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# OSTEOTECH<sup>INC.</sup>

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A N N U A L R E P O R T

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Joining  
Lives



Enhancing  
Life

*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.*

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f i n a n c i a l

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*h i g h l i g h t s*

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

For the Year	<b>2003</b>	2002	2001
Net revenues	<b>\$94,433</b>	\$83,374	\$75,715
Income (loss) from continuing operations	<b>10,867</b>	(1,248)	(3,817)
Income (loss) from continuing operations per share			
Basic	<b>.64</b>	(.08)	(.28)
Diluted	<b>.62</b>	(.08)	(.28)
Total assets	<b>127,213</b>	114,732	107,017
Stockholders' equity	<b>96,220</b>	84,023	68,125
Cash flow from operations	<b>4,784</b>	(1,633)	(2,019)



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*Dear Fellow Shareholder:*

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Osteotech experienced improved financial performance in 2003 marked by some very significant highlights. We improved upon our 10% revenue growth in 2002 by growing the business 13% in 2003 to \$94.4 million. Net income improved dramatically to \$10.9 million in 2003 from a loss of \$1.2 million in 2002. The improvement in net income reflects an overall improvement in the Company's business dynamics and settlement of a lawsuit, which contributed \$4.5 million to net income. Our organization is proud of our improved financial performance in 2003, but we are aggressively attacking the future. We expect to expend additional resources in 2004 to accelerate research, development and marketing programs. Although this will impact our profitability in 2004, these activities should position Osteotech for future profitability and growth.

Osteotech achieved a major milestone by processing our three millionth graft in December, 2003. This is a major milestone, not only for Osteotech, but also for our many client donation partners, the surgeons who implant the allografts and the patients who benefit from the allografts. Most importantly, it is a credit to all the donor families, who have given the gift of tissue donation and entrusted Osteotech with this awesome responsibility, all at a time of the greatest of family tragedies. Osteotech has embraced that trust and responsibility by doing everything we can to maximize the generous gift of donation through technology, innovation and by providing a broad array of tissue forms for surgeons to use in orthopaedic and periodontal surgery. We're also very proud that we've been able to achieve all this since March 11, 1987, when we processed our first graft, while maintaining a perfect tissue safety record.

And we keep achieving industry milestones. In March, 2004, "Spine", a prestigious medical journal, published a study sponsored by Osteotech describing the first prospective randomized clinical trial ever conducted with demineralized bone matrix in a carrier, Grafton® DBM Gel. The study, which was conducted at seven U.S. medical centers involving 120 patients, demonstrated that Grafton® DBM Gel, when combined with one third the amount of iliac crest bone, was equivalent to the use of iliac crest bone alone in achieving lumbar spine fusion.

In 2003, Osteotech continued implementation of its three major growth strategies, which will remain our growth strategies for 2004 and the foreseeable future. These three strategies are:

- Build our product line and sales presence in the domestic hospital-based spinal fusion market.
- Expand our DBM carrier technology into the domestic orthopaedic markets that are not a key focus for our spine oriented sales force.
- Expand our tissue technology and products globally.

**Build our product line and sales presence in the domestic hospital-based spinal market.**

Much has occurred to position ourselves for successful implementation of this strategy. The most significant event was our decision in March, 2004 to exit the metal spinal implant business and focus all our attention and resources on maximizing our presence within our core tissue technology competency. In the most fundamental terms, the strategy of marketing metal spinal implants with our Grafton® DBM and

Graftech® Bio-implant product lines was sound, however, we were not able to successfully execute the metal spinal implant component profitably. As a result of our exit from the metal spinal implant business, we made the decision to invest an incremental \$3.6 million in our tissue business in 2004 to increase activities primarily in sales, marketing, research and development and clinical research, all with the goal of improving our competitive position in an increasingly competitive domestic marketplace. A portion of these funds is also being allocated to further our expansion globally, but more on this later.

Other events to note were the successful introduction of Grafton® DBM Matrix Strips, clinical evaluation of new instrumentation and bio-implants for transverse lumbar interbody fusion procedures for full market introduction in 2004, increased commissions to our agency sales force on Grafton® DBM to increase their sales resources and selling time spent on the brand, a major promotion on Grafton Plus® DBM that enables our sales force to match competitive price discounting and the introduction of a new sales force training and target account program to maximize our Grafton® DBM and Graftech® Bio-implant market penetration in key, high-density hospitals.

**Expand our DBM carrier technology into the domestic orthopaedic markets that are not a key focus for our spine oriented sales force.**

In December, 2002, we announced our second agreement in support of this strategy when we completed the private label arrangement with LifeNet™, DePuy Orthopaedics and DePuy Spine. Our first agreement, with our partner BioHorizons, Inc., a leading supplier of dental implants, continues to provide significant growth as they market a complete line of Grafton® DBM products for a variety of dental implant applications. The LifeNet™ and DePuy agreement began generating revenue for Osteotech in first quarter 2003.

In April, 2004, we announced our third agreement, a major new initiative with the Orthopaedic Division of Smith & Nephew, Inc. under which Osteotech will supply a private label DBM product line and cancellous chips to be marketed domestically by Smith & Nephew in all orthopaedic segments other than spine. We expect to begin shipments to Smith & Nephew in early third quarter 2004 and expect their selling activity to begin shortly thereafter. Smith & Nephew is a leading competitor in trauma and total joints and we expect that they will do an excellent job penetrating these markets with a broad line of DBM carrier products provided to them by Osteotech.

Osteotech does not plan to stop with these three agreements. We will continue to pursue our strategy of partnering with companies that don't represent a competitive threat to our core franchise businesses in spine.

**Expand our tissue technology and products globally.**

There is a saying in business, "It's nice to see when a plan comes together." This best describes Osteotech's globalization efforts, which date back to the late 1990's and has resulted in spectacular success in 2003. In the late 1990's, we recognized that there was a tremendous opportunity to globalize the tissue business. Surgeons overseas wanted access to allograft tissue products but they generally were not available to them. Many more weren't aware of tissue technology and the products spawned from this

technology and only needed to be exposed to it to quickly see its benefits. In many ways, the global market for tissue based products was similar to the US market in the 1980's. Surgeons needed to be educated on the benefits of tissue derived products and then needed access to them. This is precisely what Osteotech did in the domestic market starting in 1987 and is what we began implementing, globally, in the late 1990's. The strategy really began to materialize with our acquisition of OST Developpement, which is headquartered in France, in 1999. The people at OST have done a wonderful job developing the infrastructure for success from donation of tissue through distribution throughout the world.

In 2003, OST Developpement increased their revenue by 74% to \$8.4 million and Grafton® DBM revenue was up 143% for the year. OST Developpement accounted for 9% of the Company's 2003 consolidated revenue, which is an increase from 6% in 2002. I'm pleased to report that OST turned profitable in 2002 and was significantly more profitable in 2003.

We believe that the success of OST Developpement and our globalization strategy in 2003 is only the beginning of a long line of future successes. We believe this because we have yet to introduce Osteotech's complete line of products to markets presently served by OST. We also believe this because our plans call for greater profitability when we begin processing full cadaveric donors at OST's facilities in Europe instead of shipping donors to our Eatontown, New Jersey facility and shipping finished product back to OST for distribution. And, we believe this because there are many new global markets to enter where we have yet to establish a presence.

In closing, I'm confident that we have implemented the correct actions to be more competitive in the domestic hospital-based spinal fusion market and we have significant growth opportunities in front of us due to our DBM partnership agreements and the success of our globalization plans. I want to thank the employees of Osteotech for their hard work, perseverance and willingness to do whatever it takes to get the job done and I want to thank our shareholders for their continued support as we implement our strategies, which will result in greater revenue growth and profits in the coming years.

Sincerely,



Richard W. Bauer  
President and Chief Executive Officer  
May 5, 2004

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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, 2003

Commission File Number 0-19278

OSTEOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or  
organization)

13-3357370

(I.R.S. Employer Identification No.)

51 James Way, Eatontown, New Jersey

(Address of principal executive offices)

07724

(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.

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

The aggregate market value of the voting and non-voting common equity, held by non-affiliates of the registrant as of June 30, 2003 was approximately \$223,548,000.

The number of shares of the registrant's common stock, \$.01 par value, outstanding as of March 10, 2004 was 17,117,720.

Documents Incorporated by Reference

The registrant's definitive 2004 Proxy Statement, which will be filed pursuant to Regulation 14A, is incorporated by reference into Items 10, 11, 12 and 14 of Part III of this Annual Report on Form 10-K.

**OSTEOTECH, INC.**

**2003 Form 10-K Annual Report**

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The following trademarks and service marks appear in this Annual Report: Plexus™, OsteoActive™, Ovation™ Polyaxial System, Sentinal™ Top Tightening Spinal System, Affirm™ Anterior Surgical Plate System and Clear Bone™ are trademarks and Osteotech®, Grafton® Demineralized Bone Matrix (DBM), Grafton Plus® DBM Paste, Graftech® Bio-Implants, bio-d® Threaded Cortical Bone Dowel, D-Min® Aseptic Tissue Demineralization and Allogard® Packaging are registered trademarks of Osteotech, Inc.; LUBBOC® and LADDEC® are registered trademarks of OST Developpement SA and OsteoPure™ is a trademark of OST Developpement SA; Allowash™ is a trademark of Lifenet; VBR® Vertebral Body Replacement is a registered trademark of Heinrich C. Ulrich, K.G.; C3™ Anterior Cervical Plate System, PLUS™ Pivot Link Universal System, and Uni-Thread™ Versatile Thoraco-Lumbar Spinal System are trademarks of SpineVision, Inc.

We maintain a website at [www.osteotech.com](http://www.osteotech.com) to provide information to the general public and our shareholders on our tissue forms, products, resources and services, along with general information on Osteotech and its management, career opportunities, financial results and press releases. Copies of our most recent Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q or our other reports filed with the Securities and Exchange Commission, or SEC, can be obtained, free of charge as soon as reasonably practicable after such material is electronically filed with, or furnished to the SEC, from our Investor Relations Department by calling 732-542-2800, through an e-mail request from our website at [www.osteotech.com/finrequest.htm](http://www.osteotech.com/finrequest.htm), through the SEC's website by clicking the direct link from our website at [www.osteotech.com/finrequest.htm](http://www.osteotech.com/finrequest.htm) or directly from the SEC's website at [www.sec.gov](http://www.sec.gov). Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Our Board of Directors has adopted a Code of Business Conduct that is applicable to all of our directors, officers and employees, a copy of which is attached as an exhibit to this annual report. Any material changes made to our Code of Business Conduct or any waivers granted to any of our directors and executive officers will be publicly disclosed by filing a current report on Form 8-K within five business days of such material change or waiver. We intend to make a copy of the Code of Business Conduct as well as charters for our Audit Committee and Nominating and Corporate Governance Committee, which comply with the recently adopted corporate governance rules of Nasdaq, available on our website at [www.osteotech.com](http://www.osteotech.com). In addition, a copy of such documents will also be made available to our shareholders upon request by contacting our Investor Relations Department by calling 732-542-2800 or through an e-mail request from our website at [www.osteotech.com/finrequest.htm](http://www.osteotech.com/finrequest.htm).

## 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.

#### **Cessation of Marketing and Distribution Efforts for Metal Spinal Implant Products**

In January, 2004, we announced that we would terminate the Distribution Arrangement dated February 1, 2003 with SpineVision, S.A. and SpineVision, Inc., in accordance with the provisions of the agreement, effective February 17, 2004. Also, in September, 2003 we gave notice to Alphatec Manufacturing, Inc., the manufacturer of the Affirm™ Anterior Surgical Plate System and the Sentinal™ Top Tightening Spinal System, that we would not renew the distribution agreement upon the completion of the current two-year term, which expires on March 31, 2004. In addition, we announced in March, 2004 that we would discontinue our marketing and distribution efforts for all remaining metal spinal implant product lines no later than June 30, 2004. Revenues generated from metal spinal implants were \$4,907,000, \$4,166,000 and \$2,617,000, in 2003, 2002 and 2001, respectively. As a result of these discussions, we expect to take a charge of approximately \$2.4 million in first quarter 2004 for inventory and instrument set write-offs and severance related to this decision.

#### **Temporary Suspension of Base Tissue Segment Processing**

On September 30, 2002, we voluntarily and temporarily suspended Base Tissue Segment processing due to a higher than normal incidence of sterility failures on finished forms of processed allograft bone tissue, which occurred in our Eatontown facility, and subsequently, in our Shrewsbury facility. In addition, as a precaution, we voluntarily retrieved certain tissue from 15 whole donors and five individual pieces of tissue from five different donors that had previously been shipped to clients although all such tissue was tested and found to be sterile. In October, 2002, we restarted Base Tissue Segment processing in our Shrewsbury facility, and in November, 2002 we restarted Base Tissue Segment processing in our Eatontown facility.

As a result of the temporary suspension of Base Tissue Segment processing, we placed tissue processed in third quarter 2002 from 693 donors in quarantine. We released a portion of the quarantined tissue in 2003 and expect to release the remainder in 2004. In 2002, we recorded the costs which we estimated we would incur in order to rework the quarantined tissue and allow

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it to be distributed. In order to successfully rework the remaining tissue, we will need to continue to meet certain technical, scientific and regulatory requirements. We believe that we will be able to meet such requirements, however, there can be no certainty that we will be able to meet all such requirements or be able to rework the remaining tissue for our estimate.

## Company Overview

We provide services and products primarily focused on 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:

- Demineralized Bone Matrix (DBM) Segment, or the DBM Segment (formerly referred to as the Grafton® DBM Segment); and
- Base Allograft Tissue Segment, or Base Tissue Segment.

Our other products are aggregated under the category of "other."

In the DBM Segment we process and market Grafton® DBM, which domestically is primarily distributed by our clients to the end-user. Internationally Grafton® DBM is distributed by agents and distributors. We also distribute Grafton® DBM processed from allograft bone tissue recovered by TRO's on our behalf domestically directly to end-users under our own label. The distribution of Grafton® DBM directly by us to end-users under our own label from allografts bone tissue recovered by TRO's on our behalf represented an immaterial portion of consolidated revenues in 2003. However, we expect revenue generated from Grafton® DBM distributed directly to end-users by us under our own label from allografts bone tissue recovered on our behalf to represent a growing percentage of our consolidated revenues in future years.

We process Grafton® 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.

The DBM Segment also includes revenues from our processing of a private label DBM, which is marketed by DePuy Orthopaedics, Inc. and DePuy Acromed, Inc., or collectively DePuy, and distributed by LifeNet. Effective January 1, 2003, we entered into a five-year agreement with, DePuy and LifeNet for the processing and distribution to the United States hospital market of a private label DBM. Under the terms of the agreement, we process the DBM product to specifications determined by LifeNet, from bone supplied by LifeNet. DePuy markets

and promotes the DBM carrier product to surgeons performing trauma, joint revision and spinal procedures and LifeNet ships and invoices the private label DBM to hospitals and surgeons.

In the Base Tissue Segment, we process primarily mineralized weight-bearing allograft bone tissue. Graftech® Bio-implant spacers and ramps for spinal fusion procedures, which are included in this segment, are marketed and generally distributed domestically by us and other tissue forms processed in this Segment are generally marketed and distributed domestically by our clients. Internationally, these tissue forms are generally marketed and distributed to the end-user through distributors. To the extent that TRO's recover allograft bone tissue on our behalf, we process and distribute this tissue either as bio-implants or other tissue forms primarily to domestic end-users. In 2003, our direct distribution of bio-implants and other tissue forms processed from allograft bone tissue which has been recovered for us has not represented a material portion of consolidated revenues. We expect revenues generated from bio-implants and other tissue forms processed from allograft bone tissue recovered for us and distributed by us to end-users to represent a growing percentage of consolidated revenues in future years. In this segment, we also process in OST Developpement, SA, or OST, our subsidiary located in Clermont-Ferrand, France, OsteoPure™ Femoral head bone tissue, which we market and distribute internationally.

In April, 2002, pursuant to the settlement agreement with Medtronic Sofamor Danek, Inc., Sofamor Danek L.P. and Sofamor Danek Holdings, Inc., we agreed to cease processing, marketing, distributing, advertising and promoting the bio-d® Threaded Cortical Bone Dowel, or bio-d®, no later than January 31, 2003. In accordance with this settlement agreement, we completed the removal of the bio-d® from the market on January 31, 2003. Revenues generated from this tissue form were \$46,000, \$1,216,000, and \$2,361,000 in 2003, 2002 and 2001, respectively.

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 DBM Segment and Base Tissue Segment, we market and distribute primarily in the United States, metal spinal implant products. As previously announced, we expect to discontinue our marketing and distribution efforts related to metal spinal implant products in the second quarter of 2004. OST also processes, markets and distributes, primarily in Europe, Asia and the Middle East, bovine bone tissue products which are utilized as bone graft substitutes by surgeons.

We estimate that the total bone graft market in the U.S. for 2003 was approximately \$1.5 billion, of which the allograft bone tissue portion, which includes allograft (the use of processed bone tissue from cadavers) bone tissue, synthetic graft substitutes and growth factors, in 2003 was approximately \$793 million. We estimate that 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 (the use of a patient's own bone) 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 or quality of their own harvestable bone for use in a procedure.

We believe that our market position is attributable to our proprietary product line; the expanded network of TRO's and tissue banks supplying allograft bone tissue to us; 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 us and our clients, has significantly reduced the risk of transmission of infectious agents.

We operate under a number of different business models in the DBM and Base Tissue Segments based upon the distribution method used and for whom the tissue is recovered. In the DBM Segment, the majority of our revenues are processing revenues generated from our clients in consideration for processing and marketing Grafton® DBM on their behalf. In this business model our clients distribute the Grafton® DBM to end users. A portion of our revenue in the DBM Segment is generated from our direct distribution of Grafton® DBM processed from allograft bone tissue provided to us by our clients or from allograft bone tissue which was processed from donor tissue recovered directly for us by TRO's and certain tissue banks. In this business model we reimburse our clients, TRO's and tissue banks who recover allograft bone tissue on our behalf for their services. We expect that the revenues generated by this direct distribution business model will represent an increasing portion of our revenues in the DBM Segment in the future. Beginning in 2003, we processed a private label DBM for LifeNet, which is marketed by DePuy and distributed to end users by LifeNet.

In the Base Tissue Segment, the majority of our revenues are generated from Graftech® Bio-implants, which we processed for our clients, but are marketed and generally distributed by us to hospitals and surgeons, or in certain cases distributed by our clients. We also generate revenues from our clients on a per donor basis for the processing of our clients' donor tissue into non-proprietary standard allograft bone tissue forms. We also distribute Graftech™ Bio-implants and non-proprietary standard allograft bone tissue forms to hospitals and surgeons that were processed from tissue that was recovered directly for us. We expect the revenues from our distribution of Graftech® Bio-implants and non-proprietary standard allograft bone tissue forms processed from tissue that was recovered for us to increase in the future.

In the United States we process allograft bone tissue pursuant to contracts with a number of clients, including three large not-for-profit organizations, American Red Cross Tissue Services, or ARC, Musculoskeletal Transplant Foundation, or MTF, and LifeNet. 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, our contract with MTF expires in December, 2008 and our contract with LifeNet expires in December, 2007. In October, 2002, the ARC processing agreement was amended, which among other items, removed the requirements that ARC exclusively provide all tissue recovered by ARC to us for processing and, in its place, provided that ARC provide a monthly minimum number of donors to us for

processing. Effective June 1, 2002, we entered into a new processing agreement with MTF, under which MTF will supply a certain increasing minimum annual amount of donor tissue for processing into non-proprietary standard allograft bone tissue forms, Grafton® DBM and Graftech® Bio-implants, all of which will be distributed to hospitals and surgeons by MTF under the MTF label, and provide an additional certain increasing minimum annual amount of tissue from donors for us to process into non-proprietary standard allograft bone tissue forms, Grafton® DBM and Graftech™ Bio-implants, all of which will be distributed to hospitals and surgeons by us under our label. 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 Graftech® Bio-Implants. The label for these bio-implants displays both the LifeNet name and the Osteotech Graftech® brand name. These bio-implants are marketed and distributed to hospitals and surgeons by us on behalf of LifeNet. The LifeNet agreement has been amended several times to provide for us to process non-proprietary standard allograft base tissue forms and specialty allograft tissue forms for LifeNet. In addition, in January, 2003, we entered into a five-year marketing agreement with LifeNet and DePuy for the processing of LifeNet allograft bone tissue into a private label DBM, which will be marketed by DePuy and distributed by LifeNet.

Additionally, we process allograft bone tissue for several smaller tissue banks in the United States and Europe. The processed tissue forms are distributed by either the client or by us depending on the individual client agreements.

