow us to bring existing and new products to major markets around the world.

**Fully Integrated Orthobiologics Company** – Our strategy has always been to control our own destiny, especially in what we consider the core competency of our business, which is musculoskeletal tissue technology. For us, that has meant being directly involved in all aspects of the tissue business from processing tissue through presenting our unique tissue technology and services to the spinal surgeon. This is why we continue to market our products in the United States through our own direct and agent sales force and have not delegated this critical function to a marketing partner. It is also why we made the strategic decision back in 1996 to invest in our own development engineering function so we could internally design bio-implant systems for what we envisioned to be an emerging, fast growing new market segment. As a result of these decisions and others, such as our investment in a new state of the art processing facility and investment in research and development, we feel confident that we will continue to prosper in the future.

**Complementary and Competitive Products** – Our understanding of the marketplace, particularly the spinal fusion market, was a driving force behind our moving from a “Grafton® DBM Company” to a company offering a broader product portfolio. This is because we knew we needed to have a broader product line than Grafton® DBM if we were going to successfully compete for the spinal surgeon’s business. As a result, we expanded into bio-implant and metal implant systems while expanding our breadth in all three product categories. For example, in the last two years we have expanded our Grafton® DBM line from three to six tissue forms, increased our bio-implant line from one to six systems and introduced four new metal implant systems. Clearly, our sales representatives are in a much better competitive position today because they can offer the spinal surgeon a line of metal implants to stabilize the spine, a line of bio-implants to provide spinal column support, and a line of grafting materials to help aid in the fusion process.

**Large, Well Trained Sales Force** – In today’s and tomorrow’s market, a major component for success is having a sales force that can professionally and knowledgeably interface with the spinal surgeon in order to present the features and benefits of our products. Additionally, they must be willing to provide unsurpassed service to the surgeon and operating room staff. Often this means delivering instruments in time for surgery, training the surgeon and staff on the use of instruments and implants and being available in surgery to answer any questions that

may come up from the operating room staff. We have such a sales force in the 25 people we employ directly and the approximately 175 independent sales agents we contract with to represent our products.

**Tissue Supply** - As a business whose primary focus is on musculoskeletal tissue technology, having adequate and consistent access to tissue sources is critical to our continuing success. Clearly, a major component to our less than stellar performance in 2001 was the fact that we had available to us 33% fewer donors than the previous year. This is why we have put so much emphasis on developing new sources of domestic and international tissue in addition to our existing tissue recovery organization relationships. This emphasis is beginning to show success as evidenced by our recent partnership with LifeNet, one of the largest Organ Procurement Organization based tissue banks in the United States, and overseas with the new and exclusive tissue agreement with the Bulgarian government. Beyond that we've implemented five new agreements that will provide significant incremental tissue in 2002.

**Innovative Research and Development** - This function within Osteotech has always been a critical component in our past successes and will continue to be a driving force behind our future successes. We have always been recognized as an industry leader in musculoskeletal tissue science because we understand the importance of innovation to the long-term success of the business. One such innovation, which we believe represents a major breakthrough, is our plexus technology and the impact it will have on our bio-implant business. At the present time we, as well as others in the industry, have a difficult time keeping up with surgeon demand for bio-implants as surgeons desire to move away from metal intervertebral devices. This supply problem is a direct result of limited donated tissue and the fact that bio-implants can only be made from very specific pieces of tissue, such as the femur, and in many cases only the diaphysis, or shaft, of the femur. The plexus technology solves most of this problem. Since the plexus technology provides us with the ability to reassemble bone from a donor into any shape, it allows us to more fully utilize the donor's tissue and substantially improve the number of bio-implants that can be derived from that donor. And, it will allow for the use of donated tissue that is presently not utilized for weight bearing bio-implants, which will expand the overall number of donors available to be transformed into bio-implants. The business implications of this are clear, the plexus technology will reduce the loss of unused tissue inherent in how bio-implants are processed today. This is extremely important because tissue recovery organizations want to know that they are having their tissue processed by an organization that can maximize the gift of donation. We have not yet determined if products processed with the plexus technology will be regulated by the Food and Drug Administration as banked human tissue or a medical device.

Growing Global Presence – The musculoskeletal tissue industry as we know it today in the United States is virtually non-existent internationally. However, the need for products and services that we provide are substantial in many markets around the world. This is because surgeries are being performed just as they are in the United States but are being done without tissue forms such as Grafton® DBM and bio-implants. In the absence of these products, harvesting of the patient's own bone, usually from the iliac crest, is often done to obtain weight bearing and non-weight bearing tissue to be used elsewhere, such as in the spine. Also, the use of synthetics such as hydroxyapatite is popular as a grafting material. Both have drawbacks that can be solved with our technology. This is why we have invested heavily to expand our business globally. We acquired OST Développement in 1999 to serve as the hub for this expansion and we will be marketing tissue in approximately 14 countries in 2002. Our strategy recognizes that due to limited donation in the United States, donated U.S. tissue cannot be considered as an integral part of our long term plans to globalize. Therefore, in addition to building demand for our technology, we are developing local donation sources in order to maintain a balance between demand for tissue products and availability of donated tissue. This is why we are so pleased to have a continuing strong relationship with our existing European clients such as the Netherlands Bone Bank Foundation, Bio Implant Services Foundation, Osteo Banque D'Auvergne and our new relationship with the Bulgarian Federal Agency for Transplantation Management. We believe, just as we have been in the United States, that we are well out in front of our competition in establishing our technology and business model on a global basis.

In conclusion, we hope you, our shareholders, are as excited about the future as we are. We believe that well thought out strategies produce results and that results produce shareholder value. We greatly appreciate your continued support as we manage our way out of the recent difficult years and work to restore revenue and net income growth to their historical highs.

Sincerely,



Richard W. Bauer  
President and Chief Executive Officer  
May 8, 2002

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934

For the fiscal year ended December 31, 2001

Commission File Number 0-19278

OSTEOTECH, INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation or organization)	<u>13-3357370</u> (I.R.S. Employer Identification No.)
<u>51 James Way, Eatontown, New Jersey</u> (Address of principal executive offices)	<u>07724</u> (Zip Code)

Registrant's telephone number, including area code (732) 542-2800

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

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

Common Stock - \$.01 Par Value  
(Title of class)

Preferred Stock Purchase Rights  
(Title of class)

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

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

The aggregate market value of the Common Stock, par value \$.01 per share, held by non-affiliates based upon the reported last sale price of the Common Stock on March 15, 2002 was approximately \$103,950,000.

As of March 15, 2002, there were 14,100,264 shares of Common Stock, par value \$.01 per share, outstanding.

Documents Incorporated by Reference

The registrant's definitive 2002 Proxy Statement which will be filed pursuant to Regulation 14A is incorporated by reference into Items 11 and 12 of Part III of this Annual Report on Form 10-K.

# OSTEOTECH, INC.

## 2001 Form 10-K Annual Report

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The following trademarks and service marks appear in this Annual Report: Threaded Cortical Bone Dowel, Graftech™ Bio-Implants, OsteoActive™, Ovation™ Low Back Fixation System, Sentinel™ Pedicle Screw System, Affirm™ Cervical Plating System, Clear Bone™, and Grafton Plus™ DBM are trademarks and Osteotech®, Grafton® Demineralized Bone Matrix (DBM), bio-d®, and Allogard® Packaging are registered trademarks of Osteotech, Inc.; D-MIN<sup>sm</sup> is a service mark of Osteotech, Inc.; LUBBOC® AND LADDEC® are registered trademarks of OST Developpement SA and OsteoPure™ is a trademark of OST Developpement SA; Vertebral Body Replacement (VBR™) is a trademark of Heinrich C. Ulrich, K.G.

## PART I

### Item 1. Business

Information contained throughout this Annual Report contains "forward-looking statements" which can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or variations thereon or comparable terminology, or by discussions of strategy. No assurance can be given that the future results covered by the forward-looking statements will be achieved. Some of the matters set forth in the "Risk Factors" section of this Annual Report and elsewhere in this Annual Report constitute cautionary statements identifying factors with respect to such forward-looking statements, including certain risks and uncertainties, that could cause results to vary materially from the future results indicated in such forward-looking statements. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements.

#### Company Overview

We provide services and products primarily focused in the repair and healing of the musculoskeletal system. These products and services are marketed primarily to the orthopaedic, spinal, neurological, oral/maxillofacial, dental and general surgery markets in the United States and Europe. Based on our knowledge of the allograft bone tissue industry, we believe that we are the world's largest processor and developer of human bone and bone connective tissue, or allograft bone tissue, forms. The allograft bone tissue we process is procured by independent tissue banks or other Tissue Recovery Organizations, or TRO's, primarily through the donation of tissue from deceased human donors and is used for transplantation. We have two primary operating segments:

- the Grafton<sup>®</sup> Demineralized Bone Matrix (DBM) Segment, or the Grafton<sup>®</sup> DBM Segment; and
- the Base Allograft Bone Tissue Segment, or the Base Tissue Segment.

All of our other products and services are aggregated under the category of "other."

In the Grafton<sup>®</sup> DBM Segment we process and market Grafton<sup>®</sup> DBM which is generally distributed by our clients. We also process allograft bone tissue recovered by TRO's on our behalf and distribute such tissue under our own label. Although our distribution of allograft bone tissue under our own label has represented an immaterial portion of our revenue through 2001, we expect revenue generated from allograft bone tissue distributed by us under our own label to represent a growing percentage of our Grafton<sup>®</sup> DBM revenues in the future. See Item 7. "Management's Discussion And Analysis of Financial Condition and Results of Operations" for a discussion on the anticipated impact of this method of distributing tissue on our gross profit margins.

We process Grafton<sup>®</sup> DBM using our validated, advanced, proprietary demineralization process. When applied to cortical bone, this process yields allograft bone tissue which has

osteoinductive (the process by which bone is induced to grow) and osteoconductive (the matrix provided by allograft bone tissue into which the host bone can grow) capabilities greater than currently available forms of mineralized allograft bone tissue, and we believe, greater than other competitive demineralized allograft bone tissue forms.

In the Base Tissue Segment we process primarily mineralized weight-bearing allograft bone tissue. Bio-implants, which are included in this segment, are marketed and generally distributed by us and other tissue forms processed in this Segment are generally marketed and distributed by our clients. To the extent that TRO's recover allograft bone tissue on our behalf, we will process and distribute such tissue directly to the end-user. Through 2001, our direct distribution of allograft bone tissue has not represented a material portion of the Base Tissue Segment's revenue. However, we expect revenue generated from allograft bone tissue distributed directly by us to end-users to represent a growing percentage of our Base Tissue Segment revenues in the future. See Item 7. "Management's Discussion And Analysis of Financial Condition and Results of Operations" for a discussion on the anticipated impact of this method of distributing tissue on our gross profit margins. We also process the bio-d® Threaded Cortical Bone Dowel for posterior and anterior spinal fusion procedures, the Graftech™ Bio-implant spacers and ramps for posterior and anterior spinal fusion procedures and OsteoPure™ Femoral head bone tissue in the Base Tissue Segment.

We have leveraged our expertise in musculoskeletal tissue technology to develop innovative processes and proprietary products that are widely used by orthopaedic, spinal, neurological and oral/maxillofacial surgeons for spinal fusion procedures; to repair and replace bone loss caused by trauma or certain disease states; to augment prosthetic implant procedures; and to replace damaged ligaments and tendons.

In addition to our Grafton® DBM Segment and Base Tissue Segment, we provide ceramic and titanium plasma spray coating services and ceramic products which are used as bone graft substitutes, to orthopaedic and dental implant manufacturers. We distribute these products in Europe and the Middle East through our operations based in Leiden, The Netherlands. In the United States, we also market and distribute metal spinal implant products, including the Ovation™ Low Back Fixation System, or Ovation™, a titanium, lumbosacral spine fixation system with an innovative polyaxial screw. We also market the Vertebral Body Replacement, or VBR™, a patented device approved as a vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma.

In February, 2001, we entered into a distribution agreement with Alphatec Manufacturing, Inc. to market and distribute the Sentinal™ Pedicle screw system and the Affirm™ Cervical plating system in the United States and Canada. Under the terms of this distribution agreement, which is for an initial term of two (2) years from February, 2002, the date that the first order for the systems was completed, we are required to purchase an aggregate minimum of \$6 million of the two systems. The agreement is automatically renewed for two (2) year periods unless either party cancels it upon six months prior written notice. If the agreement is renewed after its original term, we are required to purchase an aggregate minimum of \$8 million of the two systems in the

two year renewal period. Thereafter, any minimum purchase obligations are to be negotiated in advance of each renewal.

Through OST Developpement, SA, or OST, our subsidiary located in Clermont-Ferrand, France, we also process, market and distribute primarily in Europe, Asia and the Middle East, bovine bone tissue products which are utilized as bone graft substitutes by surgeons and OsteoPure™ Femoral head processed human allograft bone tissue grafts. We also market and distribute Grafton® DBM through OST in these same markets.

We estimate that the total bone graft market in the U.S. for 2001 was approximately \$521 million, which includes allograft bone tissue procedures, synthetic graft substitutes and autograft bone tissue procedures (transplant tissue harvested from the patient). We estimate that the allograft bone tissue portion of the total bone graft market in the U.S. in 2001 was approximately \$310 million. The allograft bone tissue market is growing at a substantially faster rate than the general bone grafting market, as allograft bone tissue is increasingly becoming accepted as either an augment to, or a surgical alternative to autograft procedures. Autograft bone tissue often requires a second surgical procedure to harvest bone from the patient's own body and, therefore, exposes the patient to increased risk associated with blood loss, infection and chronic pain. We believe, increased use of allograft bone tissue will continue as physicians become increasingly educated about the benefits of allograft bone tissue. Moreover, we believe allograft bone tissue is increasingly preferred for use in elderly patients, who often lack sufficient quantity of their own harvestable bone for use in a procedure.

Based upon our knowledge of the allograft bone tissue industry, we estimate that we process about 40% of the allograft bone tissue grafts distributed in the U.S. We believe that our strong market position is attributable to our proprietary product line; our clients' national donor recovery programs; our national sales and marketing organization; and the substantial investment we have made in processing technology to ensure stringent standards and rigorous quality control which, combined with extensive donor screening and testing performed by our clients, has significantly reduced the risk of transmission of infectious agents.

Our clients pay us fees for our processing of the allograft bone tissue that they provide to us. In the Grafton® DBM Segment, our clients pay us fees on a per unit basis for the Grafton® DBM tissue forms we process and they generally distribute. In the Base Tissue Segment, our clients pay us fees on a per donor basis, and in the case of bio-implants, our clients pay us fees on a per unit basis for the bio-implants we process and generally distribute. In the second half of 2001 we implemented a new revenue model whereby we bill the end-user for Grafton® DBM and bio-implants we distribute, in addition to our historical revenue model in which we bill our clients for Grafton® DBM and bio-implants they distribute. In the future, we expect to generate revenue from a combination of these two distribution methods.

In the United States we process allograft bone tissue pursuant to contracts with a number of clients, including two large not-for-profit organizations, American Red Cross Tissue Services, or ARC, and Musculoskeletal Transplant Foundation, or MTF. Our clients are responsible for donor procurement and generally for the distribution of the allograft bone tissue we process for

them. Our contract with ARC expires in December, 2006 and our contract with MTF expires in August, 2005. However, the MTF contract may be canceled at any time upon either party giving six months prior written notice. We also are currently in litigation with MTF related to our Grafton® DBM patents and other matters. See Item 3 "Legal Proceedings." Additionally, we process allograft bone tissue for several smaller tissue banks in the United States and Europe.

In January, 2002, we entered into a five year agreement with LifeNet, one of the largest Organ Procurement Organizations, or OPO based tissue banks and processors in the United States. Under the terms of this agreement, LifeNet will supply Allowash™ processed tissue to us and we will process the tissue into our broad line of bio-d® and Graftech™ Bio-Implants. All of those bio-implants will display the LifeNet name and Osteotech product brand names. The bio-implants will be marketed through our national agent and direct sales organizations and will be distributed to hospitals by us on behalf of LifeNet. The agreement with LifeNet also provides us with the opportunity for the future processing and marketing of LifeNet labeled tissue carrier products through a mutually agreed upon third party.

We market our proprietary allograft bone tissue products such as Grafton® DBM and our line of bio-implants through independent agents and direct field sales personnel. Generally, our clients market the non-proprietary products we process in our Base Tissue Segment, primarily using direct field personnel. Our products are gaining wide acceptance among surgeons in a broad spectrum of orthopaedic procedures due to their flexibility, unique handling characteristics and ability to enhance bone growth.

Revenue in our Grafton® DBM Segment was \$43,637,000 in 2001 as compared to \$45,226,000 in 2000 and 2001 revenue in our Base Tissue Segment was \$27,692,000 as compared to 2000 revenue of \$26,204,000. We expect that both our Grafton® DBM and Base Tissue Segments will continue to be important contributors to the growth of our consolidated revenues and profits in 2002, as processed allograft bone tissue forms continue to gain increased acceptance.

Information relating to our revenues for the years ended December 31, 2001, 2000 and 1999 by geographic area is summarized as follows:

<i>(in thousands)</i>	United States	Europe	Consolidated
Revenues			
For the year ended December 31,			
2001	\$71,776	\$ 6,070	\$77,846
2000	71,468	4,215	75,683
1999	71,517	4,093	75,610

For a discussion of (1) our long-lived assets as of December 31, 2001, 2000 and 1999 respectively see Note 16 of "Notes to Consolidated Financial Statements" and (2) our deferred tax assets for the years ended December 31, 2001, 2000 and 1999 respectively see Note 10 of "Notes to Consolidated Financial Statements".

## Strategy

### *Overview*

We intend to expand our business as follows:

- We intend to use our position as a leader in allograft bone tissue processing and marketing to become a leading orthopaedic/musculoskeletal company by continuing to bring to market innovative and cost-effective allograft bone tissue forms and non-allograft products. We also will expand into new markets globally.
- We will continue to educate the medical community and the general public concerning the benefits of allograft bone tissue. We intend to accomplish this by sponsoring workshops, conducting grand rounds presentations, increasing our presence at conventions, publishing clinical studies, white papers and articles and expanding our medical education internet site.
- We intend to use our strong research and development capabilities and expertise in musculoskeletal science to:
  - \* enhance the performance of our existing allograft bone tissue forms;
  - \* expand the safety claims of these tissue forms using proprietary processes; and
  - \* continue to introduce new tissue forms with enhanced performance profiles.
- We intend to add additional metal spinal implant systems to our product line in order to provide the spinal surgeon with a greater breadth of products.
- We intend to utilize our marketing and distribution network to enhance the market share of both our allograft bone tissue forms and non-allograft product lines.
- To ensure that we have an adequate supply of allograft bone tissue to meet the market demand for existing tissue forms that we process and for any new tissue forms that we may process, we intend to work with existing clients to expand the amount of tissue they recover, obtain additional tissue bank clients and contract directly with TRO's to obtain tissue on our behalf.

### *Grafton<sup>®</sup> DBM Segment*

In the near term, we will continue to focus on marketing Grafton<sup>®</sup> DBM through our direct marketing organization, our national agent network and medical education programs. We will support these programs through prospective clinical and outcome studies to further validate the performance, utility and safety of our processed tissue. We also will continue to expand the

Grafton® DBM tissue line by adding additional forms and continue our expansion globally. In this regard, in February, 2002, we launched Grafton Plus™ DBM which contains a starch carrier instead of our traditional glycerol carrier and has improved handling characteristics which we believe will enable us to compete more effectively against competitive paste-like products.

We expect to expand sales of Grafton® DBM through:

- providing the surgeon an expanded line of metal implant products and allograft bone tissue forms which are usable with Grafton® DBM so that we can better meet the needs of the surgeon;
- surgeon identified new procedures;
- surgeon oriented medical education programs;
- in-depth sales agent training programs;
- published clinical support;
- product line extensions;
- global expansion with an initial European focus; and
- continued expansion of the allograft bone tissue market in both the United States and globally.

#### *Base Tissue Segment*

We expect to achieve continued growth in the Base Tissue Segment through:

- introduction of additional allograft bone tissue grafts with application in spinal and other surgical procedures;
- use of our new packaging system and, a new ClearBone™ Viral inactivation system;
- global expansion of base allograft bone tissue grafts and the tissue processing business in selected countries, initially in Europe;
- development of proprietary tissue processing technology through internal research;
- introduction of new allograft bone tissue forms with enhanced performance profiles; and
- obtaining additional bone tissue processing clients and sources of bone tissue.

## *Other*

### *Non-Allograft Bone Tissue Spinal Implant Products*

Our strategy in the non-allograft bone tissue spinal implant product lines of business is to:

- continue focusing our European non-allograft bone tissue operations to capture available opportunities for ceramic coating services and ceramic products;
- capitalize on high-growth opportunities in the U.S. spinal products market with innovative non-allograft bone tissue products;
- enter into agreements with other health care product companies to utilize our technology and expertise in the non-allograft bone tissue area for the development and manufacture of proprietary product components; and
- expand our metal implant product line, either through internal development or acquisition or licensing of products from other companies, in order to increase our market share and provide the surgeon with a more comprehensive product line so that we will be able to meet all the surgical implant needs of the surgeon.

### *Spinal Strategy*

Our strategy consists of two primary components involving our Grafton<sup>®</sup> DBM and Base Tissue Segments and our non-allograft bone tissue spinal implant product line of business:

- continue the U.S. market penetration of our metal spinal implant products, including our products currently on the market, the Ovation<sup>™</sup> System, the Affirm<sup>™</sup> Cervical plate system, the VBR<sup>™</sup> and the Sentinal<sup>™</sup> Pedicle screw system which we began to market in February, 2002;
- market our allograft bone tissue bio-implants and our metal spinal implant products together with Grafton<sup>®</sup> DBM through our national sales agency network.

Our intention is to educate surgeons to use Grafton<sup>®</sup> DBM, our allograft bone tissue bio-implants and our metal spinal systems, either alone or in conjunction with each other. Spinal implant products, both allograft and non-allograft, which we add to our product mix in the future will be included in this strategy.

## Business Summary

Bone and related tissue transplants are often necessary to correct deformities and repair and reconstruct defects caused by congenital malformations, trauma, infections, cancer and other disease conditions. For certain procedures, autograft bone tissue can be acquired from another part of the patient's skeleton by an additional operative procedure. For a large number of procedures for which autograft bone tissue is not feasible or desirable, allograft bone tissue previously obtained from cadavers or surgical patient donors can be utilized. Allograft bone tissue is procured primarily from cadavers by a network of organ procurement organizations and/or directly by tissue banks.

We process allograft bone tissue for our clients and bone tissue recovered by TRO's for us in both our Grafton<sup>®</sup> DBM and Base Tissue Segments. Once processed, we typically return the allograft bone tissue to our clients for distribution to surgeons and hospitals, or if recovered by TRO's on our behalf, or by agreement with certain clients, we distribute it directly to surgeons and hospitals. The surgeons and hospitals pay the fees established and charged by our clients or us. The surgeons and hospitals in turn charge their patients for the various aspects of transplant surgery performed by them, including standard charges established by the surgeon or institution for each unit of processed allograft bone tissue used. The cost to the patient for the processed allograft bone tissue is generally reimbursable by medical insurance carriers as part of the overall cost of the procedure.

In both our Grafton<sup>®</sup> DBM and Base Tissue Segments, our processing yields a wide array of freeze-dried, frozen and demineralized allograft bone tissue forms that are used by orthopaedic, neurological, plastic, dental, periodontal and oral/maxillofacial surgeons for:

- spinal fusion procedures;
- repair and replacement of bone loss caused by trauma or certain disease states;
- augmentation of prosthetic implant procedures; and
- replacement of damaged ligaments and tendons.

We believe our processing methods, our clients' tissue recovery techniques and the multiple screening and testing procedures employed, significantly reduce the risk of transmission of infectious agents by the allograft bone tissue we process.

In our Grafton<sup>®</sup> DBM Segment, we have a validated viral inactivation process for our demineralized bone tissue. Studies completed by an independent testing laboratory specializing in viral inactivation studies demonstrated that this proprietary demineralization process virtually inactivates and eliminates viruses such as HIV, hepatitis B, hepatitis C, cytomeglia and polio.

We are in the process of implementing additional proprietary processing technologies that, once fully implemented, will enable us to expand our viral inactivation claims to include the mineralized weight-bearing allograft bone tissue processed in our Base Tissue Segment.

We believe that allograft bone tissue transplantation is one of the fastest growing areas of transplant medicine. We estimate that in 2001 there were approximately 583,000 grafting procedures in the U.S. for which allograft bone tissue could have been utilized, representing an estimated available allograft bone tissue market of approximately \$521 million. Currently, allograft tissue competes with autograft bone tissue procedures and synthetic graft substitutes for the total bone graft market in the United States. We estimate that the allograft bone tissue portion of the total bone graft market in the U.S. in 2001 was approximately \$310 million. Industry data indicates that the musculoskeletal surgical market is growing. We believe this will expand the potential market for allograft bone tissue in both our Grafton<sup>®</sup> DBM and Base Tissue Segments, due to a number of factors, including:

- increasing frequency of surgical procedures that incorporate bone grafting techniques;
- the desire by surgeons to avoid the additional procedure needed to acquire autograft bone tissue, which often increases operating time and risks such as excessive blood loss, infection and chronic pain;
- a reduction in the possibility of transmission of infectious agents and toxicity because of improved allograft bone tissue processing techniques and donor screening;
- increased awareness by, and training of, the medical community with respect to the use of allograft bone tissue;
- an increasing number of musculoskeletal surgical procedures which require more bone tissue than can be obtained through autograft procedures;
- an increase in the number of patients who do not possess the quality of bone tissue required for autograft procedures as a result of the general aging of the population; and
- an increase in the availability of allograft bone tissue due to an increase in bone tissue donations and improved recovery and processing techniques.

Allograft bone tissue is employed in surgical procedures because of its biologic and biomechanical properties. Bone from various locations in the body can be processed to yield either dense cortical bone, porous cancellous bone or units comprised of both cortical and cancellous bone. Cortical bone, the thick outer portion of bone, provides biomechanical strength which allows the bone to be weight-bearing, and therefore, is commonly used in surgery in the spine and in the extremities and in other procedures requiring strong transplant material. Cancellous bone, the spongy portion of bone tissue, is preferable for surgical procedures, or aspects thereof, in which rapid penetration of new bone into the pores of the transplant, a process known as osteoconduction, is desirable but where weight-bearing strength is not paramount.

Therefore, cancellous bone is often used to fill smaller areas of bone loss and to augment more extensive reconstructive procedures including knee and hip replacements. Most procedures using allograft bone tissue, however, employ a combination of cortical and cancellous bone in a variety of forms, shapes and sizes.

### Allograft Bone Tissue Processing

#### *Grafton® DBM Segment*

In addition to the proprietary procedures which are particular to the processing of Grafton® DBM, the technologies used in processing allograft bone tissue in the Base Tissue Segment are also used in processing Grafton® DBM. The methods used to process Grafton® DBM have been validated as a viral inactivation process. This proprietary process virtually inactivates and eliminates viruses such as HIV, hepatitis B, hepatitis C, cytomeglia and polio.

We have developed an advanced proprietary demineralization process for cortical bone which yields Grafton® DBM — a form of allograft bone tissue which can be used to aid in the formation of new bone through the processes of osteoconduction and osteoinduction. Osteoconduction is the process of providing the matrix into which bone will grow and osteoinduction is the process by which bone is induced to grow. Cortical bone is believed to be the principal reservoir for various factors which are instrumental in osteoinduction. These biological properties of cortical bone, however, are inhibited by the bone's structure and various minerals, lipids and other substances comprising the bone. Our process removes these inhibiting factors.

In our Grafton® DBM Segment, in addition to the newly introduced Grafton Plus™ DBM, we currently process five forms of Grafton® DBM:

- Grafton® DBM Gel – a gel-like substance with unique handling characteristics which are useful in performing bone graft procedures as part of spinal fusions, joint replacements and repairs of osseous defects;
- Grafton® DBM Putty – a moldable putty-like graft of entangled fibers of demineralized bone, which is mixed easily with marrow and other grafts, minimizes migration, can be molded easily and retains its shape even in larger defects;
- Grafton® DBM Flex – a flexible "pressed fiber" form of demineralized bone processed by utilizing a pressed fiber technique, providing surgeons a pliable form of bone graft. It is available in square or strip forms, conforms to the body's natural anatomy and can be easily cut for precise adaptation to host bone;
- Grafton® DBF Matrix – a flexible "pressed fiber" form of demineralized bone processed by utilizing a pressed fiber technique, providing the surgeon with a pliable form of bone graft. It also contains a "trough" into which the surgeon can place autologous bone and bone marrow to aid in the osteoinduction process; and

- Grafton<sup>®</sup> DBM Crunch – a ready to use mixture of demineralized bone fibers and demineralized cortical cubes which packs and locks into bone defects, providing structure and support to the graft site.

