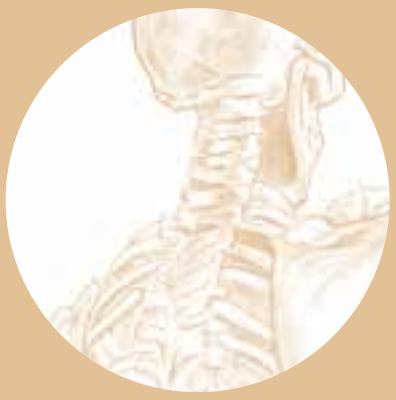


ORTHOVITA, INC. 2001 ANNUAL REPORT

CORTOSS™ and RHAKOSS™ are under development and are not available for commercial distribution in the United States.

ORTHOVITA, INC. 2001 ANNUAL REPORT

CORTOSS™ and RHAKOSS™ are under development
and are not available for commercial distribution in the United States.

TO OUR SHAREHOLDERS

In last year's annual report, we set out four key goals for 2001:

- Increasing product sales significantly,
- Obtaining regulatory approval of our CORTOSS™ product in Europe,
- Initiating clinical studies of CORTOSS in the United States,
- Completing financings to support our product development efforts.

In this year's report, we are pleased to report on our progress against our 2001 goals and to set out our goals for 2002.

Sales for 2001 were $3,940,000, an increase of $3,200,000 from 2000. Sales for the fourth quarter of 2001 were $1,626,000, an increase of approximately $1,400,000 from last year's fourth quarter and a 43% increase from the third quarter of 2001. The fourth quarter of 2001 also marks the fifth consecutive quarter with an increase in product sales. Primarily as a result of the increase in sales, our operating loss for the year decreased by over $300,000 in 2001 as compared to 2000.

As rewarding as our sales accomplishments were, we received as much satisfaction from the excellent performance of our VITOSS™ product in the hands of orthopaedic surgeons who used it successfully in over 6,000 bone-grafting procedures in 2001.

Our 2001 goals also included entering into a collaboration with a partner for VITOSS in Japan, which we achieved in April 2001 when we entered into an agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"). MDM has been a leading importer and distributor of orthopaedic products to hospitals and other medical institutions in Japan for over 25 years. We were pleased that as part of the collaborative arrangement, MDM made an investment of $1,000,000 in our common stock.

In October 2001, we obtained CE certification allowing us to affix the CE Mark to CORTOSS for use in screw augmentation and permitting the sale of CORTOSS in the countries of the European Union and several other countries around the world for this use. CORTOSS is our bone-bonding, bioactive, synthetic cortical bone structural graft. It can provide immediate support and stability to patients who have diminished ability to heal and regenerate new bone. Receipt of the CE certification for CORTOSS is the culmination of years of effort by Orthovita's employees. From testing and developing in research to commercial production in our newly-constructed CORTOSS manufacturing facility, Orthovita employees have often gone "beyond the call of duty" to bring this important new product to the European orthopaedic community. CORTOSS is currently the subject of a clinical trial in the U.S. and is not yet available for U.S. commercial distribution.

To support the development of our emerging product pipeline, in 2001, we raised $26,000,000 through several financings. These financings included a $10,000,000 financing with Paul Capital Royalty Acquisition Fund, L.P. The financing provides for Paul Capital to receive royalties on sales of our VITOSS, CORTOSS and RHAKOSS™ products in North America and Europe, and included the purchase by Paul Capital of approximately 2,586,000 shares of our common stock.

We believe one of the most important pieces of financial information we provide is net cash operating loss, which is our loss adjusted for non-cash expenses such as depreciation. Our goal is to move Orthovita to positive operating cash flow while making the investments to bring exciting new products like RHAKOSS to the marketplace. In 2001, we made significant progress toward achieving that goal by decreasing the net cash operating loss by over $400,000. We also ended the year with approximately $12,900,000 in cash.

We are proud of what was accomplished in 2001 and have now turned our efforts to achieving our primary goals for 2002, which are:

- Achieving our sales targets and reducing our net cash operating loss,
- Expanding the CE Mark label for CORTOSS in Europe to permit its use in vertebral augmentation,
- Enrolling a majority of the patients in the ongoing clinical studies in the United States for the use of CORTOSS in screw augmentation,
- Completing the enrollment of patients in the initial clinical studies of RHAKOSS in Europe.

Continuing our growth in sales is critical for 2002. To achieve this goal, our U.S. and European organizations will work closely with our sales agents and distributors. Reducing our net cash operating loss must be done in careful balance with driving our products through the process to regulatory submission. For example, if given the opportunity to accelerate enrollment in our CORTOSS and RHAKOSS clinical studies, we will certainly do so even if it would increase our cash spending.

We will be seeking to expand the clinical indications for CORTOSS through the completion of clinical studies in Europe in vertebral augmentation, a procedure in which CORTOSS is used to treat patients who suffer compression fractures of the vertebrae as a result of osteoporosis. In the U.S., the FDA approved our Investigational Device Exemption application, which now enables us to enroll patients in a clinical study for the use of CORTOSS in screw augmentation. We expect that this study will involve over twelve sites and will be a primary focus of our U.S. clinical development efforts in 2002.

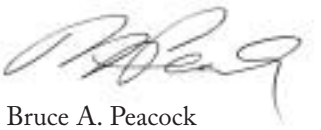
Spinal repair procedures, particularly spinal fusions, continue to be one of the fastest growing segments in orthopaedics. We reviewed the positive and negative qualities of the products now used in these procedures, obtained input from spine surgeons and conducted market research to develop a set of criteria for a new product which could provide improved performance in this area. Our expertise in biomaterials was applied to engineer and develop

RHAKOSS, which we believe will address many of the shortcomings of today's fusion devices. RHAKOSS is a unique bone-bonding implant that allows for the assessment of fusion rates by surgeons. We have initiated pre-clinical studies of RHAKOSS and are on target for our goal of conducting human clinical trials in Europe in 2002.

The year 2001 was marked by the continued achievement of several important milestones in Orthovita's progress towards becoming a leader in the application of biomaterials science to orthopaedics. Through the development of the VITOSS™ Synthetic Cancellous Bone Void Filler, CORTOSS™ Synthetic Cortical Bone Void Filler and RHAKOSS™ Synthetic Bone Spinal Implants, we continue to focus on under served and high-potential market opportunities in orthopaedics with a specific focus on products for use in surgical procedures in the spine and in treating osteoporotic fractures. Orthovita today is a fully integrated orthopaedic biomaterials company with products in the marketplace and multiple new product opportunities. We look forward to using our technological, financial and human resources to compete successfully in the coming year, and we thank you for your support and confidence.

Sincerely,

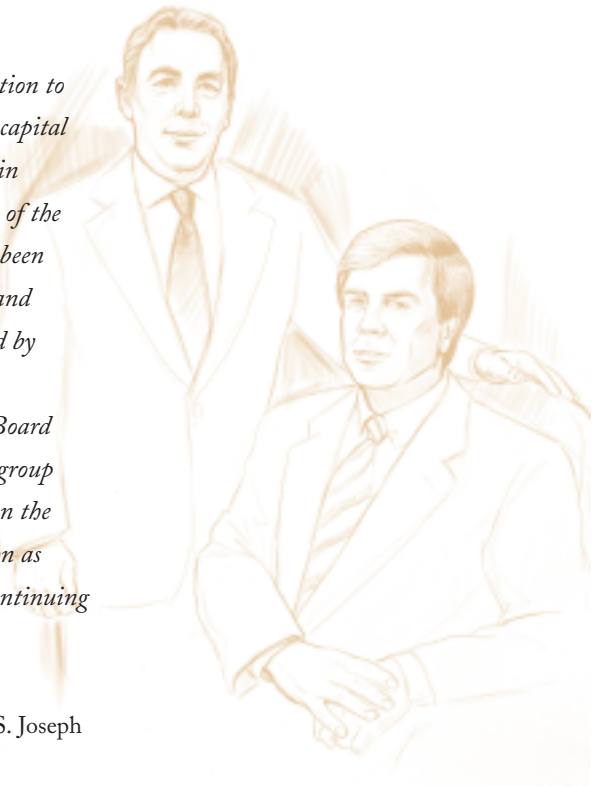
David S. Joseph
Chairman of the Board of Directors



Bruce A. Peacock
President and Chief Executive Officer

On a more personal note, as I transition to expanding my interests in healthcare venture capital in association with Liberty Venture Partners in Philadelphia, I leave Orthovita as Chairman of the Board of Directors at a point when much has been accomplished, with a sound foundation built and an outstanding management team in place led by Bruce Peacock and focused on building value for all of our stakeholders. My thanks to the Board of Directors for their support, to a wonderful group of motivated employees and to my colleagues on the management team. While I am stepping down as Chairman in May 2002, I look forward to continuing my service to Orthovita as a Board member.