We market our proprietary allograft bone tissue forms such as Grafton® DBM and our line of Graftech® Bio-implants through independent agents and direct field sales personnel. Generally, our clients market the non-proprietary standard allograft bone tissue forms that we process in our Base Tissue Segment, primarily using direct field personnel. The tissue forms we process in the Base Tissue Segment 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 DBM Segment was \$46,294,000 in 2003 as compared to \$44,926,000 in 2002, and revenue in our Base Tissue Segment was \$41,465,000 in 2003 as compared to 2002 revenue of \$32,115,000. We expect that both our DBM and Base Tissue Segments will be the major contributors to the growth of our consolidated revenues and profits in 2004, as processed allograft bone tissue forms continue to gain increased acceptance.

Information relating to our revenues for the years ended December 31, 2003, 2002 and 2001 by geographic area is summarized as follows:

<i>(in thousands)</i>	United States	Europe	Consolidated
Revenues			
For the year ended December 31,			
2003	\$86,070	\$8,363	\$94,433
2002	\$78,576	\$4,798	\$83,374
2001	71,776	3,939	75,715

For a discussion of (1) our long-lived assets as of December 31, 2003, 2002 and 2001 see Note 18 of "Notes to Consolidated Financial Statements" and (2) our deferred tax assets for the years ended December 31, 2003 and 2002 see Note 12 of "Notes to Consolidated Financial Statements".

## Strategy

### *Overview*

We intend to expand our business as follows:

- We expect to maintain our leading global position as an orthobiologics company by utilizing our expertise in allograft bone tissue processing and science to market innovative and cost-effective proprietary allograft bone tissue forms.
- 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 leverage our intellectual property to establish private label and licensing arrangements with other major orthopaedic companies.
- We intend to utilize our domestic and international marketing and distribution network to enhance the market share of our allograft bone tissue forms.
- 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 continue to work with existing clients to expand the amount of tissue they recover, obtain additional tissue bank clients, continue to contract directly with TRO's to obtain tissue on our behalf and continue to expand our international tissue bank.

### *DBM Segment*

In the near term, we will continue to focus on marketing Grafton® DBM domestically and internationally through our direct marketing organization, our agent network, distributors 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 will continue to expand the Grafton® DBM tissue line by adding additional forms aimed at competitive products, specific surgical applications and product enhancements and improvements.

We are primarily focused on providing tissue forms for spinal surgical applications. However, tissue forms, such as Grafton® DBM, have applications across a broad range of orthopaedic surgical procedures. In order to expand the use of our Grafton® DBM technology to those other areas of orthopaedic surgery, we intend to establish relationships with existing and new partners to provide private label DBMs for use beyond spinal surgery.

In addition, we expect to expand sales of Grafton® DBM by:

- providing the surgeon an expanded line of Graftech® Bio-implants and other allograft bone tissue forms, which are usable with Grafton® DBM so that we can better meet the needs of the surgeon;
- expanding Grafton® DBM's application to additional surgeon identified new procedures;
- providing surgeon oriented medical education programs;
- providing in-depth sales agent training programs;
- publishing clinical support;
- developing product line extensions; and
- continuing our global expansion of Grafton® DBM.

### *Base Tissue Segment*

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

- introducing additional Graftech® Bio-implants and other non-proprietary allograft bone tissue grafts with application in spinal and other surgical procedures, which also have enhanced performance profiles;
- continuing our global expansion of Graftech® Bio-implants and other non-proprietary allograft bone tissue forms;
- developing proprietary tissue processing technology through internal research; and
- attaining additional domestic and international bone tissue processing clients and sources of bone tissue, which will allow us to continue to meet and expand demand.

### *Spinal Strategy*

Our spinal strategy consists of two primary components involving our DBM and Base Tissue Segments:

- continuing to meet surgeon demand and preference by introducing additional Graftech® Bio-implants; and
- marketing our Graftech® Bio-implants together with Grafton® DBM through our network of direct sales representatives and our national sales agency network.

Our intention is to market and distribute two complementary product lines to meet surgeons' needs for non weight-bearing tissue grafting products (Grafton® DBM) and weight-bearing bio-implants (Graftech® Bio-implants). We will educate surgeons concerning the benefits of using our product lines either alone or in conjunction with each other. Allograft bone tissue forms, which we expect to 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 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 from allograft bone tissue provided by our clients, and also for ourselves from allograft bone tissue recovered by TRO's and tissue banks for us in both our DBM and Base Tissue Segments. Once processed, the allograft bone tissue is distributed to surgeons and hospitals by our clients or by us. 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 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, tissue recovery techniques utilized by our clients, TROs and tissue banks and the multiple screening and testing procedures employed, significantly reduce the risk of transmission of infectious agents by the allograft bone tissue we process.

We have a validated viral inactivation process utilized to produce Grafton® DBM. 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 completing development of additional proprietary processing technologies that, once fully implemented, will enable us to expand our viral inactivation claims to include 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 2003 there were approximately 771,000 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 \$1.5 billion. Currently, allograft tissue competes with autograft bone tissue procedures, growth factors 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 2003 was approximately \$793 million. Industry data indicates that the musculoskeletal surgical market is expected to continue to expand over the next five years. We believe this will expand the potential market for allograft bone tissue in both our 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 increased bone tissue donations and improved recovery and processing techniques.

Allograft bone tissue is employed in surgical procedures because of its biological 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 bone graft, 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, spinal surgical procedures in the cervical spine 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**

### *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 DBM Segment, we currently process seven 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 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;
- Grafton® 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;

- Grafton Plus™ DBM – a ready-to-use putty-like paste of demineralized bone containing a non-toxic starch carrier, which is easily moldable into a variety of shapes and sizes and maintains its characteristics even under vigorous irrigation; and
- Grafton® DBM Matrix Strips – a ready-to-use flexible “pressed fiber” form of demineralized bone providing surgeons a pliable form of bone graft. It is available in interlocking strips designed specifically for posterior spinal fusions requiring grafting of several levels of the spine. The tissue form is designated for use in scoliosis procedures, but can be used in most spinal procedures.

We expect that as we continue to educate surgeons about the capabilities of our Grafton® DBM technology to stimulate bone growth in grafting procedures on a cost-effective basis, we will achieve wider distribution and deeper market penetration of Grafton® DBM utilizing our national network of independent agents in combination with our direct marketing force, and through our expansion into European markets and our marketing of Graftech® Bio-implants.

Effective January 1, 2003, we entered into a five-year agreement to process a private label DBM for LifeNet from bone supplied from LifeNet, which will be distributed by LifeNet and marketed by DePuy.

#### *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 and 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, chips, blocks 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. In addition, we perform sterility testing procedures throughout the processing of the tissue and up through final packaging and release. 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.

Our Graftech® Bio-Implants product line includes the Graftech® Posterior Ramp, Graftech® Anterior Ramp, Graftech® Cervical Spacer, the Graftech® Cortical Spacer, the Graftech® Cervical Dowel and the Graftech® TLIF. In addition to our normal processing techniques, Graftech® Bio-Implants are processed using our OsteoActive™ Process which transforms the typically non-osteoinductive weight bearing graft into an osteoinductive weight bearing graft, thus allowing for faster incorporation of the graft into the host bone. Additionally, these grafts are processed using a technology which allows it to be available in a non-frozen form. All of our bio-implant grafts have been tested and shown to withstand loads comparable to those reported for their respective indication in the spine. Additionally, these bio-implant grafts can be used with Grafton® DBM. Therefore, the bio-implants will provide structural support and, with Grafton® 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 domestic and international market demand for Graftech® Bio-Implants, Grafton® DBM and non-proprietary allograft bone tissue forms that we process and for any new tissue forms that we may process in the future, we have been engaged in an effort to solidify the relationships we have with existing clients who provide donated allograft bone tissue to us for processing. We intend to continue 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.

As a result of these efforts over the past three years, we have established relationships with a number of new tissue bank clients and TRO's, significantly increasing the amount of allograft bone tissue available to us for processing into Grafton® DBM, Graftech® Bio-implants and non-proprietary standard allograft bone tissue forms.

Further, we are developing a new processing technology, Plexus™, which is designed to maximize the utilization of donated human tissue that can be processed from a single donor's bone tissue. For example, utilizing the Plexus™ Processing technology we expect to be able to use bone tissue that was not otherwise available for weight bearing bio-implants for that purpose. Additionally, we expect that the Plexus™ Processing technology will result in significantly more processed allograft bone tissue to be available for a broad spectrum of surgical procedures. Bone tissue processed by use of the Plexus™ Processing technology may be classified by the FDA as either a medical device requiring pre-market approval or as human cellular tissue. The regulatory status of each product processed utilizing the Plexus™ Processing technology will be determined as the product is designed.

### **Expansion of Allograft Bone Tissue Business in Europe**

We are expanding operations and staff at OST, our subsidiary located in Clermont-Ferrand, France, as we use it as a base for developing our human allograft bone tissue graft and tissue processing business internationally. 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 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 throughout the world by supplying Grafton® DBM and non-proprietary 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 demand by 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 internationally. We will add facilities and staff to our current operations, as required, to support this expansion.

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 internationally 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 facility in Clermont-Ferrand to allow it to directly process the European sourced tissue.

We believe the advantages of locating our international 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.

OST 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 bone tissue products, OST will continue to market these products in certain markets.

## **Quality Assurance**

We have stringent quality assurance programs in place covering all of our lines of business, including our DBM and Base Tissue Segments. OST's processing facility in Clermont-Ferrand, has received International Standardization Organization, or ISO, certification for its 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 DBM and Base Tissue Segments, our allograft bone tissue quality assurance program commences at the time allografts bone tissue is recovered. The allograft bone tissue is recovered 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 alcohol and then cut and shaped in accordance with our or our clients' specifications. Before being released for distribution, 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, TRO's and tissue banks, 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 utilized to produce Grafton® DBM 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 DBM Segment, we are developing 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 3.0 million transplanted grafts we have processed in our 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 2003, two of our clients, ARC and MTF individually accounted for approximately 24% and 25% of our consolidated revenue, respectively. We receive revenues in both our DBM and Base Tissue Segments from each of these clients. In the Base Tissue Segment, our clients pay us fees on a per donor basis for processing, finishing and packaging our clients' mineralized,

allograft bone tissue and on a per unit basis for the processing of bio-implants. In the DBM Segment our clients pay us fees on a per unit basis. We have processing agreements with ARC and MTF which run through December 31, 2006 and December 31, 2008, respectively. See Note 13 of "Notes to Consolidated Financial Statements".

Commencing in the first quarter of 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 under this agreement is processed in our Base Tissue Segment. Effective January 1, 2003, we entered into a five-year agreement with LifeNet and DePuy for the processing of LifeNet allograft bone tissue into a DBM carrier product, which will be marketed by DePuy and distributed by LifeNet.

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 American Tissue Services Foundation, or 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 an increasing 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 proprietary 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.

### **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, 2003, in the United States, we employed 37 persons engaged directly in efforts to educate surgeons as to the benefits and applications of processed allograft bone tissue. We complement our direct sales organization with a national network of independent sales agents who market Grafton® DBM, Graftech® Bio-implants and our other allograft and non-allograft products. These agents also educate the medical community about processed allograft bone tissue. At December 31, 2003, we had appointed 34 agencies which employ 167 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 allograft bone tissue forms in conjunction with a network of independent agents and distributors we have retained. OST's staff also markets and sells our LUBBOC® and LADDEC® Bovine bone grafts to orthopaedic surgeons and dentists.

## **Government Regulations**

Our products and our tissue banking activities are regulated in the United States by the U.S. Food and Drug Administration, or the FDA, and certain state agencies. Outside the United States, our products and tissue-banking activities are regulated by federal agencies of the respective countries. Each country maintains its own regulatory system for tissue-based products and tissue banking activities. European countries maintain a shared regulatory system for medical devices.

### *United States*

Our products are extensively regulated by federal and, in certain states, by state agencies in the United States. Failure to comply with these requirements may subject us to administrative or judicial sanctions, such as the 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 the FDA and to comply with regulations concerning tissue donor screening and testing, and related procedures and record keeping. The FDA periodically inspects tissue processors to determine compliance with these requirements. The 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 the 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. All of the metal spinal implant systems that we distribute are being marketed pursuant to 510(k) clearances.

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 the 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 the FDA's Quality Systems regulation. Marketing may commence if and when the FDA issues a premarket approval.

After premarket clearance or approval has been obtained, manufacturers and marketers of medical devices are subject to postmarketing requirements. For example, a manufacturer's quality control and manufacturing procedures and its facilities must conform to the FDA's Quality System Regulation, which governs, for instance, design, manufacture, packaging, labeling, installation, and servicing of medical devices. Certain adverse events and product malfunctions must be reported to the FDA, and product labeling and promotion must comply with FDA requirements. The FDA periodically inspects facilities to determine compliance with these requirements.

We market Grafton® DBM as a human tissue-based product pursuant to an August, 1995 designation from the FDA. In March, 2002, the FDA informed us that the agency is changing the regulatory status of Grafton® DBM and will henceforth regulate it as a medical device. We believe the 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 certain of our competitors, as medical devices. We communicated to the FDA that we believe its initial designation of Grafton® DBM as a human tissue-based product was and still is correct. In this regard, we have provided information to the FDA that we believe should cause the FDA to reconsider the position it has expressed in its March, 2002 letter as it relates to Grafton® DBM. On February 26, 2003, we met with representatives of the FDA to present our facts and views. On October 30, 2003, we received further correspondence from the FDA indicating that after considering the information we provided them in the February, 2003 meeting, the FDA still believes that a 510(k) should be submitted for Grafton® DBM. The Company has not submitted a 510(k) and we intend to continue to have a dialog with the FDA to further present our point of view regarding Grafton® DBM. If we are unsuccessful in our effort, we will be required to obtain a medical device approval or clearance for Grafton® DBM, 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 the FDA will issue any clearance or approval in a timely fashion, or at all.

We also market Grafton Plus™ DBM as a human tissue-based product. In its October 30, 2003 letter, the FDA indicated that its determination regarding Grafton® DBM is also to be applied to Grafton Plus™ DBM. If the FDA maintains its position that all products consisting of demineralized bone with a carrier should be regulated as a medical device, we would also be required to obtain FDA clearance or approval for Grafton Plus™ DBM and any other DBM

carrier product we may process, including the private label DBM we process pursuant to our agreement with LifeNet and DePuy, 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.

#### *International*

Allograft bone tissue and tissue banking activities, such as tissue donation and recovery and tissue processing, are regulated in virtually all countries in which we operate outside the United States. The regulatory schemes and specific requirements for these products and activities vary from country-to-country. There are no common or harmonized regulatory approvals or programs for these products and activities, such as there are for medical devices marketed in the European Union. We believe that we comply with the national regulations in the countries in which we currently operate or in the countries we plan to operate in the future, although there can be no assurances that we will be able to do so in the future.

In 2001, France authorized our French subsidiary, OST, to operate as a tissue bank. This authorization was based on OST's satisfaction of certain requirements, such as providing high technology as determined under applicable French regulations. This authorization was granted for a period of five years. At the end of this initial five-year period, OST can reapply to have the authorization renewed. Without this authorization, OST will not be able to operate its tissue bank in France or to directly distribute or import into France, human tissue based products. We cannot be certain that OST will be able to obtain a renewal of its authorization to operate as a tissue bank on a timely basis, or will be able to obtain such authorization.

The European Commission is working on the development and adoption of a common regulatory program for human tissue based products and tissue banking. We believe that an eventual adoption of such a common regulatory program is likely though not imminent. There can be no assurance that we would be able to meet the requirements of any such regulatory program once it is adopted.

ISO certification for production facilities was made mandatory in 1998 for companies that market or distribute products within the European Union. OST's processing 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 apply for a CE Mark for 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.

## **Research and Development**

During 2003, 2002, and 2001 we spent approximately \$3,944,000, \$3,927,000, and \$4,372,000, respectively, on research and development activities. The majority of these expenditures were made in our 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, efficacy 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. In 2004 we expect to substantially increase our spending on research and development activities in order to accelerate the development and marketing of certain new products and technologies.

## **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. Four basic categories of products or alternatives currently compete in the bone graft market:

- autograft bone tissue;
- allograft bone tissue;
- growth factors; and
- synthetic bone void fillers.

We estimate that total domestic allograft bone tissue sales in 2003 was \$793 million, comprising approximately 52% of the U.S. bone graft market. The number of bone graft procedures is expected to increase during the next five years as a result of an increase in the number of reconstructive orthopaedic surgical procedures utilizing bone grafts, particularly in spinal procedures.

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 improved recovery and processing techniques.

#### *Competitive Overview*

In both our DBM and Base Tissue Segments we compete in the bone graft market with autograft bone tissue, allograft bone tissue processed by others, growth factors and synthetic bone void fillers. Autograft bone tissue has traditionally been the primary choice for surgeons and we believe it still maintains an approximate 48% 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.

#### *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® DBM, a proprietary form of allograft bone tissue. The demineralization process used in Grafton® DBM removes most of the minerals, thus exposing the proteins that promote bone growth (osteinduction) and creating a latticework for new bone (osteoconduction). Grafton® DBM has a validated viral inactivation process for HIV, hepatitis B and C, cytomeglia and polio. Grafton®

DBM is produced in forms such as gel, flex, putty, crunch, and DBF Matrix, and is packaged in sterile, single patient delivery systems. In February, 2002, we introduced Grafton Plus™ DBM, which contains a carrier made from starch instead of glycerol. In 2003, we introduced Grafton® DBM Matrix Strips. With the varying textural and handling characteristics of its forms, Grafton® DBM can be used in virtually all non-weight-bearing bone graft procedures.

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 companies 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® II, OrthoBlast™ II and Accell™, manufactured and distributed by IsoTis OrthoBiologics; Osteofil™, processed by Regeneration Technologies, Inc. and distributed by Medtronic Sofamor Danek; AlloMatrix® and Ignite™, manufactured and distributed by Wright Medical Technologies, Inc.; InterGro™, processed and distributed by Interpore Cross International; 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; and we have entered into an agreement to process a private label DBM in order to expand into segments of the orthopaedic market that are not a focus of our spine focused sales force. We expect to enter into additional such agreements in 2004. We have also expanded our Graftech® Bio-implant line with which Grafton® DBM is used. When taken together, we are now able to provide the spinal surgeon with the full range of tissue 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 believe that Grafton® DBM was used in only a small portion of the total bone graft procedures performed in the U.S. during 2003. 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. We currently market Grafton® DBM in 11 European countries.

### *Base Tissue Segment*

For bone grafting procedures which require weight-bearing tissue, allograft bone tissue is still the only alternative to autograft bone tissue. In this segment, we process both our non-proprietary allograft bone tissue forms and Graftech® Bio-implants. We market and generally distribute these bio-implants. 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 Graftech® Bio-implants face significant competition from bio-implants processed by other tissue banks and processors such as MTF, Regeneration Technologies, Inc and LifeNet and are marketed by companies such as Medtronic Sofamor Danek, Synthes Spine and DePuy, 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 purchase. 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 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 allograft 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, Graftech® Bio-implants and non-proprietary allograft bone tissue forms 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. Also, several U.S. tissue bank organizations have formed strategic alliances with orthopaedic device firms to market allograft bone tissue grafts in European markets.

### **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 OST's processing facility in Clermont-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. 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 10, 2004, we held an aggregate of 107 United States patents and patent applications and 214 foreign patents and patent applications. We believe that our Grafton® 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 2022.

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.

### **Product Liability and Insurance**

The testing and use of allograft bone tissue and the implantation of 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 \$30 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 currently have one product liability claim asserted against us. See Item 3. "Legal Proceedings" and Note 13 of "Notes to Consolidated Financial Statements."

## **Employees**

At December 31, 2003, we had 367 employees, of whom 218 were engaged in allograft bone tissue processing and the manufacture of products; 24 were engaged in research and development; 59 were engaged in education, sales and marketing; and 66 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 a 38,000 square foot building in Eatontown, New Jersey, which is occupied pursuant to a lease which expires in December, 2008 and provides for a base annual rental of approximately \$576,000. This facility is occupied by our corporate, financial, administration, marketing, research and development, regulatory and clinical affairs staff.

In 1997, we purchased land adjacent to our principal executive offices. We constructed and validated a 73,000 square foot processing facility, which is utilized primarily by the DBM and Base Tissue Segments. We fully occupied it in June, 2002. Our credit facility is collateralized by this tissue processing facility, including all equipments and improvements therein.

We have a 45,000 square feet processing facility located in Shrewsbury, New Jersey occupied pursuant to a lease that expires in October, 2008, which provides for a base annual rental of approximately \$309,000 for the remaining term of the lease. The lease is renewable at our option for an additional five-year term. We currently use this facility for certain processing steps and for certain non-processing activities. In addition, we rent 4,600 square feet of space in Eatontown, New Jersey principally as warehouse space. The lease expires in January 2005 and provides for base annual rental of approximately \$27,000.