We expect that wider distribution and deeper market penetration of Grafton<sup>®</sup> DBM utilizing our national network of independent agents in combination with our direct marketing force, our expansion into European markets and our marketing of metal spinal implant systems will drive the further growth in the use of Grafton<sup>®</sup> DBM processed allograft bone tissue. Through December 31, 2001, Grafton<sup>®</sup> DBM forms had been utilized in over 539,000 procedures domestically.

### *Base Tissue Segment*

Unlike organs which require transplantation within hours of recovery, allograft bone tissue generally goes through a processing phase in which it is cleaned, cut into different sizes and forms for specific surgical procedures, preserved, packaged and labeled. We process the allograft bone tissue utilizing technology we have developed which yields a wide array of freeze-dried, frozen, demineralized bone and connective tissue products. Frozen tissues include whole bones and major sections thereof, bone segments, tendons and ligaments. Freeze-dried bone tissues include various wedges, strips, struts, dowels, cancellous cortical chips, blocks, strips and ribs.

The suitability of an allograft bone tissue is partly dependent on the methods used in the processing of the tissue. Processing includes the removal of certain portions of the allograft bone tissue in a manner which enables the tissue to maintain as much of the native biological characteristics relating to the use of such tissue in bone grafting procedures as possible. To provide suitable allografts, we have developed techniques that minimize the use of chemicals and procedures that might render the allograft bone tissue less suitable for use as a graft. We process allograft bone tissue in a microbially-controlled environment, substantially cleaner than that of a typical hospital operating room, created through the use of advanced air filtration, water distillation and mineral control systems and other "clean room" techniques. We believe that our use of such clean room techniques, a controlled environment, in-line disinfection and other technologies preserve the properties of the tissues that make them suitable as grafts and address the medical community's and the general public's perceptions and concerns regarding the possible transmission of infectious disease and toxicity. Once processed using our current processing methods, freeze-dried bone tissues may be stored for up to three years and frozen bone tissues may be stored for up to five years before they must be used or discarded.

In December, 1998 we began to process the bio-d<sup>®</sup> Threaded Cortical Bone Dowel for spinal fusion. In late 2000, we began to introduce the Graftech<sup>™</sup> Bio-Implants, including the Graftech<sup>™</sup> Posterior Ramp, Graftech<sup>™</sup> Anterior Ramp, Graftech<sup>™</sup> Cervical spacer and the Graftech<sup>™</sup> Cervical dowel. In addition to our normal processing techniques, the Graftech<sup>™</sup> Bio-Implants are processed using our OsteoActive<sup>™</sup> Process which transforms the typically non-osteoinductive weight bearing graft into an osteoinductive graft, thus allowing for faster incorporation of the graft into the host bone. Additionally, the graft is processed using a new

technology which allows it to be available in a non-frozen form. Previously, these types of grafts were available only in a frozen form, often resulting in the surgeon using more of the grafts to successfully perform a procedure than is necessary when a non-frozen graft is used. It is expected that the use of our new non-frozen grafts will thus significantly reduce the cost of the surgery. All of our bio-implant grafts have been tested and shown to withstand loads comparable to those reported in the lumbar spine, and their inherent natural properties, enhanced by our new processing technologies, will permit faster incorporation and remodeling. Additionally, these bio-implant grafts can be used with Grafton<sup>®</sup> DBM. Therefore, the bio-implants will provide structural support and with Grafton<sup>®</sup> DBM added, will also aid in the fusion process by inducing bone growth.

### Tissue Supply Initiative

To ensure that we have adequate supply of allograft bone tissue to meet the market demand for Graftech<sup>™</sup> Bio-Implants, Grafton<sup>®</sup> DBM and other existing tissue forms that we process and for any new tissue forms that we may process in the future, we have been engaged in an intense effort to solidify the relationships we have with existing clients who provide donated allograft tissue to us. We also intend to expand the amount of donated allograft tissue available to us by obtaining additional tissue bank clients and by contracting directly with TRO's to obtain tissue on our behalf, which we will process and distribute under our own label.

As a result of these efforts, at the end of 2000 we participated in forming the American Tissue Services Foundation, or ATSF, an independent not-for-profit tissue bank with which we have a fifteen year agreement to provide donated allograft tissue to us on an exclusive basis. In 2002, we expect ATSF to recover and provide to us donated allograft bone tissue from between 350 and 500 donors.

In January, 2002, we entered into a five year agreement with LifeNet, one of the largest OPO based tissue banks and processors in the United States. Under the terms of this Agreement, LifeNet will supply Allowash<sup>™</sup> processed tissue which we will process into our broad line of bio-d<sup>®</sup> and Graftech<sup>™</sup> Bio-Implants. All bio-implants from LifeNet supplied tissue will display the LifeNet name and Osteotech product brand names. We will market these bio-implants through our national agent and direct sales organizations and will distribute them to hospitals on behalf of LifeNet. We anticipate that tissue provided by LifeNet in 2002 will provide us the opportunity to offer to surgeons over 20,000 more bio-implants than would be available through our other existing sources of donor tissue.

Further, we are developing a new processing technology, Plexus, which is designed to maximize the utilization of donated human tissue and to increase the number of bio-implants that can be processed from a single donor's bone tissue. Utilizing the Plexus processing technology we will be able to use bone tissue that was not otherwise available for weight bearing bio-implants to be used for that purpose. Additionally, by eliminating the constraints that the anatomical structure of bone tissue places on the number of bio-implants that can currently be processed from bone tissue, the Plexus processing technology ultimately will significantly increase the number of bio-implants that can be processed from a single donor's bone tissue. We have not yet determined

if products processed with the Plexus technology will be regulated by the FDA as banked human tissue or a medical device.

### Expansion of Allograft Bone Tissue Business in Europe

OST, our subsidiary located in Clermont-Ferrand, France, manufactures and markets bovine tissue products for use as bone grafts in orthopaedic and dental surgery. These products, marketed under the trade names of LUBBOC® and LADDEC®, were developed to address the shortage of safe and effective human allograft bone grafts in France and other countries outside the United States. In the future, as a complement to our human allograft tissue products, OST will continue to market these products in certain markets.

We are expanding operations and staff at OST as we begin to use it as a base for developing our human allograft tissue graft and tissue processing business in Europe. OST has adapted its proprietary LUBBOC® and LADDEC® processing technology to develop the OsteoPure™ Process for the processing of human femoral heads recovered during hip replacement surgery. OST has concluded an agreement with OsteoBanque D'Auvergne and other European based tissue banks and further expects to enter into similar agreements with other European tissue banks for the provision of tissue for the OsteoPure™ Process in the future. Additionally, we are expanding the range of human allograft bone tissue grafts available to orthopaedic and other surgeons in various countries in Europe by supplying Grafton® DBM and other allograft bone tissue grafts processed in the U.S.

In conjunction with OsteoBanque D'Auvergne and other European tissue banks, we plan to help establish a cadaveric tissue recovery network in medical centers throughout France and other European countries in order to meet the growing demands by European surgeons for safe human allograft bone tissue forms. France will continue to be the prime base of operation in our efforts to expand the distribution of our human allograft bone tissue grafts throughout Europe on a country-by-country basis. We will add facilities and staff to our current operations, as required, to support this expansion.

We believe the advantages of locating our European operations in France are significant. The French market is one of the larger and more sophisticated European markets for bone grafts. Also, French laws and regulations governing tissue banking are well defined and the most advanced of all the major European countries. Although tissue banking operations in France are generally restricted to non-profit public health organizations approved by the government, French regulations also provide for governmental approval of for-profit organizations as tissue banks if these organizations are able to provide haute technicité (high technology) unavailable in the non-profit sector. In 2001 the French government awarded OST tissue bank status which will now enable us to operate independently as an approved tissue bank in addition to providing contract processing, marketing and management services to non-profit tissue banks.

In February, 2002, OST entered into a seven year agreement with the Bulgarian National Center For Transplant Management Bultransplant and the US-Bulgarian Fund For The Development of Medicine And Biotechnology, both of which are agencies of the Bulgarian

government responsible for overseeing all activities in Bulgaria related to the recovery, processing and allocation of human organs, tissues, cells and biomaterials for transplantation. Under this agreement, OST will be exclusively responsible for the recovery and processing of tissue, cells and biomaterials as well as the allocation and distribution of these anatomical gifts throughout Europe and the rest of the world. The bone tissue recovered under this agreement, which will meet all standards of AATB and the FDA, will initially be processed at Osteotech's facility in New Jersey and the resulting tissue forms will be distributed in Europe through OST's network of distributors and agents. Once sufficient quantities of donated tissue are obtained from this and other European sources, it is our intention to expand OST's processing facilities in Clermont-Ferrand to allow it to directly process the European sourced tissue.

## Other

### *Ceramic and Titanium Plasma Spray Coating Services and Products*

We are providing ceramic hydroxyapatite, or HA, and titanium plasma spray coating services to orthopaedic and dental implant companies in Europe. The primary advantage of coating orthopaedic and dental prosthetic devices with HA or titanium, is that it enables bone to grow onto the implanted device. This enhances the stability of the device, which, in turn, lowers the amount of bone loss and reduces pain caused by micro motion. We manufacture HA powder which we use in our plasma spray coating operations from raw materials which are readily available from several sources. We also supply HA powder to various companies for use in their in-house plasma spray coating operations. Additionally, we produce CE marked HA products that are used as grafting material to provide a matrix into which bone will grow as part of the process of the repair of bone defects.

### *Non-Allograft Bone Tissue Spinal Implants and Instruments*

The human spine is subjected to various loading conditions including tension, compression, torsion, bending and combinations of all four. When the spine has been injured by tumors, fractures, degenerative conditions or deformities, stabilizing instrumentation is required to maintain surgical correction of the condition during the healing and fusion process. We offer several metal spinal implant systems to achieve these results.

The Ovation™ System, is a lumbo-sacral spine fixation system with innovative polyaxial screw, which is marketed by our national network of direct and independent agency representatives in combination with our allograft and other non-allograft spinal products. The Ovation™ System is designed in a manner to allow the sharing of the forces to which the spine is subjected with this system, which in turn is thought to provide improved results in spinal fusion procedures.

In 2001, we began to market the VBR™. This patented device, which we distribute under an exclusive agreement with Heinrich C. Ulrich, K.G., or Ulrich, of Ulm, Germany, the manufacturer of the product, has been cleared for sale by the FDA to replace a collapsed, damaged or unstable vertebra due to a tumor or trauma.

In February, 2001, we entered into a distribution agreement to market and distribute the Sentinal™ Pedicle screw system and the Affirm™ Cervical plating system in the United States and Canada. These products are manufactured by Alphatec Manufacturing, Inc. Under the terms of this distribution agreement, which is for an initial term of two (2) years from February, 2002, the date that the first order for the systems was completed, we are required to purchase an aggregate minimum of \$6 million of the two systems. The agreement is automatically renewed for two (2) year periods unless either party cancels it upon six months prior written notice. If the agreement is renewed after its original term, we are required to purchase an aggregate minimum of \$8 million of the two systems in the two year renewal period. Thereafter, any minimum purchase obligations are to be negotiated in advance of each renewal.

We expect to continue to expand our metal spinal implant product line through acquisition or licensing of technology and products so that we are able to offer surgeons implant systems capable of solving a variety of spinal problems.

### Quality Assurance

We have stringent quality assurance programs in place covering all of our lines of business, including our Grafton® DBM and Base Tissue Segments, our HA-titanium plasma spray coating services, and our non-allograft bone tissue spinal implants and instruments. Our facilities in Clermont-Ferrand, France and Leiden, The Netherlands have received International Standardization Organization, or ISO, certification for their quality systems and our facilities in the United States are registered with the FDA and are accredited by the American Association of Tissue Banks.

In both the Grafton® DBM and Base Tissue Segments, our allograft bone tissue quality assurance program commences with the recovery of allograft bone tissue which is procured under strict aseptic conditions. The tissue is recovered primarily in hospitals and, to a lesser extent, coroners' facilities, which have been prepared for recovery. Recovered allograft bone tissue is also required to be sterilely wrapped and shipped in special containers. Upon receipt of this tissue, a quarantine period is imposed to permit serologic and microbiologic testing prior to release of allograft bone tissue for processing. Upon satisfactory completion of all testing, the allograft bone tissue is processed in a microbially-controlled environment. Under constant monitoring, the allograft bone tissue is cleaned, soaked in antibiotics and then cut and shaped in accordance with specifications. Before being released, our quality assurance team inspects and again tests all processed bone tissue for microbiological contaminants.

We believe that the serologic screening of donors, the extensive screening of donor profiles and medical histories performed by our clients and TRO's and our processing technologies substantially reduce the likelihood of the presence of infectious agents, including HIV and hepatitis viruses, in our processed allograft bone tissue. Studies completed by an independent testing laboratory specializing in viral inactivation studies demonstrated that our proprietary demineralization process used in our Grafton® DBM Segment can virtually inactivate and eliminate viruses such as HIV, hepatitis B, hepatitis C, cytomeglia and polio.

In addition to the proprietary demineralization process used in our Grafton® DBM Segment, we have begun to implement additional processing technologies that once fully implemented will enable us to expand our viral inactivation claims to include virtually all of the allograft bone tissue we process in our Base Tissue Segment. These proprietary, tissue-specific technologies are expected to further enhance graft safety while maintaining the tissue's biologic and physical properties.

To our knowledge, none of the approximately 2.6 million transplanted grafts we have processed in our Grafton® DBM and Base Tissue Segments have caused a confirmed transmission of infectious diseases. This record is due to the rigorous donor screening and tissue recovery techniques used by our clients, extensive donor testing, as well as our demanding quality assurance and processing protocols.

### **Clients**

During 2001, two of our clients, MTF and ARC each accounted for approximately 37% of our consolidated revenue. We receive revenues in both our Grafton® DBM and Base Tissue Segments from each of these clients. In the Base Tissue Segment, with the exception of the bio-d® Threaded Cortical Bone Dowel and Graftech™ Bio-implants for which we are paid on a per unit basis, we are paid fees on a per donor basis for processing, finishing and packaging our clients' mineralized, weight-bearing allograft bone tissue. In the Grafton® DBM Segment our clients pay us fees on a per unit basis. We have processing agreements with MTF and ARC which run through August 31, 2005 and December 31, 2006, respectively. The agreement with MTF may be terminated at any time by either party upon giving six (6) months prior written notice. We also are currently in litigation with MTF related to our Grafton® DBM patents and other matters. See Item 3 "Legal Proceedings."

Commencing in the first quarter 2002, we began to receive allograft bone tissue for processing from LifeNet under the terms of a five year agreement which will expire in January, 2007. The allograft bone tissue received from LifeNet will be processed in our Base Tissue Segment and under the terms of the Agreement, may also be processed in the Grafton® DBM Segment in the future if we are able to contract with a third party marketing organization acceptable to us and LifeNet to market carrier allograft products we will develop.

In June, 2000, we entered into a five year agreement with Bone Bank Allografts, or BBA, to process donor allograft bone tissue procured by BBA and in December, 2000, we entered into a fifteen year agreement with ATSF to process donor allograft bone tissue procured by ATSF. This tissue is processed in our Grafton® DBM and Base Tissue Segments.

We generally rely on our clients to obtain the donor allograft bone tissue which we process and, generally, to distribute the processed allograft bone tissue to hospitals and surgeons for transplantation. However, certain of our clients are recovering tissue on our behalf which will be distributed and invoiced directly by us to the hospitals and physicians. In the future, we expect a significant portion of our processed tissue will be distributed in this manner and a significant

portion of our revenue will be derived in this manner. We perform marketing services which generate demand for our products. See "Education and Marketing."

In the fourth quarter of 1999, we commenced using the OsteoPure™ System for processing allograft bone tissue grafts for French tissue bank clients and we also concluded a contract with BioImplant Services of The Netherlands for expanded distribution of Grafton® DBM in Europe. We began distribution of Grafton® DBM in Europe in the first quarter of 2000.

Our plasma spray coating customers and non-allograft bone tissue spinal implant product customers generally purchase our services and products pursuant to purchase orders or non-exclusive supply agreements which are cancelable at any time by either party.

### **Education and Marketing**

We believe the markets for processed allograft bone tissue will continue to be general orthopaedic, spinal, neurological, and oral/maxillofacial surgical specialties. Our future growth in these areas will depend upon availability of adequate supplies of allograft bone tissue and a wider acceptance by these specialties of the use of allograft bone tissue as an alternative to autograft bone tissue and other available materials and treatments.

As of December 31, 2001, in the United States, we employed 15 persons engaged directly in efforts to educate surgeons as to the benefits and applications of processed allograft bone tissue and nine employees engaged in training our independent sales agents. We complement our direct sales organization with a national network of independent sales agents who market Grafton® DBM, our bio-implant allograft bone tissue spinal implants and our non-allograft bone tissue spinal implant products. These agents also educate the medical community about processed allograft bone tissue. At December 31, 2001, we had appointed 38 agencies which employ over 176 sales representatives.

Currently, a small group of marketing and sales employees of OST located in Clermont-Ferrand, France markets and sells our OsteoPure™ Femoral head and cancellous bone grafts, Grafton® DBM and other human allograft tissue products in conjunction with a network of independent agents and distributors we have retained. This staff also markets and sells our LUBBOC® and LADDEC® Bovine bone grafts to orthopaedic surgeons and dentists.

A small in-house marketing staff located at our Leiden facility markets our plasma spray coating services. These marketing activities consist primarily of attendance at trade shows, placement of advertisements in trade journals and direct mailings to orthopaedic and dental implant companies. We market our HA powders and ceramic products directly and through a small number of independent contract representatives in Europe.

### **Government Regulations**

Our products are extensively regulated by federal and state agencies in the United States and in other countries. Failure to comply with these requirements may subject us to

administrative or judicial sanctions, such as FDA's refusal to clear pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, civil penalties, injunctions and/or criminal prosecution.

In the United States, the allograft bone tissues that we process are regulated by the FDA as human tissue-based products under section 361 of the Public Health Service Act, and under certain circumstances, may be regulated as a medical device under the Food, Drug, and Cosmetic Act.

FDA regulations do not require that human tissue-based products be cleared or approved before they are marketed. We are, however, required to register and list these products with FDA and to comply with regulations concerning tissue donor screening and testing, and related procedures and record keeping. FDA periodically inspects tissue processors to determine compliance with these requirements. FDA has proposed, but not yet finalized, "Good Tissue Practice" regulations that would impose requirements on the manufacture of human tissue-based products, including tissue recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The human tissue-based product category is a relatively new one in FDA regulations, and it is possible that FDA will change its approach to human tissue-based products in general or to particular categories of products to require FDA clearance or approval or otherwise restrict distribution.

The metal spinal implant products that we distribute in the United States are regulated by the FDA as medical devices. Medical devices generally require FDA approval or clearance before they may be marketed. There are two processes by which medical devices can receive approval or clearance. Some products may qualify for clearance under the 510(k) process, in which the manufacturer or processor demonstrates that its product is substantially equivalent to another lawfully marketed product (i.e., that it has the same intended use and is as safe and effective as a lawfully marketed product and does not raise different questions of safety and effectiveness as the lawfully marketed product). 510(k) submissions usually include safety and performance data, and in some cases, the submission must include clinical data. Marketing may commence if and when FDA issues a letter finding substantial equivalence.

If a medical device does not qualify for the 510(k) process, the product may not be distributed until a premarket approval application has been approved by FDA. Premarket approval applications must demonstrate product safety and effectiveness. A premarket approval application is typically a complex submission, usually including the results of preclinical and clinical studies. The manufacturer must also pass a premarket inspection of its compliance with FDA's Quality Systems regulation. Marketing may commence if and when FDA issues a premarket approval. The Ovation™ System, the VBR™ System, the Sentinal™ Pedicle screw system and Affirm™ Cervical plate system are being marketed pursuant to 510(k) clearances.

After premarket clearance or approval has been obtained, manufacturers and marketers of medical devices are subject to postmarket requirements. For example, a manufacturer's quality control and manufacturing procedures and its facilities must conform to FDA's Quality System Regulation, which governs, for instance, design, manufacture, packaging, labeling, installation,

and servicing. Certain adverse events and product malfunctions must be reported to the FDA, and product labeling and promotion must comply with FDA requirements. FDA periodically inspects facilities to determine compliance with these requirements.

We market Grafton<sup>®</sup> DBM as a human tissue-based product pursuant to an August, 1995 designation from FDA. In March, 2002, FDA informed us that the agency is changing the regulatory status of Grafton<sup>®</sup> DBM and will henceforth regulate it as a medical device as well. We believe FDA's change in its position regarding Grafton<sup>®</sup> DBM results from its decision to regulate all demineralized bone with a carrier, including those processed and marketed by certain of our competitors, as medical devices. We intend to try to persuade FDA that its initial designation of Grafton<sup>®</sup> DBM as a human tissue-based product was and still is correct. If we are unsuccessful in that effort, we will be required to obtain a medical device approval or clearance, and to comply with medical device postmarketing obligations. We believe that Grafton<sup>®</sup> DBM will be eligible for 510(k) clearance, but we cannot be sure that we will not be required to obtain premarket approval, or that FDA will issue any clearance or approval in a timely fashion, or at all. In its March letter regarding Grafton<sup>®</sup> DBM, FDA stated that it intends to allow us a reasonable period of time to obtain clearance for Grafton<sup>®</sup> DBM, and we will continue to process and distribute Grafton<sup>®</sup> DBM during this period.

We also market Grafton Plus<sup>™</sup> DBM as a human tissue-based product. FDA's determination regarding Grafton<sup>®</sup> DBM is also likely to be applied to Grafton Plus<sup>™</sup> DBM. If FDA maintains its position that all demineralized bone with a carrier is a medical device, we would also be required to obtain FDA clearance or approval for Grafton Plus<sup>™</sup> DBM, and to comply with other medical device requirements for that product.

The procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas, with the exception of removal and implantation. We make payments to certain of our clients and TRO's for their services related to their recovering tissue on our behalf.

The procurement of human tissue is also subject to state anatomical gift acts and some states have statutes similar to NOTA. In addition, some states require that tissue processors be licensed by the state. Failure to comply with state laws could also result in enforcement action against us.

Allograft bone tissue and tissue processing operations are regulated in most major countries, though with different regulations and standards in each country. We believe that we and our subsidiaries comply with the national regulations of the various countries in which we currently, or plan to operate, although there can be no assurances that we will be able to in the future.

ISO certification for production facilities was made mandatory in 1998 for companies that market or distribute products within the European Union. Our facility located in Clermont-Ferrand, France has received ISO 9002 certification for the quality systems used in the manufacture of bovine tissue products. Upon receiving certification, a company may then affix a CE Mark to its device products, thus allowing for the sale of the products throughout the European Union. The LUBBOC® and LADDEC® Bovine Grafts produced and marketed by OST are regulated as medical devices in Europe and most other international markets in which these products are marketed.

Our European HA plasma spray coating services meet existing regulatory requirements in the specific countries where they are marketed. Our facility in Leiden, The Netherlands has received ISO 9001 certification for its quality systems used in the development and manufacture of ceramic products and ceramic and titanium spray coatings.

Ceramic products produced by us in The Netherlands are currently distributed only in Europe. These products meet existing regulatory requirements in the specific countries where they are marketed. We do not currently intend to market these products in the United States; however, if we decide to do so, these products would require premarket clearance by the FDA as medical devices.

## **Research and Development**

During 2001, 2000, and 1999 we spent approximately \$4,599,000, \$5,772,000, and \$5,506,000, respectively, on research and development activities. The majority of these expenditures were made in our Grafton® DBM and Base Tissue Segments. We are engaged in continuing research and development efforts in the allograft bone tissue processing field which include our continuing efforts to improve upon and maintain the safety and performance of the processed allograft bone tissue, increase the amount of transplantable allograft bone tissue derived from each donor, reduce processing costs through efficiency advances and develop new forms of allograft bone tissue.

## **Competition**

### *Market Overview*

The bone grafting market is an extension of the general orthopaedic surgery market, as bone grafts are used adjunctively in a broad range of reconstructive orthopaedic surgical procedures such as the repair of fractures and skeletal defects, spinal and joint arthrodeses, and revision arthroplasties. These procedures are performed by virtually all orthopaedic subspecialties and by neurosurgeons, some plastic surgeons and certain other surgical specialties. Dental and other oral maxillofacial procedures are not considered to be a primary portion of the bone graft market, but are instead considered to constitute a secondary market. Three basic categories of products or alternatives currently compete in the bone graft market:

- autograft bone tissue;

- allograft bone tissue; and
- synthetic bone void fillers.

A fourth product category, growth factor products, is still in the investigational stage. One such growth factor, Osteogenic Protein 1, or OP-1, has recently received humanitarian device exemption status, or HDE status, from the FDA for use as an alternative to autograft in long-bone nonunions where use of autograft is unfeasible and alternative treatments have failed. In addition, in January, 2002, the Orthopaedic Advisory Panel of the FDA recommended approval of InFuse™, a combination of an absorbable collagen sponge and rhBMP-2. If the FDA agrees and grants premarket approval, InFuse™ will be limited to use in single level lumbar, anterior procedures with the LT™ Cage only.

We estimate that total domestic allograft bone tissue sales in 2001 was \$310 million, comprising approximately 60% of the U.S. bone graft market.

U.S. Bone Graft Market		
2001		
<u>Specialty</u>	<u>Graft Procedures<sup>1</sup></u>	<u>Allograft Market Size<sup>1</sup></u>
Spinal Fusions	281,000	
General Orthopaedics	215,000	
Craniomaxillofacial	<u>87,000</u>	
Total	583,000	
Average Selling Price <sup>2</sup>	\$ 894	
Market Size (000)	\$521,000	\$310,000 (59.5%)

(1) Source: Datamonitor, "US Bone Substitutes"

(2) Source: Osteotech estimate

The number of bone graft procedures is forecast to increase during the next five years due to an expected increase in the number of reconstructive orthopaedic surgical procedures utilizing bone grafts, particularly in spinal procedures using bio-implants, pedicle screw implants and spinal cages.

Factors producing the continued growth in the number of reconstructive orthopaedic surgical procedures that incorporate a bone graft include the following:

- the aging of the U.S. population;
- improving success rates for surgical procedures that involve a bone graft procedure;
- development of less invasive reconstructive orthopaedic surgical procedures that will be used in a wider patient population; and
- the increasing number of revision, spinal fusion and joint arthroplasty procedures resulting from a more active and longer living U.S. population.

While the general bone graft market has experienced growth in recent years, we estimate that allograft bone tissue sales have increased at a significantly higher rate than the general bone graft market. This displacement trend is expected to continue as physicians gain confidence in, and experience with, allograft bone tissue. Some of the factors contributing to the increased use of allograft bone tissue include:

- the desire by surgeons to avoid the additional procedure needed to acquire autograft bone tissue, which often increases costs due to additional operating time, medical supplies and extended hospital stay, and patient risks due to excessive blood loss, infection, chronic pain and morbidity;
- increased awareness by, and training of, the medical community with respect to the use and safety of processed allograft bone tissue;
- an increase in the number of patients who do not possess the quality of bone tissue required for autograft procedures as a result of the general aging of the population; and
- an increase in the availability of allograft bone tissue due to an increase in bone tissue donations and to improved recovery and processing techniques.

#### *Competitive Overview*

In both our Grafton<sup>®</sup> DBM and Base Tissue Segments we compete in the bone graft market with autograft bone tissue, allograft bone tissue processed by others and synthetic bone void fillers. Autograft bone tissue has traditionally been the primary choice for surgeons and we believe it still maintains an approximate 40% share of the U.S. bone graft market. Due to factors such as the increased cost and potential complications associated with an additional procedure needed to acquire autograft bone tissue, more surgeons are beginning to choose allograft bone tissue over autograft bone tissue for their bone grafting needs.

#### *Grafton<sup>®</sup> DBM Segment*

We have been successful in persuading many surgeons to switch to Osteotech processed allograft bone tissue through the introduction of our proprietary tissue processing technology. We have expanded the applications of allograft bone tissue through Grafton<sup>®</sup> DBM, a proprietary form of allograft bone tissue. The demineralization process used in Grafton<sup>®</sup> DBM removes most of the minerals, thus exposing the proteins that promote bone growth (osteinduction) and creating a lattice work for new bone (osteoconduction). Grafton<sup>®</sup> DBM has a validated viral inactivation process for HIV, hepatitis B and C, cytomeglia and polio. Grafton<sup>®</sup> DBM is produced in five forms – gel, flex, putty, crunch, and DBF Matrix – and is packaged in sterile, single patient delivery systems. We introduced Grafton<sup>®</sup> DBM Crunch, a mixture of demineralized bone fibers and demineralized cortical cubes, into the market in December, 1999 and Grafton<sup>®</sup> DBF Matrix in January, 2001. With the varying textural and handling characteristics of its five forms, Grafton<sup>®</sup> DBM can be used in virtually all non-weight-bearing bone graft procedures and has been used in over 539,000 procedures through December 31, 2001.

In February, 2002, we introduced Grafton Plus™ DBM, which contains a carrier made from starch instead of glycerol.

Given its osteoinductive and osteoconductive properties, Grafton® DBM has a distinct advantage over synthetic bone void fillers, all of which are exclusively osteoconductive.