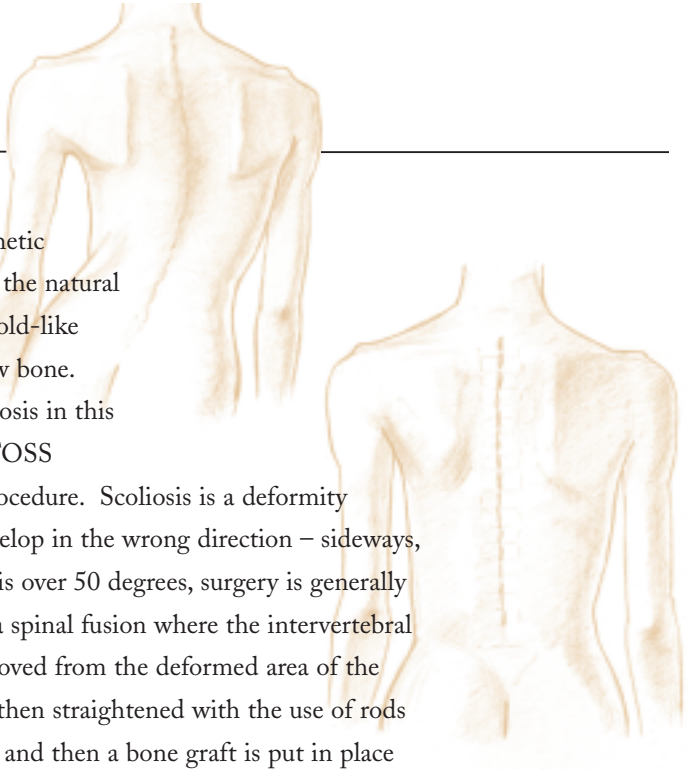
David S. Joseph



PRODUCT PIPELINE

Through its expertise in composites engineering, polymer science, solution chemistry, and ceramic-glass science, Orthovita has the ability to continually create novel biomaterials used to make new orthopaedic products. Orthovita's product pipeline includes products on the market today, including VITOSS™ in the U.S., Europe and Australia and CORTOSS™ in Europe and Australia, as well as products under development, including VITOSS in Japan, CORTOSS in the U.S. and Japan, and RHAKOSS™.

VITOSS: **Spinal Fusion**

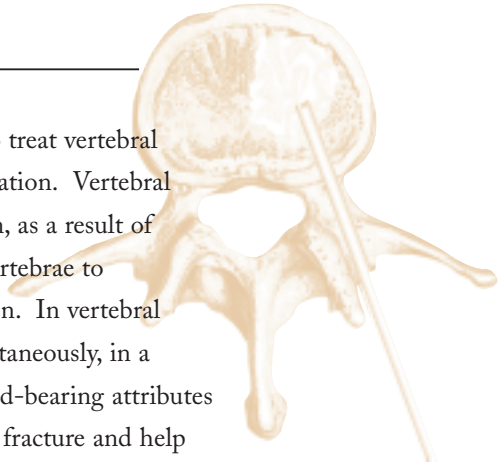


Orthovita's VITOSS Synthetic Cancellous Bone Void Filler guides the natural healing process by providing a scaffold-like matrix to support the growth of new bone. In a surgery to treat idiopathic scoliosis in this teenage girl, large quantities of VITOSS were used in a multi-level fusion procedure. Scoliosis is a deformity where the spine's natural curves develop in the wrong direction – sideways, instead of front to back. If a curve is over 50 degrees, surgery is generally considered. The surgery is usually a spinal fusion where the intervertebral discs between the vertebrae are removed from the deformed area of the spine, the vertebrae in this area are then straightened with the use of rods and wires attached to the vertebrae, and then a bone graft is put in place of the discs that were removed so that the vertebrae fuse together to make one long bone. Because VITOSS was used in this procedure, this young girl was able to avoid the need for a painful bone harvest from her own hip or for donor bone harvested from cadavers.

CORTOSS: **Compression Screw Augmentation**

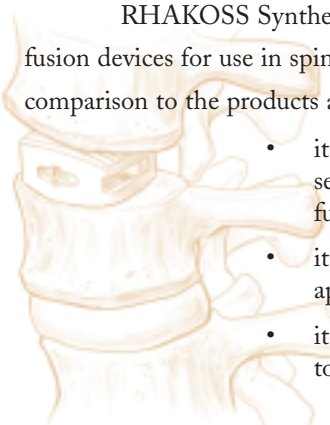
CORTOSS Synthetic Cortical Bone Void Filler is approved for use in Europe and Australia to augment screws that fail to hold in osteoporotic bone. In clinical studies in elderly patients in Europe, CORTOSS was used to augment compression hip screws, allowing the use of a hip screw where it might not otherwise be able to gain hold. CORTOSS thereby helps to avoid the need for a hip implant. CORTOSS also helps to prevent the walk-out of the screw once the patient become ambulatory. In this application, CORTOSS may permit the patient to regain mobility rapidly. CORTOSS has also been used successfully in patients for long bone screw augmentation and pedicle screw augmentation. CORTOSS is not available for commercial distribution in the U.S.

CORTOSS: **Vertebral Augmentation**



CORTOSS is in clinical studies in Europe for use to treat vertebral compression fractures in a procedure called vertebral augmentation. Vertebral compression fractures occur in elderly patients, usually women, as a result of osteoporosis, which weakens the spinal column causing the vertebrae to collapse upon itself resulting in a painful, debilitating condition. In vertebral augmentation, CORTOSS is injected through the skin, percutaneously, in a minimally invasive procedure. We believe the fast-setting, load-bearing attributes of CORTOSS can rapidly stabilize the vertebral compression fracture and help bring about rapid pain relief and mobility.

RHAKOSS: **Interbody Fusion Device**



RHAKOSS Synthetic Bone Spinal Implants are under development as interbody fusion devices for use in spinal fusion procedures. RHAKOSS has unique properties in comparison to the products available in the market today, including:

- its radiolucency, which allows the surgeon to both see it and see through it in order to better assess the quality of the spinal fusion healing process,
- its bone-bonding bioactive interface, which permits direct bony apposition, and
- its mechanical strength characteristics, which have been engineered to match that of normal bone.

VICE PRESIDENTS
Back Row *(left to right)*: McIlhenny, Koblish, Paiva
Front Row: Erbe, Wicklund, Persenaire

OFFICERS

David S. Joseph
Chairman and Director

Bruce A. Peacock
President and Chief Executive Officer and Director

Antony Koblish
Senior Vice President, Commercial Operations

Joseph M. Paiva
Vice President and Chief Financial Officer

Erik M. Erbe, Ph.D.
Vice President, Research & Development

David J. McIlhenny
Vice President, Quality Systems & Operations Support

Maarten Persenaire, M.D.
Vice President, Medical Affairs

Jeffrey J. Wicklund
Vice President, Manufacturing & Process Technology

BOARD OF DIRECTORS

Paul Ducheyne, Ph.D.
Founder and Chairman Emeritus

David S. Joseph
Chairman, Orthovita

Randal R. Betz, M.D.
Chief of Staff, Shriners Hospitals for Children

Morris Cheston, Jr.
Partner, Ballard Spahr Andrews & Ingersoll, LLP

James M. Garvey
Chief Executive Officer and Managing Partner, Schroder Ventures Life Sciences

Robert M. Levande
President, Palantir Group, Inc.

Bruce A. Peacock
President and Chief Executive Officer, Orthovita

Jos B. Peeters, Ph.D.
Managing Director, Capricorn Venture Partners, n.v.

CORPORATE DATA

COMPANY ADDRESS

Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355, USA
Telephone: (610) 640 1775
Facsimile: (610) 640 2603
Web Site: www.orthovita.com
NASDAQ NM: VITA
NASDAQ EUROPE: VITA

FORM 10-K

The Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission, may be obtained by writing the company address listed above, Attention: *Investor Relations*.

COUNSEL

Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921, USA

INDEPENDENT AUDITORS

Arthur Andersen, LLP
1601 Market Street
Philadelphia, PA 19103-2499, USA

TRANSFER AGENT

StockTrans, Inc.
44 West Lancaster Avenue
Ardmore, PA 19003-2318, USA
Telephone: (610) 649 7300
Facsimile: (610) 649 7302

Shareholder inquiries regarding change of address should be directed to the above address.

ANNUAL MEETING

Shareholders are cordially invited to attend the *2002 Annual Meeting of Shareholders* which will be held at 10:00AM on Friday, May 24, 2002, at the Company's offices, 41 Great Valley Parkway, Malvern, Pennsylvania, 19355, USA.