Our subsidiary in France, OST, which is engaged in the production, processing and distribution of human allograft tissue products and bovine bone graft substitute 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 90,000 Euros (approximately \$113,000 at the December 31, 2003 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 the activities of its tissue bank, OsteoCentre Europe, at an annual rental of 30,000 Euros (approximately \$38,000 at the December 31, 2003 exchange rate). The lease on this facility expires in February 2010. OST's Bulgarian subsidiary, Medical Technical Laboratory OsteoCentre Bulgaria EAD, leases a 3,900 square foot facility in Sofia, Bulgaria utilized for its tissue banking activities. The annual rental on this facility is 34,000 Euros (approximately \$42,000 at the December 31, 2003 exchange rate) and expires in February, 2010.

### **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<sup>®</sup> DBM process. In December 2001, as a result of a trial commenced in the United States District Court for the Central District of California, we were awarded damages in the amount of \$17,533,634 for GenSci's infringement of our patents. This damage award was reduced by the \$3.0 million previously paid by DePuy in 1999 and 2000 in settlement of our claims against DePuy in this lawsuit. We did not recognize any portion of this net award of \$14,533,634 in our consolidated financial statements. On December 21, 2001, GenSci filed for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code.

On May 30, 2003, we entered into a definitive agreement to settle our claims with GenSci arising out of the patent lawsuit. The settlement is for an aggregate of \$7.5 million. In August, 2003, the parties amended the definitive settlement agreement to adjust the payment terms of the settlement. Pursuant to the amended agreement, we will receive \$2.5 million from GenSci upon its exit from bankruptcy and GenSci's merger with IsoTis B.V. ("IsoTis") and the balance of \$5.0 million in 20 equal payments of \$250,000 plus interest at the federal judgment rate as measured at the end of each quarter to a maximum of 3% per annum. To secure the future amounts to be paid, GenSci will provide an irrevocable letter of credit in the amount of \$5.0 million. On October 14, 2003, the Bankruptcy Court signed an Order confirming GenSci's Plan of Reorganization at which time GenSci emerged from bankruptcy. GenSci's merger with IsoTis was consummated on October 27, 2003. On October 29, 2003, we received the initial payment of \$2.5 million, an interest bearing Promissory Note in the amount of \$5.0 million and the \$5.0 million letter of credit collateralizing the Promissory Note.

The settlement also provides that we covenant not to sue GenSci for infringing any of our existing patents with respect to GenSci's products currently marketed under the names Accell<sup>™</sup>, DynaGraft<sup>®</sup> II and OrthoBlast<sup>™</sup> II, as long as GenSci does not change the formulation and composition of such products. Additionally, the parties agreed to dismiss all other litigation that was currently pending between them.

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 and an attempt to monopolize the market for demineralized bone matrix and for entering into 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 for unlawful and unfair business practices in violation of Section 17200 of the California Unfair Competition Law. On December 20, 2001, GenSci filed a bankruptcy petition with the United States Bankruptcy Court for the Central District of California. GenSci did not seek relief from the automatic stay to pursue this action. On May 30, 2003, the parties executed a Joint Settlement Agreement that, inter alia, requires the dismissal of this action with prejudice within ten days after the Bankruptcy Court's approval of GenSci's Plan of Reorganization. The Bankruptcy Court signed an Order on October 14, 2003 confirming GenSci's plan of Reorganization. The Consent Judgment and Stipulation of Dismissal were filed with the Court on November 5, 2003, dismissing all claims with prejudice.

"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, Osteotech Implants BV, formerly known as CAM Implants BV. 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. We successfully moved to dismiss plaintiffs' claims for negligence and strict liability. Remaining are claims for breach of warranties, negligent misrepresentation, fraud, and violation of the New Mexico Unfair Trade Practices Act. Plaintiffs are seeking monetary damages in an amount to be determined at trial. On October 8, 2003, a Rule 16 Settlement Conference was conducted and the parties reached a tentative settlement agreement, which does not obligate us to pay monetary damages to the plaintiffs, but assigns certain of our rights under our insurance policies to the plaintiffs. The parties are now in the process of negotiating and preparing mutually acceptable definitive agreements. On October 10, 2003, the Court issued an order staying all proceedings in the action and vacating case management deadlines. On December 18, 2003, the Court extended the stay of all proceedings until March 27, 2004. In the event the parties are unable to consummate a settlement by March 27, 2004, and no further extension is granted, the Court will lift the stay of the proceedings and the parties will return to active litigation.

Regner v. Inland Eye & Tissue Bank of Redlands; Thacker v. Inland Eye & Tissue Bank of Redlands; Savitt v. Doheny Eye and Tissue Bank; Sorrels, Decker and Blake v. Inland Eye & Tissue Bank, et al.

We are a defendant with other defendants in several actions pending in the Superior Court for the State of California, Los Angeles County. The Regner case sought class action status and initially alleged causes of action based on a violation of the California Business and Professional Code Section 17200, 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 the allegation that defendants are engaging in the activity of buying or selling organs or tissue for valuable consideration or profit, and certain negligence claims remain with respect to the actions. In addition, the plaintiffs through the Regner case sought class action status and injunctive relief and "restitution" with respect to their California Business and Professional Code claims. To the extent any of the other causes of action lie against us, plaintiffs are seeking damages in an unspecified amount.

In September, 2003, a settlement was entered into by the parties in the Savitt case, and plaintiffs subsequently dismissed this lawsuit with prejudice. Also in September, 2003, a global settlement was negotiated in the Regner, Thacker and Sorrels cases. The settlements in the Savitt, Regner, Thacker and Sorrels cases had no impact on our financial position or results of operations. Settlement documents have been finalized, and on November 6, 2003 the Court issued an order dismissing the cases, with prejudice.

Scroggins v. Zimmer Holdings, Inc.

On or about June 24, 2002, we received a complaint filed in the United States District Court for the Eastern District of Louisiana against numerous defendants, including us. The complaint alleges that plaintiff received defective medical hardware in connection with a certain hip replacement procedure in May, 1992, and that such hardware was manufactured or distributed by certain of the defendants other than us. The procedure involved the use of allograft bone tissue processed by us and provided by one of our clients. Plaintiff alleges personal injuries and \$1,000,000 in damages.

On April 8, 2003, we filed a Motion for Summary Judgment seeking dismissal of plaintiff's claims with prejudice. On May 9, 2003, the Court granted our Motion for Summary Judgment dismissing plaintiff's claims as to us with prejudice.

Alphatec Manufacturing v. Osteotech, Inc.

Alphatec Manufacturing, Inc., the manufacturer of the Affirm™ Anterior Cervical Plate System ("Affirm™"), filed an action on July 3, 2002 against us in the United States District Court for the Southern District of California. The complaint sets forth causes of action for recovery of contractual penalty, breach of contract, fraud and trade libel arising out of a distribution agreement between the parties. Alphatec is seeking \$1.4 million plus interest on the contractual penalty claim, \$600,000 on the fraud claim and additional unspecified compensatory damages.

On August 3, 2003, we answered the complaint denying all allegations and asserted counterclaims setting forth causes of action for breach of contract, breach of implied covenant of good faith and fair dealing, fraudulent misrepresentation, fraudulent concealment, unjust enrichment, unfair competition, cancellation or rescission of the contract and indemnification. We are seeking compensatory and punitive damages in an amount to be determined at trial as well as reasonable attorney's fees. Discovery has commenced and will continue through May 7, 2004.

We believe that Alphatec's claims are without merit and intends to vigorously defend against such claims. In the fourth quarter of 2002, we recorded a provision of approximately \$2.5 million, which includes an estimate of the penalty that would be due for the expected shortfall in the second year purchase commitment and an amount to fully reserve all implant inventory and instrumentation associated with Affirm™.

Anthonsen v. Allosource, Inc.

In January, 2004, we were served with a complaint in an action brought in the Lake Superior Court of Lake County, State of Indiana against numerous defendants, including us. The complaint alleges that plaintiff received defective implants and medical hardware in connection with cervical surgery performed on plaintiff, and that such implants and hardware were manufactured, processed or distributed by defendants. Plaintiff alleges personal injuries and unspecified damages. In February, 2004, the action was removed to the United States District Court, Northern District of Indiana, Hammond Division. We are currently reviewing the complaint and a response is due on March 17, 2004.

We maintain a product general liability insurance policy and have notified the insurance company of this action. The insurance company has agreed to defend this action.

Other than the foregoing matters, we are 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 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 currently unable to estimate the ultimate 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® 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, 2003 and 2002 based on transaction data as reported by the Nasdaq Stock Market®.

<u>Year Ended December 31, 2003</u>	<u>High</u>	<u>Low</u>
First Quarter	\$7.70	\$6.17
Second Quarter	\$14.32	\$6.40
Third Quarter	\$16.06	\$8.25
Fourth Quarter	\$8.80	\$7.25

<u>Year Ended December 31, 2002</u>	<u>High</u>	<u>Low</u>
First Quarter	\$9.37	\$5.75
Second Quarter	\$8.29	\$6.39
Third Quarter	\$11.01	\$5.16
Fourth Quarter	\$6.92	\$4.59

As of March 8, 2004, there were 320 holders of record of Osteotech Common Stock. We believe that there are approximately 5,200 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.

We have three stock option plans all of which have been approved by our shareholders. Two of the plans, the 1991 Stock Option Plan and the 1991 Independent Directors Stock Option Plan, do not have any shares available to grant new options and all shares underlying outstanding options that expire or are forfeited prior to exercise are not available for future option grants under these plans. See Note 14 of "Notes to Consolidated Financial Statements." The following table sets forth certain information relative to our stock option plans.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u> (a)	<u>Weighted-average exercise price of outstanding options, warrants and rights</u> (b)	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u> (c)
Equity compensation plans approved by security holders	2,499,762	\$9.10	1,112,000
Equity compensation plans not approved by security holders <sup>(1)</sup>			
Total	2,499,762	\$9.10	1,112,000

(1) We do not have any equity compensation plans which have not been approved by our security holders.

## 6. Selected Financial Data

Set forth below is selected financial data for the five years ended December 31, 2003. 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."

Selected Financial Data (dollars in thousands except per share data) For the Year ended December 31,	2003	2002	2001	2000	1999
<b>Consolidated Results of Operations</b>					
Net revenues	\$ 94,433	\$ 83,374	\$ 75,715	\$ 74,111	\$ 73,642
Gross profit	52,362	37,103	42,735	47,518	50,690
Operating expenses	41,730	42,183	48,628	40,199	32,694
Income (charge) from litigation settlements	7,500	(1,785)		1,000	2,000
Operating income (loss)	18,132	(6,865)	(5,893)	8,319	19,996
Other income (expense), net	(386)	29	129	1,019	1,133
Income (loss) from continuing operations before income taxes	17,746	(6,836)	(5,764)	9,338	21,129
Income (loss) from continuing operations	10,867	(1,248)	(3,817)	5,247	12,572
Income (loss) from continuing operations per share					
Basic	.64	(.08)	(.28)	.37	.90
Diluted	.62	(.08)	(.28)	.37	.86
Dividends per share	0	0	0	0	0
<b>Year End Financial Position</b>					
Working capital	\$ 56,384	\$ 42,447	\$ 24,778	\$ 29,239	\$ 37,171
Total assets	127,213	114,732	107,017	104,362	89,671
Long-term obligations, net of current portion	13,262	15,922	18,683	19,930	6,359
Stockholders' equity	96,220	84,023	68,125	71,967	69,495

In 2003, 2002 and 2001, we recorded certain gains and charges that are detailed in Note 4 of the "Notes to Consolidated Financial Statements." In July, 2002, we completed the sale of the business and substantially all of the assets, including the assumption of certain liabilities, of our operations located in Leiden, The Netherlands. See Note 5 of "Notes to Consolidated Financial Statements." The consolidated statements of operations for all periods have been restated to reflect this divestiture as a discontinued operation.

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

**For the Three Years Ended December 31, 2003, 2002, and 2001**

### **Results of Operations**

#### **Overview**

We provide services and products primarily focused on the repair and healing of the musculoskeletal system. Our services and technology are associated with making human tissue safe for transplantation and for use in a variety of surgical procedures. 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. The allograft bone tissue we process is procured by independent tissue banks and other Tissue Recovery Organizations, or TRO's, primarily through the donation of tissue from deceased human donors and is used for transplantation. We process allograft bone tissue for our clients from allograft bone tissue provided by them, and also for us from allograft bone tissue recovered by TRO's and tissue banks for us in both our DBM and Base Tissue Segments.

We perform the medical education to teach surgeons about the uses of these tissue forms. Prior to 2001, our clients generally distributed these tissue forms to hospitals and surgeons. Commencing in the first half of 2001, we began to distribute tissue forms directly to hospitals and surgeons. We expect to continue to expand our direct distribution efforts in future periods. As a result, we expect that revenues from direct distribution of tissue will continue to grow over the next several years. For the years ended December 31, 2003, 2002 and 2001, 54%, 61% and 79%, respectively, of our consolidated revenues were generated from processing tissue that our clients distributed.

This change in distribution methodology has impacted our liquidity and cash flow. We have had to make additional investments in deferred processing costs to support our direct distribution efforts, future programs and initiatives, which may deplete our available cash balance. As a greater percentage of our revenues are generated from direct shipments to hospitals and surgeons, which typically pay invoices slower than our historical tissue bank customer base, we expect that our investment in accounts receivable will increase. We believe that available cash, cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet forecasted cash needs in 2004. However, we may seek additional funding to meet the needs of our long-term strategic plan. 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 our 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 an on-going 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 including purchase commitments, deferred processing costs including rework reserves, 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 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 bone tissue form returns based upon historical experience. If future returns are less than our historical experience, 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 excess, obsolescence or unmarketable products and allograft bone tissue forms equal to the difference between cost and the estimated market value based upon assumptions about future demand and market conditions. Excess and obsolescence could occur from numerous factors, including, but not limited to, the competitive nature of the market, technological change, expiration and changes in surgeon preference. If actual market conditions are less favorable than those projected by management, additional write-downs may be required. In addition, we provide reserves, if any, for the difference between our contractual purchase commitments and our projected purchasing patterns based upon the maintenance of adequate inventory levels and forecasted revenues. If actual revenue is less favorable than those forecasted by management, additional reserves may be required; alternatively, if revenue is stronger than forecasted by management, such reserves would be reduced.
- 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 we determine 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.
- Litigation is subject to many uncertainties and we are unable to predict the outcome of the pending suits or claims. When we are reasonably able to determine the probable minimum or ultimate liability, if any, that may result from any of the pending litigation, we will record a provision for such liability, and if appropriate, will reduce such liability to the extent covered by insurance. If the outcome or resolution of the pending suit or claim is for amounts greater than we have accrued, an adjustment will be charged to income in the period the determination is made. Alternatively, should the suit or claim be for less than we have accrued, we would increase income in the period the determination is made.

### **Cessation of Marketing and Distribution Efforts for Metal Spinal Implant Products**

In January, 2004, we announced that we would terminate the Distribution Agreement dated February 1, 2003 with SpineVision, S.A. and SpineVision, Inc. in accordance with the provisions of the agreement effective February 17, 2004. In addition, we announced in March, 2004 that we would discontinue our marketing and distribution efforts for all remaining metal spinal implant product lines. Revenues generated from metal spinal implants were \$4,907,000, \$4,166,000 and \$2,617,000 in 2003, 2002 and 2001, respectively. We are currently developing and implementing the plans to transition our surgeon users from our metal spinal implant systems and expect to completely cease the marketing and distribution of metal spinal implant in the second quarter of 2004. In addition, we expect to take a charge of approximately \$2.4 million in the first quarter 2004 for inventory and instrumentation write-offs and severance related to this decision.

### **Temporary Suspension of Base Tissue Segment Processing**

On September 30, 2002, we voluntarily and temporarily suspended Base Tissue Segment processing due to higher than normal incidence of sterility failures on finished forms of processed allograft bone tissue, which occurred in our Eatontown facility, and subsequently, in our Shrewsbury facility. In addition, as a precaution, we voluntarily retrieved certain tissue from

15 whole donors and five individual pieces of tissue from five different donors that had previously been shipped to clients although all such tissue was tested and found sterile. In October, 2002, we restarted Base Tissue Segment processing in our Shrewsbury facility, and in November, 2002 we restarted Base Tissue Segment processing in our Eatontown facility.

As a result of the temporary suspension of Base Tissue Segment processing, we placed tissue processed in third quarter 2002 from 693 donors in quarantine. We released a portion of the quarantined tissue in 2003 and expect to release the remainder in 2004. We estimated that the total cost to rework this tissue is \$840,000. In order to successfully rework the remaining tissue, we will need to continue to meet certain technical, scientific and regulatory requirements. We believe that we will be able to meet such requirements, however, there can be no certainty that we will be able to meet all such requirements or be able to rework the remaining tissue for our estimated cost.

These events negatively impacted our 2002 operating results. We have estimated that the third quarter 2002 Base Tissue Segment revenues were negatively impacted by approximately \$1,300,000 and gross profit was impacted by the lost revenues and by the \$840,000 estimated cost to rework the tissue in quarantine. We have estimated that the fourth quarter 2002 Base Tissue Segment revenues were negatively impacted by approximately \$1,100,000, while gross profit was impacted by the lost revenues and the effects of negative production variances, which we estimate were approximately \$3,000,000.

### **Income (Loss) from Continuing Operations**

Consolidated income from continuing operations was \$10,867,000 or \$.62 diluted income per share in 2003, compared to a consolidated loss from continuing operations in 2002 of \$1,248,000 or \$.08 diluted loss per share and a consolidated loss from continuing operations of \$3,817,000 or \$.28 diluted loss per share in 2001. In 2003 income from continuing operations included an after tax gain of \$4,500,000 related to the settlement with GenSci. In 2002, the loss from continuing operations included after tax charges of: \$504,000 for the estimated cost to rework the tissue from donors placed in quarantine in the third quarter of 2002; a reserve of \$647,000 for the penalty associated with metal spinal implants, primarily Affirm™, that we do not expect to purchase, which are subject to purchase commitments; \$2,801,000 for excess and obsolete inventory related to spinal implant systems, including the bio-d® Threaded Cortical Bone Dowel, which we removed from the market on January 31, 2003 in connection with the lawsuit settlement with Medtronic, Inc.; and \$1,071,000 associated with payment to Medtronic in connection with the litigation settlement; partially offset by the recognition of an income tax benefit of \$2,557,000 related to liabilities for tax benefits recorded in 1997 that are no longer required and an after tax gain of \$830,000 related to the sale of the PolyActive™ polymer biomaterial technology and patents to IsoTis BV. The loss from continuing operations in 2001 includes after tax charges of: \$1,107,000 related to provisions for excess inventory and instrument sets for metal spinal implant systems; \$1,372,000 for equipment which is no longer utilized in the processing of allograft bone tissue; and \$420,000 primarily for severance costs associated with the departure of an executive officer.

Consolidated income from continuing operations before taxes was \$17,746,000 in 2003 compared to a consolidated loss from continuing operations before income taxes of \$6,836,000 in 2002 and \$5,764,000 in 2001.

### **Discontinued Operations**

Effective June 30, 2002, we completed the sale of the business and substantially all of the assets, including the assumption of certain liabilities, of our operations in Leiden, The Netherlands for \$1,000,000 in cash and a non-interest bearing note with a face value of \$1,500,000, which we discounted based on the acquirer's incremental borrowing rate of 5.75%. These operations represented our ceramic and titanium plasma spray coating services and products. We recognized a loss on the sale of this business of \$291,000 in the second quarter of 2002. Revenues from this business were \$1,630,000 in 2002 through the date of sale and were \$2,131,000 in 2001. The business had net income of \$384,000 in 2002 through the date of sale, compared to a net loss of \$370,000 in 2001.

### **Net Income (Loss)**

Consolidated net income was \$10,867,000 or \$.62 diluted net income per share in 2003 compared to net losses in 2002 and 2001 of \$1,155,000 or \$.07 diluted net loss per share and \$4,187,000 or \$.30 diluted net loss per share, respectively.

The following is a discussion of factors affecting results of operations for the years ended December 31, 2003, 2002, and 2001 after giving effect to the divestiture of the operations of our subsidiary in The Netherlands in 2002.

### **Net Revenues**

Consolidated net revenues increased 13% in 2003 to \$94,433,000 compared to consolidated revenues of \$83,374,000 in 2002. Consolidated net revenues increased 10% in 2002 to \$83,374,000 compared to consolidated revenues of \$75,715,000 in 2001. The increases in 2003 and 2002 were primarily due to increased revenues in all segments mainly as a result of increased volume, and to a lesser extent by price increases effective January 1 of each period and the favorable impact, primarily in 2003, of exchange rates between the U.S. dollar and the Euro. Consolidated revenues in 2002 were negatively impacted by the temporary suspension of Base Tissue Segment processing operations and from placing tissue in quarantine that otherwise would have been released and invoiced to our clients, and by the suspension of sales of Affirm™.