Grafton® DBM's advantages over synthetic grafting materials in the market for non-weight-bearing applications include:

- superior handling and performance qualities, including providing a matrix for bone to grow into and inducing bone to grow; and
- the suitability of Grafton® DBM for all non-weight-bearing bone graft procedures versus the limited applications of competitive products.

In recent years, Grafton® DBM has faced increasing competitive pressures, which we expect will continue in the future, as more companies have developed products with characteristics similar to Grafton® DBM. Certain of these competitors have, in turn, partnered with large orthopaedic and spine companies to market the competitors' products. Many of these competitors have research and development, marketing and other resources that are significantly greater than ours. They also offer a full line of metal implants and other products used in spinal surgeries, which could give them a competitive advantage over us since they can offer surgeons a more complete line of products than we currently can.

Grafton® DBM primarily competes with DBM products including: DynaGraft™, manufactured and distributed by GenSci; Osteofil™, processed by Regeneration Technologies, Inc. and distributed by Medtronic Sofamor Danek; AlloMatrix™, manufactured and distributed by Wright Medical Technologies, Inc.; and DBX®, processed by MTF and distributed by Synthes Spine.

To counter this competition, we have expanded our line of Grafton® DBM in order to offer the surgeon the ability to expand the type of procedures that DBM grafting materials can be used in. Additionally, we introduced Grafton Plus™ DBM in February, 2002, which offers improved handling characteristics. We have also expanded our bio-implant line which Grafton® DBM is used with and also expanded our line of metal spinal implant devices. When taken together, we are now able to provide the spinal surgeon with the full range of products needed to achieve the outcomes the surgeon is seeking for the patient.

Notwithstanding the increasing competition, Grafton® DBM has significant opportunities for growth. Currently, Grafton® DBM sales are primarily domestic. We estimate that Grafton® DBM was used in only 15% of the total bone graft procedures performed in the U.S. during 2001. We estimate the potential non-domestic bone graft market to be at least as large as that of the U.S. market. The European market, in particular, provides us with an opportunity in an area where we already have a sales presence, and, therefore, we began marketing Grafton® DBM in nine European countries during 2000.

## Grafton® DBM U.S. Procedure Penetration

2001			
Grafton® DBM			
<u>Specialty</u>	<u>Potential</u> <sup>1</sup>	<u>Actual</u> <sup>2</sup>	<u>Percent Penetration</u>
Spinal Fusions	281,000	41,792	14.9%
General Orthopaedics	215,000	32,083	14.9%
Craniomaxillofacial	<u>87,000</u>	<u>13,673</u>	<u>15.7%</u>
Total	583,000	87,548	15.0%

(1) Source: Data monitor, "US Bone Substitutes"

(2) Source: Osteotech estimate

### *Base Tissue Segment*

Allograft bone tissue is still the only alternative to autograft bone tissue for bone grafting procedures which require weight-bearing tissue. We plan to continue to differentiate our Base Tissue Segment operations from those of other allograft bone tissue processors by expanding our viral inactivation claim to include our mineralized weight-bearing bone tissue and through continued technological advances. Our bio-implants face significant competition from bio-implants processed by other tissue banks and processors such as MTF and Regeneration Technologies, Inc. and which are marketed by companies such as Medtronic Sofamor Danek and Synthes Spine which have larger marketing forces and significantly greater resources than we have. Typically, weight-bearing tissues are not osteoinductive. In late 2001, we introduced our OsteoActive™ surface treatment of weight-bearing bone tissue. Application of this process to weight-bearing tissue allows the surface of the tissue to become osteoinductive, allowing for faster incorporation of the tissue into a patient's own bone, thereby aiding the process of spinal fusions. We also introduced our non-frozen version of weight-bearing tissue which allows these grafts to be stored on the shelf instead of in freezers and for the surgeon to be more precise in selecting the grafts he will use in a procedure, thus reducing the number of grafts a hospital must order. Once we are able to use our new Plexus processing technology on a commercial basis, of which there can be no assurance, it should allow us to utilize more of the available allograft bone tissue in the future for weight-bearing grafts, thus increasing the availability of such grafts. All of these innovations will continue to differentiate Osteotech processed bone from our competitors and, we believe, increase the demand for our processed tissue in the future.

In this segment, we process both our base allograft bone tissue and bio-implants. In December, 1998, we introduced the bio-d® Threaded Cortical Bone Dowel for posterior and anterior spinal fusion procedures. In the fourth quarter 2000, we began the limited market introduction of the Graftech™ Bio-implant line of spacers and ramps for posterior and anterior lumbar spinal fusion procedures and for cervical spinal fusion procedures. The Graftech™ Bio-implant tissue forms became available nationally over the course of 2001. We market these bio-

implants and, currently, our clients generally distribute them. However, we have also begun to directly distribute bio-implants and, in the future, expect a significant portion of the bio-implants we process to be distributed in this manner.

In order to maintain our leading position in the allograft bone tissue processing market and to encourage more surgeons to switch from autograft bone tissue to our processed allograft bone tissue, we plan to:

- leverage our knowledge of allograft bone tissue processing to expand our proprietary tissue safety claims to our weight-bearing mineralized allograft bone tissue;
- expand our external scientific presence through publication and presentation of clinical research and outcome studies;
- continue to expand our market differentiation through tissue performance improvements, including line extensions of existing base allograft bone tissue products and new product introductions; and
- increase education of surgeons regarding the use of allograft bone tissue through expanded grand rounds, seminars, workshops and the internet.

The various national markets in Europe for bone grafts are currently dominated by the use of autograft and synthetic bone graft substitutes. Autograft remains the bone graft of choice due to surgeons' attitudes and concerns about bone graft safety and performance. There is also a significant number of surgeons who have not yet become aware of the safety and performance advantages of processed allografts and who continue to use unprocessed autografts. Our OsteoPure™ Process, Grafton® DBM and base allograft bone tissue are designed to address these needs. However, other firms have developed or are developing allograft bone tissue grafts and allograft bone tissue-based products to also address these needs. Tissue Bank of France, a unit of Groupe Lepine of France and Tutogen, Inc. of Germany offer allograft bone tissue grafts which directly compete with the OsteoPure™ Processed human femoral head tissue grafts in certain European countries. Also, several U.S. tissue bank organizations have formed strategic alliances with orthopaedic device firms to market allograft bone tissue grafts in European markets.

#### *Other*

Our ceramic and titanium plasma spray coating and HA product operations face competition in Europe from divisions and subsidiaries of several large corporations engaged in providing such services and products to others and from several smaller independent companies. In addition, we also face competition from medical implant companies which have in-house plasma spray coating operations. We compete primarily on the quality of our coatings and price. We believe that the spraying technology we use, which is computer controlled and utilizes robotics enables us to provide high quality coatings at competitive prices. It should be noted, however, that the ceramic and titanium coating industry is highly competitive.

Although we have not been a significant competitor in the metal spinal implant market to date, we are expanding into this market, which is highly competitive.

### **Environmental Matters**

Our allograft bone tissue processing in both the United States and Europe generates waste which, in the United States, is classified as medical waste and/or hazardous waste under regulations promulgated by the United States Environmental Protection Agency and the New Jersey Department of Environmental Protection. We segregate our waste materials and dispose of them through a licensed hazardous waste transporter in compliance with applicable regulations. In our facility in Clarmont-Ferrand, France, we segregate both bovine and human tissue waste and dispose of it in a manner specified by the appropriate regulatory authorities responsible for environmental matters in France. The production of HA powder at our facility in The Netherlands generates small amounts of hazardous waste, which we segregate and dispose of through a licensed hazardous waste transporter. Although we believe we are in compliance with applicable environmental regulations, the failure to fully comply with any such regulations could result in the imposition of penalties, fines and/or sanctions which could have a material adverse effect on our business.

### **Patents and Proprietary Rights**

We consider our processing technology and procedures proprietary and rely primarily on trade secrets to protect our technology and innovations. Significant research and development activities have been conducted on our behalf by consultants employed by third parties or in conjunction with unaffiliated medical institutions. Accordingly, disputes could arise in the future concerning the proprietary rights to information applied to our projects which have been independently developed by the consultants or researchers at the medical institutions.

At March 22, 2002, we held an aggregate of 114 United States patents and patent applications and 200 foreign patent and patent applications consisting of: (i) 40 United States patents and 25 foreign patents relating to our aseptic processing technology and our transplant support products, including 16 United States Grafton<sup>®</sup> DBM patents and 6 foreign Grafton<sup>®</sup> DBM patents, (ii) 6 United States and 41 foreign patents relating to our biomaterials technology, (iii) 50 United States and 117 foreign patent applications relating to aspects of our processing technology and our osteogenic and other products under development, (iv) 1 United States patent related to instrumentation, (v) 4 United States patent applications and 10 foreign patent applications relating to our biomaterials technology and (vi) 13 United States patent applications and 7 foreign patent applications relating to instrumentation. We believe that our Grafton<sup>®</sup> DBM patents are significant in maintaining our competitive position. These patents expire on various dates ranging from 2009 to 2020. Our other patents expire at various dates ranging from 2007 to 2020.

We can not assure you that any pending patent applications will result in issued patents or that any currently issued patents, or patents which may be issued, will provide us with sufficient protection in the case of an infringement of our technology or that others will not independently develop technology comparable or superior to ours. We are currently involved in three patent-related lawsuits. See Item 3. "Legal Proceedings."

### Product Liability and Insurance

The testing and use of allograft bone tissue and the implantation of medical devices coated with our HA powder, medical devices developed with our biomaterials technology and medical devices manufactured by others and distributed by us entail inherent risks of medical complications for patients, and therefore may result in product liability claims against us. Further, our agreements with our bone tissue processing clients provide them with indemnification by us for liabilities arising out of defects in allograft bone tissue caused as a result of processing performed by us.

We presently maintain product liability insurance in the amount of \$70 million per occurrence and per year in the aggregate. We cannot assure you that we will be able to maintain such insurance in the future or that such insurance will be sufficient to cover the amount of claims asserted against us on all types of liabilities. We have had product liability claims asserted against us in two pending lawsuits. See Item 3 "Legal Proceedings."

### Employees

At December 31, 2001, we had 365 employees, of whom 214 were engaged in allograft bone tissue processing, ceramic plasma spray coating and the manufacture of products; 30 were engaged in research and development; 57 were engaged in education, sales and marketing; and 64 were engaged in regulatory, finance and administration. Our employees are not covered by any collective bargaining agreement. We consider relations with our employees to be good.

### Item 2. Properties

Our principal executive offices are located in an approximately 38,000 square foot building in Eatontown, New Jersey, which is occupied pursuant to a lease which expires in December, 2004 and provides for a base annual rental of approximately \$264,000. This facility is occupied by our corporate, financial, administration, marketing, research and development, regulatory and clinical affairs staff.

Our processing facility is located in approximately 45,000 square feet of space in Shrewsbury, New Jersey, which is occupied pursuant to a lease which expires in October, 2008 and provides for a base annual rental of approximately \$247,000 through October 2003 and \$309,000 for the remaining term of the lease. The lease is renewable at our option for an additional five year term. Both the Grafton<sup>®</sup> DBM and Base Tissue Segments utilize this facility. Once we complete the move of our processing operations into our new facility, discussed below,

we intend to use this facility for certain processing and as backup to our new processing facility, as a pilot plant and for research and development. In addition, we rent 4,600 square feet of space in Eatontown, New Jersey principally as warehouse space for our non-allograft bone tissue spinal implant products. The lease expires in January 2005 and provides for base annual rental of approximately \$27,000.

In 1997, we purchased land adjacent to our Eatontown, New Jersey facility. We are currently completing the construction and validation of a new 74,000 square foot processing facility built on this land, which will be utilized by the Grafton® DBM and Base Tissue Segments. We began occupying this facility in the first quarter of 2002 and expect to fully occupy it by June, 2002. We have financed the construction of this facility with a \$4.5 million mortgage loan and a \$17 million equipment line of credit from our bank, which is secured, in part, by the equipment purchased with the proceeds from this loan facility and through our cash reserves and cash generated by operations. This facility is held by us subject to a mortgage which secures the \$4.5 million mortgage loan, our equipment line of credit and a \$5 million revolving line of credit with our bank.

Our subsidiary in Leiden, the Netherlands, which is engaged in the biomaterial business line, occupies a 21,000 square foot facility. The lease for this facility expires in May, 2008 and the annual rent is 284,000 euros (approximately \$253,000 at the December 31, 2001 exchange rate). We are subleasing 6,400 square feet of this facility to an unrelated third party at an annual rent of 100,000 euros (approximately \$95,000 at the December 31, 2001 exchange rate). The sublease agreement expires in March, 2004.

Our subsidiary in France, OST Developpement SA, which is engaged in the production, processing and distribution of bovine bone graft substitute products and human allograft tissue products, occupies an 11,000 square foot facility in Clermont-Ferrand, France. The lease for this facility expires in June, 2005 and has an annual rent of 85,000 Euros (approximately \$76,000 at the December 31, 2001 exchange rate). We have the option to acquire the building and related land for the fair market value of the property at the time of purchase as determined by an independent appraisal. OST also occupies a 3,100 square foot facility which it utilizes for administrative purposes at an annual rental of 29,000 Euros (approximately \$26,000). The lease on this facility expires in December, 2009.

### Item 3. Legal Proceedings

#### GenSci Regeneration Laboratories, Inc. v. Osteotech, Inc.; Osteotech, Inc. v. GenSci Regeneration Sciences, Inc.

In January, 1998, we filed a patent infringement action against GenSci Regeneration Laboratories, Inc. ("GenSci Labs") and GenSci Regeneration Sciences, Inc. ("GenSci Sciences", collectively, "GenSci") alleging that GenSci violated claims of one of the patents involving our Grafton® Demineralized Bone Matrix (DBM) process. Approximately two weeks after our filing, GenSci Labs filed a suit against us alleging that our Grafton® DBM Flex tissue form infringes two patents assigned to GenSci Labs in addition to allegations against us for tortious interference with

a business expectancy, negligent interference with a prospective economic advantage and inducing breach of contract and seeking a declaratory judgment of the invalidity of our patents U.S. Patent Nos. 5,284,655 (the "655 Patent") and 5,290,558 (the "558 Patent") covering Grafton<sup>®</sup> DBM. In February, 1998, GenSci Labs amended its complaint alleging essentially the same causes of action but adding a third patent to the allegation of patent infringement. In August, 1998, the actions were consolidated into one case before the United States District Court for the Central District of California. In April, 2000, GenSci Labs and GenSci Sciences agreed to dismiss with prejudice all of GenSci's patent infringement claims against us. Between September, 1998 and September, 2001, there were numerous amendments to the complaints of both parties and both parties filed numerous motions with the Court.

On October 31, 2001, the trial commenced in the United States District Court for the Central District of California. In November, 2001, the jury returned a verdict that the 558 Patent and the 655 Patent are valid and that GenSci infringed on both patents through their sales of DynaGraft<sup>™</sup> Gel and Putty products. In arriving at its verdict, the jury rejected all of GenSci's defenses.

In December, 2001, we were awarded damages in the amount of \$17,533,634 for GenSci's infringement of our patents. This damage award will be reduced by the \$3.0 million previously paid by DePuy in settlement of our claims against DePuy in this lawsuit. On December 21, 2001, GenSci filed for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code.

GenSci Orthobiologics, Inc. v. Osteotech, Inc.

On March 6, 2000, GenSci Orthobiologics, Inc. ("GenSci") filed a complaint in the United States District Court for the Central District of California against us, alleging unlawful monopolization, attempt to monopolize the market for demineralized bone matrix and for entering agreements in restraint of trade, in violation of Sections 1 and 2 of the Sherman Antitrust Act and Section 3 of the Clayton Act; and that we engaged in unlawful and unfair business practices in violation of Section 17200 of the California Unfair Competition Law. GenSci has alleged that we have monopoly power in the market for demineralized bone matrix products in the United States, and have engaged in anticompetitive conduct by improperly asserting our patents through patent infringement actions, seeking to have the Food and Drug Administration remove certain of GenSci's products from the market, restricting competitors' access to raw materials, interfering with GenSci's arrangements to manufacture demineralized bone matrix implants, interfering with GenSci's marketing and distribution arrangements, and disparaging GenSci's products. GenSci seeks compensatory, incidental, consequential, and punitive damages in an unspecified amount, and injunctive relief to stop us from restricting the tissue banks for which we process tissue from supplying processed demineralized bone matrix to our competitors and distributing the demineralized bone matrix implant products of our competitors. Certain of these allegations had previously been asserted by GenSci in its patent litigation with us in the Central District of California federal court.

In April, 2000, we reached an agreement with GenSci whereby tort claims that were dismissed from the patent litigation would be transferred to this action and this action was stayed pending completion of the trial of our patent infringement case against GenSci. This case has remained stayed.

We believe the claims made in this lawsuit are without merit and intend to vigorously defend against these claims.

Osteotech, Inc. v. GenSci Orthobiologics, Inc.

On October 25, 2000, we filed suit against GenSci Orthobiologics, Inc. ("GenSci"), in the United States District Court for the Central District of California, alleging that GenSci's demineralized bone matrix materials sold under the name Orthoblast, infringe our U.S. Patent No. 5,290,558 and infringe the re-examined claims of our U.S. Patent No. 5,676,146. Our complaint seeks injunctive relief, treble damages, costs and attorneys' fees.

In its Second Amended Answer and Counterclaim filed in March, 2001, GenSci denies infringement, asserts a number of affirmative defenses, and asserts a counterclaim seeking a declaratory judgement that the patents-in-suit are invalid, not infringed and/or unenforceable, together with costs and attorneys' fees.

We intend to pursue our claims against GenSci and vigorously defend against the counterclaims.

"O" Company, Inc. v. Osteotech, Inc.

In July, 1998, a complaint was filed against us in the Second Judicial District Court, Bernalillo County, New Mexico, which alleges negligence, strict liability, breach of warranties, negligent misrepresentation, fraud, and violation of the New Mexico Unfair Trade Practices Act arising from allegedly defective dental implant coating and coating services provided to plaintiffs by our subsidiary, Cam Implants BV. Plaintiffs have demanded unspecified monetary damages. In August, 1998, we removed this action to the United States District Court for the District of New Mexico and filed and served our answer, denying any and all liability in this action, and moved to dismiss five of the seven claims alleged against us. In March, 1999, the court dismissed with prejudice the plaintiff's negligence and strict liability claims. Remaining are claims for breach of warranties, negligent misrepresentation, fraud, and violation of the New Mexico Unfair Trade Practices Act. As to those claims, we have moved for summary judgement on the basis that all of the remaining claims are barred by their applicable statutes of limitations. At plaintiffs' request, the Court permitted limited discovery on the matters related to the statute of limitations issue, which is ongoing. As a result, the motion remains pending.

We believe that the claims made against us in this action are without merit and will continue to vigorously defend against such claims.

University of Florida Tissue Bank, Inc. v. Osteotech, Inc.

In February, 1999, a complaint was filed against us in the United States District Court for the Northern District of Florida. This action, which has been brought by plaintiffs, University of Florida Tissue Bank, Inc., Regeneration Technologies, Inc., Sofamor Danek Group, Inc., and Sofamor Danek L.P. alleges that our bio-d™ Threaded Cortical Bone Dowel and Endodowel infringe on the claims of U.S. Patent Nos. 5,814,084, 4,950,296 and 6,096,081. The plaintiffs have sought injunctive relief and monetary damages of approximately \$1.5 million. In May, 1999, we filed our answer and counterclaim seeking declaratory judgment that the patents in question in this action are invalid and otherwise not infringed by us.

Trial in this action is currently scheduled for September, 2002.

Discovery on all of the claims asserted in this litigation is ongoing. We believe that the claims made against us in this action are without merit and will continue to vigorously defend against such claims.

Medtronic Sofamor Danek, Inc., Sofamor Danek L.P. and Sofamor Holdings, Inc. v. Osteotech, Inc.

In July, 1999, Medtronic Sofamor Danek Inc., Sofamor Danek L.P. and Sofamor Danek Holdings, Inc. (collectively, "Danek") sued us in the United States District Court for the Western District of Tennessee alleging that certain instruments and instrument sets relating to cortical bone dowel products, including the bio-d™ Threaded Cortical Bone Dowel and Endodowel, manufactured, sold and/or otherwise distributed by us infringe on certain claims of U.S. Patent Nos. 5,741,253, 5,484,437 and 6,096,038 which are owned by Danek. In addition to injunctive relief, the plaintiffs seek monetary damages of \$2.5 million. We filed our answer and counterclaims seeking a declaratory judgment that the patents in question in this action are invalid and otherwise not infringed by us.

Currently pending before the Court are both parties' motions for summary judgement. Trial in this matter has been scheduled for April, 2002.

We believe that the claims made against us in this action are without merit and will continue to vigorously defend against such claims.

Regner v. Inland Eye & Tissue Bank of Redlands; Thacker v. Inland Eye & Tissue Bank of Redlands

In May, 2000, Regner brought suit against us and fifteen or more other defendants in the Superior Court for the State of California, San Bernardino County. The suit seeks class action status and alleges a cause of action based on a violation of the California Business and Professional Code, as well as a number of common law causes of action, including negligence, deceit, and intentional and negligent infliction of emotional distress. Through dismissals, either by the Court or voluntarily by plaintiffs, only the California Business and Professional Code

claims, which are based on allegations that defendants are engaging in the activity of buying or selling organs or tissue for valuable consideration or profit, and negligence claims remain. It appears that the plaintiff is seeking only injunctive relief with respect to their California Business and Professional Code claims. To the extent any of the other causes of action exist against us, the plaintiffs are seeking damages in an unspecified amount in addition to class certification.

Defendants, including us, have filed demurrers seeking dismissal of the negligence claims. A hearing on those demurrers was scheduled for February 21, 2002. The Court granted the demurrer with respect to the negligence claim asserted in the Thacker action. Additionally, the Court indicated that the actions will be combined and treated as a single action.

We deny that we are engaged in the activity complained of and assert that we are licensed by the State of California to do precisely what we are doing, and that our activities are fully in accord with all state and federal laws. Therefore, we believe this suit to be without merit and will vigorously defend against the claims.

#### Condos v. Musculoskeletal Transplant Foundation

In July, 2000, we were served with an action brought in the United States District Court for the District of Utah against us and MTF. The suit alleges causes of action for strict liability, breach of implied warranty and negligence arising from allegedly defective allograft bone tissue processed and/or provided by us and MTF which was allegedly implanted into the plaintiff, Chris Condos, during two spinal surgeries. Plaintiffs, which include Mr. Condo's family members, demand monetary damages in an unspecified amount. On July 25, 2000, we answered the complaint, denying any and all liability. Discovery on all of the claims in this action has commenced.

In January, 2002, plaintiffs amended their complaint, but no new claims were asserted. In February, 2002, we moved for summary judgment in our favor on all claims asserted against us. MTF has sought the same relief. Both motions remain pending.

We maintain a general liability insurance policy and have notified the insurance company of this action. We believe the claims made against us in this action are without merit and will vigorously defend against the claims. The insurance company has agreed to defend the action.

#### Musculoskeletal Transplant Foundation v. Osteotech, Inc.

In October, 2000, MTF filed a complaint in the United States District Court for the District of New Jersey against us seeking a declaratory judgment that MTF, through its manufacture, use, sale and/or offer for sale of demineralized bone matrix products, known as DBX<sup>®</sup>, does not infringe any claim of our U.S. Patent Nos. 5,284,655 and 5,290,558, and that the claims of those patents are invalid and unenforceable. The complaint was then amended to add Synthes Spine Company, L.P. ("Synthes") as a plaintiff. MTF and Synthes seek declaratory and injunctive relief.

We answered the complaint, denying all claims asserted and we have asserted claims against MTF and Synthes for patent infringement, unfair competition, misappropriation of trade secrets, product disparagement, breach of implied covenant of good faith and fair dealing, intentional interference with contractual relations, and for constructive trust, arising from certain wrongful acts committed by MTF and/or Synthes in developing and selling MTF's DBX<sup>®</sup> products and/or its underlying technology.

In June, 2001, we made a motion for an order preliminarily enjoining MTF and Synthes from selling or offering to sell their DBX<sup>®</sup> products. A hearing was held on that motion on July 23, 2001. On September 18, 2001, the Court denied that motion. Discovery is otherwise continuing in this case.

We are seeking injunctive relief and monetary damages in an amount to be determined. MTF and Synthes have denied any liability. We believe that the claims made against us in this action are without merit and will vigorously defend against the claims, and will vigorously pursue our claims against MTF and Synthes.

Glancy v. Interpore International, Inc.

In November, 2000, plaintiffs Bonnie and Ivan Glancy commenced an action in the United States District Court for the Northern District of Indiana against Interpore International, Inc. and Interpore Cross International, Inc. (collectively, "Interpore") and us. In January, 2002, we settled all claims pending against us in this case for an insignificant amount. The Court dismissed us from this case in February, 2002.

Criti-Cal, Inc. v. Osteotech, Inc.

In December, 2000, Criti-Cal, Inc. commenced an action in the Superior Court for the State of California, Orange County, against us, Second Act Medical, Inc. and Ronald Letner. The plaintiff alleges causes of action for breach of contract, misappropriation of trade secrets, quantum meruit and violations of the California Independent Wholesale Sales Representatives Contractual Relations Act of 1990 arising from the termination of an agreement between us and plaintiff. In addition to injunctive relief, plaintiff seeks unspecified monetary damages.

In March, 2001, we answered the complaint, denying any and all liability. In January, 2002, the Court dismissed plaintiff's claim for misappropriation of trade secrets. In February, 2002, the parties agreed to submit this matter to mediation, which proved to be unsuccessful.

We answered the complaint denying any and all liability and intend to vigorously defend against all claims.

Medtronic, Inc. v. Osteotech, Inc.

In February, 2001, Medtronic, Inc. and Medtronic Sofamor Danek, Inc. (collectively, "Medtronic") brought suit against us and Medtronic's former employee, Timothy R. Miller, in the Circuit Court for Shelby County, Tennessee. The plaintiff sought to enjoin Mr. Miller, whom we had recently hired, from using and disclosing any of their trade secrets or other confidential information to any third party, including us, and from working for us for a period of twelve months

On April 25, 2001, the Court lifted a temporary restraining order preventing Mr. Miller from working with us and entered an order preliminarily enjoining Mr. Miller from working with us in the area of spine surgery products. In November, 2001, the parties settled this matter and the Court dismissed this action.

Younger v. Hayes Medical Center, Inc.

In April, 2001, we were served in an action brought in the Twentieth Judicial District Court in Ellis County, Kansas, against Hayes Medical Center, Inc., the Musculoskeletal Transplant Foundation, Metropath, Inc. and us. With respect to us, the suit alleges a cause of action for negligence in connection with allegedly defective allograft bone tissue provided by the defendants and allegedly implanted in the plaintiff during a surgical procedure. The plaintiff seeks monetary damages in excess of \$75,000.

In May, 2001, we answered the complaint denying any and all liability. Discovery in this action has commenced.

We maintain a general liability insurance policy and have notified the insurance company of this action. We believe the claims made against us in this action are without merit and will vigorously defend against the claims. The insurance company has agreed to defend the action.

Wright Medical Technology, Inc. v. Osteotech, Inc.

In June, 2001, we received a complaint filed by Wright Medical Technologies, Inc. in an action in the United States District Court for New Jersey, which alleges against us claims for false advertising, and tortious interference with business relations and prospective business advantage relating to certain statements allegedly made by us regarding a FDA Warning Letter received by the plaintiff with respect to a tissue product marketed by the plaintiff. In addition to injunctive relief, plaintiff seeks monetary damages in an unspecified amount. On June 15, 2001, the Court granted plaintiffs a temporary restraining order against us. On June 20, 2001, we obtained a stay of that order from the United States Court of Appeals for the Third Circuit, pending an appeal of that order. On June 29, 2001, the District Court issued an order granting plaintiffs' motion for a preliminary injunction, and amended the order on July 2, 2001, enjoining us from making the accused statements and requiring us to issue a clarification of such statements. We issued a

corrective statement in a timely fashion and have appealed the District Court's order to the Third Circuit Court of Appeals. That appeal is pending.

On October 22, 2001, we received an amended complaint in this action, wherein plaintiffs named as additional defendants unidentified "Roe" parties and alleged further misconduct on our part giving rise to the claims described therein. We deny any and all liability. Discovery in this action has commenced.

Other than the foregoing matters, we are not a party to any material pending legal proceeding. Litigation is subject to many uncertainties and we are unable to predict the outcome of the pending suits and claims. It is possible that our results of operations or liquidity and capital resources could be adversely affected by the ultimate outcome of the pending litigation or as a result of the costs of contesting such lawsuits. We are unable to estimate the potential liability, if any, that may result from the pending litigation.

Item 4. Submissions of Matters to a Vote of Security Holders

None.

## PART II

### Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters

Our Common Stock has been listed on the Nasdaq Stock Market<sup>®</sup> under the trading symbol "OSTE" since our initial public offering in July 1991.

The following table sets forth the high and low sale prices for the Common Stock for each of the fiscal quarters during the years ended December 31, 2001 and 2000 based on transaction data as reported by the Nasdaq Stock Market<sup>®</sup>.