Except for historical information, the statements made herein are forward-looking statements involving risks and uncertainties. These risks and uncertainties, including those related to the timing or successful completion of the Company's product commercialization activities, are detailed in the Company's filings with the Securities and Exchange Commission.

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 *[No Fee Required]* for the fiscal year ended December 31, 2001 or

__ Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 *[No Fee Required]* for the transition period from to .

Commission file number 0-24517

ORTHOVITA, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of incorporation or organization)

23-2694857
(I.R.S. Employer Identification No.)

45 Great Valley Parkway
Malvern, Pennsylvania
(Address of principal executive offices)

19355
(Zip Code)

Registrant's telephone number, including area code: (610) 640-1775

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

(Title of class)	Name of each exchange on which registered
None	None

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

Common Stock, par value $.01 per share
(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 [X] 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 the definitive proxy statement incorporated by reference in Part III of this annual report on Form 10-K or any amendment to this annual report on Form 10-K. [X]

As of March 22, 2002, the aggregate market value of the Common Stock held by non-affiliates of the registrant was $22,491,090. Such aggregate market value was computed by reference to the closing sale price of the Common Stock as reported on the Nasdaq National Market on such date. For purposes of making this calculation only, the registrant has defined affiliates as including all directors, executive officers and beneficial owners of more than ten percent of the registrant's Common Stock.

As of March 22, 2002, there were 20,874,536 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

As stated in Part III of this annual report on Form 10-K, portions of the following document are incorporated herein by reference:

Definitive proxy statement to be filed within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

Unless the context indicates otherwise, the terms "Orthovita" and "Company" refer to Orthovita, Inc. and, where appropriate, one or more of its subsidiaries.

TABLE OF CONTENTS

PART I

PART II

PART III

PART IV

PART I

ITEM 1. BUSINESS

The use of the words "Orthovita," the "Company," "we," "us" or "our" herein refers to Orthovita, Inc. In addition to historical facts or statements of current conditions, this report contains forward-looking statements. When used in this Form 10-K, the words "may," "will," "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and similar expressions are generally intended to identify forward-looking statements, but are not the exclusive expressions of forward-looking statements. Forward-looking statements involve risks and uncertainties; therefore, readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date made. Furthermore, we undertake no obligation to publicly update any forward-looking statements. We claim the protections afforded by the Private Securities Litigation Reform Act of 1995, as amended, for our forward-looking statements. The following risk factors are addressed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations — Certain Risks Related to Our Business" section of this Form 10-K. These forward-looking statements are based on current expectations of future events that involve risks and uncertainties, including without limitation, the following risk factors that could cause actual events or results to differ materially from those expressed or implied by forward-looking statements:

- We are dependent on the commercial success of CORTOSS™ and VITOSS™;
  - We may be unable to increase sales of our approved products
  - We may not be able to operate an effective sales and distribution network
  - We may not train a sufficient number of surgeons to create demand for our products
  - If health care providers cannot obtain third-party reimbursement for procedures using our products, we may never become profitable
- We have experienced negative cash flows since our inception;
- If we fail to obtain and maintain regulatory approvals necessary to sell our products, sales could be delayed or never realized;
- If we do not manage commercial scale manufacturing capability and capacity for our products, our product sales may suffer;
- It may be difficult to operate in international markets;
- If losses continue in the long term, it could limit our growth and slow our generation of revenues;
- If we fail to meet our obligations under a revenue-sharing agreement, the investor could foreclose on certain assets that are essential to our operations, and we may be required to repurchase from an investor its right to receive revenues on certain of our product sales;
- Our results of operations may fluctuate due to factors out of our control;
- Our business will be damaged if we are unable to protect our proprietary rights to the technologies used in our products;
- We may lack the financial resources needed to respond to technological changes and other actions by competitors;

- We may acquire technologies or companies in the future, and these acquisitions could result in dilution to our shareholders;
- Provisions of Pennsylvania law or our Articles of Incorporation may deter a third party from seeking to obtain control of us;
- Our executive officers and directors own a large percentage of our voting stock and could exert significant influence over matters;
- We do not intend to pay cash dividends;
- Our stock price is volatile;
- If our shares are delisted from the Nasdaq National Market, it may be difficult to sell your investment in our company;
- If we are sued in a product liability action, we could be forced to pay substantial damages;
- Our business could suffer if we cannot attract and retain the services of key employees.

Orthovita, Inc. (“Orthovita” or the "Company") is a Pennsylvania corporation with proprietary technologies applied to the development of biostructures, which are synthetic, biologically active, tissue engineering products for restoration of the human skeleton. Our focus is on developing products for use in spine surgery and in the repair of osteoporotic fractures. We are addressing a broad range of clinical needs in the trauma market.

We have developed several products to date:

- VITOSS™ Scaffold Synthetic Cancellous Bone Void Filler
  - IMBIBE™ Bone Marrow Aspirate Syringe to be used with VITOSS
- CORTOSS™ Synthetic Cortical Bone Void Filler
  - ALIQUOT™ Microdelivery System to be used with CORTOSS

In addition, we are developing RHAKOSS™ Synthetic Bone Spinal Implants.

VITOSS is a resorbable, beta-tricalcium phosphate scaffold used as a bone void filler in trauma and spinal procedures. CORTOSS is a high-strength, bone-bonding, self-setting composite intended for use in the augmentation of screws used in a variety of orthopaedic procedures and in vertebral augmentation. RHAKOSS is under development as a high-strength, bone-bonding preformed composite. RHAKOSS is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets.

We received regulatory clearance for VITOSS in the U.S. from the United States Food and Drug Administration (“FDA”) in December 2000 and the CE Mark in the European Union from our notified body in July 2000. The CE Mark permits us to sell VITOSS in all of the countries of the European Union, as well as in other countries such as Switzerland and Israel, that have adopted the European Union’s regulatory standards. These regulatory approvals allow us to market VITOSS for use as a cancellous bone void filler for bony voids or gaps of the skeletal system, including the extremities, spine and pelvis. We also received regulatory approval in March 2001 to sell VITOSS for this use in Australia. We launched VITOSS in Europe in October 2000 and in the United States in February 2001. In April 2001, we entered into an agreement with Japan Medical Dynamic Marketing, Inc. (“MDM”), an orthopaedic company in

Japan, under which MDM will initiate clinical studies necessary to apply for regulatory approval to market VITOSS in Japan. In September 2001, we received regulatory clearance in the United States from the FDA to market IMBIBE for use as a bone marrow aspiration syringe. IMBIBE provides spine and trauma surgeons with a simple method for harvesting a patient's own bone marrow, mixing it with VITOSS and delivering the mixture to the bone graft site.

We received the CE Mark for CORTOSS in October 2001 in the European Union and regulatory approval in March 2001 in Australia which allows us to sell CORTOSS in these territories for use in screw augmentation procedures. Screw augmentation is a procedure for the fixation of bone screws used in patients with weak bone caused by osteoporosis. We initiated a limited launch of CORTOSS in Europe in December 2001. In addition, we are conducting post-marketing human clinical studies in Europe for the use of CORTOSS in hip compression screw augmentation. We are also pursuing clinical studies of CORTOSS in Europe seeking to expand its label to include its use in vertebral augmentation. During 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the U.S. for the use of CORTOSS for vertebral augmentation. In addition, during 2002, we received approval from the FDA to conduct a pivotal clinical study in the U.S. for the use of CORTOSS for long bone screw augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

Our ALIQUOT Microdelivery System facilitates effective delivery of our CORTOSS product directly to the surgical site. A two-part system of catheter and dispenser is designed to assure effective delivery of CORTOSS in screw augmentation procedures.

RHAKOSS is designed to mimic the strength and flexibility characteristics of bone, as well as its radiolucency, which means its degree of transparency to x-rays and other radiation. RHAKOSS can be manufactured into any size or shape to optimize anatomic fit. RHAKOSS is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets. We initiated pre-clinical studies for our RHAKOSS spinal implants in December 2000, and our goal is to initiate human clinical studies in Europe in 2002.

We have assembled a network of independent stocking distributors in Europe, Australia and Israel and commissioned sales agencies in the U.S. in order to market VITOSS, and we are utilizing this network for CORTOSS in Europe, Australia and Israel. If MDM is successful in obtaining approval to market VITOSS, it will distribute, sell and market VITOSS in Japan. We plan to seek a similar arrangement for CORTOSS in Japan.

We incorporated in Pennsylvania in 1992. Our principal offices are located at 45 Great Valley Parkway, Malvern, Pennsylvania 19355.