Domestic net revenues increased 10% to \$86,070,000 in 2003 and increased 9% in 2002 to \$78,576,000 from \$71,776,000 in 2001. The increase in domestic revenues in 2003 was primarily related to increased base allograft tissue processing revenues, revenues from the private label DBM processed for LifeNet and marketed by DePuy, a 13% increase in bio-implant revenues and revenues from the three metal spinal implant systems we were distributing for SpineVision and annual price increases, partially offset by a 9% decline in Grafton® DBM revenues and the loss of revenue related to the suspension of sales of Affirm™. The increase in domestic revenues in 2002 was due primarily to increased unit volume in Grafton® DBM, bio-implants and spinal metal implants and increased pricing in Grafton® DBM and bio-implants, partially offset by a 29% decline in base allograft tissue processing revenues due to the temporary

suspension of base tissue processing and a decrease in the number of donors processed for our clients in 2002 compared to 2001 and by the suspension of sales of Affirm™. Foreign-based revenues increased 74% to \$8,363,000 in 2003 and increased 22% in 2002 to \$4,798,000 from \$3,939,000 in 2001. The increase in foreign-based revenues was due principally to increased unit sales volume in all product lines and the favorable impact, primarily in 2003, of exchange rates between the U.S. dollar and the Euro.

DBM Segment revenues, consisting primarily of Grafton® DBM revenues, increased 3% to \$46,294,000 in 2003 from \$44,926,000 in 2002. The increase in 2003 principally relates to a 143% increase in international Grafton® DBM revenues as well as revenues from the private label DBM processed for LifeNet and marketed by DePuy, partially offset by a 9% decline in domestic Grafton® DBM revenues. Domestic DBM Segment revenues declined 4% in 2003 to \$41,338,000 from 2002 revenues of \$42,883,000. Foreign-based DBM Segment revenues increased 143% in 2003 to \$4,956,000 from \$2,043,000 in 2002. DBM Segment revenues increased 3% in 2002 to \$44,926,000 from \$43,637,000 in 2001 primarily due to increased worldwide unit volume and the impact of 2002 price increases. Domestic DBM Segment revenues increased 3% in 2002 to \$42,883,000 from 2001 revenues of \$41,683,000. Foreign-based DBM Segment revenues increased 5% in 2002 to \$2,043,000 from \$1,954,000 in 2001. In all periods, domestic Grafton® DBM revenues were negatively impacted by increased competition. We expect domestic Grafton® DBM will continue to face increasing competition as more companies develop and market products with similar characteristics.

Base Tissue Segment revenues increased 29% in 2003 from \$41,465,000 from \$32,115,000 in 2002, primarily due to a 56% increase in revenues from the processing of donor tissue for our clients and a 13% increase in bio-implant revenues resulting from an increase in unit sales volume and the January 1, 2003 price increase. Base Tissue Segment revenues were negatively impacted in 2002 from the temporary suspension of Base Tissue Segment processing. Base Tissue Segment revenues increased 16% to \$32,115,000 in 2002 from \$27,692,000 in 2001. The increase is principally the result of a 70% increase in bio-implant revenues, partially offset by a 26% decrease in base tissue processing revenues resulting from the temporary suspension of base tissue processing and a decrease in the number of donors processed for our clients in 2002 compared to 2001. The increase in bio-implant revenues is principally due to increased unit volume in 2002 compared to 2001 when several bio-implant tissue forms were in a launch mode, the ability to charge higher unit sale prices as a result of our direct distribution of principally all of those units to hospitals and surgeons, and the effects of the January 1, 2002 price increases.

Revenues from other product lines, which are mainly metal spinal implant products and bovine tissue, increased 5% in 2003 to \$6,674,000 from 2002 revenues of \$6,333,000. The increase in 2003 primarily relates to revenues from the three metal spinal implant systems we were distributing for SpineVision, partially offset by a decline in bovine revenues and the suspension of sales of Affirm™. Revenues from other product lines increased 44% in 2002 to \$6,333,000 from \$4,386,000 in 2001. The increase principally resulted from improved volume in spinal metal implant systems and bovine products.

In January, 2004 we announced that we would terminate the Distribution Agreement dated February 1, 2003 with SpineVision, S.A. and SpineVision, Inc. in accordance with the provisions of the agreement effective February 17, 2004. In addition, we announced in March,

2004 that we would discontinue our marketing and distribution efforts for all remaining metal spinal implant product lines. Revenues generated from metal spinal implants were \$4,907,000, \$4,166,000 and \$2,617,000 in 2003, 2002 and 2001, respectively. We are currently developing and implementing the plans to transition our surgeon users from our metal spinal implant systems and expect to completely cease the marketing and distribution of metal spinal implant in the second quarter of 2004.

During 2003, 2002, and 2001, two of our clients, MTF and ARC, in the DBM and Base Tissue Segments together accounted for 49%, 59%, and 77% of consolidated net revenues, respectively. We have processing agreements with each of these clients, which expire in December, 2008 and December, 2006, respectively. See Item 1. "Clients" and Note 13 of "Notes to Consolidated Financial Statements" for more information on these processing agreements.

### **Gross Profit**

Gross profit as a percentage of net revenues was 55% in 2003, 45% in 2002, and 56% in 2001. The increase in gross profit as a percentage of revenues in 2003 compared to 2002 is principally due to the increase in revenues, which has improved the absorption of fixed costs. Gross profit as a percentage of revenues was negatively impacted in 2002 primarily from the items discussed below. The decline in gross profit as a percentage of revenues in 2002 compared to 2001 is primarily due to pre-tax charges of \$6,588,000 for the estimated cost to rework the tissue from donors placed in quarantine in 2002, excess and obsolete inventory related to spinal implant systems and reserves for metal spinal implants that we do not expect to purchase, which are subject to a firm purchase commitments. In addition, the decline in base tissue processing revenues due to the temporary suspension of base tissue processing, the decline in donors processed for our clients, and the negative impact of underabsorption of production variances in the fourth quarter due to lower than normal allograft bone tissue processing levels due to the temporary suspension of base tissue processing in our two production facilities.

We expect that gross profit as a percentage of revenues will decline in 2004 from 2003 levels primarily due to the expected charge of approximately \$2.4 million for inventory and instrumentation write-offs and severance related to our decision to discontinue marketing and distribution of metal spinal implant products, lower margins in the DBM Segment associated with lower margin international sales volume and private label DBM revenues, increased facility costs related to terminal sterilization and viral inactivation systems and increased insurance costs, especially for product liability.

We believe that the continued expansion of our direct distribution efforts from tissue recovered directly for us will have a positive impact on our future 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 and which they distribute. In addition, we continue to develop and implement 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.

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

In 2003, marketing, selling, general and administrative expenses were \$37,786,000 compared to 2002 expenses of \$38,256,000. Marketing, selling, general and administrative expenses decreased 14% in 2002 to \$38,256,000 from \$44,256,000 in 2001. Marketing, selling, general and administrative expenses remained relatively flat in 2003 compared to 2002 primarily due to a reduction in legal fees and the rescission of our funding of the American Tissue Services Foundation, partially offset by increased costs for marketing and sales programs, an increase in the number of direct sales representatives, increased commissions related to increased revenues, and an approximate 50% increase in the effective commission rate for domestic Grafton® DBM revenues effective July 1, 2003. The decrease in 2002 relates mainly to decreased legal fees due to the settlement of a number of our lawsuits in late 2001 and 2002, a reduction in our funding of the American Tissue Services Foundation, decreased marketing costs due to the launch in 2001 of new bio-implant tissue forms, which increased 2001 marketing costs, and in 2001 provisions of \$1,190,000 for reserves primarily for excess instruments sets associated with spinal implant systems and \$700,000 for severance costs primarily related to the departure of an executive officer. We expect marketing, selling, general and administrative expenses to increase slightly in 2004 compared to 2003 as a result of increased commission costs related to increased revenues and the increase in the effective commission rate for Grafton® DBM and a severance charge of approximately \$600,000 related to the reorganization of our sales and marketing functions in first quarter 2004.

## **Research and Development Expenses**

In 2003, research and development expenses were \$3,944,000 compared to 2002 research and development expenses of \$3,927,000. Research and development expenses decreased 10% in 2002 to \$3,927,000 from \$4,372,000 in 2001. Research and development expenses were relatively flat in 2003 compared to 2002 as existing projects continued to be developed and new projects were started after other projects were completed. The decrease in 2002 from 2001 principally related to the completion of the development of bio-implant tissue forms, which were launched in 2001, the completion of new processing technology and packaging, which were implemented in 2001, and the completion of development of Grafton Plus™ DBM, which was launched in the first quarter of 2002. We expect research and development costs to increase in 2004 primarily due to decisions to fund additional projects in 2004 and to contribute additional resources to previously under-funded projects.

## **Income (Charge) From Litigation Settlement**

In May, 2003, as amended in August, 2003, we entered into a definitive settlement agreement with GenSci to settle all claims arising out of our patent litigation with GenSci. The settlement agreement was for an aggregate of \$7,500,000 and was subject to GenSci exiting bankruptcy and completing its merger with IsoTis B.V. In October, 2003, GenSci emerged from bankruptcy and merged with IsoTis. Pursuant to the settlement agreement, we received an initial payment of \$2,500,000 in cash, an interest bearing \$5,000,000 promissory note and a \$5,000,000 letter of credit collateralizing the promissory note. The promissory note is to be repaid in 20 equal payments of \$250,000 plus interest. As a result, in connection with this settlement, we recognized pre-tax income of \$7,500,000 in the fourth quarter of 2003.

In April, 2002, we settled a patent lawsuit and agreed to pay an aggregate of \$1,900,000 in 24 equal monthly installments without interest. We recorded a charge of \$1,785,000 related to this settlement representing the present value of the amounts due.

### **Operating Income (Loss)**

Consolidated operating income in 2003 was \$18,132,000 compared to a consolidated operating loss of \$6,865,000 in 2002. DBM Segment operating income increased 108% in 2003 to \$20,646,000 from \$9,913,000 in 2002. The increase in DBM Segment operating income in 2003 results principally from the income of \$7,500,000 from the GenSci settlement, increased revenues and a decline in operating expenses, primarily due to lower legal fees. Operating income in the Base Tissue Segment was \$2,703,000 in 2003 compared to an operating loss in of \$8,927,000 in 2002. The improvement in operating income in 2003 compared to 2002 results primarily from increased revenues, the impacts in 2002 on revenue and gross profit related to the temporary suspension of base tissue processing and a number of reserves and provisions recorded in 2002 related to rework reserves, excess and obsolete bio-d® Threaded Cortical Bone Dowel inventory and the litigation settlement charge, partially offset by increased operating expenses in 2003 associated with sales and marketing programs. Operating losses associated with other revenues were \$5,217,000 and \$7,851,000 in 2003 and 2002, respectively. The operating loss in 2003 results primarily from metal spinal implant revenues for which there is not sufficient unit volume to cover overhead costs, and increased legal fees.

We incurred a consolidated operating loss in 2002 of \$6,865,000 compared to a consolidated operating loss of \$5,893,000 in 2001. DBM Segment operating income increased 41% in 2002 to \$9,913,000 from \$7,031,000 in 2001. The increase in DBM Segment operating income results principally from decreased legal fees due to the resolution of lawsuits in late 2001 and second quarter 2002, increased revenue levels, lower research and development costs associated with the development of Grafton Plus™ DBM, which was launched in the first quarter of 2002, and lower marketing and selling costs. We incurred an operating loss in the Base Tissue Segment of \$8,927,000 in 2002 compared to an operating loss of \$7,877,000 in 2001. The Base Tissue Segment operating loss principally resulted from the underabsorption of production variances due to lower than normal allograft bone tissue processing levels as a result of the temporary suspension of base tissue processing in our two production facilities, the decline in base tissue processing revenues due to the temporary suspension of base tissue processing and a decline in the number of donors processed for our clients, reserves of \$840,000 related to the estimated cost to rework tissue from donors placed in quarantine, costs associated with the settlement of the patent litigation regarding the bio-d® Threaded Cortical Bone Dowel, including the cost of excess inventory of \$1,094,000 and the litigation settlement charge of \$1,785,000, increased legal fees, and a decline in donor processing revenue. Operating losses associated with other revenues were \$7,851,000 and \$5,047,000 in 2002 and 2001, respectively. The operating loss in 2002 increased over the operating loss in 2001 principally as a result of provisions of \$4,654,000 for excess inventory and instrumentation for metal spinal implant systems and reserves related to the penalty associated with metal spinal implants, primarily Affirm™, that we do not expect to purchase, which are subject to a purchase commitments, partially offset by a decline in our funding of the American Tissue Services Foundation.

## **Other Income (Expense)**

Other expense of \$386,000 in 2003 related primarily to interest expense on our long-term debt of \$1,107,000, partially offset by interest income on available cash balance of \$144,000 and foreign currency translation gains associated with the impact of exchange rates between the U.S. dollar and the Euro on intercompany debt.

In fourth quarter 2003, as a result of a decision to utilize excess cash flow, if any, generated by our French subsidiary to repay the remaining outstanding balance of its intercompany debt, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 52, "Foreign Currency Translation", we recognized the impact of foreign currency translation gains and losses on the outstanding balance of the intercompany debt in our results of operations. Foreign currency translation gains of \$510,000 were recognized in other income (expense) in the consolidated statement of operations for the year ended December 31, 2003 related to the impact of exchange rates between the U.S. dollar and the Euro. Future translation gains and losses may have a material impact on our results of operations in the event of significant changes in the exchange rate between the U.S. dollar and the Euro, although the impact of such gains and losses should not have any impact on consolidated cash flows.

Other income was \$29,000 in 2002 compared to other income of \$129,000 in 2001. The decrease was associated with an increase in interest expense on our long-term debt as a result of higher interest rates and the recognition of interest expense on the debt for a full year in 2002 as compared to only a portion of the year in 2001 as the interest costs were capitalized during the construction of our new allograft processing facility and a decline in interest income as a result of lower interest rates, partially offset by the \$950,000 gain on the sale of the PolyActive™ polymer biomaterial technology and patents.

## **Income Tax Provision**

Our effective income tax rate in 2003 was 39%. The effective income tax rate exceeded the federal statutory income tax rate principally due to the impact of domestic state income taxes, partially offset by federal and state tax credits.

In 2002 and 2001, we provided a benefit for income taxes primarily due to losses in our domestic operations and our ability to carryback and carryforward these losses. We did not recognize any income taxes on foreign income in 2002 due primarily to our ability to utilize previously unrecognized foreign net operating loss carryforwards, which carry a full valuation allowance. In addition, we reversed liabilities for previously deferred tax benefits of \$2,557,000 that are no longer required. In 2002, we utilized approximately \$2,000,000 of historical foreign net operating loss carryforwards to offset foreign taxable income. In 2001, no income tax benefit was recorded for foreign losses, principally as a result of the uncertainty of realization of such future tax benefits.

## Liquidity and Capital Resources

At December 31, 2003 we had cash and short-term investments of \$15,326,000 compared to \$13,988,000 at December 31, 2002. We invest excess cash in U.S. Government-backed securities and investment grade commercial paper of major U.S. corporations. Working capital increased \$13,937,000 to \$56,384,000 at December 31, 2003 compared to \$42,447,000 at December 31, 2002. The increase resulted primarily from additional investments in accounts receivable as a result of increased revenues, and deferred processing fees to continue to expand available inventories and increase our overall tissue position.

Net cash provided by operating activities was \$4,784,000 in 2003 compared to net cash used in operating activities of \$1,633,000 in 2002. The improvement resulted primarily from the increase in net income and the initial \$2,500,000 cash payment received under the GenSci settlement, partially offset by our additional investments in deferred processing costs.

Net cash provided by investing activities was \$2,893,000 in 2003 and is principally due to proceeds from the sale of investments, partially offset by capital expenditures. Net cash used in investing activities of \$7,242,000 in 2002 primarily resulted from net purchases of short-term investments and capital expenditures, partially offset by proceeds from the sale of the PolyActive™ polymer biomaterial technology and patents and proceeds from the sale of the operations of our subsidiary in The Netherlands.

Net cash used in financing activities in 2003 of \$1,979,000 relates primarily to principal payments on long-term debt, partially offset by proceeds from the exercise of stock options and sales of common stock pursuant to our employee stock purchase plan. Net cash provided by financing activities in 2002 was \$13,654,000, and relates mainly to the sale of 2.8 million shares of common stock, which in addition to the exercise of stock options and sales pursuant to our employee stock purchase plan, generated net proceeds of \$16,284,000, partially offset by principal payments on long-term debt.

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, 2003, \$3,982,000 was outstanding under the building mortgage loan and \$11,941,000 was outstanding under the equipment term loan. In 2002, to support the \$1,900,000 due under the settlement of certain patent litigation, we provided a declining irrevocable standby letter of credit in an original amount of \$1,900,000. As of December 31, 2003, the standby letter of credit has been reduced to \$428,000. Amounts committed under this standby letter of credit decrease over time based on a predetermined schedule concurrent with our monthly payments under the settlement and reduced the amounts available under the revolving line of credit. As of December 31, 2003, no amounts were outstanding under the revolving line of credit and \$4,572,000 was available. The revolving line of credit expires on April 30, 2004 at which time all amounts outstanding are due and payable and all remaining commitments are cancelled. We are currently negotiating an extension of the revolving line of credit with our lender, although there can be no assurance that we will be successful in such endeavor.

The Credit Facility, as amended, is collateralized by domestic accounts receivable, domestic inventories, our allograft tissue processing facility, including all equipment and improvements therein, and a pledge of 65% of our ownership in our foreign subsidiaries. The Credit Facility imposes certain restrictive operating and financial covenants, including a restriction on the payment of cash dividends, a restriction on incurring or maintaining additional indebtedness, a restriction on selling of assets or engaging in mergers or acquisitions and limitations on cash advances to our foreign operations or investments. In addition, if available cash, cash equivalents and short-term investments decline below \$10.0 million at the end of any calendar month, the amendment gives the bank, at its option, the right to obtain a security interest in our general intangibles, including, but not limited to, our patents and patent applications. The Credit 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 the condition or affairs, financial or otherwise, of our business, which impairs the interests of the bank. Due to our expectation of improved financial performance, our compliance with our bank covenants in 2003, and our expected compliance with our bank covenants in 2004, we continue to classify the long-term portion of our outstanding bank debt as long-term. However, there can be no assurance that our financial performance will improve or that we will comply with our bank covenants. 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, 2003, we had Federal net operating loss carryforwards of \$764,000, which expire in varying amounts beginning in 2007 through 2013, and state net operating loss carryforwards of \$6,889,000, primarily to offset New Jersey taxable income, which expire in varying amounts beginning in 2007 through 2012. We have provided valuation allowances for all of the Federal, and a corresponding amount of state, net operating loss carryforwards due to the uncertainty of realizing future tax benefits from these net operating loss carryforwards. In addition, we have state research and development and manufacturing credits of \$690,000, primarily to offset New Jersey income taxes, which expire in varying amounts beginning in 2008 through 2010. At December 31, 2003, certain of our foreign-based subsidiaries have net operating loss carryforwards aggregating \$6,580,000 expiring in varying amounts beginning 2005 through 2010. 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 12 of "Notes to Consolidated Financial Statements."

In February, 2001, we entered into a distribution agreement with Alphatec Manufacturing, Inc., or Alphatec, 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 April 1, 2002. A penalty payment equal to 50% of any shortfall in the purchase commitment is required to be paid at the end of the first year of the commitment period and quarterly beginning in the second year of the commitment period. In October, 2002,

pursuant to a letter agreement, Alphatec waived the purchase commitment of \$3,200,000 for the first year of the commitment period (April 1, 2002 to March 31, 2003) for a payment of \$600,000, \$300,000 of which was to settle the first year purchase commitment and the remaining \$300,000 was to apply to purchases made on or after October 1, 2003. The purchase commitment is \$2,800,000 for the second year (April 1, 2003 to March 31, 2004) of the commitment period. In October, 2002, because of a higher than normal level of complaints, we suspended the sale and distribution of Affirm™. Due to the continued uncertainty surrounding the re-introduction of Affirm™ into the market, we have established a provision for all implant inventory and instrumentation of \$1,430,000. In addition, due to this uncertainty, we have estimated that we will not purchase sufficient quantities of inventory to meet the aforementioned purchase commitment. Accordingly, we recorded a reserve of \$1,079,000 in 2002 for the estimated penalty for the second year commitment. We have reassessed such provision during 2003, and, based on the Alphatec litigation and other factors, have determined that the provision is adequate. See Item 3., "Legal Proceedings" and Note 13 to "Notes to Consolidated Financial Statements" for more information.

The following table summarizes our contractual obligations at December 31, 2003, 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	\$15,923	\$ 2,661	\$ 5,322	\$7,940
Non-cancelable operating lease obligations	5,640	1,234	2,264	2,142
Medtronic litigation settlement payments	317	317		
Purchase commitment <sup>(1)</sup>	<u>1,079</u>	<u>1,079</u>		
	<u>\$22,959</u>	<u>\$ 5,291</u>	<u>\$ 7,586</u>	<u>\$10,082</u>

<sup>(1)</sup> Represents the provision for the estimated penalty associated with the minimum purchase requirements pursuant to the distribution agreement with Alphatec. Due to the Alphatec litigation, no definitive date, if any, has been determined for the payment of this provision.