<u>Year Ended December 31, 2001</u>	<u>High</u>	<u>Low</u>
First Quarter	\$7.44	\$4.50
Second Quarter	\$6.00	\$4.00
Third Quarter	\$5.20	\$2.13
Fourth Quarter	\$6.35	\$2.91

<u>Year Ended December 31, 2000</u>	<u>High</u>	<u>Low</u>
First Quarter	\$20.00	\$12.75
Second Quarter	\$14.13	\$ 6.50
Third Quarter	\$14.25	\$ 8.50
Fourth Quarter	\$ 9.50	\$ 3.25

As of March 15, 2002, there were 325 holders of record of Osteotech Common Stock. We believe that there are approximately 5,400 beneficial owners of our Common Stock.

We have never paid a cash dividend and do not anticipate the payment of cash dividends in the foreseeable future as earnings are expected to be retained to finance our growth. Declaration of dividends in the future will remain within the discretion of our Board of Directors, which will review our dividend policy from time to time. Our loan agreement with our bank prohibits us from paying any cash dividend without the written consent of the bank.

## Item 6. Selected Financial Data

Set forth below is the selected financial data for the five fiscal years ended December 31, 2001. The following data should be read in conjunction with our consolidated financial statements and related notes thereto contained elsewhere herein and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All per share data have been adjusted for the three-for-two stock split in the form of a 50% stock dividend we effected in March, 1999.

Selected Financial Data (dollars in thousands except per share data) For the Year ended December 31,	2001	2000	1999	1998	1997
<b>Consolidated Results of Operations</b>					
Net revenues	\$ 77,846	\$ 75,683	\$75,610	\$59,201	\$44,931
Gross profit	43,498	48,172	51,701	41,562	29,096
Operating expenses	50,134	41,317	33,849	25,281	20,109
Income from litigation settlement	0	1,000	2,000	0	0
Operating Income (loss)	(6,636)	7,855	19,852	16,281	8,987
Other income, net	128	1,047	1,032	1,132	585
Income (loss) before income taxes	(6,508)	8,902	20,884	17,413	9,572
Net income (loss)	(4,410)	4,828	12,351	10,304	5,686
Net income (loss) per share					
Basic	(.31)	.34	.88	.78	.46
Diluted	(.31)	.34	.84	.73	.43
Dividends per share	0	0	0	0	0
<b>Year End Financial Position</b>					
Working capital	\$ 24,439	\$ 29,123	\$37,082	\$26,373	\$19,922
Total assets	107,244	104,438	89,730	57,114	43,052
Long-term obligations, net of current portion	18,683	19,930	6,359	0	203
Stockholders' equity	67,786	71,851	69,406	45,930	34,292

## Item 7. Management's Discussion And Analysis Of Financial Condition And Results Of Operations

### For the Three Years Ended December 31, 2001, 2000, and 1999 Results of Operations

#### Overview

We provide services and products primarily focused in the repair and healing of the musculoskeletal system. Based on our knowledge of the allograft bone tissue industry, we believe that we are the world's largest processor and developer of human bone and bone connective tissue. Historically, we have provided services and technology associated with making human tissue safe for transplantation. We also develop and process new forms of tissue for use in a variety of surgical procedures. While we perform the medical education to teach surgeons about the uses of these tissue forms, the tissue forms are generally distributed to hospitals by our tissue bank clients. See below for a discussion of an additional method we are utilizing to generate tissue processing revenues. For the years ended December 31, 2000 and 1999, 93% and 94%, respectively, of our consolidated revenues were generated from these tissue service activities.

Commencing in the first half of 2001, and expanding in the second half, we began to distribute tissue forms directly to hospitals. We expect to continue to expand our direct distribution efforts to hospitals in 2002 and beyond. As a result, we expect that revenues from direct distribution of tissue will continue to grow over the next several years. In turn, beginning in late 2002, this should have a positive impact on our gross profit margins and operating income because although we will incur recovery costs in connection with tissue we distribute directly, we will not share a portion of the invoice price on these tissue forms with our tissue bank clients as we do with the tissue that we process for them, but they distribute. For the year ended December 31, 2001, 80% of our consolidated revenues were generated from processing tissue that our tissue bank clients distributed.

This change in distribution methodology has impacted our liquidity and cash flow. We have had to make additional investments in inventories and deferred processing costs to support our direct distribution efforts, and expect to make additional investments in inventory and deferred processing costs, as necessary, to support our efforts to expand direct distribution. In addition, our days sales in accounts receivable have increased from 65 days in 2000 to 71 days in 2001, primarily as a result of the change in our customer mix resulting from our direct distribution efforts. As a greater percentage of our revenues are generated from direct shipments to hospitals and other healthcare providers, which typically pay invoices slower than our historical tissue bank customer base, we expect that our days sales in accounts receivable will remain at 2001 levels or increase slightly.

For the year ended December 31, 2001, we experienced a substantial decrease in available cash and cash equivalents due to our continued investments in our business. We expect to continue to make investments in our business to support our direct distribution efforts and future programs and initiatives, which may further deplete our available cash balances. We believe that our available cash and cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet our forecasted cash needs in 2002. However, we intend to seek additional funding to meet the needs of our long-term strategic plan and to re-build cash reserves. There can be no assurance that such additional funds will be available, or if available, that such funds will be available on favorable terms.

### Critical Accounting Policies and Estimates

Our discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that effect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On a continual basis, we evaluate our estimates and may adjust them based upon the latest information available to us. These estimates generally include those related to product returns, bad debts, inventories, deferred processing costs, intangible assets, income taxes and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

- We maintain allowances for doubtful accounts primarily for our direct distribution accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.
- We record reductions to revenue for estimated product and allograft tissue forms returns based upon historical experience. If future returns are less than our historical experience, a reduction in estimated reserves would increase revenue. Alternatively, should returns exceed historical experience, additional allowances would be required, which would reduce revenue.
- We write down inventory and deferred processing costs for estimated obsolescence or unmarketable products and allograft tissue forms equal to the difference between cost and the estimated market value based upon assumptions about future demand and market conditions. Obsolescence could occur from numerous factors, including, but not limited to, the competitive nature of the market, technological change and changes

in surgeon preference. If actual market conditions are less favorable than those projected by management, additional write-downs may be required.

- We depreciate/amortize our property, plant and equipment based upon our estimate of the respective asset's useful life. In addition, we evaluate impairments of our property, plant and equipment based upon an analysis of estimated undiscounted future cash flows. If the Company determines that a change is required in the useful life of an asset, future depreciation/amortization is adjusted accordingly. Alternatively, should we determine that an asset has been impaired, an adjustment would be charged to income based on its fair market value, or discounted cash flows if the fair market value is not readily determinable, reducing income in that period.
- We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we have considered future taxable income, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period such determination was made.
- We accrue current and future tax liabilities based upon levels of taxable income, tax planning strategies and assessments of the timing of taxability of tax attributes. While we have considered current tax laws in establishing our tax liabilities, in the event we were to settle our tax liabilities for less than amounts accrued we would increase income in the period such determination was made. Should we determine it would cost us more to settle our tax liabilities, an adjustment would be charged to income thus reducing income in that period.

#### *Net Income (Loss)*

We incurred a consolidated net loss in 2001 of \$4,410,000 or \$.31 diluted loss per share compared to net income of \$4,828,000 or \$.34 diluted income per share in 2000 and \$12,351,000 or \$.84 diluted income per share in 1999. The net loss in 2001 includes, before income tax benefit: (i) a provision of \$1,845,000 primarily related to provisions for excess inventory and instrument sets for spinal implant systems; (ii) a provision of \$2,287,000 for equipment which will no longer be utilized in the processing of allograft tissue; and (iii) a provision of \$700,000 primarily for severance costs associated with the departure of an executive officer. Net income in 2000 and 1999 included approximately \$600,000 or \$.04 diluted income per share and \$1,200,000 or \$.08 diluted income per share, respectively, related to the patent litigation settlement with DePuy AcroMed, Inc. ("DePuy"). Consolidated loss before income taxes was \$6,508,000 in 2001 compared to income before taxes of \$8,902,000 in 2000 and \$20,884,000 in 1999. Income before income taxes in 2000 and 1999 included \$1,000,000 and \$2,000,000, respectively, related to the patent litigation settlement with DePuy.

The following is a discussion of factors affecting results of operations for the years ended December 31, 2001, 2000, and 1999.

### *Net Revenues*

Consolidated net revenues increased 3% in 2001 to \$77,846,000, compared to consolidated revenues of \$75,683,000 in 2000. The increase in 2001 was principally due to higher revenues in bio-implants and product lines included in other revenues mainly as a result of increased volume, partially offset by a decrease in Grafton<sup>®</sup> DBM revenues as a result of reduced unit sales volume and a decrease in base tissue processing revenues as a result of processing 33% fewer donors in 2001 compared to 2000. Domestic net revenues increased slightly in 2001 to \$71,776,000 from \$71,468,000 in 2000. Foreign-based revenues increased 44% to \$6,070,000 in 2001 from \$4,215,000 in 2000. The increase in foreign-based revenues was primarily as a result of increased unit sales volume in all product lines. Consolidated net revenues in 2000 were \$75,683,000 as compared to \$75,610,000 in 1999. Domestic net revenues, were \$71,468,000 in 2000 as compared to \$71,517,000 in 1999. Revenues from bio-implants increased in 2000 due to increased unit sales volume offsetting a decline in base allograft tissue processing revenues, which resulted from a 16% decline in the number of donors processed, and a decline in domestic Grafton<sup>®</sup> DBM revenues as a result of lower unit volume. Foreign net revenues were \$4,215,000 in 2000 compared to \$4,093,000 in 1999. Revenues associated with the European introduction of Grafton<sup>®</sup> DBM and an increase in OsteoPure<sup>™</sup> Femoral head processing revenue offset decreased revenues from bovine tissue sales and ceramic and titanium coating services.

Grafton<sup>®</sup> Demineralized Bone Matrix ("DBM") Segment, or Grafton<sup>®</sup> DBM Segment, revenues were \$43,637,000 in 2001, a decrease of 4% from revenues of \$45,226,000 in 2000. Foreign-based Grafton<sup>®</sup> DBM Segment revenues increased 119% in 2001 to \$1,954,000 from \$891,000 in 2000, principally due to an increase in unit sales volume. Domestic Grafton<sup>®</sup> DBM Segment revenues decreased \$2,652,000 or 6% to \$41,683,000 in 2001. Domestic Grafton<sup>®</sup> DBM Segment revenues were negatively impacted by a decrease in unit sales volume as a result of increased competition. In 2001, Grafton<sup>®</sup> DBM faced, and we expect it will continue to face, increasing competition as more companies develop and market products with characteristics similar to Grafton<sup>®</sup> DBM.

Base Tissue Segment revenues increased 6% to \$27,692,000 in 2001 from \$26,204,000 in 2000. The increase is principally the result of a 225% increase in bio-implant revenues and a 29% increase in OsteoPure<sup>™</sup> Femoral head processing revenues, partially offset by a 31% decrease in base tissue processing revenues resulting from a 33% decline in donors processed for our clients. The increase in bio-implant revenues is principally due to increased unit volume and the ability to charge higher unit sale prices as a result of our direct distribution of some of those units to hospitals.

Revenue from other product lines increased 53% in 2001 to \$6,517,000 from \$4,253,000 in 2000. The increase principally resulted from improved volume in spinal metal implant systems, coatings, ceramic products and bovine products. Metal spinal implant systems accounted for 65% and coating revenues accounted for 16% of the overall increase in other revenues.

Grafton<sup>®</sup> DBM Segment net revenues in 2000 were \$45,226,000 as compared to \$45,136,000 in 1999. Grafton<sup>®</sup> DBM Segment revenues were positively effected by the introduction of Grafton<sup>®</sup> DBM in Europe, which offset a 2% decrease in domestic revenues. In 2000, Grafton<sup>®</sup> DBM revenues were adversely impacted by increased competition. Base Tissue Segment net revenues increased 2% in 2000 to \$26,204,000 from \$25,751,000 in 1999. The increase was principally due to a 111% increase in bio-implant processing revenues and a 162% increase in OsteoPure<sup>™</sup> Femoral head processing revenues. These increases were partially offset by a 7% decline in base allograft tissue processing revenues as a result of a 16% decline in the number of donors processed, due in part to the decline in base tissue needs of surgeons as they shift to using more highly advanced tissues such as our line of Graftech<sup>™</sup> bio-implants.

During 2001, 2000, and 1999, two of our clients, MTF and ARC, in the Grafton<sup>®</sup> DBM and Base Tissue Segments together accounted for 75%, 90%, and 94% of consolidated net revenues. We have processing agreements with each of these clients which expire in August, 2005 and December, 2006, respectively. The agreement which expires in August 2005, may be terminated by either us or MTF upon six months prior written notice, which has not been given by either party as of the date of this report.

#### *Gross Profit*

Gross profit as a percentage of net revenues was 56% in 2001, 64% in 2000, and 68% in 1999. The decline in gross profit as a percentage of revenues in 2001 compared to 2000 principally resulted from: (i) our direct distribution efforts which reduced gross profit margin by two percentage points in 2001 as a result of incurring additional costs equivalent to the incremental revenue we are recognizing from these efforts; (ii) the underabsorption of fixed costs due to increased capacity as a result of our new processing facility and a 33% decline in the number of donors processed, costs associated with implementation of new processing technologies, and bio-implant and metal spinal implant product lines that have not yet achieved revenue levels sufficient to fully absorb production costs; (iii) a decline in base tissue processing revenue as a result of a 33% decline in the number of donors processed; (iv) charges for excess metal spinal implant inventory of \$655,000; and (v) a \$2,287,000 charge for equipment which will no longer be utilized in our processing of allograft tissue.

We expect that as our direct distribution efforts continue to expand and we incur the incremental costs and expenses, including depreciation, related to our new allograft tissue processing facility, gross profit margin will decline slightly in 2002 from the level achieved in 2001. Beginning in late 2002, our direct distribution efforts should have a positive impact on our gross profit margins because although we will incur recovery costs in connection with tissue we distribute directly, we will not share a portion of the invoice price with our tissue bank clients as we do with tissue that we process for them which they distribute. In addition, we have implemented programs to improve gross profit margin through cost cutting initiatives, efficiency gains and reductions in the cost of materials. However, we cannot provide any assurance that any of these programs will be successful.

The decline in gross profit as a percentage of net revenues in 2000 resulted primarily from the underabsorption of costs related to: increased capacity, new processing technologies, a 16% decline in the number of donors processed, and allograft bone tissue forms that had not yet achieved revenue levels sufficient to fully absorb production costs while they are in launch mode.

#### *Marketing, Selling, General and Administrative Expenses*

Marketing, selling, general and administrative expenses increased 28% in 2001 to \$45,535,000 from \$35,545,000 in 2000. In 2000, marketing, selling, general and administrative expenses were 25% higher than 1999 expenses of \$28,343,000. The increase in 2001 relates mainly to: (i) activities to secure additional sources of donated allograft tissue resulting in expenditures of \$2,714,000, which included provisions related to our funding of the American Tissue Services Foundation; (ii) increased legal fees in connection with various lawsuits to which we are a party, including the GenSci patent litigation lawsuit, see Part I, Item 3, "Legal Proceedings" and Note 11 of "Notes to Consolidated Financial Statements"; (iii) increased costs related to marketing, selling and promotional activities associated with Grafton<sup>®</sup> DBM and the new bio-implant tissue forms; (iv) a provision of \$1,190,000 for excess instrument sets associated with spinal implant systems; and (v) a \$700,000 provision for severance costs related primarily to the departure of an executive officer. In 2001 and 2000, we expended \$4,158,000 and \$4,185,000, respectively, for the prosecution of our patents and resulting trial in the GenSci patent litigation. The increase in 2000 over 1999 is primarily due to increases in legal fees associated with patent lawsuits, and increased costs associated with marketing, selling and promotional activities, especially with respect to new bio-implant tissue forms.

We are committed to aggressively asserting and defending our technology and related intellectual property. As a result we are currently involved in three patent lawsuits. Prosecuting and defending these lawsuits is expensive and has had, and will likely have, a negative impact on our future operating results, although we anticipate 2002 expenditures for these activities to be significantly less than in the previous year. However, we believe it is necessary to defend our technology and related intellectual property in which we have invested and continue to invest significant amounts of money to develop.

#### *Research and Development Expenses*

Consolidated research and development expenses decreased 20% in 2001 to \$4,599,000 from \$5,772,000 in 2000. Research and development expenses in 2000 were 5% higher than 1999 research and development expenses of \$5,506,000. The decrease in 2001 was primarily related to the completion of development of bio-implant tissue forms which were launched in 2001 and the completion of new processing technology and packaging, which were implemented in 2001. The increase in 2000 was primarily attributable to increased spending in the Grafton<sup>®</sup> DBM and the Base Tissue Segments associated with the continued development of several new processing technologies, development of new allograft bone tissue forms, specifically bio-implant tissue forms, and ongoing support for existing products and services.

### *Income From Litigation Settlement*

In November, 1999, we settled all claims which we had filed against DePuy in the patent infringement lawsuit against GenSci Labs and GenSci Sciences. As part of the settlement, DePuy agreed to stop selling the GenSci products accused of infringing our patents no later than February 4, 2001 and to pay us \$3,000,000. We received payments and recognized income of \$250,000 in each quarter of 2000 and a payment of \$2,000,000 in the fourth quarter of 1999.

### *Operating Income (Loss)*

We incurred a consolidated operating loss in 2001 of \$6,636,000 compared to consolidated operating income of \$7,855,000 in 2000. Grafton<sup>®</sup> DBM Segment operating income decreased 38% in 2001 to \$7,014,000 from \$11,389,000 in 2000. The decrease results principally from: (i) increased costs associated with marketing, selling and promotional activities; (ii) increased legal fees; (iii) reduced revenue levels; and (iv) a decrease in patent litigation settlement payments of \$1,000,000. We incurred an operating loss in the Base Tissue Segment of \$7,979,000 in 2001 compared to operating income of \$694,000 in 2000. The operating loss principally resulted from lower: (i) gross margins due to our direct distribution activities, (ii) a decline in donor processing revenue, (iii) the underabsorption of processing costs, (iv) increased legal fees, (v) provisions for excess instrument sets and equipment which will no longer be utilized in our production process, and (vi) increased costs for marketing, selling and promotional activities primarily associated with bio-implants. Operating losses associated with other revenues were \$5,671,000 and \$4,228,000 in 2001 and 2000, respectively. The operating loss in 2001 increased over the operating loss in 2000 principally as a result of provisions for excess inventory and instrumentation for metal spinal implant systems and reserves for our funding of the American Tissue Services Foundation.

Consolidated operating income decreased 60% in 2000 to \$7,855,000 from \$19,852,000 in 1999 primarily as a result of declines in operating income in the Grafton<sup>®</sup> DBM Segment and Base Tissue Segments. Grafton<sup>®</sup> DBM Segment operating income decreased 33% in 2000 to \$11,389,000 from \$17,063,000 in 1999 primarily due to: (i) lower gross margins due to underabsorption of costs, (ii) increased legal fees associated with patent lawsuits, (iii) increased costs associated with marketing, (iv) selling and promotional activities, (v) and a decrease of \$1,000,000 in patent litigation settlement payments. Base Tissue Segment operating income decreased 89% in 2000 to \$694,000 from \$6,434,000 in 1999 principally as a result of: (i) lower gross margins due to underabsorption of costs, (ii) increased legal fees associated with patent lawsuits, and (iii) increased costs associated with marketing, selling and promotional activities, especially with respect to new bio-implant tissue forms. Operating income associated with other revenues declined 16% in 2000 to a loss of \$4,228,000 from a loss of \$3,645,000 in 1999.

### *Other Income (Expense)*

In 2001, other income decreased \$919,000 to \$128,000 from \$1,047,000 in 2000. The decrease was principally due to lower interest income as a result of a decline in interest rates and lower average cash balances available for investment and interest expense on our long-term debt.

Prior to 2001, the majority of our interest costs were capitalized in connection with the construction of our new allograft tissue processing facility. In late 2001, we began to charge such interest costs to earnings since the facility was substantially complete. In 2002, interest expense will continue to increase as we recognize a full year of interest expense on our long-term debt and due to increases in our interest rates. See discussion of the Amendment to our Credit Facility in "Liquidity and Capital Resources" and Note 9 of "Notes to Consolidated Financial Statements". In 2000, other income increased \$15,000 to \$1,047,000.

#### *Income Tax Provision*

In 2001, we provided a benefit for income taxes on our domestic losses due to our ability to carryback and carryforward these losses. No income tax benefit has been recorded for foreign losses, principally as a result of the uncertainty of realization of such future tax benefits. Our effective income tax rate in 2000 was 46% and 41% in 1999. The effective income tax rate exceeded the federal statutory income tax rate principally due to the non-recognition for tax purposes of foreign operating losses and the impact of domestic state income taxes.

#### **Liquidity and Capital Resources**

At December 31, 2001 we had cash and short-term investments of \$5,192,000 compared to \$12,858,000 at December 31, 2000. We invest excess cash in U.S. Government-backed securities and investment grade commercial paper of major U.S. corporations. Working capital decreased \$4,684,000 to \$24,439,000 at December 31, 2001 compared to \$29,123,000 at December 31, 2000. The decrease resulted primarily from utilization of cash and short-term investments to fund capital expenditures, including construction of the new allograft tissue processing facility, other production equipment and instruments for spinal implant systems.

Net cash used in operating activities was \$2,019,000 in 2001 compared to net cash provided by operating activities of \$10,175,000 in 2000. The decrease resulted primarily from the net loss incurred in 2001 compared to net income in 2000, investments in accounts receivable, inventories and deferred processing costs to support our direct distribution efforts, partially offset by increased non-cash charges, principally depreciation and amortization. Beginning in 2001, we began to distribute tissue forms directly to surgeons and hospitals. This change in distribution methodology has impacted our liquidity and cash flow. We have had to make additional investments in inventories and deferred processing costs to support our direct sales efforts, and expect to make additional investments in inventory and deferred processing costs, as necessary, to support our efforts to expand direct distribution. In addition, our days sales in accounts receivable have increased from 65 days in 2000 to 71 days in 2001, primarily as a result of the change in our customer mix resulting from our direct distribution efforts. As a greater percentage of our revenues are generated from direct shipments to hospitals and other healthcare providers, which typically pay billings slower than our historical tissue bank customer base, we expect that our days sales in accounts receivable will remain at 2001 levels or increase slightly.

Cash used in investing activities decreased to \$5,360,000 in 2001 from \$27,128,000 in 2000. The decrease is principally due to a decrease in capital expenditures to \$8,955,000 in 2001

from \$28,343,000 in 2000, due to reduced spending on the construction of our new allograft tissue processing facility, partially offset by proceeds from the sale of land of \$1,500,000. In the fourth quarter of 1998, we commenced construction of a new allograft tissue processing facility in Eatontown, New Jersey. See Item 2. "Properties" and Note 6 of "Notes to Consolidated Financial Statements." Through December 31, 2001, we incurred \$37,922,000 of capital expenditures, including capitalized interest of \$1,769,000, related to the new allograft tissue processing facility, of which \$19,352,000 has been funded through bank financing.

Net cash provided by financing activities in 2001 decreased to \$1,627,000 from \$11,271,000 in 2000. In 2001, we borrowed the remaining funds of \$1,468,000 available under the equipment line of credit, while in 2000 we borrowed \$13,672,000 under our equipment line of credit. In September, 2001, our equipment line of credit converted to an equipment term loan pursuant to the provisions of the credit agreement.

We have a Credit Facility with a U.S. bank that includes: a \$5,000,000 revolving line of credit, a building mortgage loan and an equipment term loan. At December 31, 2001, there were no borrowings under the revolving line of credit, \$4,415,000 was outstanding under the building mortgage loan and \$16,798,000 was outstanding under the equipment term loan. In March, 2002, the Credit Facility was amended, and among other things, the \$5,000,000 revolving line of credit, which was originally due to expire May 31, 2002, was extended to April 30, 2004. In addition, the amendment to the Credit Facility establishes a variable interest rate on all parts of the Credit Facility that changes the interest rate to range from prime minus .25% to prime plus 1.50%, or from the London Interbank Offered Rate ("LIBOR") plus 2.25% to LIBOR plus 4.0%, based upon a leverage ratio as defined. Under the terms of the amendment, the new interest rate, which initially is retroactive to January 1, 2002 and is effective through November 14, 2002, is prime plus 1.50% or LIBOR plus 4.0%, whichever we choose. Thereafter, the interest rate will be in the range described above. In certain circumstances, as defined in the amendment, the interest rate on the Credit Facility may increase up to an additional .35%.

The Credit Facility, as detailed in the amendment, is collateralized by domestic accounts receivable, domestic inventory, the new allograft tissue processing facility, including all equipment and improvements therein and a pledge of 65% of our ownership in our foreign subsidiaries. The amendment imposes on us certain restrictive operating and financial covenants. The amendment established additional covenants including a restriction on our paying cash dividends, a restriction on our incurring or maintaining additional indebtedness, a restriction on our selling of assets or engaging in mergers or acquisitions and limitations on our ability to make cash advances to our foreign operations or investments. The amendment also resets the interest coverage ratio, which we did not comply with for the year ended December 31, 2001, but the bank permanently waived such non-compliance. The amendment also includes subjective acceleration provisions. Such provisions are based upon, in the reasonable opinion of the bank, the occurrence of any adverse or material change in the condition or affairs, financial or otherwise, of our business, which impairs the interests of the bank. The bank has the right to approve, in advance, the form and substance of any equity capital transaction, except for a common stock transaction resulting in the issuance of less than 20% of our total issued and outstanding capital stock as of the date of such transaction.

Failure to comply with any of these restrictions could result in a default under this loan facility. Following a default, the bank may determine not to make any additional financing available under the revolving line of credit, could accelerate the indebtedness under the revolving credit facility, the equipment loan and/or the mortgage, and could foreclose on the real and personal property securing the loans.

At December 31, 2001, certain of our foreign-based subsidiaries have net operating loss carryforwards aggregating \$5,818,000 (\$525,000 with no expiration date; \$5,293,000 expiring 2004 through 2009). We have not recognized any benefit from these net operating loss carryforwards in the consolidated financial statements because realization of the future tax benefits is uncertain. See Note 10 of "Notes to Consolidated Financial Statements."

In February, 2001, we entered into a distribution agreement to market a pedicle screw system and a cervical plating system. This agreement requires us to make minimum purchase commitments of \$6,000,000 over the two-year period beginning on February 1, 2002. In 2001, we purchased \$3,046,000 of inventory in advance of the beginning of the two-year commitment. We expect to purchase the remaining balance of \$2,954,000 in 2002 and 2003.

In February, 2001, we entered into a Loan Agreement with the American Tissue Services Foundation, or ATSF, a not-for-profit tissue recovery organization, which expires in December, 2010. Pursuant to the Loan Agreement, ATSF has borrowed \$2,208,000 from us as of December 31, 2001 to fund its operations. In February, 2002, we amended the Loan Agreement to allow ATSF to borrow up to an aggregate of \$2,750,000. Based upon our discussions with management of ATSF, we expect that ATSF will borrow approximately \$250,000 in 2002. We have entered into a fifteen-year processing and distribution agreement with ATSF effective December 7, 2000. Michael J. Jeffries, our Executive Vice President and Chief Financial Officer, is one of the three members of ATSF's Board of Directors. ATSF is a not-for-profit corporation, and neither Mr. Jeffries nor us owns any equity or any other interest in ATSF. Mr. Jeffries receives no compensation from ATSF.

The following table summarizes our contractual obligations at December 31, 2001, and the effects such obligations are expected to have on our liquidity and cash flow in future periods.

(In thousands)	Total	Less Than One Year	1-3 Years	After 3 Years
Long-term debt	\$21,213	\$ 2,530	\$ 7,650	\$11,033
Non-cancelable operating lease obligations	5,072	996	2,424	1,652
ATSF loan commitment <sup>(1)</sup>	250	250	--	--
Purchase commitment <sup>(2)</sup>	2,954	1,477	1,477	--
	<u>\$29,489</u>	<u>\$ 5,253</u>	<u>\$11,551</u>	<u>\$12,685</u>

(1) Assumes ATSF borrows \$250,000 in 2002 and will not require the remaining portion of the commitment.

(2) Assumes the purchase commitment is satisfied ratably over the two-year commitment period.

For the year ended December 31, 2001, we experienced a substantial decrease in available cash and cash equivalents due to our continued investments in our business. We expect to

continue to make investments in our business to support our direct distribution efforts and future programs and initiatives, which may further deplete our available cash balances. We believe that our available cash and cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet our forecasted cash needs in 2002. Our future liquidity and capital requirements will depend upon numerous factors, including:

- additional investments in inventories and deferred processing costs to support our direct distribution efforts;
- the progress of our product development programs and the need and associated costs relating to regulatory approvals which may be needed to commercialize some of our products under development;
- the resources we devote to the development, manufacture and marketing of our services and products; and
- the defense and outcome of pending litigation, including any outcomes which are adverse to us, to the extent not covered by product liability or other insurance. In this regard, we have two patent lawsuits that are scheduled for trial in 2002 and in which any damages that may be awarded against us are not covered by insurance.