Orthovita's Research & Development

We employ biomaterials technologies, including composite engineering, polymer science solutions, chemistry and ceramic glass sciences to create novel biomaterials. We then use the new biomaterials to develop unique synthetic, biologically active products engineered to restore the human skeleton. Patents have been issued and patent applications filed to protect our key biomaterial developments. As of March 22, 2002, we own or control four issued U.S. patents, two allowed U.S. patent applications, ten pending U.S. patent applications and numerous

counterparts of certain of these patents and pending patent applications worldwide, including Canada, Europe, Mexico and Japan.

Our products under development to date have been the result of our internal research and development activities. We incurred approximately $7,203,000, $7,500,000 and $5,274,000 in research and development expenses in 2001, 2000 and 1999, respectively.

Our Product Pipeline and Related Clinical Applications

As further discussed in **Government Regulation** below, our products and product candidates are subject to extensive regulation as medical devices by the FDA and regulatory authorities in Europe and other jurisdictions. Product approval applications for our products must be supported by valid scientific evidence that typically includes clinical trial data, to demonstrate the safety and effectiveness of the device.

VITOSS SCAFFOLD SYNTHETIC CANCELLOUS BONE VOID FILLER

VITOSS is a resorbable, beta-tricalcium, phosphate scaffold used as a bone void filler in trauma and spinal procedures. The highly porous physical structure of VITOSS allows it to be rapidly saturated with marrow, blood and nutrients providing the cells and signals that are required for bone growth and remodeling. VITOSS provides a three-dimensional structure which, we believe, allows bone growth. VITOSS is covered by two U.S. issued patents and other U.S. and foreign patent applications are pending.

We received regulatory clearance for VITOSS in the U.S. from the FDA in December 2000 and the CE Mark in the European Union from our notified body in July 2000. The CE Mark permits us to sell VITOSS in all of the countries of the European Union, as well as in other countries such as Switzerland and Israel, that have adopted the European Union's regulatory standards. These regulatory approvals allow us to market VITOSS for use as a cancellous bone void filler for bony voids or gaps of the skeletal system, including the extremities, spine and pelvis. We also received regulatory approval in March 2001 to sell VITOSS for this use in Australia. We launched VITOSS in Europe in October 2000 and in the United States in February 2001.

Bone Defect Repair. Injury or trauma to the bone, as well as degenerative conditions, disease and aging, affect the health and viability of the human skeleton. These conditions often result in the need for the repair of bone defects through a bone grafting procedure. Approximately 500,000 bone-grafting procedures on a worldwide basis are performed each year in the spine, extremities and pelvis, representing a potential market we estimate at approximately $300 million.

Spinal Fusions. Many patients affected by severe back pain due to degeneration of one or more discs are treated with a spinal fusion procedure. We estimate that 400,000 spinal fusions are done annually on a worldwide basis. Spinal fusion involves the fusing together of adjoining vertebrae in cases where the patient has advanced disc degeneration or spinal instability. This procedure involves surgical incision in the patient's back or abdomen. Fusions frequently require the removal of the affected disc material and the surgical attachment of a metal implant or a spinal fusion cage to join the two surrounding vertebrae. The metal implant or spinal fusion cage is usually packed with bone grafting material to help promote the union of the two adjacent vertebrae. Bone grafting material is either autograft material, which is often obtained or

harvested from the iliac crest region of the patient's own hip, or allograft material, which is obtained from a cadaver, or synthetically derived materials such as VITOSS.

The autograft harvest is an additional procedure that extends surgical time, adding to costs and increasing blood loss and patient risk of infection or adverse reaction from the additional time under anesthesia. Of equal concern, harvesting bone for autograft sometimes causes protracted pain that may necessitate a trip back to the surgeon several months after the surgical procedure. Using VITOSS may avoid these potential complications of autograft harvest procedures. In addition, VITOSS avoids any patient and surgeon concerns regarding the use of cadaver-derived allograft material.

Iliac Crest Repair. The bone grafting material used to pack the metal implant and cages used in a spinal fusion procedure is often autograft material, obtained or harvested from the iliac crest region of the patient's own hip through an operating procedure. This procedure leaves an open space in the iliac crest, which is often painful and slow healing. We estimate that each year, autograft material is used in approximately 200,000 spinal fusion procedures worldwide, and that harvested material is used in another 100,000 non-spinal fusion related procedures worldwide.

VITOSS can be used to repair the bone void left by the harvest procedure at the time of surgery and may reduce pain and speed healing time. In post marketing studies of VITOSS for iliac crest repair, initial results indicate, that VITOSS performs well in the formation of new bone. The use of VITOSS also resulted in a reduction of incidence of post-operative bleeding and post-operative pain at the harvest site.

Trauma. Physical trauma such as falls and accidents can result in bone fracture or damage. Fractures of broken bones are often realigned with hardware, such as plates, rods and screws. Once the hardware has been used to recreate the skeletal anatomy, there are often defects or voids in the bone which remain. Those voids require the use of bone graft material. The goal of bone grafting in trauma applications is to rapidly heal the damaged bone. We estimate that approximately 100,000 trauma related bone graft repairs are performed annually on a worldwide basis. Autograft, cadaver allograft, as well as synthetic scaffolds, like VITOSS, are used for trauma-related bone graft repairs.

VITOSS has been used as a bone void filler in a variety of trauma applications, including those of the long bone, extremity and pelvic bone repairs. In addition, VITOSS has been used to fill bone void defects due to trauma in cancelleous fractures of the wrist, ankle, tibia and femur.

IMBIBE provides spine and trauma surgeons with a simple method for harvesting a patient's own bone marrow, mixing it with VITOSS and delivering the mixture to the bone graft site.

CORTOSS SYNTHETIC CORTICAL BONE VOID FILLER

CORTOSS is a high-strength, bone-bonding, self-setting composite, engineered specifically to mimic the strength characteristics of human cortical bone. For patients with poor bone healing capacity, as seen in osteoporotic patients, CORTOSS has been developed to be used in a variety of surgical procedures to provide structural stability and reinforcement of the bones after surgery. The surgeon's goal is to repair the patient's bone and provide mobility to the

patient as quickly as possible. Prolonged bed rest or inactivity often results in decreased overall health for older, osteoporotic patients. In order to gain mobility quickly, structural stability must be provided in a short period of time.

CORTOSS's simple mix-on-demand design allows for minimum waste and maximum ease of use and flexibility for the surgeon. CORTOSS is an injectable substance that is delivered aseptically through a prefilled, unit dose, disposable cartridge. Delivery of CORTOSS to the surgical site may be started and stopped for a prolonged period of time throughout the surgical procedure. Polymerization is initiated when CORTOSS is expressed through the static mix-tip and hardens within minutes. Laboratory tests demonstrate that CORTOSS exhibits compressive strength similar to human cortical bone. CORTOSS provides two stages of fixation: immediate mechanical interlock into porous bone, followed by intimate bone growth along the contours of the surface. CORTOSS develops a calcium phosphate-rich surface, which is equivalent in composition and structure to bone mineral. Six-month CORTOSS histology (preclinical studies) shows direct, intimate bony contact. CORTOSS is covered by two U.S. issued patents and other U.S. and foreign patent applications are pending.

We received the CE Mark for CORTOSS in October 2001 in the European Union and regulatory approval in March 2001 in Australia which allows us to sell CORTOSS in these territories for use in screw augmentation, a procedure for the fixation of bone screws used in patients with weak bone caused by osteoporosis. We initiated a limited launch of CORTOSS in Europe in December 2001. In addition, we are conducting post-marketing human clinical studies in Europe for the use of CORTOSS in hip compression screw augmentation. We are also pursuing clinical studies of CORTOSS in Europe seeking to expand its label to include its use in vertebral augmentation. During 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the U.S. for the use of CORTOSS for vertebral augmentation. In addition, during 2002, we received approval from the FDA to conduct a pivotal clinical study in the U.S. for the use of CORTOSS for long bone screw augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

Screw Augmentation. We estimate that worldwide each year, approximately 1,500,000 orthopaedic procedures are performed using internal fixation devices that involve screws. About 1,000,000 of these involve long bone fractures that are treated with metal plates and screws; the remainder involve hip fractures treated with compression screws and spinal fractures treated with pedicle screws.

Our ALIQUOT Microdelivery System facilitates effective delivery of our CORTOSS product directly to the surgical site. A two-part system of catheter and dispenser is designed to assure effective delivery of CORTOSS in screw augmentation procedures.