We expect to continue to make investments in our business to support our direct distribution efforts and future programs and initiatives, which may deplete our available cash balances. We believe that our available cash, cash equivalents and short-term investments, available lines of credit and anticipated future cash flow from operations will be sufficient to meet our forecasted cash needs in 2004. Our future liquidity and capital requirements will depend upon numerous factors, including:

- the progress of our product development programs and the need and associated costs relating to regulatory approvals, if any, which may be needed to commercialize some of our products under development, or those commercialized whose regulatory status may change; and
- the resources we devote to the development, manufacture and marketing of our services and products.

We may seek additional funding to meet the needs of our long-term strategic plan. 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, 2002, the Financial Accounting Standards Board issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 is effective for fiscal years beginning January 1, 2003. We adopted this pronouncement in 2003 and it had no impact on our financial position, results of operations or cash flows.

In November, 2002, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of SFAS Nos. 5, 57, and 107 and Rescission of FASB Interpretation No. 34" ("FIN 45"). FIN 45 clarifies the requirements of SFAS No. 5, "Accounting for Contingencies," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods after December 15, 2002. The disclosure provisions have been implemented and no disclosures were required in 2003 or 2002. The provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002, irrespective of the guarantor's year-end. FIN 45 requires that upon issuance of a guarantee, the entity must recognize a liability for the fair value of the obligation it assumes under that guarantee. Adoption of FIN 45 in 2003 did not have any effect on our results of operations, cash flows or financial position.

In January, 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities – an interpretation of ARB No. 51," and in December, 2003 FASB issued a revised FIN 46(R), "Consolidation of Variable Interest Entities – an interpretation of ARB No. 51," (collectively referred to as "FIN 46"), both which address consolidation of variable interest entities. FIN 46 expanded the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and the adoption of this portion of FIN 46 had no impact on results of operation, cash flows, or financial position. FIN 46 applies in the first fiscal year or interim period ending after March 15, 2004, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. We do not have any SPE's or other agreements in which the counter party would be considered a variable interest entity, and therefore, we expect no impact on our results of operations, cash flows or financial position.

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

The results of operations for the periods discussed have not been materially affected by inflation. We are subject to foreign currency fluctuations for material changes in exchange rates between the U.S. dollar and the Euro. As our foreign operations continue to grow and represent a larger percentage of our consolidated revenues and profits, foreign currency translation

adjustments will impact our operating results to a greater extent. The exchange rate as of December 31, 2003 was \$1.26 U.S. dollars to one Euro compared to an exchange rate of \$1.05 U.S. dollars to one Euro as of December 31, 2002. The average exchange rate for the year ended December 31, 2003 was \$1.13 U.S. dollars to one Euro compared to an average exchange rate for the year ended December 31, 2002 of \$.94 U.S. dollars to one Euro.

In fourth quarter 2003, as a result of a decision to utilize excess cash flow, if any, generated by our French subsidiary to repay the remaining outstanding balance of its intercompany debt, in accordance with SFAS No. 52, "Foreign Currency Translation", we recognized the impact of foreign currency translation gains and losses on the outstanding balance of the intercompany debt in our results of operations. Foreign currency translation gains of \$510,000 were recognized in other income (expense) in the consolidated statement of operations for the year ended December 31, 2003 related to the impact of exchange rates between the U.S. dollar and the Euro. Future translation gains and losses may have a material impact on our results of operations in the event of significant changes in the exchange rate between the U.S. dollar and the Euro, although the impact of such gains and losses should not have any impact on consolidated cash flows.

Foreign currency exchange fluctuations did not have a material impact on results of operations in 2002 or 2001.

### **Litigation**

We are involved in various legal proceedings involving product liability and other matters and claims. For a complete discussion of these matters see, Item 3. "Legal Proceedings" and Note 13 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.*

We expect to continue to make investments in our business to support our direct distribution efforts and future programs and initiatives, which may deplete our available cash balances. We believe that our available cash, cash equivalents, and short-term investments, available lines of credit and anticipated future cash flow from operations will be sufficient to meet our forecasted cash needs in 2004. Our future liquidity and capital requirements will depend upon numerous factors, including

- the progress of our product development programs and the need and associated costs relating to regulatory approvals, if any, which may be needed to commercialize some of our products under development, or those commercialized whose regulatory status may change; and
- the resources we devote to the development, manufacture and marketing of our services and products.

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. 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.*

Our credit facility provides for a revolving line of credit, an equipment loan and a mortgage. It also imposes on us certain restrictive operating and financial covenants. The 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 without the consent of the bank. 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 line of credit, 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. We may not have the funds to repay the debt upon acceleration.

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

Commencing in the first 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 future periods. 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 may negatively impact our future cash flow. 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 accounts receivable balances may increase.

*We are dependent upon two primary clients who together provide approximately half of our revenues.*

We are the processor of allograft bone tissue for large national and international not-for-profit organizations. During 2003, MTF and ARC accounted for approximately 25% and 24%, respectively, of our consolidated revenues. We entered into a 10-year exclusive processing agreement with ARC in December, 1996, which we amended in 2002, and a non-exclusive processing agreement with MTF in June, 2002, which expires on December 31, 2008. 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, TRO's and tissue banks that 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 willing 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. Although we have taken steps to address this tissue supply problem, we cannot assure you that these efforts will be successful in the future 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, growth factors and allograft bone tissue processed by others. Autograft bone tissue has traditionally been the primary choice for surgeons and we believe autograft bone tissue still maintains approximately a 48% 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.

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.

In recent years, our Grafton® DBM products have faced increasing competitive pressures as more companies have developed, or have announced they are developing, products with characteristics similar to Grafton® 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 can.

*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 customers, which are typically hospitals. The ability of hospitals to pay fees to our clients, or directly to us for allograft bone tissue 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 or our procurement of tissue.*

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law 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, with the exception of removal and implantation and receive payments for all such services. We make payments to certain of our clients, TRO's and tissue banks for their services related to recovering allograft bone 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 TRO's 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 bone 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 forms, 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.

Our products are extensively regulated by federal and, in certain states, by state agencies in the United States. Failure to comply with these requirements may subject us to administrative or judicial sanctions, such as the 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 the FDA and to comply with regulations concerning tissue donor screening and testing, and related procedures and record keeping. The FDA periodically inspects tissue processors to determine compliance with these requirements. The 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 the 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.

Allograft bone tissue and tissue banking activities, such as tissue donation and recovery and tissue processing, are regulated in virtually all countries in which we operate outside the United States. The regulatory schemes and specific requirements for these products and activities vary from country-to-country. There are no common or harmonized regulatory approvals or programs for these products and activities, such as there are for medical devices marketed in the European Union. We believe that we comply with the national regulations in the countries in which we currently operate or in the countries we plan to operate in the future, although there can be no assurances that we will be able to do so in the future.

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

In March, 2002, the FDA informed us that the agency is changing the regulatory status of Grafton® DBM and will henceforth regulate it as a medical device. Medical device regulation is a more stringent category of regulation and, in particular, medical devices require FDA clearance or approval. We believe the 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 communicated to the FDA that we believe its initial designation of Grafton® DBM as a human tissue-based product was and still is correct. In this regard, we have provided information to the FDA that we believe should cause the FDA to reconsider the position they have expressed in their March, 2002 letter as it relates to Grafton® DBM. On February 26, 2003, we met with representatives of the FDA to present our facts and views. On October 30, 2003, we received further correspondence from the FDA indicating that after considering the information we provided them in the February, 2003 meeting, the FDA still believes that a 510(k) should be submitted for Grafton® DBM. We have not submitted a 510(k) and we intend to continue to have a dialog with the FDA to further present our point of view regarding Grafton® DBM. If we are unsuccessful in our effort, we will be required to obtain a medical device approval or clearance for Grafton® DBM, 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 the FDA will issue any clearance or approval in a timely fashion, or at all. In its March, 2002 letter regarding Grafton® DBM, the 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 the FDA will clear or approve our submission or will clear or approve any or all claims that we currently make for Grafton® DBM. Failure to obtain FDA clearance or approval of Grafton® DBM, or any limitation on Grafton® DBM claims could materially adversely affect our results of operations and financial position.

We also market Grafton Plus™ DBM as a human tissue-based product. In its October 30, 2003 letter, the FDA indicated that its determination regarding Grafton® DBM is also to be applied to Grafton Plus™ DBM. If the 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 any other DBM carrier product we may process, 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.

Prosecuting and defending patent lawsuits is very expensive. 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 new patent litigation 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 a patent lawsuit 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 a patent lawsuit 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.

*Our products face competitive threats from alternate technologies.*

The primary advantage of synthetic bone substitutes and growth factors 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 and growth factors as safer than allograft-based bone tissue. The allograft bone tissue we process may be incapable of competing successfully with synthetic bone substitutes and 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. Companies are also developing artificial disks, which would be used to replace a patient's own injured, degenerated or diseased spinal disks. If these disks are successfully developed and commercialized, they could have a negative impact on our bio-implant business and, therefore, have a material adverse effect on our financial condition and results of operations.

*We may incur losses from product liability lawsuits.*

The testing and use of human allograft bone tissue, bovine tissue products 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.

We presently maintain product liability insurance in the amount of \$30 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.

Our failure to fully comply with any environmental regulations could result in the imposition of penalties, 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. 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 sales 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 5,000,000 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 our 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, 2003 cash and cash equivalents and long-term debt, a 1% change in interest rates would have a negligible impact on our results of operations.

The value of the U.S. dollar affects our financial results. Changes in exchange rates may positively or negatively affect revenues, gross margins, operating expenses and net income. 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, primarily the Euro, 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, 2003, a 10% change in the exchange rates would impact our net income 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.

## **Item 9A. Controls and Procedures**

### *Evaluation of Disclosure Controls and Procedures*

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2003 (the "Evaluation Date"). Based upon that evaluation, and taking into consideration the additional procedures discussed below, the Chief Executive Officer and Chief Financial Officer concluded that as of the Evaluation Date our disclosure controls and procedures were effective in timely alerting them to the material information relating to us (or our consolidated subsidiaries) required to be included in our periodic SEC filings.

### *Changes in Internal Controls*

There were no significant changes made in our internal controls over financial reporting during the period covered by this report, however, in March, 2004, as described below, we made changes in our internal controls over financial reporting.

On March 2, 2004, we announced that we would restate our consolidated financial statements as a result of over accruals of certain expenses caused by a previously undetected flaw in our computer software that is used to maintain certain accounting records. Executive management and the Audit Committee were informed by our independent auditors that they considered that there was a "material weakness" (as defined under standards established by the American Institute of Certified Public Accountants) relating to the timely review and monitoring of certain account analyses, including the account related to this portion of our computer software. Other than the matters discussed above related to the previously undetected flaw in our computer system, no other matters were identified that required adjustment to or disclosure in our consolidated financial statements. We have corrected the flaw in our computer software and have instituted more comprehensive review and monitoring procedures to mitigate the risk of errors occurring in the future.

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## PART II

**Item 10. Directors and Executive Officers of the Registrant**The sections of our 2004 Proxy Statement entitled "Election of Directors" and "Business Experience of Executive Officers" are incorporated herein by reference.

**Item 11. Executive Compensation**

The section of our 2004 Proxy Statement entitled "Executive Compensation" is incorporated herein by reference.

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

The sections of our 2004 Proxy Statement entitled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" are incorporated herein by reference.

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

None.

**Item 14. Principal Accountant Fees and Services**

The section of our 2004 Proxy Statement entitled "Principal Accountant Fees and Services" is incorporated herein by reference.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a)(1) and (2). The response to this portion of Item 16 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 (incorporated by reference to Exhibit 3.1 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002)	*
3.2	Third Amended and Restated Bylaws of Osteotech (incorporated by reference to Exhibit 3.2 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002)	*
3.3	Form of Stock Certificate (incorporated by reference to Exhibit 3.4 to Registrant's Registration Statement on Form S-1 (File No. 33-40463), filed on June 14, 1991)	*
3.4	Certificate of Retirement and Prohibition or Reissuance of Shares of Osteotech, Inc. dated April 4, 2002 (incorporated by reference to Exhibit 3.4 to Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2002)	*
4.1	Rights Agreement dated as of February 1, 1996 between Osteotech, Inc. and Registrar and Transfer Co., as amended (incorporated by reference to Exhibit 4.3 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002)	*
10.1	1991 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.1 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002) ^	*
10.2	1991 Independent Directors Stock Option Plan, as amended (incorporated by reference to Exhibit 28.2 to Registrant's Registration Statement on Form S-8 (File No. 33-44547), filed on December 17, 1991) ^	*

- 10.3 Processing Agreement between Osteotech and Stichting Eurotransplant Nederland, dated September 26, 1988 (incorporated by reference to Exhibit 10.7 to Registrant's Registration Statement on Form S-1 (File No. 33-40463), filed on May 9, 1991) # \*
- 10.4 Form of Confidentiality Agreement and Non-Competition Agreement with executive officers (incorporated by reference to Exhibit 10.10 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002) \*
- 10.5 Agreement dated December 10, 1996 between American Red Cross Tissue Services and Osteotech (incorporated by reference to Exhibit 10.26 to Registrant's Annual Report on Form 10-K, filed on March 27, 1997) # \*
- 10.6 Lease for Osteotech's Shrewsbury, New Jersey processing facility (incorporated by reference to Exhibit 10.2 to Registrant's Registration Statement on Form S-1 (File No. 33-40463), filed on May 9, 1991) \*
- 10.7 Sixth Modification of Lease for Osteotech's Shrewsbury, New Jersey processing facility (incorporated by reference to Exhibit 10.22 to Registrant's Quarterly Report on Form 10-Q, filed on November 13, 1998) \*
- 10.8 Employment Agreement with Michael J. Jeffries dated January 1, 1998 (incorporated by reference to Exhibit 10.35 to Registrant's Annual Report on Form 10-K, filed on March 31, 1998) ^ \*
- 10.9 Employment Agreement with James L. Russell dated December 18, 1997 (incorporated by reference to Exhibit 10.37 to Registrant's Annual Report on Form 10-K, filed on March 31, 1998) ^ \*
- 10.10 The Management Performance Bonus Plan (incorporated by reference to Exhibit 10.29 to Registrant's Annual Report on Form 10-K, filed on March 31, 1999) ^ \*
- 10.11 Employment Agreement with Richard Russo dated April 1, 1997 (incorporated by reference to Exhibit 10.30 to Registrant's Annual Report on Form 10-K, filed on March 31, 1999) ^ \*

- 10.12            Employment Agreement with Richard W. Bauer dated December 4, 1998 (incorporated by reference to Exhibit 10.32 to Registrant's Annual Report on Form 10-K, filed on March 31, 1999) ^ \*
- 10.13            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 (incorporated by reference to Exhibit 10.33 to Registrant's Quarterly Report on Form 10-Q, filed on August 16, 1999) \*
- 10.14            Amended and Restated Processing Agreement entered into September 11, 2000 by Osteotech, Inc., Musculoskeletal Transplant Foundation and Biocon, Inc. (incorporated by reference to Exhibit 10.36 to Registrant's Quarterly Report on Form 10-Q, filed on November 14, 2000) # \*
- 10.15            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 (incorporated by reference to Exhibit 10.37 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) \*
- 10.16            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 (incorporated by reference to Exhibit 10.38 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) \*
- 10.17            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 (incorporated by reference to Exhibit 10.39 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) \*
- 10.18            Distribution Agreement entered into February, 2001 by Osteotech, Inc. and Alphatec Manufacturing, Inc. (incorporated by reference to Exhibit 10.40 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) # \*

- 10.19 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 (incorporated by reference to Exhibit 10.41 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) \*
- 10.20 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 (incorporated by reference to Exhibit 10.42 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) \*
- 10.21 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 (incorporated by reference to Exhibit 10.43 to Registrant's Annual Report on Form 10-K, filed on April 2, 2001) \*
- 10.22 Primary Agreement Carrier and Bio-Implant Allografts by and between LifeNet and Osteotech dated January 4, 2002 (incorporated by reference to Exhibit 10.44 to Registrant's Current Report on Form 8-K, filed on March 8, 2002) \*
- 10.23 Amended and Restated 2000 Stock Plan (incorporated by reference to Exhibit 10.41 to Registrant's Quarterly Report on Form 10-Q, filed on August 14, 2003) ^ \*
- 10.24 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 (incorporated by reference to Exhibit 10.47 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002) \*

- 10.25 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 (incorporated by reference to Exhibit 10.48 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002) \*
- 10.26 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 (incorporated by reference to Exhibit 10.49 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002) \*
- 10.27 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 (incorporated by reference to Exhibit 10.51 to Registrant's Annual Report on Form 10-K, filed on March 27, 2002) \*
- 10.28 Amendment to License and Option Agreement between IsoTis N.V. and H.C. Implants B.V. and Osteotech dated April 8, 2002 (incorporated by reference to Exhibit 10.55 to Registrant's Quarterly Report on Form 10-Q, filed on April 19, 2002) \*
- 10.29 Second Amended and Restated Processing Agreement by and among Musculoskeletal Transplant Foundation, Biocon, Inc., and Osteotech, Inc. dated as of June 1, 2002 (incorporated by reference to Exhibit 10.57 to Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2002) # \*
- 10.30 Settlement Agreement and Release by and among Osteotech, Inc. and Osteotech Investment Corporation, the Musculoskeletal Transplant Foundation, and Synthes Spine Company, L.P., dated as of June 1, 2002 (incorporated by reference to Exhibit 10.56 to Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2002) \*

- 10.31 License Agreement by and among Osteotech, Inc., Osteotech, Inc., Osteotech Investment Corporation, Musculoskeletal Transplant Foundation, Biocon, Inc., and Synthes Spine Company, L.P., dated as of June 1, 2002 (incorporated by reference to Exhibit 10.58 to Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2002) # \*
- 10.32 Asset Purchase Agreement between Cam Implants B.V. and Cam Acquisition B.V. dated July 10, 2002 (incorporated by reference to Exhibit 10.59 to Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2002) # \*
- 10.33 Settlement Agreement between Medtronic, Inc. on behalf of itself and as owner, directly or indirectly, of Medtronic Sofamor Danek, Inc. (formerly known as Sofamor Danek Group, Inc.), Sofamor Danek Holding, Inc., Medtronic Sofamor Danek USA, Inc., SDGI Holdings, Inc., Sofamor Danek L.P. and Osteotech, Inc., effective May 15, 2002 (incorporated by reference to Exhibit 10.60 to Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2002) \*
- 10.34 Form of Change in Control Agreement with Executive Officers except Marc Burel (incorporated by reference to Exhibit 10.61 to Registrant's Quarterly Report on Form 10-Q, filed on November 14, 2002) ^ \*
- 10.35 Employment Agreement, as amended, with Marc Burel dated April 18, 2000 (incorporated by reference to Exhibit 10.62 to Registrant's Quarterly Report on Form 10-Q, filed on November 14, 2002) ^ \*
- 10.36 Change in Control Agreement by and between Osteotech, Inc. and Marc Burel dated April 19, 2000, superceded by the Change in Control Agreement dated September 8, 2002 (included as Exhibit 10.36) (incorporated by reference to Exhibit 10.63 to Registrant's Quarterly Report on Form 10-Q, filed on November 14, 2002) ^ \*
- 10.37 Change in Control Agreement by and between Osteotech, Inc. and Marc Burel dated September 8, 2002 (incorporated by reference to Exhibit 10.64 to Registrant's Quarterly Report on Form 10-Q, filed on November 14, 2002) ^ \*

- 10.38 Allonge to Agreement of Amendment to the 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, SA, and OST Developpement SA. dated November 13, 2002 (incorporated by reference to Exhibit 10.37 to Registrant's Annual Report on Form 10-K, filed on March 31, 2003) \*
- 10.39 Exclusive Marketing Agreement, by and among Osteotech, Inc., LifeNet, Depuy Orthopaedics, Inc. and Depuy Acromed, Inc. dated December 13, 2002 (incorporated by reference to Exhibit 10.38 to Registrant's Annual Report on Form 10-K, filed on March 31, 2003) # \*
- 10.40 Letter Amendment to Agreement dated December 10, 1996, by and between the American Red Cross and Osteotech, Inc. dated October 27, 2002 (incorporated by reference to Exhibit 10.39 to Registrant's Annual Report on Form 10-K, filed on March 31, 2003) # \*
- 10.41 Second Allonge to Loan and Security Agreement among Fleet National Bank, Successor in Interest to Summit Bank, Osteotech, Inc., Osteotech, B.V., H.C. Implants, B.V., Cam Implants, B.V., Osteotech/Cam Services, B.V., Osteotech Implants, B.V., Osteotech S.A. and OST Developpement dated March 27, 2003 (incorporated by reference to Exhibit 10.40 to Registrant's Quarterly Report on Form 10-Q, filed on May 13, 2003) \*
- 10.42 Joint Settlement Agreement and Release by and among Osteotech, Inc., GenSci Orthobiologics, Inc. and GenSci Regeneration Sciences, Inc., dated as of May 29, 2003 (incorporated by reference to Exhibit 10.42 to Registrant's Quarterly Report on Form 10-Q, filed on August 14, 2003) \*
- 10.43 First Amendment to Joint Settlement Agreement and Release by and among Osteotech, Inc., GenSci Orthobiologics, Inc. and GenSci Regeneration Sciences, Inc., dated as of August 2003 (incorporated by reference to Exhibit 10.43 to Registrant's Quarterly Report on Form 10-Q, filed on November 13, 2003) \*
- 10.44 Lease for Osteotech's Eatontown facility (incorporated by reference to Exhibit 10.30 to Registrant's Annual Report on Form 10-K, filed on March 30, 1995) \*

10.45	First Modification to Lease for Osteotech's Eatontown facility	+
10.46	Osteotech's Code of Business Conduct	+
21.1	Subsidiaries of the Registrant	+
23.1	Consent of PricewaterhouseCoopers LLP	+
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	+
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	+
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	+
*	Previously filed; incorporated herein by reference	
+	Filed herewith	
^	Management contracts or compensatory plans and arrangements required to be filed pursuant to Item 10(iii)	
#	Copy omits information for which confidential treatment has been granted	

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

On November 3, 2003, we filed with the Commission a Current Report on Form 8-K to announce the completion and closing of the settlement agreement associated with certain patent litigation between us and GenSci.