We intend to seek additional funding to meet the needs of our long-term strategic plan and to re-build cash reserves. We can provide no assurance that such additional funds will be available, or if available, that such funds will be available on favorable terms.

#### **Recent Accounting Developments**

In June, 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets". As a result of SFAS No. 141, all acquisitions completed after June 30, 2001 are accounted for using the purchase method of accounting. We had no such transactions in 2001. SFAS No. 142 primarily addresses the accounting of goodwill and intangible assets subsequent to their initial recognition. SFAS No. 142 requires that goodwill and indefinite life intangible assets no longer be amortized but rather be tested for impairment annually. Intangible assets with a finite life shall continue to be amortized over the estimated useful life. SFAS No. 141 is effective for business combinations initiated after June 30, 2001. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. SFAS No. 142 requires that the elimination of amortization is to be applied on a prospective basis and prior periods are not to be restated. SFAS No. 142 requires that goodwill be tested annually for impairment using a two-step process. The first step is to identify a potential impairment and, in transition, this step is to be measured as of the beginning of the fiscal year and must be completed within six months of adoption. The second step, which must be completed by the end of the Company's fiscal year, measures the amount of the impairment loss, if any, as of the beginning of the year of adoption.

In June, 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 establishes accounting standards for the recognition and measurement of a liability associated with the retirement of a tangible long-lived asset that results

from the acquisition, construction, or development and/or normal operations of a long-lived asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002.

In August, 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets" which addresses financial accounting and reporting for the impairment or disposal of long-lived assets and discontinued operations. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001.

We are currently evaluating the impact of these pronouncements to determine the effect they may have on the consolidated financial position and results of operations. Under the provisions of SFAS No. 142, beginning in 2002 we will no longer amortize goodwill. Amortization of goodwill in 2001 was \$384,000.

### **Impact of Inflation and Foreign Currency Exchange Fluctuations**

The results of operations for the periods discussed have not been materially affected by inflation or foreign currency fluctuations.

### **Litigation**

We are involved in various legal proceedings involving product liability and patent infringement claims. For a complete discussion of these matters see, Part I, Item 3. "Legal Proceedings" and Note 11 of "Notes to Consolidated Financial Statements." It is possible that our results of operations or liquidity and capital resources could be adversely affected by the ultimate outcome of the pending litigation or as a result of the costs of contesting such lawsuits.

### **Risk Factors**

*We may need to secure additional financing to fund our long-term strategic plan and to re-build cash reserves.*

For the year ended December 31, 2001, we experienced a substantial decrease in available cash and cash equivalents due to our continued investments in our business. We expect to continue to make investments in our business to support our direct distribution efforts and future programs and initiatives, which may further deplete our available cash balances. We believe that our available cash and cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet our forecasted cash needs in 2002. Our future liquidity and capital requirements will depend upon numerous factors, including

- additional investments in inventories and deferred processing costs to support our direct distribution efforts;
- the progress of our product development programs and the need and associated costs relating to regulatory approvals which may be needed to commercialize some of our products under development;
- the resources we devote to the development, manufacture and marketing of our services and products; and

- the defense and outcome of pending litigation, including any outcomes which are adverse to us, to the extent not covered by product liability or other insurance. In this regard we have two patent lawsuits that are scheduled for trial in 2002 and in which any damages that may be awarded against us are not covered by insurance.

We may need to raise additional funds through the issuance of equity and/or debt financing in private placements or public offerings to provide funds to meet the need of our long-term strategic plan and to re-build cash reserves. As noted in Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations," we intend to seek such funding. Additional funds may not be available, or if available, may not be available on favorable terms. Further equity financings, if obtained, may substantially dilute the interest of our pre-existing shareholders. Any additional debt financings may contain restrictive terms that limit our operating flexibility. As a result, any future financings could have a material adverse effect on our business, financial condition or results of operations.

*Failure to comply with covenants under our loan and security agreement could materially adversely impact our business, financial condition and results of operations.*

We have recently amended our loan and security agreement and mortgage relating to our headquarters and manufacturing facility in Eatontown, New Jersey, among other things, to obtain a waiver of a breach of a financial covenant for the year ended December 31, 2001, to provide revised financial covenants, to grant additional security and to extend our revolving line of credit for an additional two year period through April, 2004. This loan facility provides a revolving credit facility, an equipment loan and a mortgage. It also imposes on us certain restrictive operating and financial covenants. The loan facility includes a covenant that provides for a .35% increase in the interest rate payable under the loan facility if we fail to raise at least \$15 million of additional equity capital by June 30, 2002, which rate is subject to reduction to the initial rates only after we have subsequently raised such additional capital. The loan covenants significantly limit or prohibit, among other things, our ability to advance or incur additional indebtedness, create liens on our assets, pay dividends, sell assets, engage in mergers or acquisitions, or make investments. Failure to comply with any of these restrictions could result in a default under this loan facility. The loan facility also includes subjective acceleration provisions. Such provisions are based upon, in the reasonable opinion of the bank, the occurrence of any adverse or material change in our condition or affairs, financial or otherwise, which impairs the interests of the bank. Following a default, the lender may determine not to make any additional financing available under the revolving line of credit, could accelerate the indebtedness under the revolving credit facility, the equipment loan and/or the mortgage, and could foreclose on the real and personal property securing the loans. Foreclosure would adversely affect our continued operations and our ability to repay the indebtedness under the loan facility. Without the availability of the financing under the revolving line of credit, we may not be able to meet our liquidity requirements during 2002 and would be required to curtail our operations or raise additional funds, which may not be available. We also may not have the funds to repay the debt upon acceleration. Even if available, the terms of any additional debt or equity financing that we may incur could restrict our operational flexibility and thereby adversely affect our business, results of operations and financial condition.

*Our cash flows are expected to be adversely impacted by our focus on direct distribution.*

Commencing in the first half of 2001, and expanding in the second half of 2001, we began to distribute tissue forms directly to surgeons and hospitals. We expect to continue to expand our direct distribution efforts to surgeons and hospitals in 2002 and beyond. As a result, we expect that revenues from direct distribution of tissue will grow significantly as a percentage of our consolidated revenues over the next several years. This change in distribution methodology has impacted and is expected to continue to have an impact on our cash flow. Our days sales in accounts receivable have increased from 65 days in 2000 to 71 days in 2001, primarily as a result of the change in our customer mix resulting from our direct distribution efforts. As a greater percentage of our revenues are generated from direct shipments to hospitals and other healthcare providers, which typically pay invoices slower than our historical customer base, we expect that our days sales in accounts receivable will remain at 2001 levels or increase slightly.

*We are dependent upon two primary clients who provide the bulk of our revenues.*

We are the processor of allograft bone tissue for large national and international not-for-profit organizations. During 2001, MTF and ARC each accounted for approximately 37% of our revenues. We entered into a 10-year exclusive processing agreement with ARC in December, 1996 and a five year non-exclusive processing agreement with MTF in September, 2000. However, the MTF contract may be canceled at any time upon either party giving six months prior written notice. We are currently in litigation against MTF. See Item 3 "Legal Proceedings." The loss of either MTF or ARC as a client or a substantial reduction in the amount of allograft bone tissue which we process for either entity would have a material adverse effect on our business, financial condition and results of operations.

*Our dependence upon a limited supply of human donors may curtail business expansion.*

Our allograft bone tissue processing business primarily depends upon the availability of bone and related connective tissue from human donors recovered by our clients and TRO who recover donated human cadaveric tissue for us. We rely on the efforts of not-for-profit donor procurement agencies, including our current clients, to educate the public and foster an increased willingness to donate bone tissue. These organizations may not be able to find a sufficient number of persons to donate, or may not be willing to provide, sufficient amounts of tissue to meet present or future demand for either allograft bone tissue or any allograft bone tissue-based osteogenic materials we are developing. To date, our inability to obtain sufficient amounts of donated tissue to fulfill the demand for our bio-implants has limited the growth of revenues we receive from these tissue forms. Although we have taken steps to address this tissue supply problem, we cannot assure you that these efforts will be successful or that we will otherwise be able to secure a sufficient supply of tissue. Our inability to secure enough donor tissue to meet our demands could have a material adverse effect on our business, financial condition and results of operations.

*We face strong competitive threats from firms with greater financial resources and lower costs.*

The allograft bone tissue we process competes in the bone graft market with autograft bone tissue, synthetic bone void fillers and allograft bone tissue processed by others, primarily tissue banks. Autograft bone tissue has traditionally been the primary choice for surgeons and we believe autograft bone tissue still maintains approximately a 40% share of the United States bone graft market. In Europe, bone graft substitutes, such as bovine bone tissue and synthetics, currently comprise most of the bone grafting market. Many of our competitors have greater financial resources than we do. For numerous circumstances and procedures for which autograft bone tissue transplantation is either not feasible or not desirable, there are a number of competing alternatives available, including allograft bone tissue processed by others and bone graft substitutes.

In recent years, our Grafton<sup>®</sup> DBM products have faced increasing competitive pressures as more companies have developed, or have announced they are developing, products with characteristics similar to Grafton<sup>®</sup> DBM. Certain of those competitors have, in turn, partnered with large orthopaedic and spine companies to market the competing products they have developed. We expect that this competition will continue in the future. Many of these competitors have research and development, marketing and other resources that are significantly greater than ours. They also offer a full line of metal implants and other products used in spinal surgeries. This could give them a competitive advantage over us since they can offer surgeons a more complete line of products than we currently can. The intense competition in the Grafton<sup>®</sup> DBM segment has caused our revenues in this Segment to stop growing and to decline slightly in 2001.

We believe that a majority of the cadaveric bone banks operating in the United States are engaged in processing allograft bone tissue for transplantation. Many of these bone tissue banks are not-for-profit organizations, and, as such, they may be able to supply processing services at a lower cost than we can. Several for-profit companies, certain of which have substantially greater resources than we do, are processing, marketing and distributing allograft tissue. We compete with such entities on the basis of our advanced processing technology and the quality and quantity of the bone tissue our processing yields. Since we introduced our allograft bone tissue processing technology in 1987, certain competing processors have claimed to have developed technology similar to that which we use. We may not be able to compete successfully in the area of allograft bone tissue processing and distribution.

*We are currently involved in patent litigation which could have a significant adverse impact on our business. We may become involved in additional patent litigation in the future.*

We are currently involved in litigation involving our patents and patents held by certain of our competitors. Prosecuting and defending these lawsuits is very expensive and these expenses have had, and are likely to have, an adverse affect on our results of operations and financial condition. We are committed to aggressively asserting and defending our technology and related

intellectual property which we have spent a significant amount of money to develop. In addition, the industry in which we compete is known for having a great deal of litigation involving patents. These factors could cause us to become involved in additional patent litigations in the future. The expense of prosecuting or defending these future lawsuits could also have a material adverse effect on our business, financial condition and results of operations.

If we were to lose those litigations in which another party is asserting that our products infringe its patents, we would likely be prohibited from marketing those products and could also be liable for significant damages. Either or both of these results may have a material adverse effect on our business, financial condition and results of operations. If we lose those litigations in which we are claiming that another party's products are infringing our patents and thus, are unable to enforce our patents, it may have a material adverse effect on our business, financial condition and results of operations.

As noted in Item 3 "Legal Proceedings," two patent lawsuits pending against us are scheduled for trial in 2002. Given the current limitations on our liquidity discussed in Item 7 "Management's Discussion and Analysis of Results of Operations and Financial Conditions – Liquidity and Capital Resources", we may be unable to pay any significant damages should a judgment be entered against us in these lawsuits or other lawsuits in which we are a party or we may be unable to obtain a bond necessary to appeal any such judgment. Also, a judgement entered against us in any of these lawsuits could cause us to violate one or more of the covenants of our loan agreement.

During the course of the patent litigations in which we are involved, interim information about the status of each of these litigations may be released. Although these interim releases may differ from the final determinations in these litigations, such information may have a material adverse effect on the market price of our common stock. See Part I, Item 3 "Legal Proceedings".

*Our revenues will depend upon reimbursement from public and private insurers and national health systems.*

The continued ability of our clients to pay our processing charges for the processing of allograft bone tissue, depends upon our clients' ability to distribute processed allograft bone tissue and collect fees from their clients, which are typically hospitals. The ability of hospitals to pay fees to our clients, or directly to us for allograft bone tissue or non-allograft spinal implant systems distributed directly by us to the hospitals, depends in part on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from government health administration authorities, private health coverage insurers and other organizations. We may have difficulty gaining market acceptance for our products and services if government and third-party payors do not provide adequate coverage and reimbursement.

*The medical community could choose not to use our allograft bone tissue products.*

We believe the market for allograft bone tissue will continue to be based primarily upon the use of such products by physicians specializing in the orthopaedic, neurological and

oral/maxillofacial surgical areas. Our future growth depends in part upon such physicians' wider use of allograft bone tissue as an alternative to autograft bone tissue and other available materials and treatments. We have tried to educate physicians through our marketing activities. Our future efforts in this regard may fail to generate additional demand for our allograft tissue forms.

*Governmental regulation could restrict the use of our products.*

In the United States, the procurement and transplantation of allograft bone tissue are subject to federal regulation pursuant to NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas and receive payments for all such services, with the exception of removal and implantation. We pay TROs and certain of our clients in connection with their procuring tissue on our behalf. If NOTA is interpreted or enforced in a manner which prevents us from receiving payment for services we render or which prevents us from paying TROs or certain of our clients for the services they render for us, our business could be materially, adversely affected. We are engaged through our direct sales employees and our independent sales representatives in ongoing efforts designed to educate the medical community as to the benefits of processed allograft bone tissue and in particular our allograft tissue forms, and we intend to continue our educational activities. Although we believe that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of our allograft bone tissue products, payments in connections with such education efforts are not exempt from NOTA's restrictions and our inability to make such payments in connection with our education efforts may prevent us from paying our sales representatives for their education efforts and could adversely affect our business and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft bone tissue-based material which our processing technologies may generate. Assuming that NOTA applies to our processing of allograft bone tissue, we believe that we comply with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be adopted in the future which would call into question one or more aspects of our method of operations.

In various countries outside the United States, national laws and regulations restrict or control the availability and/or use of tissues. There can be no assurance that more restrictive laws, regulations or interpretations will not be adopted in the future which would call into question one or more aspects of our method of operations in those countries.

In the United States, the allograft bone tissues that we process are regulated by the FDA as human tissue-based products under section 361 of the Public Health Service Act, and under certain circumstances, may be regulated as a medical device under the Food, Drug, and Cosmetic Act.

FDA regulations do not require that human tissue-based products be cleared or approved before they are marketed. We are, however, required to register and list these products with FDA and to comply with regulations concerning tissue donor screening and testing, and related procedures and record keeping. FDA periodically inspects tissue processors to determine compliance with these requirements. FDA has proposed, but not yet finalized, "Good Tissue Practice" regulations that would impose requirements on the manufacture of human tissue-based products, including tissue recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The human tissue-based product category is a relatively new one in FDA regulations, and it is possible that FDA will change its approach to human tissue-based products in general or to particular categories of products to require FDA clearance or approval or otherwise restrict distribution.

The metal spinal implant products that we distribute in the United States are regulated by the FDA as medical devices. Medical devices generally require FDA approval or clearance before they may be marketed. There are two processes by which medical devices can receive approval or clearance. Some products may qualify for clearance under the 510(k) process, in which the manufacturer or processor demonstrates that its product is substantially equivalent to another lawfully marketed product (i.e., that it has the same intended use and is as safe and effective as a lawfully marketed product and does not raise different questions of safety and effectiveness as the lawfully marketed product). 510(k) submissions usually include safety and performance data, and in some cases, the submission must include clinical data. Marketing may commence if and when FDA issues a letter finding substantial equivalence.

If a medical device does not qualify for the 510(k) process, the product may not be distributed until a premarket approval application has been approved by FDA. Premarket approval applications must demonstrate product safety and effectiveness. A premarket approval application is typically a complex submission, usually including the results of preclinical and clinical studies. The manufacturer must also pass a premarket inspection of its compliance with FDA's Quality Systems regulation. Marketing may commence if and when FDA issues a premarket approval. The Ovation™ System, the VBR™ System, the Sentinal™ Pedicle screw system and Affirm™ Cervical plate system are being marketed pursuant to 510(k) clearances.

*FDA has changed the regulatory status of our Grafton® DBM products and the consequences of that decision are uncertain.*

In March, 2002, FDA informed us that it is changing the regulatory status of Grafton® DBM and will henceforth regulate it as a medical device as well. Medical device regulation is a more stringent category of regulation and, in particular, medical devices require FDA clearance or approval. We believe FDA's change in its position regarding Grafton® DBM results from its decision to regulate all demineralized bone with a carrier, including those processed and marketed by some of our competitors, as medical devices. We intend to persuade FDA that its initial designation of Grafton® DBM as a human tissue-based product was and still is correct. If we are unsuccessful in that effort, we will be required to obtain a medical device approval or clearance, and to comply with medical device postmarketing obligations. We believe that Grafton® DBM

will be eligible for 510(k) clearance, but we cannot be sure that we will not be required to obtain premarket approval, or that FDA will issue any clearance or approval in a timely fashion, or at all. In its March letter regarding Grafton® DBM, FDA stated that it intends to allow us a reasonable period of time to obtain clearance for Grafton® DBM, and we will continue to process and distribute Grafton® DBM during this period. We cannot be sure that FDA will clear or approve our submission or will clear or approve all claims that we currently make for Grafton® DBM. Failure to obtain FDA clearance or approval or limitation on Grafton® DBM claims could adversely affect us.

We also market Grafton Plus™ DBM as a human tissue-based product. FDA's determination regarding Grafton® DBM is also likely to be applied to Grafton Plus™ DBM. If FDA maintains its position that all demineralized bone with a carrier is a medical device, we would also be required to obtain FDA clearance or approval for Grafton Plus™ DBM, and to comply with other medical device requirements for that product. Failure to obtain FDA clearance or approval, if required, or any limitation on Grafton Plus™ DBM could adversely affect us.

*Loss of key persons could limit our success.*

Our success depends upon the continued contributions of our executive officers and scientific and technical personnel. The competition for qualified personnel is intense, and the loss of services of our key personnel, particularly members of senior management, could adversely affect our business.

*If we are unable to enforce our patents or if it is determined that we infringe patents held by others it could damage our business.*

We consider our allograft bone tissue processing technology and procedures proprietary and rely primarily on trade secrets and patents to protect our technology and innovations. Consultants employed by third parties and persons working in conjunction with medical institutions unaffiliated with us have conducted significant research and development for our products. Accordingly, disputes may arise concerning the proprietary rights to information applied to our projects which have been independently developed by such consultants or medical institutions. In addition, you should recognize that although we have attempted to protect our technology with patents, our existing patents may prove invalid or unenforceable as to products or services marketed by our competitors. Our pending patent applications may not result in issued patents. Moreover, our existing or future products and technologies could be found to infringe the patents of others. We are currently involved in three lawsuits in which we are accused of infringing patents held by others. See Part I, Item 3 "Legal Proceedings."

*Our products face competitive threats from alternate technologies.*

The primary advantage of synthetic bone substitutes as compared to allograft bone tissue is that they do not depend on the availability of donated human tissue. In addition, members of the medical community and the general public may perceive synthetic materials as safer than allograft-based bone tissue. The allograft bone tissue we process may be incapable of competing

successfully with synthetic bone substitutes and recombinant bone growth factors which are developed and commercialized by others, which could have a material adverse effect on our business, financial condition and results of operations.

*Our spray coating, HA products and bovine tissue products operations face intense competition.*

Our plasma spray coatings, HA products and bovine tissue products operations face intense competition in Europe from divisions and subsidiaries of several large corporations engaged in providing such services and products to others and from several smaller independent companies. In addition, we also face competition from medical implant companies which have in-house plasma spray coating operations. We compete primarily on the quality of our coatings, bovine tissue products and our prices. We believe that the spraying technology we use, which is computer-controlled and utilizes robotics, enables us to provide high quality coatings at competitive prices. You should note, however, that the industries in which we compete in Europe are highly competitive, certain of our competitors have greater resources than we do, and we may be unable to compete successfully.

*We may incur losses from product liability lawsuits.*

The testing and use of human allograft bone tissue, bovine tissue products and the implantation of medical devices coated with our HA powder or titanium and medical devices manufactured by others and which we distribute, entail inherent risks of medical complications for patients and therefore may result in product liability claims against us. Further, our agreements with our allograft bone tissue processing clients provide for indemnification by us for liabilities arising out of defects in allograft bone tissue they distribute which is caused by our processing. See Part I, Item 3 "Legal Proceedings."

We presently maintain product liability insurance in the amount of \$70 million per occurrence and per year in the aggregate. We may be unable to maintain such insurance in the future and such insurance may not be sufficient to cover all claims made against us or all types of liabilities which may be asserted against us.

*We face potential lawsuits or governmental enforcement activities based on hazardous waste we generate in our operations.*

Our allograft bone tissue processing in both the United States and Europe generates waste materials, which, in the United States, are classified as medical waste and/or hazardous waste under regulations promulgated by the United States Environmental Protection Agency and the New Jersey Department of Environmental Protection. We segregate our waste materials and dispose of them through a licensed hazardous waste transporter in compliance with applicable regulations in both the United States and Europe. The production of HA powder at our facility in The Netherlands generates small amounts of hazardous waste, which we segregate and dispose of through a licensed hazardous waste transporter.

Our failure to fully comply with any environmental regulations could result in the imposition of penalties, fines and/or sanctions or, in some cases, private lawsuits, which could have a material adverse effect on our business, financial condition and results of operations.

*We rely on our independent sales agents and sales representatives to educate surgeons concerning our products and to market our products.*

Our success depends largely upon arrangements we have with independent sales agents and sales representatives whereby they educate surgeons concerning our products and market our products. These independent sales agents and sales representatives may terminate their relationship with us, or devote insufficient sales efforts to our products. We do not control our independent sales agents and they may not be successful in implementing our marketing plans. Our failure to attract and retain skilled independent sales agents and sale representatives could have an adverse effect on our operations.

*The issuance of preferred stock may adversely affect rights of common stockholders or discourage a takeover.*

Under our amended and restated certificate of incorporation, our board of directors has the authority to issue up to 5,675,595 shares of preferred stock and to determine the price, rights, preferences and privileges of those shares without any further vote or action by our stockholders. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of any shares of preferred stock that may be issued in the future.

In January, 1996, our board of directors authorized shares of Series E Preferred Stock in connection with its adoption of a stockholder rights plan, under which we issued rights to purchase Series E Preferred Stock to holders of the common stock. Upon certain triggering events, such rights become exercisable to purchase common stock (or, in the discretion of our board of directors, Series E Preferred Stock) at a price substantially discounted from the then current market price of the Common Stock. Our stockholder rights plan could generally discourage a merger or tender offer involving our securities that is not approved by our board of directors by increasing the cost of effecting any such transaction and, accordingly, could have an adverse impact on stockholders who might want to vote in favor of such merger or participate in such tender offer.

While we have no present intention to authorize any additional series of preferred stock, such issuance, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could also have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock. The preferred stock may have other rights, including economic rights senior to the Common Stock, and, as a result, the issuance thereof could have a material adverse effect on the market value of the common stock.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

In the United States, we are exposed to interest rate risk. Changes in interest rates affect interest income earned on cash, cash equivalents and short-term investments and interest expense on short-term and long-term debt. We do not enter into derivative transactions related to our cash, cash equivalents, short-term investments or debt. Accordingly, we are subject to changes in interest rates. Based on our December 31, 2001 cash and cash equivalents and long-term debt, a 1% change in interest rates would impact our results of operations by approximately \$100,000.

The value of the U.S. dollar affects our financial results. Although currently not significant, changes in exchange rates may positively or negatively affect revenues, gross margins, operating expenses and net income in the future. We do not maintain hedging programs to mitigate the potential exposures of exchange rate risk. Accordingly, our results of operations are adversely affected by the strengthening of the U.S. dollar against currencies in which we sell products and services or a weakening exchange rate against currencies in which we incur costs. Based on the operating results of our foreign operations for the year ended December 31, 2001, a 10% change in the exchange rates would impact our results of operations by approximately \$100,000.

Because of the foregoing factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance.

**Item 8. Financial Statements and Supplementary Data**

The response to this item is submitted as a separate section of this Annual Report commencing on page F-1.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

PART III

**Item 10. Directors and Executive Officers of the Registrant**

Our directors and executive officers, including their ages, are as follows as of March 25, 2002:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard W. Bauer <sup>(1)</sup> .....	57	Chief Executive Officer, President, Chief Operating Officer and Director
Michael J. Jeffries.....	59	Executive Vice President, Chief Financial Officer, Secretary and Director
Donald D. Johnston <sup>(1) (2) (3)</sup> .....	77	Chairman of the Board
Kenneth P. Fallon, III <sup>(2)</sup> .....	63	Director
John Phillip Kostuik, M.D., FRCS(C) <sup>(3)</sup> .....	64	Director
Stephen J. Sogin, Ph.D. <sup>(1) (2) (3)</sup> .....	60	Director
James L. Russell, Ph.D. ....	51	Executive Vice President and Chief Scientific Officer
Richard Russo.....	53	Executive Vice President and General Manager

<sup>(1)</sup> Member of the Executive Committee of our Board of Directors.

<sup>(2)</sup> Member of the Compensation Committee of our Board of Directors.

<sup>(3)</sup> Member of the Audit Committee of our Board of Directors.

*Richard W. Bauer, 57, has served as our Chief Executive Officer and a member of the Board since he joined Osteotech in February, 1994. Mr. Bauer also served as our President from February, 1994 until September, 1999 and effective with Mr. Alfaro's resignation on November 15, 2001 is serving as Osteotech's President and Chief Operating Officer. Prior to joining Osteotech, from 1992 to 1993, Mr. Bauer was President of the Prosthetic Implant Division of Zimmer, Inc., a subsidiary of Bristol-Myers Squibb Company. From 1991 through 1992, Mr. Bauer served as Senior Vice President and General Manager of Zimmer's Fracture Management Division, and as Vice President of Marketing of its Orthopaedic Implant Division from 1989 to 1991. Mr. Bauer previously served in positions of significant responsibility with Professional Medical Products, Inc., Support Systems International, Inc. and the Patient Care Division of Johnson & Johnson, Inc. Mr. Bauer is a former member of the Board of Directors of the New Jersey Chapter of the Arthritis Foundation. Mr. Bauer has B.S. and M.B.A. degrees from Fairleigh Dickinson University.*

*Michael J. Jeffries, 59, Executive Vice President, Chief Financial Officer, Secretary and member of the Board of Directors, has been with Osteotech for more than eleven years. He joined Osteotech in January, 1990, originally as Senior Vice President and Chief Financial Officer, became Secretary in May, 1991 and a director in July, 1991, and was appointed Executive Vice President in October, 1992. Mr. Jeffries also served as our Chief Operating Officer from January,*

1994 until September, 1999. Prior to joining Osteotech, Mr. Jeffries had more than 25 years of business experience in various positions of increasing responsibility in a number of publicly and privately held companies, for some of which he was also a member of the board of the directors. Mr. Jeffries serves as Chair of the American Association of Tissue Bank's Finance Committee. He also is a member of the Board of Directors of the American Tissue Services Foundation, which is a client of Osteotech's. See Item 13 "Certain Relationships and Related Transactions". Mr. Jeffries has a B.B.A. degree from the City College of New York and a M.B.A. degree in finance from Fordham University.

*Donald D. Johnston*, 77, has been a director of Osteotech since September, 1991. Mr. Johnston became Chairman of the Board in June, 1992. Over the course of 25 years Mr. Johnston held various positions of increasing responsibility with Johnson & Johnson, Inc. At the time of his retirement in May, 1986 he was a member of the Executive Committee and the Board of Directors of Johnson & Johnson, Inc. From 1992 to 1998, Mr. Johnston was a founding Director and a member of the Audit, Compensation and Executive Committees of Human Genome Sciences, Inc. He is currently a member of the Board of Directors and Chairman of the Audit Committee of Diversa Corp. Mr. Johnston has a B.A. in economics from the University of Cincinnati.

*Kenneth P. Fallon, III*, 63, was elected to serve on the Board in June, 1995 and is Chief Executive Officer and a Director of Axya Medical Inc., a Massachusetts based, privately held medical device firm. In 1997, Mr. Fallon was President of the surgical business at Haemonetics Corporation. In 1994 and 1995, Mr. Fallon served as Chief Executive Officer and Chairman of the Board of UltraCision Incorporated, a manufacturer of advanced technology medical devices. UltraCision was sold to Ethicon EndoSurgery, a unit of Johnson & Johnson, Inc., in November, 1995. From 1992 through 1994, Mr. Fallon served as President and Chief Executive Officer of American Surgical Technologies Corporation. Mr. Fallon was President, U.S. Operations of Zimmer, Inc., a subsidiary of Bristol-Myers Squibb Company from 1991 to 1992. From 1985 through 1991 he served as President of Zimmer's Orthopaedic Implant Division, and from 1983 to 1985 as its Vice President of Marketing. Mr. Fallon previously served in positions of significant responsibility with the Codman and Orthopedic Divisions of Johnson & Johnson, Inc. Mr. Fallon has a B.B.A. degree in marketing from the University of Massachusetts and a M.B.A. degree from Northeastern University.