Long Bone Screw Augmentation. In long bone fractures, screws are placed into the plate and serve to compress the fracture, permitting faster healing. We estimate these screws "strip" or fail to hold in approximately 150,000 osteoporotic patients each year due to poor bone quality, as is often the case in osteoporotic bone. Where screws fail to hold, current treatment options include: (i) replacement of the screw with a screw of larger diameter, which may further weaken the bone and is not always possible because of the size of the screw holes and/or the bone, (ii)

replacing the plate with a longer plate with more screw holes to span the failed screw holes, which adds considerable time to the procedure, creates a larger wound area, increases the risk of other screws failing due to their removal and reimplantation, and in certain situations is anatomically not possible, (iii) leaving the plate with the failed screws as it is and giving the patient a non-load bearing cast for a prolonged period of time, which increases the risk of post-operative complications related to immobilization, such as deep venous thrombosis, or (iv) augmenting the screws with PMMA bone cement, which is cumbersome and time-consuming because it needs to be manually mixed and transferred into a syringe for application and, after mixing there only is a small time window in which it can be used before it sets, making it difficult to augment more than one screw at a time. Additionally, PMMA bone cement is not approved by the FDA for this indication.

The use of CORTOSS to anchor the screw in a quick and efficient way will allow the full function of the screw to be restored. We are not aware of any cement products that have received FDA approval or CE marking that would be in competition with CORTOSS for this indication.

A 37-patient multi-center clinical study in Europe of patients undergoing surgery to repair bone fractures demonstrated that CORTOSS allowed the successful use of metal screws in the repair procedures despite patients' poor bone quality. The three-month study showed CORTOSS restored the holding power of 98 percent of previously failed bone screws, permitting the use of a plate to stabilize the fracture and healing in all 37 patients with no adverse events related to CORTOSS reported.

During 2002, we received approval from the FDA to conduct a pivotal clinical study in the United States for the use of CORTOSS for long bone screw augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

Pedicle Screw Augmentation. Many spinal surgeries today have become possible only due to the availability of instrumentation systems that allow manipulation and fixation of the individual elements of the spine. These instrumentation systems are attached to the spine by means of screws placed in the pedicle region of the vertebrae. In patients with sub-optimal bone quality, such as osteoporotic patients, the purchase or "bite" of these screws may be insufficient to maintain the integrity of the construction.

There are approximately 280,000 patients in which pedicle screws are placed each year on a worldwide basis. We estimate that approximately 35,000 may require the augmentation of screws due to osteoporosis. We do not know of any approved product for this procedure.

We believe CORTOSS has the potential to ensure secure fixation of the screws, allowing the instrumentation systems to restore maximum fixation and stabilize the spine. We believe CORTOSS's mix-on-demand delivery system makes its use here convenient and practical.

Compression Screw Augmentation. We estimate approximately 750,000 hip fractures occur annually worldwide, of which an estimated 250,000 are repaired using compression screw augmentation.

Many osteoporotic patients, particularly elderly women, suffer a fracture of the hip whereby the head or the "ball" of the hip and socket of the femur leg bone is separated from the

rest of the bone. These fractures are often treated through the use of compression hip screws, which are placed through the bone and into the femoral head to stabilize and compress the fracture to permit healing. The healing of a fracture is directly proportional to the degree of stabilization. The failure of screws to purchase or hold is common, especially in osteoporotic bone. Additionally in many cases, even after the screw gains initial hold, the screw's sharp thread edges may cause the screw to cut through the bone and fail to hold. Such a failure during or after the surgical procedure will result in the need for an artificial hip implant.

We believe the use of CORTOSS to anchor the screw in a quick and efficient way will allow the full function of the screw to be restored. We are not aware of any products approved for this indication that would be in competition with CORTOSS.

In two separate clinical studies in Europe, CORTOSS has been used to increase the holding power of screws in the bone and to protect the bone from the screw's sharp threads. The first study included 25 patients with subtrochanteric fractures, which had been treated with dynamic hip screws. The holding power of the screw was shown to increase significantly in all patients. This holding power was evidenced by an increase in torque resistance. To date, none of the augmented screws has shown movement. A second clinical study, which included 21 patients with intra-capsular fractures of the hip, evaluated the effect of CORTOSS for the augmentation of two parallel screws used to reduce and fix the hip fracture. Initial results indicate a potential reduction in the normally high failure rate for this technique. This has the potential to reduce the need for a second corrective surgery.

Vertebral Augmentation. We estimate there are approximately 700,000 patients worldwide with compression of the vertebrae due to fractures caused by osteoporotic bone or bone cancer resulting in severe pain and immobility. Of these, approximately 260,000 fractures are diagnosed. The traditional treatments, e.g., bed rest, bracing, narcotics or injections, do not address the underlying fracture. Vertebral augmentation is a procedure for repairing the fractured vertebrae, which can be performed on an outpatient or short-stay basis. Vertebral augmentation has been reported to provide almost immediate pain relief in over 90% of osteoporotic patients. Early relief of pain provided by vertebral augmentation allows patients to maintain better functional capacity. Functional capacity, in turn, is believed to be directly related to the ability to live independently and unassisted. We are not aware of any products that have received FDA approval or European approval for use in this procedure; however, surgeons currently use PMMA "off-label".

We believe that CORTOSS may have several advantages over PMMA in vertebral augmentation, such as its ability to be seen by physicians when using imaging equipment in performing the procedure without adding additional materials such as barium, its lower temperature setting time, its higher compression strength and its ability to be mixed on demand. We have initiated clinical studies of CORTOSS in vertebral augmentation in Europe and believe these are the only controlled studies in this field. Upon completion of these studies, if successful, we intend to seek to expand CORTOSS's clearance for use in Europe to include vertebral augmentation.

During 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the United States for the use of CORTOSS for vertebral augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for this use.

RHAKOSS SYNTHETIC BONE SPINAL IMPLANTS

RHAKOSS is under development as a synthetic bone-bonding, load-bearing, spinal implant product for use in spinal repair procedures including vertebral interbody fusion and spine reconstruction. We believe that RHAKOSS Implants represent a potential alternative to titanium/carbon fiber cages and allograft cadaver bone implants. RHAKOSS is designed to mimic the radiolucency of bone, as well as the strength and flexibility characteristics of bone, and can be manufactured into any size or shape to optimize anatomic fit. We are developing RHAKOSS to combine the best features of first generation interbody fusion devices while eliminating many of the disadvantages of some currently available materials, such as inconsistent structural integrity, inability to visualize the graft material, lack of mechanical bonding to bone, potential concerns about disease transmission and potential limited supply. RHAKOSS can be injection molded or machined, thus generating an unlimited supply and consistent material performance.

Spinal Fusion. The current worldwide market estimate for interbody fusion devices including titanium cages, carbon fiber cages and cadaver bone dowels and spacers is approximately $445 million. We believe RHAKOSS implants potentially offer the surgeon and patient the consistency of engineered synthetics, with similar characteristics to those of human bone implants. We have completed the final formulation, initial acute pre-clinical studies and the design of the RHAKOSS synthetic implants. Our goal is to initiate RHAKOSS human clinical studies in 2002 in Europe.

Patents and Proprietary Intellectual Property

An integral part of our product development strategy is to seek protection for our product technologies and manufacturing methods through the use of United States and foreign patents. We have filed or intend to file applications as appropriate for patents covering our technologies, products and processes. We cannot be certain that any of our patent applications will be issued, or if issued, that they will not be challenged by third parties. We cannot be certain that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications for such inventions for the following reasons:

- patent applications filed prior to December 2000 in the United States are maintained in secrecy until issued;
- patent applications filed after November 2000 are maintained in secrecy until eighteen months from the date of filing;
- publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries.

Further, there can be no assurance that the claims allowed under any issued patents will be sufficiently broad as to protect our proprietary position in the technology. In addition, there can be no assurance that any patents issued to us will not be challenged, invalidated or circumvented, or that the rights granted thereunder will provide commercially useful competitive advantages to us. As of March 22, 2002, we own or control four issued U.S. patents, two allowed U.S. patent applications, ten pending U.S. patent applications and numerous counterparts of certain of these patents and pending patent applications worldwide, including Canada, Europe, Mexico and Japan.

Physician Advisory Panels

We have two physician advisory panels. Our Surgeon Clinical Panel is comprised of international physician experts that provide advice and guidance to us in our product development programs regarding potential clinical uses of our products. Our Scientific Advisory Board is made up of international physician experts that guide us regarding design and scientific issues. Certain members of the physician panels have received options to purchase our Common Stock, a practice that we may continue in the future.

Manufacturing and Product Supply

The manufacture of our products is subject to regulation and periodic inspection by various regulatory bodies for compliance with Good Manufacturing Practice ("GMP") regulations, Quality System Requirements ("QSR"), International Standards Organization ("ISO") 9000 Series standards and equivalent requirements.