On October 21, 2003, we filed with the Commission a Current Report on Form 8-K to announce our financial results for the quarter ended September 30, 2003.

On October 3, 2003, we filed with the Commission a Current Report on Form 8-K to announce preliminary financial results for the quarter ended September 30, 2003, guidance for the remainder of 2003 and initial guidance for 2004.

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 15, 2004

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 15, 2004
<u>/s/RICHARD W. BAUER</u> Richard W. Bauer	President, Chief Executive Officer (Principal Executive Officer) and Director	March 15, 2004
<u>/s/MICHAEL J. JEFFRIES</u> Michael J. Jeffries	Executive Vice President Chief Financial Officer (Principal Financial Accounting Officer), Secretary and Director	March 15, 2004
<u>/s/KENNETH P. FALLON III</u> Kenneth P. Fallon III	Director	March 15, 2004
<u>/s/JOHN P. KOSTUIK</u> John P. Kostuik	Director	March 15, 2004
<u>/s/STEPHEN J. SOGIN</u> Stephen J. Sogin	Director	March 15, 2004

**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 AUDITORS

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 subsidiaries (the "Company") at December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. 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.

As discussed in Note 2, the Company has adopted Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", effective January 1, 2002.

PricewaterhouseCoopers LLP

Florham Park, New Jersey  
March 1, 2004

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

December 31,	2003	2002
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,326	\$ 10,040
Short-term investments		3,948
Accounts receivable, net of allowance of \$1,487 in 2003 and \$943 in 2002	15,187	11,545
Deferred processing costs	29,013	15,433
Inventories	3,581	4,820
Income tax receivable	135	3,357
Deferred tax assets	5,511	5,431
Prepaid expenses and other current assets	1,699	1,023
Total current assets	70,452	55,597
Property, plant and equipment, net	47,107	53,535
Goodwill, net of accumulated amortization of \$404 in 2003 and in 2002	1,669	1,669
Other assets	7,985	3,931
Total assets	\$127,213	\$114,732
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 11,407	\$ 10,489
Current maturities of long-term debt	2,661	2,661
Total current liabilities	14,068	13,150
Long-term debt	13,262	15,922
Other liabilities	3,663	1,637
Total liabilities	30,993	30,709
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,000,000 shares authorized; no shares issued or outstanding		
Common stock, \$.01 par value; 70,000,000 shares authorized; issued and outstanding 17,117,720 shares in 2003 and 17,001,372 shares in 2002	171	170
Additional paid-in capital	64,170	63,368
Accumulated other comprehensive income	605	78
Retained earnings	31,274	20,407
Total stockholders' equity	96,220	84,023
Total liabilities and stockholders' equity	\$127,213	\$114,732

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,	2003	2002	2001
<b>Net revenues:</b>			
Service	\$87,759	\$77,041	\$71,329
Product	6,674	6,333	4,386
	<u>94,433</u>	<u>83,374</u>	<u>75,715</u>
Cost of services	37,034	37,292	29,835
Cost of products	5,037	8,979	3,145
	<u>42,071</u>	<u>46,271</u>	<u>32,980</u>
<b>Gross profit</b>	52,362	37,103	42,735
Marketing, selling, and general and administrative	37,786	38,256	44,256
Research and development	3,944	3,927	4,372
	<u>41,730</u>	<u>42,183</u>	<u>48,628</u>
Income (charge) from litigation settlements	7,500	(1,785)	
<b>Operating income (loss)</b>	18,132	(6,865)	(5,893)
Other income (expense):			
Interest income	144	246	506
Interest expense	(1,107)	(1,342)	(406)
Gain on sale of patents		950	
Other	577	175	29
	<u>(386)</u>	<u>29</u>	<u>129</u>
Income (loss) from continuing operations before income taxes	17,746	(6,836)	(5,764)
Income tax provision (benefit)	6,879	(5,588)	(1,947)
Income (loss) from continuing operations	10,867	(1,248)	(3,817)
Income (loss) from discontinued operations, net of loss on disposal of \$291 in 2002		93	(370)
<b>Net income (loss)</b>	<u>\$10,867</u>	<u>\$ (1,155)</u>	<u>\$ (4,187)</u>
Net income (loss) per share:			
Basic:			
Income (loss) from continuing operations	\$ .64	\$ (.08)	\$ (.28)
Discontinued operations		.01	(.02)
Net income (loss)	<u>\$ .64</u>	<u>\$ (.07)</u>	<u>\$ (.30)</u>
Diluted			
Income (loss) from continuing operations	\$ .62	\$ (.08)	\$ (.28)
Discontinued operations		.01	(.02)
Net income (loss)	<u>\$ .62</u>	<u>\$ (.07)</u>	<u>\$ (.30)</u>
Shares used in computing net income (loss) per share:			
Basic	17,059,495	15,904,132	14,030,623
Diluted	17,520,959	15,904,132	14,030,623

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, 2003, 2002, and 2001

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Retained Earnings	Total Stockholders' Equity
	Shares	Amount					
<b>Balance at December 31, 2000</b>	13,989,307	\$ 138	\$ 46,577	\$ (497)	\$ 25,749	\$ 71,967	
Net loss					(4,187)	(4,187)	
Currency translation adjustments						(156)	
Total comprehensive loss						(4,343)	
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)	21,562	68,125	
Net loss					(1,155)	(1,155)	
Currency translation adjustments				731		731	
Total comprehensive loss						(424)	
Sale of common stock	2,800,000	28	15,728			15,756	
Exercise of stock options	47,500	1	172			173	
Common stock issued pursuant to employee stock purchase plan	55,608	1	354			355	
Tax benefits related to stock options			38			38	
<b>Balance at December 31, 2002</b>	17,001,372	170	63,368	78	20,407	84,023	
Net income					10,867	10,867	
Currency translation adjustments				527		527	
Total comprehensive income						11,394	
Exercise of stock options	80,437	1	375			376	
Common stock issued pursuant to employee stock purchase plan	35,911		305			305	
Tax benefits related to stock options			122			122	
<b>Balance at December 31, 2003</b>	17,117,720	\$ 171	\$ 64,170	\$ 605	\$ 31,274	\$ 96,220	

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,	2003	2002	2001
<b>Cash Flow From Operating Activities</b>			
Net income (loss)	\$ 10,867	\$ (1,155)	\$ (4,187)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	8,498	8,230	8,598
Deferred income taxes	2,230	(1,840)	(2,786)
Gain on sale of patents		(950)	
Reversal of tax liability		(2,557)	
Income tax benefit related to stock options	122	38	
Changes in assets and liabilities:			
Accounts receivable	(2,978)	3,934	(2,146)
Deferred processing costs	(13,459)	(3,938)	(5,390)
Inventories	1,392	3,614	(5,073)
Prepaid expenses and other current assets	2,732	(2,445)	2,459
Note receivable from GenSci litigation settlement	(5,000)		
Accounts payable and other liabilities	380	(4,564)	6,506
Net cash provided by (used in) operating activities	4,784	(1,633)	(2,019)
<b>Cash Flow From Investing Activities</b>			
Capital expenditures	(1,571)	(4,911)	(8,955)
Proceeds from sale of foreign operation		1,000	
Proceeds from sale of investments	3,948		5,860
Purchases of investments		(3,948)	(3,925)
Proceeds from sale of patents		1,000	
Proceeds from the sale of land			1,500
Other, net	516	(383)	160
Net cash provided by (used in) investing activities	2,893	(7,242)	(5,360)
<b>Cash Flow From Financing Activities</b>			
Proceeds from issuance of common stock	681	16,284	499
Proceeds from issuance of long-term debt			1,468
Principal payments on long-term debt	(2,660)	(2,630)	(340)
Net cash provided by (used in) financing activities	(1,979)	13,654	1,627
Effect of exchange rate changes on cash	(412)	69	21
Net increase (decrease) in cash and cash equivalents	5,286	4,848	(5,731)
Cash and cash equivalents at beginning of year	10,040	5,192	10,923
Cash and cash equivalents at end of year	\$ 15,326	\$ 10,040	\$ 5,192

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 allograft bone tissue forms processed by the Company are used in a variety of surgical procedures.

Beginning in 2001, the Company began to distribute tissue forms directly to hospitals. The Company expects to continue to expand its direct distribution efforts to hospitals in future years. This change in distribution methodology has impacted liquidity and cash flow. The Company has had to make additional investments in deferred processing costs to support the direct distribution efforts. The Company expects to continue to make investments in the business to support the direct distribution efforts and future programs and initiatives, which may deplete available cash balances. The Company believes that available cash, cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet forecasted cash needs in 2004. The Company's future liquidity and capital requirements will depend upon numerous factors, including:

- the progress of product development programs and the need and associated costs relating to regulatory approvals, if any, which may be needed to commercialize some of the products under development, or those commercialized whose regulatory status may change; and
- the resources to be devoted to the development, manufacture and marketing of services and products.

The Company has two primary operating segments: the Demineralized Bone Matrix (DBM) Segment (the "DBM Segment"), formerly referred to as 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 domestically, and processes, markets and distributes bovine bone tissue products outside of the United States.

In January, 2004, the Company notified SpineVision SA that effective February 17, 2004 it would no longer distribute the three metal spinal implant systems manufactured by SpineVision. In September, 2003, the Company provided written notice to Alphatec Manufacturing, Inc. ("Alphatec"), the manufacturer of the Sentinal<sup>™</sup> Pedicle Screw System and the Affirm<sup>™</sup> Anterior Surgical Plate System, that the Company would not renew the distribution agreement upon the completion of the current two-year term, which expires on March 31, 2004. In addition, as a result of an assessment of the remaining metal spinal implant systems in first quarter 2004, the Company decided to cease the marketing and distribution of metal spinal implant product during 2004. The Company anticipates recording an estimated charge of approximately \$2.4 million in first quarter 2004 related to metal spinal implant inventories and instrumentation and severance. In addition, as a result of the reorganization of our sales and marketing departments, the Company will record a provision for severance in first quarter 2004 of approximately \$600,000.

**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 judgments 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 including purchase commitments, deferred processing costs including rework reserves, 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 judgments 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 judgments and estimates used in the preparation of the consolidated financial statements.

- The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of the Company's 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 bone tissue form 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 excess, obsolescence, or unmarketable products and allograft bone tissue forms equal to the difference between cost and the estimated market value based upon assumptions about future demand and market conditions. Excess and obsolescence could occur from numerous factors, including, but not limited to, the competitive nature of the market, technological change, expiration and changes in surgeon preference. If actual market conditions are less favorable than those projected by management, additional write-downs may be required. In addition, the Company provides reserves, if any, for the difference between its contractual purchase commitments and its projected purchasing patterns based upon maintenance of adequate inventory levels and forecasted revenues. If actual revenue is less favorable than those forecasted by management, additional reserves may be required; alternatively, if revenue is stronger than forecasted by management, such reserves would be reduced.
- 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 expected 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 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 it 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 the 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.
- Litigation is subject to many uncertainties and management is unable to predict the outcome of the pending suits or claims. When the Company is reasonably able to determine the probable minimum or ultimate liability, if any, that may result from any of the pending litigation, the Company will record a provision for such liability, and if appropriate, will reduce such liability to the extent covered by insurance. If the outcome or resolution of the pending suit or claim is for amounts greater than accrued, an adjustment will be charged to income in the period the determination is made. Alternatively, should the suit or claim be for less than accrued, the Company would increase income in the period the determination is made.

**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.

**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, upon shipment of such allograft tissue to customers or clients, except for consigned inventory, when delivery is considered to have occurred at the time that 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 upon shipment of non-allograft products to customers, except for consigned inventory, when delivery is considered to have occurred at the time the product is consumed by the customer.

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

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

**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, except for consigned inventory, whose costs are deferred until the allograft bone tissue is consumed by the customer.

**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 other product lines.

**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 estimated future cash flows if fair market value is not readily determinable.

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

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

**Goodwill**

Beginning in 2002, pursuant to the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets", the Company is no longer amortizing goodwill. Prior to 2002, the Company amortized goodwill on a straight-line basis over 15 years. The Company's goodwill arose in the acquisition of its French subsidiary in 1999 and relates mainly to the Company's activities in the DBM Segment. Goodwill related to the Company's subsidiary in The Netherlands was written off in 2002 when the Company sold the business and substantially all of the assets, net of certain liabilities of this operation. Amortization of goodwill included in continuing operations was \$132,000 in 2001 and discontinued operations included \$252,000 of goodwill amortization in 2001. Aggregately, the net loss in 2001 would have been reduced by \$384,000 and basic and diluted net loss per share would have been reduced by \$.03 if the non-amortization provisions of SFAS No. 142 had been retroactively applied to 2001.

The Company, pursuant to SFAS No. 142, evaluates goodwill annually for impairment. In accordance with the provisions of SFAS No. 142, the Company completed an evaluation of the carrying value of its goodwill as of January 1, 2003 and determined that there was no impact on the Company's consolidated financial statements as a result of such evaluation.

**Other Intangible Assets**

The Company's other intangibles, which principally represent patents, patent applications and licenses of \$3,800,000 and \$3,268,000 as of December 31, 2003 and 2002 are recorded at cost. The carrying value of such intangibles are \$2,378,000 and \$2,105,000 for the same respective periods. Patents and licenses are amortized over their estimated useful lives ranging from five to ten years. Patent application costs are amortized upon grant of the patent or expensed if the application is rejected or withdrawn. Amortization expense for these intangibles was \$262,000, \$245,000 and \$227,000 for the years ended December 31, 2003, 2002, and 2001, respectively. Amortization expense for the next five years is: \$210,000 in 2004; \$99,000 in 2005; \$79,000 in 2006; \$51,000 in 2007; and \$20,000 in 2008. The Company reviews other intangibles to assess recoverability from future operations using undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that carrying value exceeds fair value determined based on the net present value of estimated future cash flows.

**Research and Development**

Research and development costs, which principally relate to internal costs for the development of new technologies, processes and products, are expensed as incurred.

**Stock Options**

The Company has adopted the "disclosure only" provisions of SFAS No. 123, "Accounting for Stock Based Compensation", 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 on a fair value basis. For purposes of the pro forma disclosures, the estimated fair value of the options is amortized on a straight-line basis to expense over the options' vesting period.

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

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

The following table shows the estimated effect on earnings and per share data as if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation.

<i>(in thousands except per share data)</i>	2003	2002	2001
<u>Net income (loss)</u>			
As reported:			
Income (loss) from continuing operations	\$ 10,867	\$ (1,248)	\$ (3,817)
Discontinued operations		93	(370)
Net income (loss)	<u>\$ 10,867</u>	<u>\$ (1,155)</u>	<u>\$ (4,187)</u>
Impact on income (loss) from continuing operations and net income (loss) related to stock-based employee compensation expense, net of tax	<u>\$ 929</u>	<u>\$ 292</u>	<u>\$ 1,554</u>
Pro forma:			
Income (loss) from continuing operations	\$ 9,938	\$ (1,540)	\$ (5,371)
Discontinued operations		93	(370)
Net income (loss)	<u>\$ 9,938</u>	<u>\$ (1,447)</u>	<u>\$ (5,741)</u>
<u>Net income (loss) per share</u>			
As reported			
Basic:			
Income (loss) from continuing operations	\$ .64	\$ (.08)	\$ (.28)
Discontinued operations		.01	(.02)
Net income (loss)	<u>\$ .64</u>	<u>\$ (.07)</u>	<u>\$ (.30)</u>
Diluted:			
Income (loss) from continuing operations	\$ .62	\$ (.08)	\$ (.28)
Discontinued operations		.01	(.02)
Net income (loss)	<u>\$ .62</u>	<u>\$ (.07)</u>	<u>\$ (.30)</u>
Pro forma			
Basic:			
Income (loss) from continuing operations	\$ .58	\$ (.10)	\$ (.39)
Discontinued operations		.01	(.02)
Net income (loss)	<u>\$ .58</u>	<u>\$ (.09)</u>	<u>\$ (.41)</u>
Diluted:			
Income (loss) from continuing operations	\$ .58	\$ (.10)	\$ (.39)
Discontinued operations		.01	(.02)
Net income (loss)	<u>\$ .58</u>	<u>\$ (.09)</u>	<u>\$ (.41)</u>

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:

	2003	2002	2001
Expected life (years)	5	5	5
Risk free interest rate	2.88%	3.33%	4.62%
Volatility factor	86.00%	80.00%	70.00%
Dividend yield	0.00%	0.00%	0.00%

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

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

**Translation of Foreign Currency**

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

In fourth quarter 2003, as a result of a decision to utilize excess cash flow, if any, generated by the Company's French subsidiary to repay the remaining outstanding balance of its intercompany debt, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 52, "Foreign Currency Translation", the Company recognized the impact of foreign currency translation gains and losses on the outstanding balance of the intercompany debt in the Company's results of operations. Foreign currency translation gains of \$510,000 were recognized in other income (expense) in the consolidated statement of operations for the year ended December 31, 2003 related to the impact of exchange rates between the U.S. dollar and the Euro. Future translation gains and losses may have a material impact on the Company's results of operations in the event of significant changes in the exchange rate between U.S. dollars and the Euro, although the impact of such gains and losses should not have any impact on the Company's consolidated cash flows.

**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 49%, 59% and 77% of consolidated revenues in 2003, 2002, and 2001, respectively. As of December 31, 2003 and 2002, these two customers together accounted for 32% and 46%, respectively, of consolidated outstanding accounts receivable. For one of these customers, the Company has a contractual right of offset.

**Fair Value of Financial Instruments**

The carrying value of financial instruments, including short-term investments, accounts receivable, notes receivable, accounts payable and other accrued expenses, approximate their fair values. Short-term investments are designated as available-for-sale, are of investment grade quality securities and are not subject to significant market risk. 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 2003 presentation.

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

**3. RECENT ACCOUNTING PRONOUNCEMENTS**

In June, 2002, the Financial Accounting Standards Board issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 is effective for fiscal years beginning January 1, 2003. The Company adopted this pronouncement in 2003 and it had no impact on the Company's financial position, results of operations or cash flows.

In November, 2002, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of SFAS Nos. 5, 57, and 107 and Rescission of FASB Interpretation No. 34" ("FIN 45"). FIN 45 clarifies the requirements of SFAS No. 5, "Accounting for Contingencies," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods after December 15, 2002. The disclosure provisions have been implemented and no disclosures were required in 2003 or 2002. The provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002, irrespective of the guarantor's year-end. FIN 45 requires that upon issuance of a guarantee, the entity must recognize a liability for the fair value of the obligation it assumes under that guarantee. Adoption of FIN 45 in 2003 did not have any effect on the Company's results of operations, cash flows or financial position.

In January, 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities – an interpretation of ARB No. 51," and in December, 2003 FASB issued a revised FIN 46(R), "Consolidation of Variable Interest Entities – an interpretation of ARB No. 51," (collectively referred to as "FIN 46"), both of which address consolidation of variable interest entities. FIN 46 expanded the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and the adoption of this portion of FIN 46 had no impact on the Company's results of operation, cash flows, or financial position. FIN 46 applies in the first fiscal year or interim period ending after March 15, 2004, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The Company does not have any SPE's or other agreements in which the counter party would be considered a variable interest entity, and therefore, the Company expects no impact on its results of operations, cash flows or financial position.