*John Phillip Kostuik, M.D., FRCS(C)*, 64, was elected to serve on the Board in June, 1997. Dr. Kostuik is currently and has since 1991 been a Professor and Chairman of the Department of Orthopaedic Surgery, Johns Hopkins University, School of Medicine, Chief Spine Division. He is the past president of the Scoliosis Research Society and the North American Spine Society and he has served on the Executive Committee of the North American Spine Society. He has B.A. and M.D. degrees from Queens University, graduating in 1961.

*Stephen J. Sogin, Ph.D.*, 60, has served as a director of Osteotech since October, 1988. From December, 1984 until January 1, 1995, he was a founding general partner of Montgomery Medical Ventures. Dr. Sogin currently serves as a venture capital consultant and serves on the Board of Directors of Finet Inc, and three private corporations. Dr. Sogin is also currently Chairman and Chief Executive Officer of Icomomed, a start-up internet based medical information data base.

He has a B.S., M.S. and Ph.D. in microbiology from the University of Illinois. On July 1, 1997, Dr. Sogin consented to a cease and desist order issued by the Securities and Exchange Commission involving his late filing of Forms 3, 4 and 5, which he was required to file in his capacity as a General Partner of Montgomery Medical Ventures II. None of the Commission's findings involve charges that Dr. Sogin received improper gains or personal benefits as a result of these violations. Dr. Sogin has advised Osteotech that the trades in question were conducted by the partnership (Montgomery Medical Ventures II) and none of these trades were executed by him personally.

*James L. Russell, Ph.D.*, 51, joined Osteotech in December, 1995 as Executive Vice President and Chief Scientific Officer. He previously held research and development positions of increasing responsibility for 16 years with Proctor & Gamble Company, or P&G. Dr. Russell oversaw the development of several products, in a variety of therapeutic areas, including bone-related therapeutic agents for the treatment of Paget's disease, hypocalcemia of malignancy and osteoporosis. In his prior position at P&G, he served as the Pharmaceutical Division's Director of Product Development. Dr. Russell holds a B.S. in Biology from Boston State College and a Ph.D. in Cellular Immunology from Purdue University.

*Richard Russo*, 53, joined Osteotech in September, 1991, and was elected Executive Vice President and General Manager, International on July 1, 2000. From April, 1998 to June, 2000 Mr. Russo served as Executive Vice President, Strategic Planning and Business Development and from October, 1995 to April, 1998 he served as Senior Vice President, Strategic Planning and Business Development. Prior thereto Mr. Russo had held a number of progressively more responsible positions with Osteotech in the areas of marketing, business development, clinical research and regulatory affairs. Prior to joining Osteotech, Mr. Russo worked for several leading healthcare companies, having positions of responsibility in marketing, sales, business development, regulatory affairs and clinical research management. Mr. Russo earned a B.A. in philosophy from Boston College and a M.B.A. in marketing from Columbia University.

#### **Item 11. Executive Compensation**

The section of our 2002 Proxy Statement entitled "Executive Compensation" is incorporated herein by reference.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management**

The section of our 2002 Proxy Statement entitled "Security Ownership of Certain Beneficial Owners and Management" is incorporated herein by reference.

#### **Item 13. Certain Relationships and Related Transactions**

In February, 2001, we entered into a Loan Agreement with the American Tissue Services Foundation ("ATSF") or ATSF which expires in December, 2010. Pursuant to the Loan Agreement, as amended ATSF has borrowed \$2,208,000 from us as of December 31, 2001. In February, 2002, we amended the Loan Agreement to allow ATSF to borrow up to an aggregate of

\$2,750,000. We expect that ATSF will borrow approximately \$250,000 in 2002. Each loan matures five (5) years from the date it is made and bears interest at a rate per annum equal to the five year Treasury Bill rate as reported in the Wall Street Journal on the date immediately proceeding the date such loan is made, plus one percent (1%). Interest is payable on a quarterly basis. ATSF is a not-for-profit corporation organized under the laws of the State of Delaware which we were involved in founding in December, 2000. Michael J. Jeffries, our Executive Vice President and Chief Financial Officer, is one of three directors of ATSF. Neither Mr. Jeffries nor we own any interest in ATSF. ATSF procures human bone and related connective soft tissue on our behalf pursuant to a long-term agreement which expires in December, 2015. We believe the amounts we pay ATSF for its services to us under this agreement are comparable to those we pay other TROs who procure tissue on our behalf.

PART IV

**Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

(a)(1) and (2). The response to this portion of Item 14 is submitted as a separate section of this report commencing on page F-1.

(a)(3) and (c). Exhibits (numbered in accordance with Item 601 of Regulation S-K).

<u>Exhibit Number</u>	<u>Description</u>	<u>Number</u>
3.1	Restated Certificate of Incorporation of Osteotech, as amended	E-2
3.2	Third Amended and Restated Bylaws of Osteotech	E-14
3.3	Form of Stock Certificate	**
4.3	Rights Agreement dated as of February 1, 1996 between Osteotech, Inc. and Registrar and Transfer Co., as amended	E-41
10.1	1991 Stock Option Plan, as amended ^	E-110
10.2	1991 Independent Directors Stock Option Plan, as amended ^	***
10.4	Senior Management Loan Program ^	E-118
10.6	Processing Agreement between Osteotech and Stichting Eurotransplant Nederland, dated September 26, 1988 [*]	**
10.10	Form of Confidentiality Agreement and Non-Competition Agreement with executive officers	E-119
10.13	Agreement dated December 10, 1996 between American Red Cross Tissue Services and Osteotech [*]	*****
10.14	Lease for Osteotech's Shrewsbury, New Jersey processing facility, as amended through third modification	**
10.16	Credit Agreement between Osteotech b.v. and ING Bank N.V. dated March 14, 1996	+++++
10.21	License & Option Agreement between HC Implants BV and Matrix Medical Holding BV dated June 27, 1997 (Matrix Medical Holdings BV subsequently changed its name to IsoTis, BV)	+++++
10.22	Change in Control Agreement by and between Osteotech and Richard W. Bauer dated September 8, 1997^	+++++
10.23	Change in Control Agreement by and between Osteotech and Michael J. Jeffries dated September 8, 1997^	+++++
10.24	Change in Control Agreement by and between Osteotech and James L. Russell dated September 8, 1997 ^	+++++
10.26	Employment Agreement with Michael J. Jeffries dated January 1, 1998 ^	^^
10.27	Employment Agreement with James L. Russell dated December 18, 1997 ^	^^
10.28	The Management Performance Bonus Plan ^	^^^
10.29	Employment Agreement with Richard Russo dated April 1, 1997 ^	^^^
10.30	Change in Control Agreement by and between Osteotech Inc. and Richard Russo ^	^^^
10.31	Employment Agreement with Richard W. Bauer dated December 4, 1998 ^	^^^
10.32	Employment Agreement with Arthur A. Alfaro dated	^^^

	September 13, 1999 ^	
10.33	Change in Control Agreement by and between Osteotech Inc. and Arthur A. Alfaro^	^^^^
10.34	Settlement Agreement and General Release Between DePuy Acromed, Inc. and DePuy, Inc. and Osteotech, Inc.	^^^^
10.35	Loan and Security Agreement among Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Cam Implants B.V., Osteotech/CAM Services B.V. and OST Developpement dated June 10, 1999. [Includes Equipment Loan Note, Convertible Revolving Note, and Mortgage Term Note as exhibits.]	^^^^
10.36	Amended and Restated Processing Agreement entered into September 11, 2000 by Osteotech, Inc., Musculoskeletal Transplant Foundation and Biocon, Inc.[*]	^^^^
10.37	Mortgage Term Note among Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/CAM Services, B.V. and OST Developpement dated December 8, 2000	^^^^
10.38	Allonge to Loan and Security Agreement among Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/CAM Services, B.V. and OST Developpement dated December 8, 2000	^^^^
10.39	Allonge to Equipment Loan Note among Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/CAM Services, B.V. and OST Developpement dated December 8, 2000	^^^^
10.40	Distribution Agreement entered into February, 2001 by Osteotech, Inc. and Alphatec Manufacturing, Inc. [*]	^^^^
10.41	Second Allonge to Loan and Security Agreement among Fleet National Bank, Successor in Interest to Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V. and OST Developpement dated March 8, 2001	^^^^
10.42	Second Allonge to Equipment Loan Note among Fleet National Bank, Successor in Interest to Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V. and OST Developpement dated March 8, 2001	^^^^
10.43	Allonge to Convertible Revolving Note among Fleet National Bank, Successor in Interest to Summit Bank,	^^^^

	Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V. and OST Developpement dated March 8, 2001	
10.44	Primary Agreement Carrier and Bio-Implant Allografts by and between LifeNet and Osteotech dated January 4, 2002	###
10.45	2000 Stock Plan dated February 9, 2000	E-126
10.46	Loan Agreement between American Tissue Services Foundation and Osteotech dated November 27, 2000, as amended	E-137
10.47	Third Allonge to Loan and Security Agreement among Fleet National Bank, Successor in Interest to Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V. and OST Developpement dated September 10, 2001	E-143
10.48	Third Allonge to Equipment Loan Note among Fleet National Bank, Successor in Interest to Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V. and OST Developpement dated September 10, 2001	E-152
10.49	Second Allonge to Convertible Revolving Note among Fleet National Bank, Successor in Interest to Summit Bank, Osteotech, Inc., Osteotech Investment Corp., Cam Implants Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V. and OST Developpement dated September 10, 2001	E-155
10.50	Separation Agreement and General Release by and between Arthur A. Alfaro and Osteotech^	E-157
10.51	Agreement of Amendment to Loan and Security Agreement, Mortgage, Assignment of Leases and Other Documents by and among Fleet National Bank, Osteotech, Inc., Osteotech Investment Corporation, Cam Implants, Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/CAM Services, B.V., Osteotech, S.A., and Ost Developpement S.A. dated March 13, 2002	E-170
21.1	Subsidiaries of the Registrant	E-212
23.1	Consent of PricewaterhouseCoopers LLP	E-213
**	Previously filed as exhibits to Osteotech's Registration Statement on Form S-1 (File No. 33-40463) and incorporated herein by reference thereto.	
***	Previously filed as exhibits to Osteotech's Registration Statement on Form S-8 (File No. 33-44547) and incorporated herein by reference thereto.	

- \*\*\*\*\* Previously filed as exhibits to Osteotech's Annual Report on Form 10-K for the fiscal year ended December 31, 1996 and incorporated herein by reference thereto.
- +++++ Previously filed as exhibits to Osteotech's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 and incorporated herein by reference thereto.
- ++++++ Previously filed as exhibits to Osteotech's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 and incorporated herein by reference thereto.
- +++++++ Previously filed as exhibits to Osteotech's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997 and incorporated herein by reference thereto.
- ^ Management contracts or compensatory plans and arrangements required to be filed pursuant to Item 10(iii)
- ^^ Previously filed as Exhibits to Osteotech's Annual Report on Form 10-K for the fiscal year ended December 31, 1997 and incorporated herein by reference thereto.
- ^^^ Previously filed as Exhibits to Osteotech's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 and incorporated herein by reference thereto.
- ^^^^ Previously filed as exhibits to Osteotech's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999 and incorporated herein by reference thereto.
- ^^^^^ Previously filed as exhibits to Osteotech's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference thereto.
- ^^^^^^ Previously filed exhibit to Osteotech's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 and incorporated herein by reference thereto.
- ^^^^^^^ Previously filed exhibit to Osteotech's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 and incorporated herein by reference thereto.
- ### Previously filed exhibit to Osteotech's Current Report on Form 8-K filed with the Commission on March 8, 2002 and incorporated herein by reference thereto.
- / Previously filed exhibit to Osteotech's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998 and incorporated herein by reference thereto.
- [\*] Copy omits information for which confidential treatment has been granted.
- [ ] Copy omits information for which confidential treatment has been requested.

(b) Reports on Form 8-K

On December 12, 2001, we announced that in connection with the patent lawsuit trial conducted in the United States District Court for the Central District of California against GenSci Regeneration Sciences, Inc. and its subsidiary GenSci Orthobiologics, Inc. (collectively, "GenSci"), we have been awarded damages in the amount of \$17,533,634. This damage award will be reduced by the \$3 million previously paid by DePuy AcroMed in settlement of Osteotech's claims against DePuy AcroMed in this lawsuit. On November 29, 2001, the jury determined that Osteotech's U.S. Patent Nos. 5,290,558 (the " '558 Patent") and 5,284,655 (the " '655 Patent") are valid and that GenSci infringed both the '558 and '655 Patents through their sale of DynaGraft™ Gel and Putty products.

On November 30, 2001, we announced that the conclusion of the liability phase of the trial being conducted in the United States District Court for the Central District of California, the jury returned a verdict that Osteotech's U.S. Patent Nos. 5,290,558 (the " '558 Patent") and 5,284,655 (the " '655 patent") are valid and that both GenSci Regeneration Sciences, Inc. and its subsidiary GenSci Orthobiologics, Inc. (collectively, "GenSci") infringe both the '558 and '655 Patents through their sale of DynaGraft™ Gel and Putty products. In arriving at its verdict, the jury rejected all of GenSci's defenses.

On November 15, 2001, we announced that Arthur A. Alfaro had departed from the Company, effective November 15, 2001, as its President and Chief Operating Officer.

On November 8, 2001, we announced that at the patent lawsuit trial, which commenced on Wednesday, October 31, 2001 in the United States District Court, Central District of California, in which GenSci Orthobiologics and GenSci Regeneration Science ("GenSci") are accused of infringing the claims of two of Osteotech's patents, U.S. Patent 5,290,558 (the '558 Patent) and 5,284,655 (the '655 Patent), the Court has granted Osteotech's motion to exclude a patent recently issued to GenSci from being entered into evidence at the trial. GenSci had attempted to enter the patent, U.S. Patent 6,309,659 (the "659 Patent") titled "Reverse Phase Connective Tissue Repair Composition", which was described in its press release of October 31, 2001, into evidence in order to support its defense of reverse doctrine of equivalents. As a result of the Court's ruling, GenSci may not introduce at trial or refer to evidence concerning its '659 Patent.

On October 24, 2001, we announced that at the Annual TechVest Conference, Osteotech would announce that it expects to begin limited commercialization of its revolutionary new-patented Plexus technology at the end of 2001. Utilizing this technology, bone tissue is reduced to particulate and reassembled together at the molecular level into virtually any shape or size. The Plexus technology is designed to maximize the utilization of donated human tissue and it increase the yield of bio-implants.

## SIGNATURES

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

Dated: March , 2002

OSTEOTECH, INC.

By: /s/Richard W. Bauer  
Richard W. Bauer  
President, Chief Executive Officer  
(Principal Executive Officer) and Director

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/DONALD D. JOHNSTON</u> Donald D. Johnston	Chairman of the Board of Directors	March 26, 2002
<u>/s/RICHARD W. BAUER</u> Richard W. Bauer	President, Chief Executive Officer (Principal Executive Officer) and Director	March 26, 2002
<u>/s/MICHAEL J. JEFFRIES</u> Michael J. Jeffries	Executive Vice President Chief Financial Officer (Principal Financial Accounting Officer), Secretary and Director	March 26, 2002
<u>/s/KENNETH P. FALLON III</u> Kenneth P. Fallon III	Director	March 26, 2002
<u>/s/JOHN P. KOSTUIK</u> John P. Kostuik	Director	March 26, 2002
<u>/s/STEPHEN J. SOGIN</u> Stephen J. Sogin	Director	March 26, 2002

OSTEOTECH, INC. AND SUBSIDIARIES

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AND FINANCIAL STATEMENT SCHEDULE**

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All schedules, except for the one set forth above, have been omitted since the information required is included in the financial statements or accompanying notes or have been omitted as not applicable or not required.

## REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and  
Stockholders of Osteotech, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Osteotech Inc. and its subsidiaries (the "Company") at December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers LLP

Florham Park, New Jersey  
March 13, 2002

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
*(dollars in thousands)*

December 31,	2001	2000
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,192	\$ 10,923
Short-term investments		1,935
Accounts receivable, net of allowance of \$303 in 2001 and \$123 in 2000	15,093	13,503
Deferred processing costs	11,165	5,914
Inventories	8,803	3,584
Deferred income taxes	2,002	683
Prepaid expenses and other current assets	2,025	4,027
Total current assets	44,280	40,569
Property, plant and equipment, net	56,736	58,290
Goodwill, net of accumulated amortization of \$2,861 in 2001 and \$2,477 in 2000	2,910	3,294
Other assets	3,318	2,285
Total assets	\$107,244	\$104,438
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 17,311	\$ 11,345
Current maturities of long-term debt	2,530	101
Total current liabilities	19,841	11,446
Long-term debt	18,683	19,930
Other liabilities	934	1,211
Total liabilities	39,458	32,587
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,675,595 shares authorized; no shares issued or outstanding		
Common stock, \$.01 par value; 70,000,000 shares authorized; issued and outstanding 14,098,264 shares in 2001 and 13,989,307 shares in 2000	140	138
Additional paid-in capital	47,076	46,577
Accumulated other comprehensive loss	(653)	(497)
Retained earnings	21,223	25,633
Total stockholders' equity	67,786	71,851
Total liabilities and stockholders' equity	\$107,244	\$104,438

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

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
*(dollars in thousands, except per share data)*

Year ended December 31,	2001	2000	1999
Net revenues:			
Service	\$72,811	\$72,546	\$72,418
Product	5,035	3,137	3,074
License fee and other revenue			118
	<u>77,846</u>	<u>75,683</u>	<u>75,610</u>
Cost of services	30,582	24,811	22,004
Cost of products	3,766	2,700	1,905
	<u>34,348</u>	<u>27,511</u>	<u>23,909</u>
Gross profit	43,498	48,172	51,701
Marketing, selling, and general and administrative	45,535	35,545	28,343
Research and development	4,599	5,772	5,506
	<u>50,134</u>	<u>41,317</u>	<u>33,849</u>
Income from litigation settlement		1,000	2,000
Operating income (loss)	<u>(6,636)</u>	<u>7,855</u>	<u>19,852</u>
Other income (expense):			
Interest income	506	1,087	891
Interest expense	(406)	(14)	(62)
Other	28	(26)	203
	<u>128</u>	<u>1,047</u>	<u>1,032</u>
Income (loss) before income taxes	(6,508)	8,902	20,884
Income tax provision (benefit)	(2,098)	4,074	8,533
Net income (loss)	<u>\$ (4,410)</u>	<u>\$ 4,828</u>	<u>\$12,351</u>
Net income (loss) per share:			
Basic	\$ (.31)	\$ .34	\$ .88
Diluted	\$ (.31)	\$ .34	\$ .84
Shares used in computing net income (loss) per share:			
Basic	14,030,623	14,057,931	14,024,468
Diluted	14,030,623	14,335,641	14,618,786

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

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
*(dollars in thousands)*

Years ended December 31, 2001, 2000, and 1999

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Retained Earnings	Total Stockholders' Equity
	Shares	Amount		Income (Loss)	Earnings		
<b>Balance at December 31, 1998</b>	13,380,291	\$ 133	\$ 37,332	\$ 11	\$ 8,454	\$ 45,930	
Net income					12,351	12,351	
Currency translation adjustments				(387)		(387)	
Total comprehensive income							
Exercise of stock options	791,512	7	4,553			11,964	
Common stock issued pursuant to employee stock purchase plan	22,323		410			410	
Tax benefits related to stock options			6,542			6,542	
<b>Balance at December 31, 1999</b>	14,194,126	140	48,837	(376)	20,805	69,406	
Net income					4,828	4,828	
Currency translation adjustments				(121)		(121)	
Total comprehensive income							
Exercise of stock options	74,261	1	304			418	
Common stock issued pursuant to employee stock purchase plan	51,420		418			418	
Repurchase of common stock	(330,500)	(3)	(3,121)			(3,124)	
Tax benefits related to stock options			139			139	
<b>Balance at December 31, 2000</b>	13,989,307	138	46,577	(497)	25,633	71,851	
Net loss					(4,410)	(4,410)	
Currency translation adjustments				(156)		(156)	
Total comprehensive loss							
Exercise of stock options	10,138	1	41			42	
Common stock issued pursuant to employee stock purchase plan	98,819	1	458			459	
<b>Balance at December 31, 2001</b>	14,098,264	\$ 140	\$ 47,076	\$ (653)	\$ 21,223	\$ 67,786	

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

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(dollars in thousands)*

Year ended December 31,	2001	2000	1999
<b>Cash Flow From Operating Activities</b>			
Net income (loss)	\$ (4,410)	\$ 4,828	\$ 12,351
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	8,598	4,597	3,298
Deferred income taxes	(2,937)	775	(121)
Income tax benefit related to stock options		139	6,542
Changes in assets and liabilities:			
Accounts receivable	(2,146)	1,629	(2,876)
Inventories	(5,073)	(218)	(1,393)
Deferred processing costs	(5,390)	(604)	(2,690)
Prepaid expenses and other current assets	2,459	764	(2,457)
Accounts payable and other liabilities	6,880	(1,735)	1,805
Net cash provided by (used in) operating activities	(2,019)	10,175	14,459
<b>Cash Flow From Investing Activities</b>			
Capital expenditures	(8,955)	(28,343)	(18,743)
Acquisition of business			(1,523)
Proceeds from sale of investments	5,860	5,888	10,610
Purchases of investments	(3,925)	(3,877)	(11,634)
Proceeds from the sale of land	1,500		
Other, net	160	(796)	(883)
Net cash used in investing activities	(5,360)	(27,128)	(22,173)
<b>Cash Flow From Financing Activities</b>			
Proceeds from issuance of common stock	499	723	4,970
Repurchase of common stock		(3,124)	
Proceeds from issuance of notes payable			116
Principal payments on notes payable			(725)
Proceeds from issuance of long-term debt	1,468	13,672	6,359
Principal payments on long-term debt and obligations under capital leases	(340)		(1,332)
Net cash provided by financing activities	1,627	11,271	9,388
Effect of exchange rate changes on cash	21	(165)	(23)
Net increase (decrease) in cash and cash equivalents	(5,731)	(5,847)	1,651
Cash and cash equivalents at beginning of year	10,923	16,770	15,119
Cash and cash equivalents at end of year	\$ 5,192	\$ 10,923	\$ 16,770

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

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS**

Osteotech, Inc. (the "Company") provides services and develops, markets and sells products to the orthopaedic, neurological, oral/maxillofacial, dental and general surgery markets in the United States and Europe. The Company's current technology, products and services, and those under development, are focused primarily on the repair and healing of the musculoskeletal system. The Company is engaged in the processing of human bone and bone connective tissue (collectively, "allograft bone tissue") used for transplantation. The Company also develops and processes new forms of tissue for use in a variety of surgical procedures. While the Company performs the medical education to teach surgeons about the uses of these tissue forms, the tissue forms are generally distributed to hospitals by the Company's tissue bank clients.

Commencing in the first half of 2001, and expanding in the second half, the Company began to distribute tissue forms directly to hospitals. The Company expects to continue to expand the direct distribution efforts to hospitals in 2002 and beyond. This change in distribution methodology has impacted liquidity and cash flow. The Company has had to make additional investments in inventories and deferred processing costs to support the direct distribution efforts, and expects to make additional investments in inventory and deferred processing costs, as necessary, to support the efforts to expand direct distribution. For the year ended December 31, 2001, the Company experienced a substantial decrease in available cash and cash equivalents due to continued investments in the business. The Company expects to continue to make investments in the business to support the direct distribution efforts and future programs and initiatives, which may further deplete available cash balances. The Company believes that available cash and cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet forecasted cash needs in 2002. The Company's future liquidity and capital requirements will depend upon numerous factors, including:

- additional investments in inventories and deferred processing costs to support direct distribution efforts;
- the progress of product development programs and the need and associated costs relating to regulatory approvals which may be needed to commercialize some of the products under development;
- the resources to be devoted to the development, manufacture and marketing of services and products; and
- the defense and outcome of pending litigation, including any outcomes which are adverse to the Company, to the extent not covered by product liability or other insurance. In this regard there are two patent lawsuits that are scheduled for trial in 2002 and in which any damages that may be awarded against the Company are not covered by insurance.

The Company intends to seek additional funding to meet the needs of the long-term strategic plan and to re-build cash reserves. The Company can provide no assurance that such additional funds will be available, or if available, that such funds will be available on favorable terms.

The Company has two primary operating segments: the Grafton<sup>®</sup> Demineralized Bone Matrix (DBM) Segment (the "Grafton<sup>®</sup> DBM Segment") and Base Allograft Bone Tissue Segment (the "Base Tissue Segment"). In addition to these two primary segments, the Company markets and distributes metal spinal implant products, and processes, markets and distributes bovine bone tissue products outside of the United States. The Company also provides ceramic and titanium plasma spray coating services and ceramic products used as bone graft substitutes to orthopaedic and dental implant manufacturers.

OSTEOTECH, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Critical Accounting Policies and Estimates

The preparation of these financial statements requires the Company to make estimates and judgements that effect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates the estimates and may adjust them based upon the latest information available. These estimates generally include those related to product returns, bad debts, inventories, deferred processing costs, intangible assets, income taxes and contingencies and litigation. The Company bases the estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The Company believes the following critical accounting policies affect the more significant judgements and estimates used in the preparation of the consolidated financial statements.

- The Company maintains allowances for doubtful accounts primarily for its direct distribution accounts for estimated losses resulting from the inability of these customers to make required payments. If the financial condition of these customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.
- The Company records reductions to revenue for estimated product and allograft tissue forms returns based upon historical experience. If future returns are less than historical experience, reduction in estimated reserves would increase revenue. Alternatively, should returns exceed historical experience, additional allowances would be required, which would reduce revenue.
- The Company writes down inventory and deferred processing costs for estimated obsolescence, or unmarketable products and allograft tissue forms equal to the difference between cost and the estimated market value based upon assumptions about future demand and market conditions. Obsolescence could occur from numerous factors, including, but not limited to, the competitive nature of the market, technological change and changes in surgeon preference. If actual market conditions are less favorable than those projected by management, additional write-downs may be required.
- The Company depreciates/amortizes its property, plant and equipment based upon the Company's estimate of the respective asset's useful life. In addition, the Company evaluates impairments of its property, plant and equipment based upon an analysis of estimated undiscounted future cash flows. If the Company determines that a change is required in the useful life of an asset, future depreciation/amortization is adjusted accordingly. Alternatively, should the Company determine that an asset has been impaired, an adjustment would be charged to income based on its fair market value, or discounted cash flows if the fair market value is not readily determinable, reducing income in that period.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

- The Company records a valuation allowance to reduce deferred tax assets to the amount that is more likely than not to be realized. While the Company has considered future taxable income, in the event that the Company would be able to realize the deferred tax assets in the future in excess of the net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. Likewise, should the Company determine that the Company would not be able to realize all or part of the net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to income in the period such determination was made.
- The Company accrues current and future tax liabilities based upon levels of taxable income, tax planning strategies and assessments of the timing of taxability of tax attributes. While the Company has considered current tax laws in establishing tax liabilities, in the event the Company was to settle the tax liabilities for less than amounts accrued the Company would increase income in the period such determination was made. Should the Company determine it would cost more to settle the tax liabilities, an adjustment would be charged to income thus reducing income in that period.

**Consolidated Financial Statements**

The consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries. All intercompany transactions and balances are eliminated in consolidation.

**Revenue Recognition**

The Company principally derives revenue from allograft bone tissue processing services and other non-allograft tissue products and services. Revenues for products and services, net of trade discounts and allowances, are recognized once delivery has occurred provided that persuasive evidence of an arrangement exists, the price is fixed or determinable, and collectibility is reasonably assured. For allograft tissue, delivery is considered to have occurred when risk of loss has transferred to the Company's clients or customers, primarily upon shipment of such allograft tissue to customers or clients, except for consigned inventory, when delivery is considered to have occurred when the allograft tissue is consumed by the customer. For non-allograft tissue products and services, delivery is considered to have occurred when title and risk of loss have transferred to the Company's customers primarily upon shipment of non-allograft products to customers or clients.

**Cash Equivalents and Short-Term Investments**

The Company considers all highly liquid investments with original maturities of three months or less, when purchased, to be cash equivalents. Investments with maturities in excess of three months but less than one year are classified as short-term investments and are stated at cost, net of any unamortized premiums or discounts, which approximates fair value.

**Deferred Processing Costs**

Deferred processing costs are stated at the lower of cost or market, with cost determined under the first-in, first-out method. Costs related to allograft bone tissue processing are deferred until the processed allograft bone tissue is released from final quality assurance testing and shipped to clients or customers.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Inventories**

Inventories are stated at the lower of cost or market, with cost determined under the first-in, first-out method. Inventories consist of supplies, which principally support the Company's two primary operating segments, and raw materials and finished goods, which principally support the Company's product lines included in Other.