Our VITOSS and CORTOSS manufacturing facilities produce commercial products and are certified as meeting the requirements of ISO 9001 and European Norm ("EN") 46001 for the period July 1, 2000 through July 1, 2003, and are subject to inspection by the FDA for compliance with FDA device manufacture requirements. In addition to the need for regulatory approval, in order to commercialize CORTOSS in the U.S., its manufacturing facility is also subject to inspection by the FDA. We are manufacturing IMBIBE and ALIQUOT through outside third-party contract manufacturers. Our third-party manufacturers are ISO 9001 certified or have been audited by us and determined to meet our quality system requirements.

Our ability to manufacture VITOSS and CORTOSS is dependent on a limited number of specialty suppliers of certain raw materials. The failure of a supplier to continue to provide us with these materials at a price or quality acceptable to us, or at all, would have a material adverse effect on our ability to manufacture these products. Moreover, our failure to maintain strategic reserve supplies of each significant single-sourced material used to manufacture VITOSS, CORTOSS and certain products that we may develop in the future may result in a breach of our material financing agreements.

Sales and Marketing

We have assembled a network of independent stocking distributors in Europe, Australia and Israel and commissioned sales agencies in the U.S. in order to market VITOSS, and we are utilizing this network in Europe, Australia and Israel for CORTOSS. If our partner in Japan is successful in obtaining clearance to market VITOSS, it will distribute, sell and market VITOSS in Japan. We plan to seek a similar arrangement with a partner for CORTOSS in Japan.

We have arrangements with independent distributors throughout Europe, one distributor in Australia and one distributor in Israel, with a combined sales force of over 200 representatives. These distributors purchase products directly from us, warehouse inventory of products purchased from us and hold title to the products purchased. In the U.S., we are represented by approximately 45 sales agencies with over 275 sales representatives in the aggregate. Sales agencies in the U.S. do not warehouse inventory. U.S. sales agencies are paid commissions by us for selling our products to the end user customers. The independent distributors outside of the U.S. and the end user customers in the U.S. do not have the right to return or exchange any products that they have purchased from us.

Competition

Extensive research efforts and rapid technological change characterize the market for products in the orthopaedic market. We face intense competition from medical device and medical products companies. Our products could be rendered noncompetitive or obsolete by competitors' technological advances. We may be unable to respond to technological advances through the development and introduction of new products. Moreover, many of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources than us and as a result may adversely impact our influence over the distribution channels for our products. These competitors may also be in the process of seeking FDA or other regulatory approvals, or patent protection, for new products. Our competitors could, therefore, commercialize new competing products in advance of our products. There can be no assurance that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations.

We believe VITOSS will face competition from products currently on the market or that may enter the market in the near future such as recombinant signaling growth factors. These proteins have the potential to significantly alter the bone grafting market. The first of these proteins is expected to enter the bone grafting market in the U.S. and Europe during 2002.

There are no known products that have received FDA approval or a CE Mark for screw augmentation and vertebral augmentation that would be in competition with CORTOSS for these indications; however, we may face off-label use of PMMA bone cement products. RHAKOSS will compete against products which are established in the market place, including those manufactured from metal carbon fiber and cadaver bone.

Government Regulation

In order to market our products, we must apply for, be granted and maintain all necessary regulatory approvals in each applicable jurisdiction. To date, we have received regulatory clearance for VITOSS in the United States from the FDA under a 510(k) (see below) in December 2000 and the CE Mark in the European Union from our notified body in July 2000. We also received regulatory approval to sell VITOSS, in March 2001, in Australia. The CE Mark permits us to sell our approved products in all of the countries of the European Union, as well as in other countries, such as Switzerland and Israel, that have adopted the European Union's regulatory standards. In September 2001, we received regulatory clearance in the United States from the FDA under a 510(k) to market our IMBIBE product for use as a bone marrow aspiration syringe. We received the CE Mark for CORTOSS in October 2001 in the European Union and regulatory approval in March 2001 in Australia which allows us to sell CORTOSS in these territories for use in securing screws in patients with weak bone caused by osteoporosis. During 2002, we submitted for review a technical file to our notified body in order to obtain CE Certification for ALIQUOT.

During 2002, we received approval from the FDA to conduct a pivotal clinical study in the United States for the use of CORTOSS for long bone screw augmentation. In addition, during 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the United States for the use of CORTOSS for vertebral augmentation. There can be no

assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

Our VITOSS and CORTOSS manufacturing facilities produce commercial products and are certified as meeting the requirements of ISO 9001 and EN 46001 for the period July 1, 2000 through July 1, 2003, and are subject to inspection by the FDA for compliance with FDA device manufacture requirements. In addition to the need for regulatory approval, in order to commercialize CORTOSS in the U.S., its manufacturing facility is also subject to inspection by the FDA. We are manufacturing IMBIBE and ALIQUOT through outside third-party contract manufacturers. Our third-party manufacturers are ISO 9001 certified or have been audited by us and determined to meet our quality system requirements.

United States

The medical devices that we manufacture and market, or intend to market, are subject to extensive regulation by the FDA. Pursuant to the Federal Food, Drug and Cosmetic Act ("FFD&C Act") and the regulations promulgated thereunder, the FDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing approvals and criminal prosecution.

In the United States, medical devices are classified into one of three classes (Class I, II or III) on the basis of the controls deemed necessary by the FDA to reasonably assure their safety and effectiveness. Under FDA regulations, Class I devices, the least regulated category, are subject to general controls and Class II devices are subject to general and special controls. Generally, Class III devices are those that must receive premarket approval by the FDA to ensure their safety and effectiveness. Our IMBIBE product is a Class II device and ALIQUOT is a Class IIa device.

Before a new device can be introduced into the market, the manufacturer must generally obtain market clearance through a 510(k) notification or premarket approval through a premarket approval application ("PMA"). A 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or II medical device, or to a Class III medical device for which the FDA has not called for a PMA. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information or data are needed before a substantial equivalence determination can be made. A request for additional data may require that clinical studies be performed to establish the device's "substantial equivalence."

Commercial distribution of a device for which a 510(k) notification is required can begin only after the FDA issues an order finding the device to be "substantially equivalent" to a predicate device. Pursuant to the FFD&C Act, the FDA must make a determination with respect to a 510(k) submission within 90 days of its receipt. The FDA may, and often does, extend this time frame by requesting additional data or information.

A "not substantially equivalent" determination, or a request for additional information, could delay or prevent the market introduction of new products for which we file such

notifications. For any of our products that are cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require new 510(k) submissions. The FDA has implemented a policy under which certain device modifications may be submitted as a "Special 510(k)," which will require only a 30-day review. Special 510(k) s are limited to those device modifications that do not affect the intended use or alter the fundamental scientific technology of the device and for which substantial equivalence can be demonstrated through design controls.

A PMA must be filed if a proposed device is not substantially equivalent to a legally marketed Class I or Class II device, or if it is a Class III device for which FDA has called for PMA. A PMA must be supported by valid scientific evidence that typically includes extensive data, including preclinical and clinical trial data, to demonstrate the safety and effectiveness of the device, as well as extensive manufacturing information.

FDA review of a PMA generally takes one to two years from the date the PMA is accepted for filing, but may take significantly longer. The review time is often significantly extended should the FDA ask for more information or clarification of information already provided in the submission.

During the PMA review period, an advisory committee, typically a panel of clinicians, will likely be convened to review and evaluate the application and provide recommendations to the FDA as to whether the device should be approved. The FDA is not bound by the recommendations of the advisory panel. Toward the end of the PMA review process, the FDA generally will conduct an inspection of the manufacturer's facilities to ensure that they are in compliance with applicable good manufacturing practices, or Quality System requirements.

If the FDA's evaluations of both the PMA and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an "approvable letter," which usually contains a number of conditions which must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue an approval letter, authorizing commercial marketing of the device for certain indications. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a "not approvable letter." The FDA may also determine that additional clinical trials are necessary, in which case PMA approval may be delayed up to several years while additional clinical trials are conducted and submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy, and a number of devices for which other companies have sought FDA approval have never been approved for marketing.