**4. CONTINUING OPERATIONS – GAINS AND CHARGES**

2003 Gains and Charges

*GenSci Settlement*

In fourth quarter 2003, the Company received the initial \$2.5 million payment, a \$5.0 million interest bearing promissory note and a \$5.0 million letter of credit collateralizing the promissory note from GenSci pursuant to the definitive \$7.5 million settlement agreement entered into in May, 2003. (See Note 13, "Commitments and Contingencies – Litigation".) Accordingly, the Company recognized a pretax gain of \$7.5 million from this settlement. Such gain is related to the Company's DBM Segment and is reflected as income from litigation settlement in the consolidated statements of operations.

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

**4. CONTINUING OPERATIONS – GAINS/CHARGES (continued)**

*Reduction in Workforce*

On September 24, 2003, the Company implemented a selective reduction in its workforce, which affected all domestic operational areas of the Company, except for the sales force, and resulted in the immediate elimination of 22 positions. As a consequence, the Company recorded a pre-tax charge of \$379,000 for severance costs in the third quarter of 2003.

2002 Gains and Charges

*Affirm™ Cervical Plating System*

In October, 2002, because of a higher than normal level of complaints, the Company temporarily suspended the sale and distribution of the Affirm™ Cervical Plating System (“Affirm™”). Affirm™, along with the Sentinal™ Pedicle Screw System, products manufactured by Alphatec Manufacturing, Inc., are subject to a firm purchase commitment. (See Note 13, “Commitments and Contingencies”).

In fourth quarter 2002, due to the continuing uncertainty surrounding the re-introduction of Affirm™ into the market, the Company recorded a pre-tax charge of \$2,509,000 to reserve all Affirm™ implant inventory and instrumentation and to record a provision for the penalty associated with the expected shortfall under the purchase commitment.

*Provision for Excess, Obsolescence and Rework*

In third quarter 2002, the Company recorded pre-tax charges to costs of service and products totaling \$4,079,000 primarily related to reserves for excess and obsolete metal spinal implant systems inventories of \$2,145,000, excess and obsolete inventories for the Company’s bio-d® Threaded Cortical Bone Dowel of \$1,094,000, which the Company removed from the market in January, 2003 in connection with the settlement of a patent lawsuit, and an \$840,000 charge for the estimated cost to rework tissue placed in quarantine in the third quarter of 2002.

*Income Tax Benefit*

In September, 2002, the Company determined liabilities of \$2,557,000 that had been established in 1997 related to certain items, which were deducted in that year’s income tax return, were no longer required, and therefore, recognized an income tax benefit related to releasing such liabilities.

*Sale of Patents*

In June, 1997, the Company entered into an exclusive worldwide License and Option Agreement for its proprietary PolyActive™ polymer biomaterials technology and patents (collectively, the “PolyActive technology”) with IsoTis BV (“IsoTis”), The Netherlands. On April 8, 2002, the Company amended the License and Option Agreement to reset the option price for IsoTis to acquire the PolyActive technology to \$1,000,000. In conjunction with the execution of the amendment, IsoTis elected to exercise its option to acquire the PolyActive technology. The Company recognized a pretax gain of \$950,000 upon closing this transaction in the second quarter of 2002.

*Medtronic Settlement*

In July, 1999, Medtronic Sofamor Danek, Inc., Sofamor Danek L.P. and Sofamor Danek Holdings, Inc. (collectively, “Medtronic”) sued the Company 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 patents owned by Medtronic.

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

**4. CONTINUING OPERATIONS – GAINS/CHARGES (continued)**

In April, 2002, Medtronic and the Company settled this lawsuit. The Company agreed to pay an aggregate of \$1,900,000 to Medtronic in 24 equal monthly installments, without interest, supported by an irrevocable standby letter of credit. (See Note 11 – “Debt and Financing Arrangements”.) In accordance with the settlement, the Company ceased the processing, marketing, distributing, advertising and promoting of the bio-d® Threaded Cortical Bone Dowel on January 31, 2003.

The Company recorded a charge of \$1,785,000 in the second quarter of 2002 representing the present value of the amounts due to Medtronic under this settlement. This charge is reflected as a litigation settlement charge in the consolidated statement of operations.

2001 Charges

*Provision for Production Equipment*

In December, 2001, the Company recorded a charge to cost of sales of \$2,287,000 related to equipment which will no longer be utilized in the processing of allograft bone tissue.

*Severance – Executive Officer*

In November, 2001, the Company recorded a charge in marketing, selling, general and administrative expenses primarily for the severance costs associated with the departure of an executive officer in the amount of \$700,000.

*Provision for Metal Spinal Implant System*

In second quarter 2001, the Company recorded pretax charges totaling \$1,845,000 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. These charges were primarily to establish reserves for excess inventory and instrumentation associated with metal spinal implant systems.

**5. DISCONTINUED OPERATIONS**

Effective June 30, 2002, the Company sold the business and substantially all of the assets, including the assumption of certain liabilities, of its operations located in Leiden, The Netherlands for \$1,000,000 in cash and a non-interest bearing note with a face value of \$1,500,000, which the Company discounted based on the acquirer’s incremental borrowing rate of 5.75%. The note is payable in increasing amounts on a quarterly basis beginning in March, 2003 through December, 2006. The Company has received all of the 2003 scheduled payments under the note. The Company has retained a security interest in all assets transferred to the acquirer and received a second mortgage on the land and building the acquirer will occupy to collateralize the note. For matters arising subsequent to the date of closing, July 10, 2002, the Company has no on-going financial or operational responsibilities with respect to the acquirer.

These operations represented the Company’s ceramic and titanium plasma spray coating services and products, which were previously reflected in the Company’s Other segment. The Company recorded a loss of \$291,000 on the sale of this business in the second quarter of 2002 to reduce the carrying value of the assets and liabilities sold to fair value. Revenues and net income for these operations were \$1,630,000 and \$384,000, respectively, in 2002 up to the effective date of sale. Revenues and net loss for these operations were \$2,131,000 and \$370,000, respectively, in 2001. The financial results of these operations prior to the sale are reflected in the statements of operations as discontinued operations and all prior periods have been reclassified to conform to this presentation.

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

**6. DEFERRED PROCESSING COSTS**

Deferred processing costs consist of the following at December 31:

<i>(in thousands)</i>	2003	2002
Donor tissue to be processed and distributed by the Company	\$ 6,758	\$ 2,411
Tissue in process	8,350	5,043
Processed implantable donor tissue to be distributed by the Company	11,962	6,234
Processed implantable donor tissue held for clients	1,943	1,745
	<u>\$29,013</u>	<u>\$15,433</u>

**7. INVENTORIES**

Inventories consist of the following at December 31:

<i>(in thousands)</i>	2003	2002
Supplies	\$ 287	\$ 223
Raw materials	765	678
Finished goods	2,529	3,919
	<u>\$ 3,581</u>	<u>\$ 4,820</u>

Metal spinal implant inventory is included in finished goods, and as a result of the Company's decision in the first quarter of 2004 to cease marketing and distribution of such products, the Company will record an estimated reserve of approximately \$2.4 million in first quarter 2004.

**8. PROPERTY, PLANT AND EQUIPMENT**

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

<i>(in thousands)</i>	2003	2002
Land	\$ 811	\$ 811
Building and improvements	14,918	14,763
Machinery and equipment	47,000	45,772
Computer hardware and software	4,966	4,475
Office equipment, furniture and fixtures	6,192	6,135
Spinal instruments	2,214	3,935
Leasehold improvements	8,325	8,107
Construction in progress	620	648
	<u>85,046</u>	<u>84,646</u>
Less accumulated depreciation and amortization	37,939	31,111
	<u>\$47,107</u>	<u>\$53,535</u>

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

**9. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES**

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

<i>(in thousands)</i>	2003	2002
Trade accounts payable	\$ 3,343	\$ 2,774
Accrued compensation	609	890
Accrued professional fees	430	1,035
Accrued commissions payable to non-employees	1,079	668
Accrued taxes payable	1,769	458
Accrued purchase commitment penalty	1,079	1,079
Litigation settlement payable	313	901
Other accrued liabilities	2,785	2,684
	<u>\$11,407</u>	<u>\$10,489</u>

**10. LEASING TRANSACTIONS**

The Company leases office and production facilities and equipment under various operating lease agreements which have non-cancelable terms through February, 2010. 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, 2003 are as follows:

<i>Year</i>	<i>Operating Leases</i>
<i>(in thousands)</i>	
2004	\$ 1,234
2005	1,165
2006	1,099
2007	1,041
2008 and thereafter	1,101
Total minimum lease payments	<u>\$ 5,640</u>

Rental expense was \$1,000,000, \$971,000, and \$936,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

**11. DEBT AND FINANCING ARRANGEMENTS**

The Company has a Credit Facility, as amended, which includes a \$5,000,000 revolving line of credit, a mortgage loan and an equipment term loan.

Beginning January 1, 2002, amounts outstanding for each loan under the Credit Facility bears interests at a variable rate ranging from prime (4.00% as of December 31, 2003) 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 in the Credit Facility. Prior to January 1, 2002, the mortgage bore interest at 7.38%, the equipment term loan bore interest at prime minus .50% or at LIBOR plus 1.75% or 2.25%, and the revolving line of credit bore interest at prime minus .75% or LIBOR plus 1.75%. The Company's effective weighted average interest rate for borrowings under the Credit Facility was 5.20% in 2003 and 6.20% in 2002.

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

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

In June, 2002, the Company obtained an irrevocable standby letter of credit to support the \$1,900,000 (\$317,000 as of December 31, 2003) due to Medtronic Sofamor Danek, Inc. pursuant to the settlement of certain patent litigation. The commitment under the standby letter of credit decreases over time based on a predetermined schedule concurrent with the Company's monthly payments under the settlement. As of December 31, 2003, the standby letter of credit has been reduced to \$428,000. The amount committed under the standby letter of credit reduces the Company's availability under its revolving line of credit. As of December 31, 2003, no amounts were outstanding under the revolving line of credit and \$4,572,000 was available.

The revolving line of credit is committed through April 30, 2004 at which time all amounts outstanding are due and payable and all remaining commitments are cancelled. The Company is currently negotiating an extension of the revolving line of credit with its lender, although there can be no assurance that the Company will be successful in such endeavor. The mortgage loan is repayable in 120 equal monthly installments of principal, based on a twenty-year amortization schedule, plus interest. Upon the 120th payment, the remaining amount of the unpaid principal will be due and payable. The equipment term loan is repayable in equal monthly installments of principal, based on a seven-year amortization schedule, plus interest.

Payments under the mortgage loan commenced in February, 2001 and payments under the equipment term loan commenced in December, 2001.

The Credit Facility, as amended, is collateralized by domestic accounts receivable, domestic inventories, the Company's 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 Credit Facility imposes certain restrictive operating and financial covenants on the Company. The Credit Facility 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. In addition, if available cash, cash equivalents and short-term investments decline below \$10.0 million at the end of any calendar month, the bank, at its option, has the right to obtain a security interest in the Company's general intangibles, including, but not limited to, the Company's patents and patent applications. The Credit 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 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 collateralizing the loans. The Company complied with these covenants in 2003.

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

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

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

<i>(in thousands)</i>	2003	2002
Domestic bank equipment term loan, repayable in monthly principal payments of \$202 plus interest through November, 2008	\$11,941	\$14,369
Domestic revolving line of credit		
Domestic building mortgage loan, repayable in monthly installments of \$19 plus interest through December, 2010 with a balloon payment of \$2,320 due December, 2010.	3,982	4,214
	15,923	18,583
Less current portion	2,661	2,661
	<u>\$13,262</u>	<u>\$15,922</u>

Aggregate maturities of long-term debt for the next five years are as follows: 2004, \$2,661,000; 2005, \$2,661,000; 2006, \$2,661,000; 2007, \$2,661,000; 2008, \$2,458,000; thereafter, \$2,821,000.

**12. INCOME TAXES**

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

<i>(in thousands)</i>	2003	2002	2001
Current:			
Federal	\$ 4,005	\$ (3,938)	\$ 265
State	644	190	574
	<u>4,649</u>	<u>(3,748)</u>	<u>839</u>
Deferred:			
Federal	1,690	(577)	(1,793)
State	540	(1,263)	(993)
	<u>2,230</u>	<u>(1,840)</u>	<u>(2,786)</u>
Income tax provision (benefit)	<u>\$ 6,879</u>	<u>\$ (5,588)</u>	<u>\$ (1,947)</u>

In 2002, the Company determined liabilities of \$2,557,000 that had been established in 1997 related to certain items, which were deducted in that year's income tax return, were no longer required, and therefore, recognized a current income tax benefit relating to releasing such liabilities.

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

**12. INCOME TAXES (continued)**

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>	2003	2002	2001
Computed tax at statutory Federal rate	\$ 6,034	\$ (2,324)	\$ (2,085)
Release of prior year tax liability		(2,557)	
State income taxes, net of Federal benefit	781	(702)	(269)
Foreign income/losses for which no tax (expense) benefit is recognized	(14)	(55)	606
Other	78	50	(199)
<b>Income tax provision (benefit)</b>	<b>\$ 6,879</b>	<b>\$ (5,588)</b>	<b>\$ (1,947)</b>

Income before income taxes from foreign operations, including discontinued operations and intercompany charges, was \$41,000 and \$161,000 in 2003 and 2002, respectively, which impacted the Company's effective income tax rate due to the utilization of historical net operating loss carryforwards that were subject to full valuation allowances in prior years to offset income taxes otherwise payable. Loss before income taxes from foreign operations, including discontinued operations and intercompany charges, was \$1,669,000 in 2001. The loss 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>	2003	2002
<b>Deferred Tax Assets:</b>		
Net operating loss carryforwards:		
Federal	\$ 260	\$ 460
Foreign	2,404	2,474
State	715	748
Tax credits:		
Federal		288
State	690	908
Inventory reserves	3,674	3,082
Other	1,918	1,973
	9,661	9,933
Less valuation allowance	2,759	2,803
<b>Deferred tax assets</b>	<b>6,902</b>	<b>7,130</b>
<b>Deferred Tax Liabilities:</b>		
Depreciation	3,376	1,518
Other	1,593	1,434
<b>Deferred tax liabilities</b>	<b>4,969</b>	<b>2,952</b>
<b>Net deferred tax asset (liability)</b>	<b>\$ 1,933</b>	<b>\$ 4,178</b>

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

**12. INCOME TAXES (continued)**

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 \$6,580,000 expiring in varying amounts beginning 2005 through 2010.

Although realization is not assured, the Company has concluded that it is more likely than not that the remaining deferred tax assets, which arise principally from domestic operations, will be realized based on the reversal of deferred tax liabilities and projected taxable income.

In 2002, the Company utilized approximately \$2,000,000 of its historical net operating loss carryforwards relating to its subsidiary in The Netherlands. Such net operating loss carryforwards were utilized against the Company's tax gain on the foreign portion of the gain on the sale of the PolyActive™ polymer biomaterial technology and patents, the tax gain on the sale of the Company's operations in The Netherlands and earnings from operations in 2002. Utilization of these net operating loss carryforwards, which were recorded subject to a full valuation allowance in prior periods, resulted in a reduction of approximately \$680,000 to income taxes otherwise payable in The Netherlands, of which approximately \$460,000 is related to discontinued operations.

At December 31, 2003, the Company has Federal and state net operating loss carryforwards of \$764,000 and \$6,889,000, respectively. The Federal net operating loss carryforwards expire in varying amounts beginning in 2007 through 2013. The state net operating loss carryforwards, which will primarily offset New Jersey taxable income, expire in varying amounts beginning in 2007 through 2012. The Company has provided valuation allowances for \$764,000 in Federal, and a corresponding amount of state, net operating loss carryforwards due to the uncertainty of realizing future tax benefits from these net operating loss carryforwards. The Company has state research and development and manufacturing credits of \$690,000, primarily to offset New Jersey income taxes, which expire in varying amounts beginning in 2008 through 2010.

**13. COMMITMENTS AND CONTINGENCIES**

**Service Agreements**

The Company is the processor of allograft bone tissue for domestic and international clients and 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.

On January 1, 1997, 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"). In October, 2002, the processing agreement was amended. The amendment, among other items, removed the requirements that ARC exclusively provide all tissue recovered by ARC to the Company for processing. In its place, the amendment requires ARC to provide a monthly minimum number of donors to the Company for processing.

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

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

Effective June 1, 2002, the Company entered into a new Processing Agreement with the Musculoskeletal Transplant Foundation ("MTF"), which will continue through December 31, 2008. Under the terms of the Processing Agreement, MTF will supply a certain increasing minimum annual amount of donor tissue to the Company for processing into standard base tissue forms, Grafton<sup>®</sup> DBM and Graftech<sup>®</sup> Bio-implants, all of which will be distributed to hospital end-users by MTF, under the MTF label, and provide a certain increasing minimum annual amount of tissue for the Company to process into standard base tissue forms, Grafton<sup>®</sup> DBM and Graftech<sup>®</sup> Bio-implant tissue forms, all of which will be distributed to hospital end-users by the Company under its own label.

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 Graftech<sup>®</sup> Bio-implants. Effective January 1, 2003, the Company entered into a five-year agreement with DePuy Orthopaedics, Inc. and DePuy Acromed, Inc. (collectively, "DePuy") and LifeNet. Under the terms of the agreement, the Company will process a private label DBM to specifications determined by LifeNet, from bone tissue supplied by LifeNet. DePuy will market and promote the private label DBM to domestic surgeons performing trauma, joint revision and spinal procedures and LifeNet will ship and bill the product to end-users.

**Purchase Commitments**

In February, 2001, the Company entered into an exclusive distribution agreement with Alphatec Manufacturing, Inc. ("Alphatec") to market and distribute the Sentinal<sup>™</sup> Pedicle Screw System and Affirm<sup>™</sup> in the United States and Canada. The term of the agreement is two years from April 1, 2002 and automatically renews for additional two-year terms unless terminated in writing by either party six months prior to the expiration of the then current two-year term. In September, 2003, the Company provided written notice to Alphatec terminating the distribution agreement upon the completion of the then current two-year term, which expires on March 31, 2004.

The Company has agreed to purchase \$6,000,000 of inventory during the first two years of the agreement. If the Company fails to make the minimum purchases, the Company is contractually required to pay Alphatec a penalty payment equal to 50% of the shortfall. In October, 2002, pursuant to a letter agreement, Alphatec waived the purchase commitment of \$3,200,000 for the first year of the commitment period (April 1, 2002 to March 31, 2003) for a payment of \$600,000, \$300,000 of which was to settle the first year purchase commitment and the remaining \$300,000 was to apply to purchases made on or after October 1, 2003. Therefore in the third quarter of 2002, the Company recorded a charge of \$300,000 for the settlement of the purchase commitment and a deposit for future purchases of \$300,000. The purchase commitment is \$2,800,000 for the second year (April 1, 2003 to March 31, 2004) of the commitment period.

In October, 2002, because of a higher than normal level of complaints, the Company suspended the sale and distribution of Affirm<sup>™</sup>. Due to the continuing uncertainty surrounding the re-introduction of Affirm<sup>™</sup> into the market, the Company does not expect to purchase sufficient inventory to meet the purchase commitment. Accordingly, the Company recorded a provision of \$1,079,000 for the penalty that will be due for the expected shortfall under the purchase commitment. (See Note 4, "Continuing Operations - Gains and Charges"). The Company has re-assessed such provision during 2003, and based upon the Alphatec litigation and other factors have determined that the provision is adequate.

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

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

In July, 2003, Alphatec filed an action against the Company for recovery of contractual penalty, breach of contract, fraud and trade libel arising out of the distribution agreement between the parties. In August, 2003, the Company answered Alphatec's complaint and asserted counterclaims setting forth causes of action for breach of contract, breach of implied covenant of good faith and fair dealing, fraudulent misrepresentation, fraudulent concealment, unjust enrichment, unfair competition, cancellation or rescission of the contract and indemnification. (See Note 13, "Commitments and Contingencies – Litigation").

**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> DBM process. In December 2001, as a result of a trial commenced in the United States District Court for the Central District of California, the Company was awarded damages in the amount of \$17,533,634 for GenSci's infringement of its patents. This damage award was reduced by the \$3.0 million previously paid by DePuy in 1999 and 2000 in settlement of the Company's claims against DePuy in this lawsuit. The Company did not recognize any portion of this net award of \$14,533,634 in its consolidated financial statements. On December 21, 2001, GenSci filed for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code.

On May 30, 2003, the Company entered into a definitive agreement to settle its claims with GenSci arising out of the patent lawsuit. The settlement is for an aggregate of \$7.5 million. In August, 2003, the parties amended the definitive settlement agreement to adjust the payment terms of the settlement. Pursuant to the amended agreement, the Company will receive \$2.5 million from GenSci upon its exit from bankruptcy and GenSci's merger with IsoTis B.V. ("IsoTis") and the balance of \$5.0 million in 20 equal payments of \$250,000 plus interest at the federal judgment rate as measured at the end of each quarter to a maximum of 3% per annum. To secure the future amounts to be paid to the Company, GenSci will provide an irrevocable letter of credit in the amount of \$5.0 million. On October 14, 2003, the Bankruptcy Court signed an Order confirming GenSci's Plan of Reorganization at which time GenSci emerged from bankruptcy. GenSci's merger with IsoTis was consummated on October 27, 2003. On October 29, 2003, the Company received the initial payment of \$2.5 million, an interest bearing Promissory Note in the amount of \$5.0 million and the \$5.0 million letter of credit collateralizing the Promissory Note. As a result, the Company recognized pre-tax income of \$7.5 million in the fourth quarter of 2003.