**Property, Plant and Equipment**

Property, plant and equipment are stated at cost. Major renewals and betterments are capitalized while maintenance and repairs are expensed as incurred. Interest, if any, is capitalized in connection with the construction of major facilities. The capitalized interest is recorded as part of the underlying asset and is amortized over the asset's estimated useful life. The cost of leasehold improvements is amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset. Depreciation is computed on the straight-line method over the following estimated useful lives of the assets:

Building and improvements	10 to 20 years
Machinery and equipment	5 to 10 years
Computer hardware and software	5 years
Office equipment, furniture and fixtures	5 years
Spinal Instruments	3 years

When depreciable assets are retired or sold, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in other income (expense) in the consolidated statement of operations.

Whenever events and circumstances indicate that the carrying value of an asset may not be recoverable, the Company reviews the asset's carrying value for impairment on an analysis of undiscounted cash flows. If an impairment is determined, the assets carrying value is written down to fair market value, or discounted cash flows if fair market value is not readily determinable.

**Goodwill**

Goodwill is being amortized on a straight-line basis over 15 years. It is the Company's policy to periodically review and evaluate whether there has been an impairment in the value of goodwill. Factors considered in the valuation include current operating results, trends, prospects and anticipated undiscounted future cash flows.

Beginning in 2002, pursuant to the provisions of SFAS No. 142, the Company will no longer amortize goodwill. See Note 3, "Recent Accounting Pronouncements".

**Translation of Foreign Currency**

Assets and liabilities of foreign subsidiaries are translated at rates of exchange in effect at the close of the period. Revenues and expenses are translated at the weighted average exchange rates during the period. Translation gains and losses are included in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity. Foreign currency transaction gains and losses are included in other income (expense).

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Concentrations of Credit Risk**

The Company invests the majority of its excess cash in U.S. Government-backed securities and investment grade commercial paper of major U.S. corporations. The Company does not believe it is exposed to any significant credit risk on its cash equivalents and short-term investments.

The Company provides credit, in the normal course of business, to its clients and customers. In addition, the Company performs on-going credit evaluations of its clients' and customers' financial condition, but generally does not require collateral in support of available credit. The Company maintains an allowance for doubtful accounts and charges actual losses to the allowance when incurred. The Company has two customers who together account for 75%, 90% and 94% of revenues in 2001, 2000, and 1999, respectively. As of December 31, 2001 and 2000, these two customers together accounted for 66% and 78%, respectively, of outstanding accounts receivable.

**Fair Value of Financial Instruments**

The carrying value of financial instruments, including accounts receivable, accounts payable and other accrued expenses, approximate their fair values. The carrying value of amounts outstanding under the credit facility approximates fair value because the debt is subject to short-term variable interest rates that were reflective of market rates of interest.

**Reclassifications**

Certain prior year amounts within the financial statements have been reclassified to conform to the 2001 presentation.

**3. RECENT ACCOUNTING PRONOUNCEMENTS**

In June, 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets". As a result of SFAS No. 141, all acquisitions completed after June 30, 2001 are to be accounted for using the purchase method of accounting. The Company has had no such transactions in 2001. SFAS No. 142 primarily addresses the accounting of goodwill and intangible assets subsequent to their initial recognition. SFAS No. 142 requires that goodwill and indefinite life intangible assets no longer be amortized but rather be tested for impairment annually. Intangible assets with a finite life shall continue to be amortized over their estimated useful life. SFAS No. 141 is effective for business combinations initiated after June 30, 2001. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. SFAS No. 142 requires that the elimination of amortization is to be applied on a prospective basis and prior periods are not to be restated. SFAS No. 142 requires that goodwill be tested annually for impairment using a two-step process. The first step is to identify a potential impairment and, in transition, this step is to be measured as of the beginning of the fiscal year and must be completed within six months of adoption. The second step, which must be completed by the end of the Company's fiscal year, measures the amount of the impairment loss, if any, as of the beginning of the year of adoption.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**3. RECENT ACCOUNTING PRONOUNCEMENTS (continued)**

In June, 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 establishes accounting standards for the recognition and measurement of a liability associated with the retirement of a tangible long-lived asset that results from the acquisition, construction, or development and/or normal operations of a long-lived asset. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002.

In August, 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets" which addresses financial accounting and reporting for the impairment or disposal of long-lived assets and discontinued operations. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001.

The Company is currently evaluating the impact of these pronouncements to determine the effect they may have on its consolidated financial position and results of operations. Under the provisions of SFAS No. 142, beginning in 2002 the Company will no longer amortize goodwill. Amortization of goodwill in 2001 was \$384,000.

**4. DEFERRED PROCESSING COSTS**

Deferred processing costs consist of the following at December 31:

<i>(in thousands)</i>	2001	2000
Unprocessed donor tissue to be distributed by the Company	\$ 492	\$ 3
Tissue in process	2,936	2,646
Implantable donor tissue to be distributed by the Company	5,359	424
Implantable donor tissue held for clients	2,378	2,841
	<u>\$11,165</u>	<u>\$ 5,914</u>

**5. INVENTORIES**

Inventories consist of the following at December 31:

<i>(in thousands)</i>	2001	2000
Supplies	\$ 245	\$ 202
Raw materials	784	891
Finished goods	7,774	2,491
	<u>\$ 8,803</u>	<u>\$ 3,584</u>

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**6. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of the following at December 31:

<i>(in thousands)</i>	2001	2000
Land	\$ 811	\$ 2,262
Building and improvements	13,821	279
Machinery and equipment	24,695	22,139
Computer hardware and software	4,264	4,165
Office equipment, furniture and fixtures	5,839	3,483
Spinal instruments	3,563	2,710
Leasehold improvements	7,850	6,741
Construction in progress	20,957	33,199
	<u>81,800</u>	<u>74,978</u>
Less accumulated depreciation and amortization	25,064	16,688
	<u>\$56,736</u>	<u>\$58,290</u>

During the fourth quarter 1998, the Company commenced construction of a new processing facility in Eatontown, New Jersey. At December 31, 2001 and 2000, approximately \$37,922,000 and \$32,197,000, respectively, had been incurred, primarily for construction of the facility, production equipment and furniture and fixtures, of which approximately \$1,769,000 and \$761,000, respectively, represents capitalized interest.

In 2001, the Company recorded additional provisions of \$2,287,000 for machinery and equipment that will no longer be utilized in the processing of allograft tissue and \$1,190,000 primarily for excess spinal instruments.

**7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES**

Accounts payable and accrued liabilities consist of the following at December 31:

<i>(in thousands)</i>	2001	2000
Trade accounts payable	\$ 8,802	\$ 3,315
Accrued compensation	878	566
Accrued professional fees	1,333	409
Accrued taxes payable	3,100	3,110
Other accrued liabilities	3,198	3,945
	<u>\$ 17,311</u>	<u>\$11,345</u>

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**8. LEASING TRANSACTIONS**

The Company leases office and production facilities and equipment under various operating lease agreements which have non-cancelable terms through October, 2008. The leases for office and production facilities include renewal provisions at the Company's option. Additionally, certain of the leases contain fair value purchase options.

Future minimum lease commitments as of December 31, 2001 are as follows:

<u>Year</u> <i>(in thousands)</i>	<u>Operating Leases</u>
2002	\$ 996
2003	925
2004	907
2005	592
2006 and thereafter	1,652
Total minimum lease payments	<u>\$ 5,072</u>

Rental expense was \$1,186,000, \$1,147,000, and \$1,157,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

**9. DEBT AND FINANCING ARRANGEMENTS**

The Company has a Credit Facility which includes: a \$5,000,000 revolving line of credit, a building mortgage loan and an equipment line of credit, the terms of which have been amended in March, 2002. See the last paragraph of this Note 9.

Prior to March, 2002, the revolving line of credit was committed through May 31, 2002. Interest was payable monthly on the outstanding amount. In the absence of default, the Company had the option to convert the revolving line of credit to a term loan and the outstanding unpaid balance would have been repayable in forty-eight equal monthly installments of principal together with accrued interest. Prior to conversion, the revolving line of credit bore interest at the prime rate (5.00% at December 31, 2001) minus .75% or the London Interbank Offered Rate ("LIBOR") plus 1.75%. After conversion, interest accrued at the four year United States Treasury Note Rate prior to conversion plus 1.75%. A facility fee of .25% was payable on the unused portion of the revolving loan. As of December 31, 2001, no amounts were outstanding under this facility and the full amount of the revolving line of credit is available to the Company.

The mortgage loan was drawn in December, 2000 and is collateralized by the building which houses the Company's new allograft tissue processing facility and the land on which the building is located. The mortgage loan is repayable in 120 equal monthly installments of principal and interest based on a twenty-year mortgage amortization schedule. Upon the 120<sup>th</sup> payment, the remaining amount of the unpaid principal will be due and payable. Interest is payable at a fixed rate of 7.38%.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. DEBT AND FINANCING ARRANGEMENTS (continued)**

The equipment line of credit is collateralized by equipment and other capital expenditures purchased using the proceeds of such line. The equipment line of credit converted to a term loan on September 10, 2001. The equipment term loan is repayable in equal monthly installments of principal plus interest based on a seven-year amortization schedule. Prior to conversion, interest only was payable monthly under the equipment line of credit at the prime rate minus .50% or LIBOR plus 1.75%. Upon conversion, interest on the term loan changed to the prime rate or LIBOR plus 2.25%.

Pursuant to the terms of the Credit Facility, the Company is required to meet certain financial covenants regarding minimum working capital, tangible net worth and interest coverage. In addition, the Credit Facility contains limitations on sales of assets other than in the ordinary course of business and additional indebtedness. The Company either complied with or obtained the necessary waivers from its lender regarding these covenants.

The effective weighted average interest rate for borrowings under the Credit Facility was 6.60% in 2001 and 8.20% in 2000.

Long-term debt consists of the following at December 31:

<i>(in thousands)</i>	2001	2000
Domestic revolving line of credit		
Domestic bank equipment term loan, repayable in monthly principal payments of \$202 plus interest through November, 2008	\$16,798	\$15,531
Domestic building mortgage loan, repayable in monthly installments of \$37, including interest through December 2010 with a balloon payment of \$3,087 due December, 2010.	4,415	4,500
	21,213	20,031
Less current portion	2,530	101
	<u>\$18,683</u>	<u>\$19,930</u>

Aggregate maturities of long-term debt for the next five years are as follows: 2002, \$2,530; 2003, \$2,540; 2004, \$2,550; 2005, \$2,560; 2006, \$2,571; thereafter, \$8,462.

In March, 2002, the Company amended its domestic Credit Facility to extend the maturity date of the revolving line of credit to April 30, 2004. The amendment to the Credit Facility establishes a variable interest rate on all three parts of the Credit Facility that changes the interest rate to range from prime minus .25% to prime plus 1.50%, or from LIBOR plus 2.25% to LIBOR plus 4.0% based upon a leverage ratio as defined. Under the terms of the amendment, the new initial interest rate, which initially is retroactive to January 1, 2002 and is effective through November 14, 2002 is prime plus 1.50% or LIBOR plus 4.0%, whichever is chosen by the Company. Thereafter, the interest rate will be in the range described above. In certain circumstances, as defined in the amendment, the interest rate on the Credit Facility may increase up to an additional .35%.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**9. DEBT AND FINANCING ARRANGEMENTS (continued)**

The Credit Facility, as detailed in the amendment, will be collateralized by domestic accounts receivable, domestic inventories, the new allograft tissue processing facility, including all equipment and improvements therein and a pledge of 65% of the Company's ownership in its foreign subsidiaries. The amendment imposes certain restrictive operating and financial covenants on the Company. The amendment established additional covenants including a restriction on the payment of cash dividends, a restriction on incurring or maintaining additional indebtedness, a restriction on selling assets or engaging in mergers or acquisitions and limitations on cash advances to the Company's foreign operations and investments. The amendment also resets the interest coverage ratio, which the Company did not comply with for the year ended December 31, 2001, but the bank permanently waived such non-compliance. The amendment also includes subjective acceleration provisions. Such provisions are based upon, in the reasonable opinion of the bank, the occurrence of any adverse or material change in the condition or affairs, financial or otherwise, of the Company which impairs the interests of the bank. The bank also has the right to approve, in advance, the form and substance of any equity capital transaction, except for a common stock transaction resulting in the issuance of less than 20% of the total issued and outstanding capital stock of the Company as of the date of such transaction.

Failure to comply with any of these restrictions could result in a default under this loan facility. Following a default, the bank may determine not to make any additional financing available under the revolving line of credit, could accelerate the indebtedness under the revolving credit facility, the equipment loan and/or the mortgage, and could foreclose on the real and personal property securing the loans.

**10. INCOME TAXES**

The income tax provision (benefit) at December 31 is summarized as follows:

<i>(in thousands)</i>	2001	2000	1999
Current:			
Federal	\$ 265	\$2,897	\$7,307
State	574	402	1,347
	839	3,299	8,654
Deferred:			
Federal	(1,921)	551	(148)
State	(1,016)	224	27
	(2,937)	775	(121)
Income tax provision (benefit)	\$ (2,098)	\$4,074	\$8,533

The difference between income tax provision (benefit) and the expected tax which would result from the use of the Federal statutory income tax rate is as follows:

<i>(in thousands)</i>	2001	2000	1999
Computed tax at statutory Federal rate	\$ (2,213)	\$3,027	\$7,309
State income taxes, net of Federal benefit	(292)	413	1,129
Foreign losses for which no tax benefit is currently available	606	660	456
Other	(199)	(26)	(361)
Income tax provision (benefit)	\$ (2,098)	\$4,074	\$8,533

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**10. INCOME TAXES (continued)**

Loss before income taxes from foreign operations was \$882,000 in 2001, \$1,151,000 in 2000, and \$591,000 in 1999. The losses before income taxes from foreign operations negatively impact the Company's effective income tax rate due to the non-recognition of such losses for tax purposes and the need for a valuation allowance in the foreign jurisdictions.

The components of the deferred tax assets and deferred tax liabilities are as follows at December 31:

<i>(in thousands)</i>	2001	2000
<b>Deferred Tax Assets:</b>		
Net operating loss carryforwards		
Federal	\$ 281	\$ 275
Foreign	2,286	1,736
State	235	24
Tax credits	1,059	62
Other, principally reserves	2,207	674
	6,068	2,771
Less valuation allowance	2,614	2,058
<b>Deferred tax assets</b>	<b>3,454</b>	<b>713</b>
<b>Deferred Tax Liabilities:</b>		
Other	678	951
<b>Deferred tax liabilities</b>	<b>678</b>	<b>951</b>
<b>Net deferred tax asset (liability)</b>	<b>\$ 2,776</b>	<b>\$ (238)</b>

The Company's valuation allowance results principally from foreign losses and related net operating loss carryforwards for which the realization of future tax benefits is uncertain. Foreign net operating loss carryforwards aggregate \$5,818,000 (\$525,000 with no expiration date; \$5,293,000 expiring 2004 through 2009). Although realization is not assured, the Company has concluded that it is more likely than not that the remaining deferred tax assets will be realized based on the scheduling of deferred tax liabilities and projected taxable income.

At December 31, the Company had prepaid Federal and state taxes of approximately \$1,331,000 in 2001 and \$1,552,000 in 2000.

**11. COMMITMENTS AND CONTINGENCIES**

**Service Agreements**

The Company is the processor of allograft bone tissue for national and international clients. The Company provides these processing services pursuant to long-term service agreements. The Company's agreements with its clients generally provide for cross-indemnification against liability arising out of performance of the agreements.

The Company entered into an exclusive ten-year processing agreement with one of its major allograft bone tissue processing clients, the American Red Cross Tissue Services ("ARC"). The agreement was effective January 1, 1997.

OSTEOTECH, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. COMMITMENTS AND CONTINGENCIES (continued)

In September, 2000, the Company entered into a five-year agreement with the Musculoskeletal Transplant Foundation ("MTF"). The agreement expires on August 31, 2005, and provides that either party has the right at any time to terminate the agreement upon six months prior written notice. Neither party has exercised their rights under such provision. Under the agreement, MTF is not required to exclusively provide all donor tissue it recovers to the Company for processing. The Company is currently in litigation with MTF. (See "Litigation" - "Musculoskeletal Transplant Foundation v. Osteotech, Inc.").

Effective January 4, 2002, the Company entered into a five-year agreement with LifeNet. Under the terms of the agreement, the Company will process allograft bone tissue provided by LifeNet into the Company's broad line of Bio-d<sup>®</sup> and Graftech<sup>®</sup> Bio-implants. The agreement also provides the future opportunity for the Company to process LifeNet labeled tissue carrier products. Such tissue carrier products would be marketed through a mutually agreed upon third party.

Customers of the Company's other products and services generally purchase such products and services pursuant to purchase orders or non-exclusive supply agreements which are cancelable at any time by either party.

Purchase Commitments

In September, 2000, the Company entered into a two-year non-cancelable purchase order with Heinrich C. Ulrich, K.G. ("Ulrich") for the purchase of \$3,000,000 of inventory of a spinal vertebral body replacement system ("VBR System"), which the Company began marketing in the United States in the first quarter of 2001. The Company purchased \$2,117,000 and \$878,000 under the agreement in 2001 and 2000, respectively.

In February, 2001, the Company entered into an exclusive distribution agreement with Alphatec Manufacturing, Inc. ("Alphatec") to market and distribute a pedicle screw system and a cervical plating system in the United States and Canada. The term of the agreement is two years from the date of completion of the initial order, which was in February, 2002. The agreement automatically renews for additional two-year terms unless terminated in writing by either party six months prior to expiration of the then current two-year term. The Company has agreed to purchase \$6,000,000 of inventory during the first two years of the agreement, and \$8,000,000 during the second two-year term, if the agreement renews. Purchase commitments for each successive renewal period would be negotiated prior to those renewals. If the Company fails to make the minimum purchases in any period, the Company will pay Alphatec a penalty payment equal to 50% of the shortfall. The Company has purchased \$3,046,000 of inventory under the agreement in 2001 in advance of the beginning of the two-year commitment, and must purchase an additional \$2,954,000 in 2002 and 2003 to meet the obligation under the first two-year commitment.

Loan Receivable

In February, 2001, the Company entered into a Loan Agreement with the American Tissue Services Foundation ("ATSF"), a not-for-profit tissue recovery organization. The Loan Agreement expires on December 31, 2010. Pursuant to the Loan Agreement, loans made by the Company mature five (5) years from the date each loan is made and bear interest at a rate per annum equal to the five year United States Treasury Bill Rate plus one percent (1%).

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**11. COMMITMENTS AND CONTINGENCIES (continued)**

Interest is payable on a quarterly basis. In February, 2002, the Company and ATSF amended the Loan Agreement to allow ATSF to borrow an aggregate of \$2,750,000 from the Company. As of December 31, 2001, the Company had loaned ATSF an aggregate of \$2,208,000 at an average interest rate of 5.57%.

The funds loaned to ATSF are being utilized by ATSF to fund its operations. The Company is providing a reserve against these loans equivalent to the accumulated operating losses of ATSF until such time that ATSF is able to generate positive cash flow from operations. For the year ended December 31, 2001, the Company has provided reserves totaling \$2,001,000 against these loans, which charge is included in marketing, selling, general and administrative expenses. The Company expects that it will loan \$250,000 to ATSF in 2002 and expects to record additional reserves against these loans. Michael J. Jeffries, the Company's Executive Vice President and Chief Financial Officer, is one of the three members of ATSF's Board of Directors. ATSF is a not-for-profit corporation, and neither Mr. Jeffries nor the Company owns any equity or any other interest in ATSF. Mr. Jeffries receives no compensation from ATSF.

The Company has entered into an exclusive fifteen-year processing and distribution agreement with ATSF effective December 7, 2000. Pursuant to the agreement, the Company has the right to process and distribute all ATSF recovered tissue. As of December 31, 2001, the Company owed ATSF \$378,000 for tissue recovery reimbursement fees, which represented the sum total of all tissue recovery reimbursement fees for 2001.

**License and Option Agreement**

In June, 1997, the Company entered into an exclusive worldwide license agreement for its proprietary PolyActive™ polymer biomaterial technology and patents with IsoTis BV ("IsoTis"), The Netherlands. IsoTis has an option to acquire the technology for approximately 1,815,000 euros (approximately \$1,618,000 at the December 31, 2001 exchange rate) commencing in the third year of the agreement and extending through the sixth year of the agreement. In accordance with the license agreement, no license fee was received in 2001 and 2000 and license fee revenue of DFL 250,000, or approximately \$118,000, was received in 1999.

Throughout the term of the agreement, which is the longer of ten years from the first commercial sale of product or the life of the patents, the Company will receive a royalty of 5% of net sales, declining to 2% of net sales subsequent to the time the option to purchase the technology is exercised. Further, the agreement requires IsoTis to achieve certain milestones during the first three years of the agreement. Failure to do so will result in its loss of exclusive rights to the patents and technology. Through December 31, 2001, IsoTis has achieved all milestones associated with the agreement. The Company has not earned any royalties under this agreement in 2001, 2000 or 1999.

11. COMMITMENTS AND CONTINGENCIES (continued)

Litigation

*GenSci Regeneration Laboratories, Inc. v. Osteotech, Inc.; Osteotech, Inc. v. GenSci Regeneration Sciences, Inc.*

In January, 1998, the Company filed a patent infringement action against GenSci Regeneration Laboratories, Inc. ("GenSci Labs") and GenSci Regeneration Sciences, Inc. ("GenSci Sciences", collectively, "GenSci") alleging that GenSci violated claims of one of the patents involving the Company's Grafton<sup>®</sup> Demineralized Bone Matrix (DBM) process. Approximately two weeks after the Company's filing, GenSci Labs filed a suit against the Company alleging that the Company's Grafton<sup>®</sup> DBM Flex tissue form infringes two patents assigned to GenSci Labs in addition to allegations against us for tortious interference with a business expectancy, negligent interference with a prospective economic advantage and inducing breach of contract and seeking a declaratory judgment of the invalidity of the Company's patents U.S. Patent Nos. 5,284,655 (the "655 Patent") and 5,290,558 (the "558 Patent") covering Grafton<sup>®</sup> DBM. In February, 1998, GenSci Labs amended its complaint alleging essentially the same causes of action but adding a third patent to the allegation of patent infringement. In August, 1998, the actions were consolidated into one case before the United States District Court for the Central District of California. In April, 2000, GenSci Labs and GenSci Sciences agreed to dismiss with prejudice all of GenSci's patent infringement claims against the Company. Between September, 1998 and September, 2001, there were numerous amendments to the complaints of both parties and both parties filed numerous motions with the Court.

On October 31, 2001, the trial commenced in the United States District Court for the Central District of California. In November, 2001, the jury returned a verdict that the 558 Patent and the 655 Patent are valid and that GenSci infringed on both patents through their sales of DynaGraft<sup>™</sup> Gel and Putty products. In arriving at its verdict, the jury rejected all of GenSci's defenses.

In December 2001, the Company was awarded damages in the amount of \$17,533,634 for GenSci's infringement of its patents. This damage award will be reduced by the \$3.0 million previously paid by DePuy in 2000 and 1999 in settlement of the Company's claims against DePuy in this lawsuit. The Company has not recognized any portion of the net award of \$14,533,634 in its financial statements. On December 21, 2001, GenSci filed for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code.

*GenSci Orthobiologics, Inc. v. Osteotech, Inc.*

On March 6, 2000, GenSci Orthobiologics, Inc. ("GenSci") filed a complaint in the United States District Court for the Central District of California against the Company, alleging unlawful monopolization, attempt to monopolize the market for demineralized bone matrix and for entering agreements in restraint of trade, in violation of Sections 1 and 2 of the Sherman Antitrust Act and Section 3 of the Clayton Act; and that the Company engaged in unlawful and unfair business practices in violation of Section 17200 of the California Unfair Competition Law. GenSci has alleged that the Company has monopoly power in the market for demineralized bone matrix products in the United States, and has engaged in anticompetitive conduct by improperly asserting its patents through patent infringement actions, seeking to have the Food and Drug Administration remove certain of GenSci's products from the market, restricting competitors' access to raw materials, interfering with GenSci's arrangements to manufacture demineralized bone matrix implants, interfering with GenSci's marketing and distribution arrangements, and disparaging GenSci's products.

OSTEOTECH, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. COMMITMENTS AND CONTINGENCIES (continued)

GenSci seeks compensatory, incidental, consequential, and punitive damages in an unspecified amount, and injunctive relief to stop the Company from restricting the tissue banks for which it processes tissue from supplying processed demineralized bone matrix to the Company's competitors and distributing the demineralized bone matrix implant products of the Company's competitors. Certain of these allegations had previously been asserted by GenSci in its patent litigation with the Company in the Central District of California federal court.

In April, 2000, the Company reached an agreement with GenSci whereby tort claims that were dismissed from the patent litigation would be transferred to this action and this action was stayed pending completion of the Company's patent infringement case against GenSci. This case has remained stayed.

The Company believes the claims made in this lawsuit are without merit and intends to vigorously defend against these claims.

*Osteotech, Inc. v. GenSci Orthobiologics, Inc.*

On October 25, 2000, the Company filed suit against GenSci Orthobiologics, Inc. ("GenSci"), in the United States District Court for the Central District of California, alleging that GenSci's demineralized bone matrix materials sold under the name Orthoblast, infringe the Company's U.S. Patent No. 5,290,558 and infringe the re-examined claims of the Company's U.S. Patent No. 5,676,146. The Company's complaint seeks injunctive relief, treble damages, costs and attorneys' fees.

In its Second Amended Answer and Counterclaim filed in March, 2001, GenSci denies infringement, asserts a number of affirmative defenses, and asserts a counterclaim seeking a declaratory judgment that the patents-in-suit are invalid, not infringed and/or unenforceable, together with costs and attorneys' fees.

The Company intends to pursue its claims against GenSci and vigorously defend against the counterclaims.

*"O" Company, Inc. v. Osteotech, Inc.*

In July, 1998, a complaint was filed against the Company in the Second Judicial District Court, Bernalillo County, New Mexico, which alleges negligence, strict liability, breach of warranties, negligent misrepresentation, fraud, and violation of the New Mexico Unfair Trade Practices Act arising from allegedly defective dental implant coating and coating services provided to plaintiffs by a subsidiary of the Company, Cam Implants BV. Plaintiffs have demanded unspecified monetary damages. In August, 1998, the Company removed this action to the United States District Court for the District of New Mexico and filed and served its answer, denying any and all liability in this action, and moved to dismiss five of the seven claims alleged against it. In March, 1999, the court dismissed with prejudice the plaintiff's negligence and strict liability claims. Remaining are claims for breach of warranties, negligent misrepresentation, fraud, and violation of the New Mexico Unfair Trade Practices Act. As to those claims, the Company has moved for summary judgment on the basis that all of the remaining claims are barred by their applicable statutes of limitations. At plaintiffs' request, the Court permitted limited discovery on the matters related to the statute of limitations issue, which is ongoing. As a result, the motion remains pending.

The Company believes that the claims made against it in this action are without merit and will continue to vigorously defend against such claims.

11. COMMITMENTS AND CONTINGENCIES (continued)

*University of Florida Tissue Bank, Inc. v. Osteotech, Inc.*

In February, 1999, a complaint was filed against the Company in the United States District Court for the Northern District of Florida. This action, which has been brought by plaintiffs, University of Florida Tissue Bank, Inc., Regeneration Technologies, Inc., Sofamor Danek Group, Inc., and Sofamor Danek L.P. alleges that the Company's bio-d™ Threaded Cortical Bone Dowel and Endodowel infringe on the claims of U.S. Patent Nos. 5,814,084, 4,950,296 and 6,096,081. The plaintiffs have sought injunctive relief and monetary damages of approximately \$1.5 million. In May, 1999, the Company filed its answer and counterclaim seeking declaratory judgment that the patents in question in this action are invalid and otherwise not infringed by the Company.

Trial in this action is currently scheduled for September, 2002.

Discovery on all of the claims asserted in this litigation is ongoing. The Company believes that the claims made against it in this action are without merit and will continue to vigorously defend against such claims.

*Medtronic Sofamor Danek, Inc., Sofamor Danek L.P. and Sofamor Holdings, Inc. v. Osteotech, Inc.*

In July, 1999, Medtronic Sofamor Danek Inc., Sofamor Danek L.P. and Sofamor Danek Holdings, Inc. (collectively, "Danek") sued the Company in the United States District Court for the Western District of Tennessee alleging that certain instruments and instrument sets relating to cortical bone dowel products, including the bio-d™ Threaded Cortical Bone Dowel and Endodowel, manufactured, sold and/or otherwise distributed by the Company infringe on certain claims of U.S. Patent Nos. 5,741,253, 5,484,437 and 6,096,038 which are owned by Danek. In addition to injunctive relief, the plaintiffs seek monetary damages of \$2.5 million. The Company filed its answer and counterclaims seeking a declaratory judgement that the patents in question in this action are invalid and otherwise not infringed by the Company.

Currently pending before the Court are both parties' motions for summary judgement. Trial in this matter has been scheduled for April, 2002.

The Company believes that the claims made against it in this action are without merit and will continue to vigorously defend against such claims.