Modifications to a device that is the subject of an approved PMA (including modifications to its labeling or manufacturing process) may require approval by the FDA of PMA supplements or new PMAs. Supplements to a PMA often require the submission of the same type of information required for an initial PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

If clinical trials of a device are required in connection with either a 510(k) notification or a PMA and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or the distributor of the device) is required to file an investigational device exemption ("IDE") application prior to commencing clinical trials. The IDE application must be supported by data, typically including the results of animal and laboratory testing. If the IDE application is reviewed and approved by the FDA and one or more appropriate Institutional Review Boards ("IRBs"), clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a "non-significant risk" to the patient, a sponsor may begin the clinical trials after obtaining approval for the study by one or more appropriate IRBs, but not the FDA. For "significant risk" devices, an IDE supplement must be submitted to and approved by the FDA before a sponsor or an investigator may make a change to the investigational plan that may affect its scientific soundness or the rights, safety or welfare of human subjects. IRB approval may be required for changes in the investigational plan for both non-significant risk and significant risk devices.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to extensive regulation by the FDA, including reporting and record keeping requirements. Device manufacturers are required to register their establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies. The FFD&C Act requires devices to be manufactured in accordance with GMP regulations that impose certain procedural and documentation requirements upon us with respect to manufacturing and quality assurance activities. Medical devices are also subject to post-market reporting requirements for deaths or serious injuries when the device may have caused or contributed to the death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or efficacy problems occur after the product reaches the market, the FDA may impose severe limitations on the use of any approved or cleared product.

Labeling and promotion activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved or uncleared uses. We, as well as our products, are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect upon our ability to do business.

We are currently manufacturing VITOSS and CORTOSS in the United States and distributing VITOSS in the United States, Europe, Australia and Israel and CORTOSS in Europe and Australia. We are manufacturing IMBIBE through outside third-party contract manufacturers for distribution in the United States. VITOSS, as well as any other products that we manufacture or distribute following the approval thereof by the FDA, will be subject to extensive regulation by the FDA. FDA may impose severe limitations on the use of any

approved product. Moreover, modifications to the approved or cleared product may require the submission of a new premarket approval application or a premarket application supplement, or a new 510(k) notification. We may not be successful in obtaining the approval or clearance of any new premarket approval applications, necessary premarket approval application supplements, or new 510(k) notifications in a timely manner, if at all. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing approvals and criminal prosecution.

Europe

In order to sell our products within the European Union, we are required to achieve compliance with the requirements of the European Union Medical Devices Directive (the "MDD") and affix a CE marking on our products to attest such compliance. To achieve this, our products must meet the "essential requirements" defined under the MDD relating to safety and performance and we must successfully undergo a verification of our regulatory compliance ("conformity assessment") by an independent notified body. We have selected the TNO, or the Netherlands Organization for Applied Scientific Research, as our notified body. The nature of the conformity assessment will depend on the regulatory class of our products. Under European law, our products, other than IMBIBE and ALIQUOT, are likely to be in Class III. In the case of Class III products, we must (as a result of the regulatory structure which we have elected to follow) establish and maintain a complete quality system for design and manufacture as described in Annex II of the MDD (this corresponds to a quality system for design in ISO 9001 and EN 46001 standards). Our notified body has audited our quality system and determined that it meets the requirements of the MDD. In addition, the notified body must approve the specific design of each device in Class III. As part of the design approval process, the notified body must also verify that the products comply with the essential requirements of the MDD. In order to comply with these requirements, we must, among other things, complete a risk analysis and may be required to present sufficient clinical data. The clinical data presented by us must provide evidence that the products meet the performance specifications claimed by us, provide sufficient evidence of adequate assessment of unwanted side effects and demonstrate that the benefits to the patient outweigh the risks associated with the device. We will be subject to continued surveillance by the notified body and will be required to report any serious adverse incidents to the appropriate authorities. We also will be required to comply with additional national requirements that are beyond the scope of the MDD.

Third-Party Reimbursement

Successful sales of our products in the United States and other markets will depend on the availability of adequate reimbursement from third-party payers. In the United States, healthcare providers, such as hospitals and surgeons that purchase medical devices for treatment of their patients, generally rely on third-party payers to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Both public and private insurance reimbursement plans are central to new product acceptance. The Health Care Financing Administration Centers for Medicare and Medicaid Services ("CMS," formerly the Health Care Financing Administration or "HCFA") administers the policies and guidelines for coverage and

reimbursement of health care providers treating Medicare beneficiaries in the United States through local fiscal intermediaries and carriers. Medicaid, designed to pay providers for care given to medically needy persons, is dually funded by federal and state appropriations and is administered by each state in the United States. If a procedure or service is deemed "medically necessary" under applicable Medicare or Medicaid rules, providers may be reimbursed under Medicare or Medicaid for the service. The United States Medicare inpatient reimbursement system is a prospective reimbursement system whereby rates are set in advance, fixed for a specific fiscal period, constitute full institutional payment for the designated health service and generally do not vary with hospital treatment costs. Medicare also reimburses outpatient services based on a predetermined fee schedule. Similarly, some states reimburse certain healthcare providers for inpatient services under their Medicaid programs by using prospective rates for diagnosis-related groups of illnesses.

Inadequate reimbursement by private insurance companies and government programs could significantly reduce usage of our products. In addition, an increasing emphasis on managed care in the U.S. has placed, and we believe will continue to place, greater pressure on medical device pricing. Such pressures could have a material adverse effect on our ability to sell our products and to raise capital. Failure by hospitals and other users of our products to obtain coverage or reimbursement from third-party payers or changes in governmental and private third-party payers' policies toward reimbursement for procedures employing our products would reduce demand for our products.

Member countries of the European Union operate various combinations of centrally financed health care systems and private health insurance systems. The relative importance of government and private systems varies from country to country. The choice of devices is subject to constraints imposed by the availability of funds within the purchasing institution. Medical devices are most commonly sold to hospitals or health care facilities at a price set by negotiation between the buyer and the seller. A contract to purchase products may result from an individual initiative or as a result of a competitive bidding process. In either case, the purchaser pays the supplier, and payment terms vary widely throughout the EU. Failure to obtain favorable negotiated prices with hospitals or health care facilities could adversely affect sales of our products.

In Japan, at the end of the regulatory approval process, the Ministry of Health, Labor and Welfare ("MHW") makes a determination of the reimbursement level of the product. The MHW can set the reimbursement level for our products at their discretion, and we may not be able to obtain regulatory approval in Japan or if such approval is granted, we may not obtain a favorable per unit reimbursement level.

Product Liability and Insurance

We manufacture medical devices that are used on patients in surgery, and we may be subject to product liability lawsuits. While we have not experienced any product liability claims to date, there can be no assurance that product liability claims will not be asserted against us. Under certain of our agreements with our distributors, we indemnify the distributor from product liability claims. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we would have to pay any amount awarded by a court in excess of policy

limits. We maintain product liability insurance in the annual aggregate amount of up to $10 million, although our insurance policies have various exclusions. Thus, we may be subject to a product liability claim for which we have no insurance coverage, in which case we may have to pay the entire amount of any award.

Employees

As of December 31, 2001, we had 70 full-time employees, with 65 employees at our Malvern, Pennsylvania headquarters and 5 employees in Europe. We had an average of 65, 51 and 42 employees in 2001, 2000 and 1999, respectively. The increase in number of employees for the period from 1999 through 2001 is attributed primarily to continued development of manufacturing, marketing and sales capabilities. In general, we consider our relations with our employees to be good.

ITEM 2. *Properties*

Our headquarters are located at the Great Valley Corporate Center in Malvern, Pennsylvania, which is a suburb of Philadelphia. We conduct all of our principal activities at two adjacent facilities that total 32,000 square feet. Our manufacturing and research and development facility is leased through July 2012, and our administrative facility is leased through July 2007. We also have our international sales and marketing activities based in our administrative office in Leuven, Belgium.

ITEM 3. *Legal Proceedings*

In July 1992, we obtained a license from FBFC International, a Belgian company, that allowed us to manufacture and sell our BIOGRAN dental grafting product. We sold the rights to sell the BIOGRAN product line to Implant Innovations, Inc. ("3i") in March, 2000. In July 1994, U.S. Biomaterials Corporation filed with the U.S. Patent and Trademark Office ("PTO") a Request for Reexamination of the U.S. patent held by FBFC for BIOGRAN, of which we had been the exclusive licensee. FBFC filed a response in this proceeding, establishing that the claims of the FBFC patent were properly allowed. As a result, a Certificate of Reexamination was issued by the PTO confirming the patentability of all claims of the FBFC patent without amendment. However, U.S. Biomaterials Corporation instituted a nullification proceeding against the European counterpart to FBFC's U.S. patent. The opposition division of the European Patent Office tentatively decided in FBFC's favor, but the matter is still proceeding under an appeal. In connection with the BIOGRAN sale to 3i, 3i has assumed control of this matter and we have agreed to reimburse 3i for the associated legal costs and to provide them with certain indemnification with respect to the matter. We do not believe there are any material liabilities with respect to the indemnification for this matter.

ITEM 4. *Submission of Matters to a Vote of Security Holders*

We did not submit any matters to a vote of security holders during the fourth quarter of 2001.