The settlement also provides that the Company covenants not to sue GenSci for infringing any of the Company's existing patents with respect to GenSci's products currently marketed under the names Accell<sup>™</sup>, DynaGraft<sup>®</sup> II and OrthoBlast<sup>™</sup> II, as long as GenSci does not change the formulation and composition of such products. Additionally, the parties agreed to dismiss all other litigation that was currently pending between them.

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

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

*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 and an attempt to monopolize the market for demineralized bone matrix and for entering into 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 for unlawful and unfair business practices in violation of Section 17200 of the California Unfair Competition Law. On December 20, 2001, GenSci filed a bankruptcy petition with the United States Bankruptcy Court for the Central District of California. GenSci did not seek relief from the automatic stay to pursue this action. On May 30, 2003, the Company and GenSci executed a Joint Settlement Agreement that, inter alia, requires the dismissal of this action with prejudice within ten days after the Bankruptcy Court's approval of GenSci's Plan of Reorganization. The Bankruptcy Court signed an Order on October 14, 2003 confirming GenSci's plan of Reorganization. The Consent Judgment and Stipulation of Dismissal were filed with the Court on November 5, 2003, dismissing all claims with prejudice.

*"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 the Company's subsidiary, Osteotech Implants BV, formerly known as CAM Implants BV. 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. The Company successfully moved to dismiss plaintiffs' claims for negligence and strict liability. Remaining are claims for breach of warranties, negligent misrepresentation, fraud, and violation of the New Mexico Unfair Trade Practices Act. Plaintiffs are seeking monetary damages in an amount to be determined at trial. On October 8, 2003, a Rule 16 Settlement Conference was conducted and the parties reached a tentative settlement agreement, which does not obligate the Company to pay monetary damages to the plaintiffs, but assigns certain of the Company's rights under its insurance policies to the plaintiffs. The parties are now in the process of negotiating and preparing mutually acceptable definitive agreements. On October 10, 2003, the Court issued an order staying all proceedings in the action and vacating case management deadlines. On December 18, 2003, the Court extended the stay of all proceedings until March 27, 2004. In the event the parties are unable to consummate a settlement by March 27, 2004, and no further extension is granted, the Court will lift the stay of the proceedings and the parties will return to active litigation.

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

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

*Regner v. Inland Eye & Tissue Bank of Redlands; Thacker v. Inland Eye & Tissue Bank of Redlands; Savitt v. Doheny Eye and Tissue Bank; Sorrels, Decker and Blake v. Inland Eye & Tissue Bank, et al.*

The Company is a defendant with other defendants in several actions pending in the Superior Court for the State of California, Los Angeles County. The Regner case sought class action status and initially alleged causes of action based on a violation of the California Business and Professional Code Section 17200, 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 the allegation that defendants are engaging in the activity of buying or selling organs or tissue for valuable consideration or profit, and certain negligence claims remain with respect to the actions. In addition, the plaintiffs through the Regner case sought class action status and injunctive relief and "restitution" with respect to their California Business and Professional Code claims. To the extent any of the other causes of action lie against the Company, plaintiffs are seeking damages in an unspecified amount.

In September, 2003, a settlement was entered into by the parties in the Savitt case, and plaintiffs subsequently dismissed this lawsuit with prejudice. Also in September, 2003, a global settlement was negotiated in the Regner, Thacker and Sorrels cases. The settlements in the Savitt, Regner, Thacker and Sorrels cases had no impact on the Company's financial position or results of operations. Settlement documents have been finalized, and on November 6, 2003 the Court issued an order dismissing the cases, with prejudice.

*Scroggins v. Zimmer Holdings, Inc.*

On or about June 24, 2002, the Company received a complaint filed in the United States District Court for the Eastern District of Louisiana against numerous defendants, including the Company. The complaint alleges that plaintiff received defective medical hardware in connection with a certain hip replacement procedure in May, 1992, and that such hardware was manufactured or distributed by certain of the defendants other than the Company. The procedure involved the use of allograft bone tissue processed by the Company and provided by one of our clients. Plaintiff alleges personal injuries and \$1,000,000 in damages.

On April 8, 2003, the Company filed a Motion for Summary Judgment seeking dismissal of plaintiff's claims with prejudice. On May 9, 2003, the Court granted the Company's Motion for Summary Judgment dismissing plaintiff's claims as to the Company with prejudice.

*Alphatec Manufacturing v. Osteotech, Inc.*

Alphatec Manufacturing, Inc., the manufacturer of the Affirm™ Anterior Cervical Plate System ("Affirm™"), filed an action on July 3, 2002 against the Company in the United States District Court for the Southern District of California. The complaint sets forth causes of action for recovery of contractual penalty, breach of contract, fraud and trade libel arising out of a distribution agreement between the parties. Alphatec is seeking \$1.4 million plus interest on the contractual penalty claim, \$600,000 on the fraud claim and additional unspecified compensatory damages.

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

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

On August 3, 2003, the Company answered the complaint denying all allegations and asserted counterclaims setting forth causes of action for breach of contract, breach of implied covenant of good faith and fair dealing, fraudulent misrepresentation, fraudulent concealment, unjust enrichment, unfair competition, cancellation or rescission of the contract and indemnification. The Company is seeking compensatory and punitive damages in an amount to be determined at trial as well as reasonable attorney's fees. Discovery has commenced and will continue through May 7, 2004.

The Company believes that Alphatec's claims are without merit and intends to vigorously defend against such claims. In the fourth quarter of 2002, the Company recorded a provision of approximately \$2.5 million, which includes an estimate of the penalty that would be due for the expected shortfall in the second year purchase commitment and an amount to fully reserve all implant inventory and instrumentation associated with Affirm™.

*Anthonsen v. Allosource, Inc.*

In January, 2004, the Company was served with a complaint in an action brought in the Lake Superior Court of Lake County, State of Indiana against numerous defendants, including the Company. The complaint alleges that plaintiff received defective implants and medical hardware in connection with cervical surgery performed on plaintiff, and that such implants and hardware were manufactured, processed or distributed by defendants. Plaintiff alleges personal injuries and unspecified damages. In February, 2004, the action was removed to the United States District Court, Northern District of Indiana, Hammond Division. The Company is currently reviewing the complaint and a response is due on March 17, 2004.

The Company maintains a product general liability insurance policy and has notified the insurance company of this action. The insurance company has agreed to defend this action.

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 ultimate liability, if any, that may result from the pending litigation and, accordingly, no material provision for any liability (except for accrued legal costs for services previously rendered) has been made for such pending litigation in the consolidated financial statements. When the Company is reasonably able to determine the probable minimum or ultimate 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.

**14. STOCKHOLDERS' EQUITY**

**Common Stock**

In May, 2002, the Company completed the sale of 2.8 million shares of its common stock representing approximately 19.8% of the then outstanding shares of common stock at \$6.25 per share to a small group of investors in a private placement transaction. The resale of these shares were registered with the Securities and Exchange Commission in May, 2002. The Company recognized net proceeds of \$15,756,000 after deducting the fees and expenses of the transaction.

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

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

**Preferred Stock**

The authorized capital of the Company includes 5,000,000 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 any time during 2003, 2002 or 2001.

**Stock Options**

The Company's 2000 Stock Plan (the "2000 Plan"), as amended pursuant to a shareholders' vote at the Company's annual meeting in 2003, authorizes the grant of up to 2,250,000 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. Prior to the shareholder vote in June, 2003, the 2000 Plan authorized the grant of up to 1,000,000 shares of common stock in the form of stock-based awards. 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 pursuant to the 2000 Plan typically have terms requiring vesting ratably over four years.

The 1991 Stock Option Plan (the "1991 Plan"), as amended, authorized the grant 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, authorized the grant of options to purchase 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 ratable 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. In September, 2001, the Directors Plan was replaced by the 2000 Plan and, therefore, options will no longer be issued under the Directors Plan.

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

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

Stock option activity for the years 2003, 2002, and 2001 is as follows:

	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1,	2,405,312	\$ 9.26	2,510,699	\$ 9.50	2,319,325	\$ 9.98
Granted	374,450	9.06	373,800	7.71	238,000	5.37
Exercised	80,437	4.74	47,500	3.68	10,138	4.10
Cancelled or expired	199,563	12.75	431,687	9.94	36,488	14.29
Outstanding at December 31,	2,499,762	\$ 9.10	2,405,312	\$ 9.26	2,510,699	\$ 9.50
Exercisable at December 31,	1,758,957	\$ 9.56	1,655,821	\$ 10.35	1,544,076	\$ 10.48
Available for grant at December 31,	1,112,000		150,105		494,500	
Weighted average fair value per share of options granted during the period		\$ 7.67		\$ 5.08		\$ 3.30

The following table summarizes the information about stock options outstanding at December 31, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at December 31, 2003	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at December 31, 2003	Weighted Average Exercise Price
\$ 2.33 To \$ 3.78	207,575	6.2	\$ 3.46	170,135	\$ 3.45
3.79 To 7.57	903,612	5.5	5.87	685,447	5.75
7.58 To 11.36	943,700	6.5	8.57	530,250	8.75
11.37 To 15.15	119,000	7.5	13.02	47,250	12.22
15.16 To 18.93	115,375	5.3	16.20	115,375	16.20
18.94 To 22.73	160,500	4.9	20.67	160,500	20.67
34.09 To 37.88	50,000	5.4	37.85	50,000	37.85
<b>\$ 2.33 To \$ 37.88</b>	<b>2,499,762</b>	<b>6.0</b>	<b>\$ 9.10</b>	<b>1,758,957</b>	<b>\$ 9.56</b>

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

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

**Stock Purchase Plan**

Prior to June, 2002, the 1994 Employee Stock Purchase Plan (the "1994 Purchase Plan") provided for the issuance of up to 375,000 shares of Common Stock. At the Company's annual meeting in June, 2002, the shareholders approved to increase the number of shares of Common Stock issuable under the 1994 Purchase Plan by 200,000 share to 575,000 shares. 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, 2003, 202,802 shares were available for future offerings under this plan.

**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.

**15. SUPPLEMENTAL STATEMENT OF OPERATIONS INFORMATION**

Maintenance and repairs expense from continuing operations for the years ended December 31, 2003, 2002, and 2001 was \$2,669,000, \$2,480,000, and \$2,415,000, respectively. Depreciation and amortization expense from continuing operations related to property, plant and equipment for the years ended December 31, 2003, 2002, and 2001 was \$8,236,000, \$7,739,000, and \$7,856,000, respectively.

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

<i>(in thousands)</i>	2003	2002	2001
Cash paid (refunded) during the year for taxes	\$ (79)	\$ 1,576	\$ 1,170
Cash paid during the year for interest, excluding amounts capitalized	874	1,227	379
Noncash investing activities:			
Note receivable from sale of foreign operation		1,273	

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

**17. 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		
	2003	2002	2001
Income (loss) from continuing operations	\$ 10,867	\$ (1,248)	\$ (3,817)
Discontinued operations		93	(370)
Net income (loss)	10,867	(1,155)	(4,187)
Denominator for basic earnings (loss) per share:			
Weighted average common shares outstanding	17,059,495	15,904,132	14,030,623
Effect of dilutive securities – stock options	461,464		
Denominator for diluted earnings (loss) per share	17,520,959	15,904,132	14,030,623
Basic earnings (loss) per share:			
Income (loss) from continuing operations	\$ .64	\$ (.08)	\$ (.28)
Discontinued operations		.01	(.02)
Net income (loss)	\$ .64	\$ (.07)	\$ (.30)
Diluted earnings (loss) per share:			
Income (loss) from continuing operations	\$ .62	\$ (.08)	\$ (.28)
Discontinued operations		.01	(.02)
Net income (loss)	\$ .62	\$ (.07)	\$ (.30)

For the year ended 2002 and 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 468,505 in 2003, 1,536,790 in 2002 and 1,744,518 in 2001. Such shares were not included because they were antidilutive.

**18. OPERATING SEGMENTS**

The Company has two primary business segments: the DBM Segment, formerly referred to as the Grafton<sup>®</sup> DBM Segment, and Base Tissue Segment. The DBM Segment engages in the processing and marketing of Grafton<sup>®</sup> and private label DBMs. 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 marketing and distributing metal spinal implant products and processing, marketing and distributing bovine tissue products.

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**

**18. OPERATING SEGMENTS (continued)**

Summarized financial information concerning the Company's segments after giving effect to the divestiture of the Company's operations in The Netherlands in 2002 is shown in the following table.

<i>(in thousands)</i>	DBM Segment	Base Tissue Segment	Other	Consolidated
<b>Revenues:</b>				
2003	\$46,294	\$41,465	\$ 6,674	\$94,433
2002	44,926	32,115	6,333	83,374
2001	43,637	27,692	4,386	75,715
<b>Operating income (loss):</b>				
2003	\$20,646	\$ 2,703	\$ (5,217)	\$18,132
2002	9,913	(8,927)	(7,851)	(6,865)
2001	7,031	(7,877)	(5,047)	(5,893)
<b>Depreciation and amortization:</b>				
2003	\$ 2,206	\$ 5,104	\$ 1,188	\$ 8,498
2002	2,411	4,488	1,331	8,230
2001	1,962	5,413	1,223	8,598

Financial information by geographic area after giving effect to the divestiture of the Company's operations in The Netherlands in 2002 is summarized as follows:

<i>(in thousands)</i>	United States	Europe	Consolidated
<b>Revenues</b>			
2003	\$86,070	\$ 8,363	\$94,433
2002	78,576	4,798	83,374
2001	71,776	3,939	75,715
<b>Long-lived Assets</b>			
2003	\$45,911	\$ 1,196	\$47,107
2002	52,408	1,127	53,535
2001	55,261	1,475	56,736

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

<i>(in thousands)</i>	2003	2002	2001
<b>Revenues</b>			
MTF	\$23,424	\$24,202	\$28,967
ARC	23,037	24,960	29,097
	<u>\$46,461</u>	<u>\$49,162</u>	<u>\$58,064</u>

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

**19. RETIREMENT BENEFITS**

The Company has a 401(k) plan which covers substantially all full time U.S. employees. Effective January 1, 2002, the Company contributes an amount equal to 35% of each participant's contribution. Previously, the Company contributed 25% of each participant's contributions. 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, 2003, 2002, and 2001 were \$414,000, \$433,000, and \$393,000, respectively.

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

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

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

The following is a summary of the unaudited quarterly results for the years ended December 31, 2003 and 2002 as restated and as originally reported. During 2003 year-end closing procedures, the Company identified a previously undetected flaw in its computer software used to maintain certain accounting records resulting in over accruals of certain expenses in the Company's accounting records over a period of years. As such, the Company has restated its consolidated financial statements to reflect the reversal of such over accruals.

<i>(in thousands except per share data)</i>	Quarter Ended			
	March 31 (Restated)	June 30 (Restated)	September 30 (Restated)	December 31 (As Reported)
<b>2003</b>				
Net revenues	\$ 22,479	\$ 24,792	\$ 23,135	\$ 24,027
Gross profit	12,693	15,328	12,004	12,337
Income (loss) from continuing operations	1,181	2,742	564	6,380
Discontinued operations				
Net income (loss)	1,181	2,742	564	6,380
Net income (loss) per share:				
Basic:				
Income (loss) from continuing operations	\$ .07	\$ .16	\$ .03	\$ .37
Discontinued operations				
Net income (loss)	\$ .07	\$ .16	\$ .03	\$ .37
Diluted:				
Income (loss) from continuing operations	\$ .07	\$ .15	\$ .03	\$ .37
Discontinued operations				
Net income (loss)	\$ .07	\$ .15	\$ .03	\$ .37

	Quarter Ended			
	March 31 (As reported)	June 30 (As reported)	September 30 (As reported)	December 31 (As reported)
<b>2003</b>				
Net revenues	\$ 22,479	\$ 24,792	\$ 23,135	\$ 24,027
Gross profit	12,672	15,276	12,271	12,337
Income (loss) from continuing operations	1,169	2,712	719	6,380
Discontinued operations				
Net income (loss)	1,169	2,712	719	6,380
Net income (loss) per share:				
Basic:				
Income (loss) from continuing Operations	\$ .07	\$ .16	\$ .04	\$ .37
Discontinued operations				
Net income (loss)	\$ .07	\$ .16	\$ .04	\$ .37
Diluted:				
Income (loss) from continuing Operations	\$ .07	\$ .15	\$ .04	\$ .37
Discontinued operations				
Net income (loss)	\$ .07	\$ .15	\$ .04	\$ .37

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

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

<i>(in thousands except per share data)</i>	Quarter Ended			
	March 31 (Restated)	June 30 (Restated)	September 30 (Restated)	December 31 (Restated)
<b>2002</b>				
Net revenues	\$ 22,085	\$ 23,009	\$ 19,691	\$ 18,589
Gross profit	13,136	12,938	7,035	3,994
Income (loss) from continuing operations	422	346	1,027	(3,043)
Discontinued operations	7	86		
Net income (loss)	429	432	1,027	(3,043)
Net income (loss) per share:				
Basic:				
Income (loss) from continuing operations	\$ .03	\$ .02	\$ .06	\$ (.18)
Discontinued operations		.01		
Net income (loss)	\$ .03	\$ .03	\$ .06	\$ (.18)
Diluted:				
Income (loss) from continuing operations	\$ .03	\$ .02	\$ .06	\$ (.18)
Discontinued operations		.01		
Net income (loss)	\$ .03	\$ .03	\$ .06	\$ (.18)

	Quarter Ended			
	March 31 (As reported)	June 30 (As reported)	September 30 (As reported)	December 31 (As reported)
<b>2002</b>				
Net revenues	\$ 22,085	\$ 23,009	\$ 19,691	\$ 18,589
Gross profit	13,065	12,751	7,002	3,970
Income (loss) from continuing operations	379	234	1,007	(3,057)
Discontinued operations	7	86		
Net income (loss)	386	320	1,007	(3,057)
Net income (loss) per share:				
Basic:				
Income (loss) from continuing operations	\$ .03	\$ .01	\$ .06	\$ (.18)
Discontinued operations		.01		
Net income (loss)	\$ .03	\$ .02	\$ .06	\$ (.18)
Diluted:				
Income (loss) from continuing operations	\$ .03	\$ .01	\$ .06	\$ (.18)
Discontinued operations		.01		
Net income (loss)	\$ .03	\$ .02	\$ .06	\$ (.18)

See Note 4, "Continuing Operations – Gains and Charges" and Note 5, "Discontinued Operations" for discussion of significant gains and charges recorded in 2003 and 2002.

**SCHEDULE II**

**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		
<b>For the year ended December 31, 2003:</b>					
Allowance for doubtful accounts	\$ 943	\$ 561	\$ 34 <sup>(a)</sup>	\$ (51) <sup>(b)</sup>	\$ 1,487
Valuation allowance for deferred tax asset	2,803		474 <sup>(a)</sup>	(518) <sup>(d)</sup>	2,759
<b>For the year ended December 31, 2002:</b>					
Allowance for doubtful accounts	303	638	15 <sup>(a)</sup>	(13) <sup>(b)</sup>	943
Valuation allowance for deferred tax asset	2,614	455 <sup>(c)</sup>	466 <sup>(a)</sup>	(732) <sup>(d)</sup>	2,803
<b>For the year ended December 31, 2001:</b>					
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

(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.

**Report of Independent Auditors 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 1, 2004, appearing on page F-2 of this Form 10-K also included an audit of the Financial Statement Schedule listed in Item 15(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 1, 2004

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s h a r e h o l d e r  
i n f o r m a t i o n

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#### 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**

Associate with the Investment Firm,  
Karas Partners.  
Retired Former Chairman of the Board  
of Axya Medical, Inc.

**Stephen S. Galliker**

Executive Vice President, Finance  
and Administration, and Chief  
Financial Officer of Dyax Corp.

**Michael J. Jeffries**

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

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

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

**Stephen 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

**Mark H. Burroughs**

Vice President,  
Finance and Treasurer

**Thomas L. Cobb**

Vice President, Operations

**Marilyn C. Murray**

Vice President, Quality  
Assurance and Regulatory

**Jeffrey M. Rosen**

Vice President, Human  
Resources

#### Common Stock

Listed on The Nasdaq Stock Market \*

Trading Symbol: OSTE

#### Corporate Office

Osteotech, Inc.  
51 James Way  
Eatontown, New Jersey 07724  
732-542-2800

#### Transfer Agent

Registrar and Transfer Company  
Cranford, New Jersey

#### SEC and General 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 10, 2004  
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)



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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 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, 2003, 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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