*Regner v. Inland Eye & Tissue Bank of Redlands; Thacker v. Inland Eye & Tissue Bank of Redlands*

In May, 2000, Regner brought suit against the Company and fifteen or more other defendants in the Superior Court for the State of California, San Bernardino County. The suit seeks class action status and alleges a cause of action based on a violation of the California Business and Professional Code, as well as a number of common law causes of action, including negligence, deceit, and intentional and negligent infliction of emotional distress. Through dismissals, either by the Court or voluntarily by plaintiffs, only the California Business and Professional Code claims, which are based on allegations that defendants are engaging in the activity of buying or selling organs or tissue for valuable consideration or profit, and negligence claims remain. It appears that the plaintiff is seeking only injunctive relief with respect to their California Business and Professional Code claims. To the extent any of the other causes of action exist against the Company, the plaintiffs are seeking damages in an unspecified amount in addition to class certification.

OSTEOTECH, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. COMMITMENTS AND CONTINGENCIES (continued)

Defendants', including the Company, have filed demurrers seeking dismissal of the negligence claims. A hearing on those demurrers was held on February 21, 2002. The Court granted the demurrer with respect to the negligence claim asserted in the Thacker action. Additionally, the Court indicated that the actions will be combined and treated as a single action.

The Company denies that it is engaged in the activity complained of and asserts that it is licensed by the State of California to do precisely what it is doing, and that its activities are fully in accord with all state and federal laws. Therefore, the Company believes this suit to be without merit and will vigorously defend against the claims.

*Condos v. Musculoskeletal Transplant Foundation*

In July, 2000, the Company was served with an action brought in the United States District Court for the District of Utah against the Company and MTF. The suit alleges causes of action for strict liability, breach of implied warranty and negligence arising from allegedly defective allograft bone tissue processed and/or provided by the Company and MTF which was allegedly implanted into the plaintiff, Chris Condos, during two spinal surgeries. Plaintiffs, which include Mr. Condos's family members, demand monetary damages in an unspecified amount. On July 25, 2000, the Company answered the complaint, denying any and all liability. Discovery on all of the claims in this action has commenced.

In January, 2002, plaintiffs amended their complaint, but no new claims were asserted. In February, 2002, the Company moved for summary judgement in its favor on all claims asserted against it. MTF has sought the same relief. Both motions remain pending.

The Company maintains a general liability insurance policy and has notified the insurance company of this action. The insurance company has agreed to defend the action. The Company believes the claims made against it in this action are without merit and will vigorously defend against the claims.

*Musculoskeletal Transplant Foundation v. Osteotech, Inc.*

In October, 2000, MTF filed a complaint in the United States District Court for the District of New Jersey against the Company seeking a declaratory judgment that MTF, through its manufacture, use, sale and/or offer for sale of demineralized bone matrix products, known as DBX<sup>®</sup>, does not infringe any claim of the Company's U.S. Patent Nos. 5,284,655 and 5,290,558, and that the claims of those patents are invalid and unenforceable. The complaint was then amended to add Synthes Spine Company, L.P. ("Synthes") as a plaintiff. MTF and Synthes seek declaratory and injunctive relief.

The Company answered the complaint, denying all claims asserted and the Company has asserted claims against MTF and Synthes for patent infringement, unfair competition, misappropriation of trade secrets, product disparagement, breach of implied covenant of good faith and fair dealing, intentional interference with contractual relations, and for constructive trust, arising from certain wrongful acts committed by MTF and/or Synthes in developing and selling MTF's DBX<sup>®</sup> products and/or its underlying technology.

In June, 2001, the Company made a motion for an order preliminarily enjoining MTF and Synthes from selling or offering to sell their DBX<sup>®</sup> products. A hearing was held on that motion on July 23, 2001. On September 18, 2001, the Court denied that motion. Discovery is otherwise continuing in this case.

OSTEOTECH, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

11. COMMITMENTS AND CONTINGENCIES (continued)

The Company seeks injunctive relief and monetary damages in an amount to be determined. MTF and Synthes have denied any liability. The Company believes that the claims made against it in this action are without merit and will vigorously defend against the claims, and will vigorously pursue its claims against MTF and Synthes.

*Glancy v. Interpore International, Inc.*

In November, 2000, plaintiffs Bonnie and Ivan Glancy commenced an action in the United States District Court for the Northern District of Indiana against Interpore International, Inc. and Interpore Cross International, Inc. (collectively, "Interpore") and the Company. In January, 2002, the plaintiffs and the Company settled all claims pending against the Company in this case for an insignificant amount. The Court dismissed the Company from this case in February, 2002.

*Criti-Cal, Inc. v. Osteotech, Inc.*

In December, 2000, Criti-Cal, Inc. commenced an action in the Superior Court for the State of California, Orange County, against the Company, Second Act Medical, Inc. and Ronald Letner. The plaintiff alleges causes of action for breach of contract, misappropriation of trade secrets, quantum meruit and violations of the California Independent Wholesale Sales Representatives Contractual Relations Act of 1990 arising from the termination of an agreement between the Company and plaintiff. In addition to injunctive relief, plaintiff seeks unspecified monetary damages.

In March, 2001, the Company answered the complaint, denying any and all liability. In January, 2002, the Court dismissed plaintiff's claim for misappropriation of trade secrets. In February, 2002, the parties agreed to submit this matter to mediation, which proved to be unsuccessful.

The Company answered the complaint denying any and all liability and intends to vigorously defend against all claims.

*Medtronic, Inc. v. Osteotech, Inc.*

In February, 2001, Medtronic, Inc. and Medtronic Sofamor Danek, Inc. (collectively, "Medtronic") brought suit against the Company and Medtronic's former employee, Timothy R. Miller, in the Circuit Court for Shelby County, Tennessee. The plaintiff sought to enjoin Mr. Miller, whom the Company hired, from using and disclosing any of their trade secrets or other confidential information to any third party, including the Company, and from working for the Company for a period of twelve months.

On April 25, 2001, the Court lifted a temporary restraining order preventing Mr. Miller from working with the Company and entered an order preliminarily enjoining Mr. Miller from working with the Company in the area of spine surgery products. In November, 2001, the parties settled this matter and the Court dismissed this action.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**11. COMMITMENTS AND CONTINGENCIES (continued)**

*Younger v. Hayes Medical Center, Inc.*

In April, 2001, the Company was served in an action brought in the Twentieth Judicial District Court in Ellis County, Kansas, against Hayes Medical Center, Inc., the Musculoskeletal Transplant Foundation, Metropath, Inc. and the Company. With respect to the Company, the suit alleges a cause of action for negligence in connection with allegedly defective allograft bone tissue provided by the defendants and allegedly implanted in the plaintiff during a surgical procedure. The plaintiff seeks monetary damages in excess of \$75,000.

In May, 2001, the Company answered the complaint denying any and all liability. Discovery in this action has commenced.

The Company maintains a general liability insurance policy and has notified the insurance company of this action. The insurance company has agreed to defend this action. The Company believes the claims made against it in this action are without merit and will vigorously defend against the claims.

*Wright Medical Technology, Inc. v. Osteotech, Inc.*

In June, 2001, the Company received a complaint filed by Wright Medical Technologies, Inc. in an action in the United States District Court for New Jersey, which alleges against the Company claims for false advertising, and tortious interference with business relations and prospective business advantage relating to certain statements allegedly made by the Company regarding a FDA Warning Letter received by the plaintiff with respect to a tissue product marketed by the plaintiff. In addition to injunctive relief, plaintiff seeks monetary damages in an unspecified amount. On June 15, 2001, the Court granted plaintiffs a temporary restraining order against the Company. On June 20, 2001, the Company obtained a stay of that order from the United States Court of Appeals for the Third Circuit, pending an appeal of that order. On June 29, 2001, the District Court issued an order granting plaintiffs' motion for a preliminary injunction, and amended the order on July 2, 2001, enjoining the Company from making the accused statements and requiring the Company to issue a clarification of such statements. The Company issued a corrective statement in a timely fashion and has appealed the District Court's order to the Third Circuit Court of Appeals. That appeal is pending.

On October 22, 2001, the Company received an amended complaint in this action, wherein plaintiffs named as additional defendants unidentified "Roe" parties and alleged further misconduct on the part of the Company giving rise to the claims described therein. The Company denies any and all liability. Discovery in this action has commenced.

Other than the foregoing matters, the Company is not a party to any material pending legal proceeding. Litigation is subject to many uncertainties and management is unable to predict the outcome of the pending suits and claims. It is possible that the results of operations or liquidity and capital resources of the Company could be adversely affected by the ultimate outcome of the pending litigation or as a result of the costs of contesting such lawsuits. The Company is currently unable to estimate the potential liability, if any, that may result from the pending litigation and, accordingly, no provision for any liability (except for accrued legal costs for services previously rendered) has been made in the consolidated financial statements. When the Company is reasonably able to determine the potential liability, if any, that may result from any of the pending litigation, the Company will record a provision for such liability to the extent not covered by insurance.

## 12. STOCKHOLDERS' EQUITY

### Preferred Stock

The authorized capital of the Company includes 5,675,595 shares of Preferred Stock, the rights and provisions of which will be determined by the Board of Directors at the time any such shares are issued, if at all. No shares of Preferred Stock were issued or outstanding at December 31, 2001 or 2000.

### Stock Repurchase Program

In May, 2000, the Board of Directors of the Company authorized the repurchase and retirement of up to 1,000,000 shares of the Company's common stock through open market purchases, or block purchases. As of December 31, 2000, the Company had repurchased and retired 330,500 shares of common stock at a cost of approximately \$3,124,000. No shares were repurchased in 2001.

### Stock Split

On February 11, 1999, the Board of Directors authorized a three-for-two stock split in the form of a 50% stock dividend that was distributed on March 19, 1999 to stockholders of record on March 5, 1999.

### Stock Options

The Company's 2000 Stock Plan (the "2000 Plan") authorizes the grant of up to 1,000,000 shares of the Company's common stock in the form of incentive stock options, non-qualified stock options or other stock-based awards to employees, directors and consultants. Incentive stock options may be granted at prices not less than 100% of the fair market value on the date of grant. Non-qualified stock options and other stock-based awards may be granted at the discretion of the Compensation Committee of the Board of Directors under terms and conditions as determined by the Compensation Committee. Options will expire ten years from the date of grant and vesting will be determined by the Compensation Committee. Options issued in 2001 and 2000 pursuant to the 2000 Plan typically have terms requiring ratably vesting over four years.

The 1991 Stock Option Plan (the "1991 Plan"), as amended, authorizes the grant of up to 4,220,648 shares of the Company's common stock in the form of incentive stock options or non-qualified stock options to employees and consultants. In June, 2000, the 1991 Plan was replaced by the 2000 Plan, and therefore, options will no longer be issued under the 1991 Plan.

The 1991 Independent Directors Stock Option Plan (the "Directors Plan"), as amended, authorizes the grant of options to purchase up to 750,000 shares of the Company's common stock to members of the Board of Directors who are not officers or employees of the Company. Option exercise prices equal 100% of the fair market value on the date of grant. Options issued prior to July 1, 1997 become exercisable in ratably installments over four years with unexercised options expiring five years from the vesting date. Effective July 1, 1997, the Directors Plan was amended to provide for options issued to become 100% exercisable on the first anniversary of the date of grant, provided that the holder of such option is on the Company's Board of Directors during such year, with unexercised options expiring ten years from the date of grant. Commensurate with the expiration of the Directors Plan in September, 2001, available options under the plan will no longer be issued.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**12. STOCKHOLDERS' EQUITY (continued)**

Stock option activity for the years 2001, 2000, and 1999 is as follows:

	2001		2000		1999	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1,	2,319,325	\$ 9.98	1,866,522	\$ 11.93	2,280,732	\$ 9.35
Granted	238,000	5.37	686,000	5.76	404,500	18.17
Exercised	10,138	4.10	74,261	4.14	791,566	5.76
Cancelled or expired	36,488	14.29	158,936	17.45	27,144	16.40
Outstanding at December 31,	2,510,699	\$ 9.50	2,319,325	\$ 9.98	1,866,522	\$ 11.93
Exercisable at December 31,	1,544,076	\$ 10.48	1,236,336	\$ 10.36	995,529	\$ 8.35
Available for grant at December 31,	494,500		714,750		669,644	
Weighted average fair value per share Of options granted during the period		\$ 3.30		\$ 3.28		\$ 10.35

The following table summarizes the information about stock options outstanding at December 31, 2001:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at December 31, 2001	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at December 31, 2001	Weighted Average Exercise Price
\$ 2.33 To \$ 3.78	402,825	8.5	\$ 3.47	109,197	\$ 3.41
3.79 To 7.58	846,249	6.9	5.64	474,499	5.40
7.59 To 11.36	545,250	6.1	8.79	501,000	8.75
11.37 To 15.15	266,000	7.4	12.59	161,500	12.54
15.16 To 18.94	176,375	7.2	16.22	107,875	16.29
18.95 To 22.73	214,500	6.9	20.68	162,755	20.68
34.09 To 37.88	59,500	7.4	37.74	52,250	37.80
<b>\$ 2.33 To \$37.88</b>	<b>2,510,699</b>	<b>7.1</b>	<b>\$ 9.50</b>	<b>1,569,076</b>	<b>\$ 10.48</b>

The Company has adopted the "disclosure only" provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation", ("SFAS No. 123") and, accordingly, no compensation cost has been recognized in the consolidated statements of operations. Pro forma information regarding net income and net income per share is required by SFAS No. 123, and has been determined as if the Company accounted for its stock options under the Fair Value Method of that Statement. For purposes of the pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**12. STOCKHOLDERS' EQUITY (continued)**

Pro forma information follows:

<i>(in thousands except per share data)</i>	2001	2000	1999
Net income (loss)			
As reported	\$ (4,410)	\$ 4,828	\$ 12,351
Pro forma	(5,964)	3,699	10,927
Net income (loss) per share			
As reported			
Basic	\$ (.31)	\$ .34	\$ .88
Diluted	(.31)	.34	.84
Pro forma			
Basic	\$ (.43)	\$ .26	\$ .78
Diluted	(.43)	.26	.75

The pro forma effect on net income (loss) for 2001, 2000, and 1999 is not representative of the pro forma effect on net income (loss) in future years because, in accordance with SFAS No. 123, it does not take into consideration pro forma compensation expense related to grants made prior to 1995.

The fair value for the option grants was estimated at the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

	2001	2000	1999
Expected life (years)	5	5	5
Risk free interest rate	4.62%	5.70%	6.10%
Volatility factor	70.00%	60.00%	60.00%
Dividend yield	0.00%	0.00%	0.00%

**Stock Warrants**

As part of financing and contract arrangements, the Company has, at certain times, issued warrants to purchase its Convertible Preferred Stock. As of December 31, 1999 there were Convertible Preferred Stock warrants to purchase 458 shares of Common Stock at an exercise price of \$3.72. During 2000, all outstanding Convertible Preferred Stock warrants expired.

**Stock Purchase Plan**

The 1994 Employee Stock Purchase Plan provides for the issuance of up to 375,000 shares of Common Stock. Eligible employees may purchase shares of the Company's Common Stock through payroll deductions of 1% to 7½% of annual compensation. The purchase price for the stock is 85% of the fair market value of the stock on the last day of each calendar quarter. At December 31, 2001, 94,321 shares were available for future offerings under this plan.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**12. STOCKHOLDERS' EQUITY (continued)**

Stockholder Rights Agreement

In January, 1996, the Board of Directors of the Company unanimously adopted a stockholder rights agreement (the "Rights Agreement") declaring a dividend of one preferred stock purchase right (the "Right") for each outstanding share of common stock. Upon the occurrence of certain events, each Right entitles the stockholder to purchase from the Company one one-hundredth of a preferred share at a price of \$170.00 per one one-hundredth of a preferred share, subject to adjustment. The Rights will not be exercisable or separable from the common shares until ten business days after a person or group acquires or tenders for 20% or more of the Company's outstanding common shares ("triggering event"). The Rights Agreement also provides that, after a triggering event occurs, the Rights convert into a Right to buy common stock and entitle its holder to receive upon exercise that number of common shares having a market value of two times the exercise price of the Right. In the event the Company is acquired in a merger or other business combination transaction, each Right will entitle its holder to receive upon exercise of the Right, at the Right's then current exercise price, that number of the acquiring company's common shares having a market value of two times the exercise price of the Right. The Company is entitled to redeem the Rights at a price of \$.01 per Right at any time prior to their becoming exercisable, and the Rights expire on March 31, 2009. The Rights Agreement was adopted to maximize the value of all stockholders' ownership interest in the Company by establishing a deterrent to abusive takeover tactics sometimes used in challenges for corporate control.

**13. SUPPLEMENTAL STATEMENT OF OPERATIONS INFORMATION**

Maintenance and repairs expense for the years ended December 31, 2001, 2000, and 1999 was \$2,498,000, \$2,551,000, and \$2,240,000, respectively. Depreciation and amortization expense related to property, plant and equipment for the years ended December 31, 2001, 2000, and 1999 was \$7,985,000, \$3,956,000, and \$2,745,000, respectively.

**14. SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION**

<i>(in thousands)</i>	2001	2000	1999
Cash paid during the year for taxes	\$ 1,170	\$ 1,895	\$ 4,476
Cash paid during the year for interest, excluding amounts capitalized	379	11	33
Acquisition of business:			
Fair value of assets acquired			2,563
Liabilities assumed			2,669

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**15. NET INCOME (LOSS) PER SHARE**

The following table sets forth the computation of basic and diluted net income (loss) per share:

<i>(dollars in thousands except per share data)</i>	Year Ended		
	2001	2000	1999
Net income (loss)	\$ (4,410)	\$ 4,828	\$ 12,351
Denominator for basic net income (loss) per share:			
Weighted average common shares outstanding	14,030,623	14,057,931	14,024,468
Effect of dilutive securities:			
Stock options		277,601	593,933
Warrants		109	385
Denominator for diluted net income (loss) per share	14,030,623	14,335,641	14,618,786
Basic net income (loss) per share	\$ (.31)	\$ .34	\$ .88
Diluted net income (loss) per share	\$ (.31)	\$ .34	\$ .84

For the year ended 2001, common equivalent shares, consisting solely of stock options, are excluded from the calculation of diluted net loss per share as their effects are antidilutive.

Weighted average shares issuable upon the exercise of stock options which were not included in the calculation of diluted net income (loss) per share were 1,744,518 in 2001, 771,498 in 2000, and 48,419 in 1999. Such shares were not included because they were antidilutive.

**16. OPERATING SEGMENTS**

The Company has two primary business segments: the Grafton<sup>®</sup> DBM Segment and Base Tissue Segment. The Grafton<sup>®</sup> DBM Segment engages in the processing and marketing of Grafton<sup>®</sup> DBM. Grafton<sup>®</sup> DBM is processed using the Company's advanced proprietary demineralization process. The Base Tissue Segment primarily engages in the processing of mineralized weight-bearing allograft bone tissue. The Company's other business units engage in providing ceramic and titanium plasma spray coating services and ceramic products to orthopaedic and dental implant manufacturers, marketing and distributing metal spinal implant products and processing, marketing and distributing bovine tissue products outside the United States.

The accounting policies of the reportable segments are the same as those described in the Summary of Significant Accounting Policies. The Company evaluates the performance of its operating segments based on revenue performance and operating results. The Company does not generate information about assets for its operating segments, and accordingly no asset information is presented in the table below. All corporate related expenses are allocated to operating segments and geographic areas in determining operating income (loss) of the respective segments. These expenses are allocated to the segments and geographic areas based on allocations that the Company considers to be a reasonable reflection of the utilization of services provided or the benefits received.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**16. OPERATING SEGMENTS (continued)**

Summarized financial information concerning the Company's segments is shown in the following table.

<i>(in thousands)</i>	Grafton®DBM Segment	Base Tissue Segment	Other	Consolidated
<b>Revenues:</b>				
2001	\$ 43,637	\$ 27,692	\$ 6,517	\$ 77,846
2000	45,226	26,204	4,253	75,683
1999	45,136	25,751	4,723	75,610
<b>Operating income (loss):</b>				
2001	\$ 7,014	\$ (7,979)	\$ (5,671)	\$ (6,636)
2000	11,389	694	(4,228)	7,855
1999	17,063	6,434	(3,645)	19,852
<b>Depreciation and amortization:</b>				
2001	\$ 1,962	\$ 5,413	\$ 1,223	\$ 8,598
2000	2,198	1,376	1,023	4,597
1999	1,203	1,153	942	3,298

Financial information by geographic area is summarized as follows:

<i>(in thousands)</i>	United States	Europe	Consolidated
<b>Revenues</b>			
2001	\$71,776	\$ 6,070	\$77,846
2000	71,468	4,215	75,683
1999	71,517	4,093	75,610
<b>Long-lived Assets</b>			
2001	\$55,261	\$ 1,475	\$56,736
2000	56,618	1,672	58,290
1999	32,068	1,927	33,995

Two of the Company's customers individually comprise 10% or more of the Company's consolidated net revenues. Revenues by customer, which are reported as part of the Company's Grafton® DBM and Base Tissue Segments, are as follows:

<i>(in thousands)</i>	2001	2000	1999
<b>Revenues</b>			
MTF	\$28,971	\$37,743	\$42,095
ARC	29,100	30,469	28,436
	<u>\$58,071</u>	<u>\$68,212</u>	<u>\$70,531</u>

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**17. RETIREMENT BENEFITS**

The Company has a 401(k) plan which covers substantially all full time U.S. employees. The Company has agreed to contribute an amount equal to 25% through December 31, 2000 and 35% effective January 1, 2001 of each participant's contribution. A participant's contribution may not exceed 15% of annual compensation, or the maximum allowed by the Internal Revenue Code, if less than 15% of compensation. Provisions of the plan include graduated vesting over five years from date of employment. Total Company contributions for the years ended December 31, 2001, 2000, and 1999 were \$393,000, \$285,000, and \$287,000, respectively.

Certain of the Company's foreign subsidiaries provide retirement benefits to their employees through the purchase of non-participating annuity contracts. The expenses for these contracts were \$42,000, \$70,000, and \$53,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

The Company does not maintain any other pension or post retirement plans.

**18. QUARTERLY FINANCIAL DATA (unaudited)**

The following is a summary of the unaudited quarterly results for the years ended December 31, 2001 and 2000:

<i>(in thousands except per share data)</i>	Quarter Ended			
	March 31	June 30	Sept. 30	Dec. 31
<b>2001</b>				
Net revenues	\$17,953	\$19,581	\$19,627	\$20,685
Cost of services and products <sup>(a)</sup>	7,364	8,805	8,051	10,128
Net income (loss) <sup>(a)</sup>	(307)	(2,130)	232	(2,205)
Net income (loss) per share				
Basic	\$ (.02)	\$ (.15)	\$ .02	\$ (.16)
Diluted	(.02)	(.15)	.02	(.16)
<b>2000</b>				
Net revenues	\$18,646	\$20,619	\$17,916	\$18,502
Cost of services and products	6,211	6,742	6,996	7,562
Net income <sup>(b)</sup>	1,969	2,524	231	104
Net income per share <sup>(b)</sup>				
Basic	\$ .14	\$ .18	\$ .02	\$ .01
Diluted	.13	.18	.02	.01

- (a) In June, 2001, the Company recorded charges of \$1,845,000 (\$1,107,000, net of tax, or \$.08 diluted net loss per share) of which \$655,000 has been recorded as cost of product and \$1,190,000 has been recorded as marketing, selling, general and administrative expense. Such charges were primarily to establish reserves associated with excess inventory and instrumentation associated with spinal implant systems.

In December, 2001, the Company recorded a charge of \$2,287,000 (\$1,372,000 net of tax, or \$.10 diluted net loss per share) related to equipment which will no longer be utilized in the processing of allograft tissue. Such charge was recorded in cost of sales. In November, 2001, the Company recorded a charge primarily for the severance costs associated with the departure of an executive officer in the amount of \$700,000 (\$420,000, net of tax, or \$.03 diluted net loss per share). Such severance charge was recorded in marketing, selling, general and administrative expenses.

- (b) Net income in 2000 included approximately \$150,000, or \$.01 net income per share, per quarter from a litigation settlement.

**OSTEOTECH, INC. AND SUBSIDIARIES**  
**VALUATION AND QUALIFYING ACCOUNTS**  
*(in thousands)*

	Balance At Beginning Of Period	Additions		Deductions	Balance At End Of Period
		Charged To Expenses	Charged To Other		
For the year ended December 31, 2001:					
Allowance for doubtful accounts	\$ 123	\$ 296	\$ (10) <sup>(a)</sup>	\$ (106) <sup>(b)</sup>	\$ 303
Valuation allowance for deferred tax asset	2,058	607 <sup>(c)</sup>	(58) <sup>(a)</sup>	7 <sup>(d)</sup>	2,614
For the year ended December 31, 2000:					
Allowance for doubtful accounts	129	1	(3) <sup>(a)</sup>	(4) <sup>(b)</sup>	123
Valuation allowance for deferred tax asset	1,749	440 <sup>(c)</sup>	(122) <sup>(a)</sup>	(9) <sup>(d)</sup>	2,058
For the year ended December 31, 1999:					
Allowance for doubtful accounts	148	(3) <sup>(e)</sup>	(10) <sup>(a)</sup>	(6) <sup>(b)</sup>	129
Valuation allowance for deferred tax asset	1,520	416 <sup>(c)</sup>	(123) <sup>(a)</sup>	(64) <sup>(d)</sup>	1,749

- (a) Represents foreign currency translation adjustments.
- (b) Represents the write-off of accounts receivable.
- (c) Represents the tax effect of temporary differences.
- (d) Represents recognition of a deferred tax asset.
- (e) Represents recovery on previously written-off accounts receivable.

**Report of Independent Accountants on  
Financial Statement Schedule**

To the Board of Directors of Osteotech, Inc.

Our audits of the consolidated financial statements referred to in our report dated March 13, 2002, appearing on page F-2 of this Form 10-K also included an audit of the Financial Statement Schedule listed in Item 14(a)(2) of this Form 10-K. In our opinion, this Financial Statement Schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

PricewaterhouseCoopers LLP

Florham Park, New Jersey  
March 13, 2002

**Board of Directors****Donald D. Johnston**

Chairman of the Board of  
Directors of Osteotech, Inc.  
Retired Former Executive  
Vice President and Director  
of Johnson & Johnson, Inc.

**Richard W. Bauer**

President and  
Chief Executive Officer  
of Osteotech, Inc.

**Kenneth P. Fallon, III**

Chief Executive Officer and  
Director of Axya Medical, Inc.

**Michael J. Jeffries**

Executive Vice President,  
Chief Financial Officer and  
Secretary of Osteotech, Inc.

**John P. Kostuik, M.D. FRCS(C)**

Professor and Chairman of the  
Department of Orthopaedic Surgery  
Johns Hopkins University School of Medicine  
Chief Spine Division

**Stephan J. Sogin, Ph.D.**

Venture Capital Consultant

**Corporate Officers****Richard W. Bauer**

President, Chief Executive Officer  
and Director

**Michael J. Jeffries**

Executive Vice President,  
Chief Financial Officer,  
Secretary and Director

**James L. Russell, Ph.D.**

Executive Vice President,  
Chief Scientific Officer

**Richard Russo**

Executive Vice President,  
General Manager, International

**Steven Annunziato**

Vice President, Marketing

**Marc Burel**

Vice President, Sales

**Mark H. Burroughs**

Vice President,  
Finance and Treasurer

**Richard Ragula**

Vice President, Operations

**Common Stock**

Listed on The Nasdaq Stock Market<sup>®</sup>  
Trading Symbol: OSTE

**Corporate Office**

Osteotech, Inc.  
51 James Way  
Eatontown, New Jersey 07724  
732-5422800

**Transfer Agent**

Registrar and Transfer Company  
Cranford, New Jersey

**General Counsel**

Carella, Byrne, Bain, Gilfillan,  
Cecchi, Stewart and Olstein  
Roseland, New Jersey

**SEC Counsel**

Dorsey & Whitney LLP  
New York, New York

**Auditors**

PricewaterhouseCoopers, LLP  
Florham Park, New Jersey

**Annual Meeting**

The Annual Meeting of Shareholders  
will be held at 9:00 A.M. June 13, 2002  
at the Sheraton Eatontown Hotel and  
Conference Center, 6 Industrial Way East,  
Eatontown, New Jersey 07724

Find Osteotech on the Internet at:  
[www.osteotech.com](http://www.osteotech.com)



Information contained in this annual report contains "forward-looking statements" which can be identified by the use of forward-looking terminology such as "believes", "expects", "may", "will", "should", or "anticipates" or the negative thereof or other variations thereon or comparable terminology or by discussions of strategy. No assurance can be given that the future results covered by the forward-looking statements will be achieved. Some of the matters set forth herein and in Osteotech's Annual Report on Form 10-K for the year ended December 31, 2001, constitute cautionary statements identifying important factors with respect to such forward-looking statements, including certain risks and uncertainties, that could cause actual results to vary materially from the future results indicated in such forward-looking statements. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements.



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