PART II

ITEM 5. *Market for Registrant's Common Equity and Related Shareholder Matters*

Our Common Stock is quoted on both the Nasdaq National Market ("Nasdaq") and Nasdaq Europe under the symbol "VITA". We began trading on Nasdaq on August 2, 2000. The following table reflects the ranges of high and low sale prices for our Common Stock as reported on the Nasdaq and Nasdaq Europe for the stated periods.

	Nasdaq		Nasdaq Europe	
	High	**Low**	**High**	**Low**
2001:				
First Quarter	$ 6.56	$ 3.50	$ 6.00	$ 3.30
Second Quarter	5.56	3.70	5.25	3.55
Third Quarter	3.76	2.00	3.65	1.90
Fourth Quarter	3.41	1.30	3.50	1.35
2000:				
First Quarter	—	—	$ 9.50	$ 4.50
Second Quarter	—	—	7.80	4.80
Third Quarter	$ 8.13	$ 5.50	7.90	5.80
Fourth Quarter	6.38	3.56	6.40	3.05

As of March 22, 2002 there were 153 holders of record of our Common Stock. Since a portion of our Common Stock is held in "street" or nominee name, we are unable to determine the exact number of beneficial holders. On March 22, 2002, the last reported sale price of the common stock as reported Nasdaq and Nasdaq Europe was $2.26 and $2.10 per share, respectively. We have never declared or paid cash dividends on our Common Stock and do not anticipate paying any cash dividends in the foreseeable future.

On December 20, 2001, we sold 625,000 shares of our Common Stock to S.A.C. Capital Associates, LLC ("S.A.C."), and 500,000 shares of our Common Stock to SDS Merchant Fund, L.P. ("SDS"). The aggregate consideration we received for these shares consisted of $2,700,000 in cash, plus the surrender and cancellation of outstanding warrants to purchase an aggregate of 1,125,000 shares of our Common Stock held by S.A.C. and SDS. The issuance of these securities was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D as an issuer transaction not involving a public offering.

ITEM 6. *Selected Consolidated Financial Data*

The following table presents selected historical consolidated financial data that have been derived from the consolidated financial statements of Orthovita, Inc. and subsidiaries as of and for each of the five years in the period ended December 31, 2001 which have been audited by Arthur Andersen LLP, independent public accountants. This data should be read in conjunction with our consolidated financial statements, including notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in this report.

	Year Ended December 31,				
	2001	2000	1999	1998	1997
Statement of Operations Data:					
Product sales (1)	$ 3,940,395	$ 740,660	$ 1,054,120	$ 2,780,658	$ 3,311,540
Cost of sales (2)	719,373	170,041	324,590	927,792	1,096,848
Operating expense	17,474,630	15,191,162	10,755,317	7,897,961	9,998,945
Other income	(88,189)	(214,273)	(529,193)	(344,307)	(228,336)
Net gain on sale of product line (1)	(375,000)	(3,070,921)	—	—	—
Accretion of preferred stock	—	—	—	391,213	536,517
Net loss applicable to common shareholders	$ (13,790,419)	$ (11,335,349)	$ (9,496,594)	$ (6,092,001)	$ (8,092,434)
Net loss per common share, basic and diluted	$ (0.82)	$ (0.92)	$ (0.83)	$ (0.73)	$ (1.60)
Shares used in computing net loss per common share, basic and diluted	16,841,970	12,281,117	11,411,896	8,314,679	5,050,397

	Year Ended December 31,				
	2001	2000	1999	1998	1997
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 12,906,557	$ 3,814,992	$ 8,873,545	$ 15,355,808	$ 2,257,902
Total assets	21,212,843	10,188,367	11,321,446	18,888,632	4,862,010
Working capital (deficit)	12,713,603	747,835	4,118,730	14,471,102	(1,080,859)
Long-term liabilities	5,634,626	1,307,425	616,726	737,427	832,991
Redeemable convertible preferred stock	—	—	—	—	7,383,090
Total shareholders' equity (deficit)	12,670,441	5,129,615	5,646,669	15,528,575	(7,712,696)

(1) For 2001, product sales primarily represent VITOSS sales in the U.S., Europe, Australia and Israel. For 2000, product sales represent VITOSS sales in Europe and BIOGRAN product sales prior to the sale of the BIOGRAN product line. On March 22, 2000, we sold the BIOGRAN dental grafting product line to Implant Innovations, Inc. ("3i") for $3,900,000 (See Note 11 of Notes to Consolidated Financial Statements).

(2) Cost of Sales for the year ended December 31, 2000 primarily reflects cost of sales of BIOGRAN, since prior to European approval of VITOSS in July 2000, costs of producing VITOSS were charged to Research & Development expenses.

Forward-Looking Statements

The use of the words "Orthovita," the "Company," "we," "us" or "our" herein refers to Orthovita, Inc. In addition to historical facts or statements of current conditions, this report contains forward-looking statements. When used in this Form 10-K, the words "may," "will," "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and similar expressions are generally intended to identify forward-looking statements, but are not the exclusive expressions of forward-looking statements. Forward-looking statements involve risks and uncertainties therefore readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date made. Furthermore, we undertake no obligation to publicly update any forward-looking statements. We claim the protections afforded by the Private Securities Litigation Reform Act of 1995, as amended, for our forward-looking statements. Some of the factors that could cause actual events or results to differ materially from those expressed or implied by forward-looking statements are addressed in the Certain Risks Related to Our Business section which is below.

Overview

Orthovita, Inc. ("Orthovita" or the Company) is a Pennsylvania corporation with proprietary technologies applied to the development of biostructures, which are synthetic, biologically active, tissue engineering products for restoration of the human skeleton. Our focus is on developing products for use in spine surgery and in the repair of osteoporotic fractures. We are also addressing a broad range of clinical needs in the trauma market. We have developed several products to date:

- VITOSS™ Scaffold Synthetic Cancellous Bone Void Filler;
  - IMBIBE™ Bone Marrow Aspirate Syringe to be used with VITOSS;
- CORTOSS™ Synthetic Cortical Bone Void Filler;
  - ALIQUOT™ Microdelivery System to be used with CORTOSS.

In addition, we are developing RHAKOSS™ Synthetic Bone Spinal Implants.

VITOSS is a resorbable, beta-tricalcium phosphate scaffold used as a bone void filler in trauma and spinal procedures. CORTOSS is a high-strength, bone-bonding, self-setting composite intended for use in the augmentation of screws used in a variety of orthopaedic procedures and in vertebral augmentation. RHAKOSS is under development as a high-strength, bone-bonding preformed composite. RHAKOSS is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets.

We received regulatory clearance for VITOSS in the U.S. from the United States Food and Drug Administration ("FDA") in December 2000 and the CE Mark in the European Union from our notified body in July 2000. The CE Mark permits us to sell VITOSS in all of the countries of the European Union, as well as in other countries, such as Switzerland and Israel, that have adopted the European Union's regulatory standards. These regulatory approvals allow us to market VITOSS for use as a cancellous bone void filler for bony voids or gaps of the skeletal system, including the extremities, spine and pelvis. We also received regulatory approval in March 2001 to sell VITOSS for this use in Australia. We launched VITOSS in Europe in October 2000 and in the United States in February 2001. In April 2001, we entered into an

agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"), an orthopaedic company in Japan, under which MDM will initiate clinical studies necessary to apply for regulatory approval to market VITOSS in Japan. In September 2001, we received regulatory clearance in the United States from the FDA to market IMBIBE for use as a bone marrow aspiration syringe. IMBIBE provides spine and trauma surgeons with a simple method for harvesting a patient's own bone marrow, mixing it with VITOSS and delivering the mixture to the bone graft site.

We received the CE Mark for CORTOSS in October 2001 in the European Union and regulatory approval in March 2001 in Australia which allows us to sell CORTOSS in these territories for use in screw augmentation procedures. Screw augmentation is a procedure for the fixation of bone screws used in patients with weak bone caused by osteoporosis. We initiated a limited launch of CORTOSS in Europe in December 2001. In addition, we are conducting post-marketing human clinical studies in Europe for the use of CORTOSS in hip compression screw augmentation. We are also pursuing clinical studies of CORTOSS in Europe seeking to expand its label to include its use in vertebral augmentation. During 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the U.S. for the use of CORTOSS for vertebral augmentation. In addition, during 2002, we received approval from the FDA to conduct a pivotal clinical study in the U.S. for the use of CORTOSS for long bone screw augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

Our ALIQUOT Microdelivery System facilitates effective delivery of our CORTOSS product directly to the surgical site. A two-part system of catheter and dispenser is designed to assure effective delivery of CORTOSS in screw augmentation procedures.

RHAKOSS is designed to mimic the strength and flexibility characteristics of bone, as well as its radiolucency, which means its degree of transparency to x-rays and other radiation. RHAKOSS can be manufactured into any size or shape to optimize anatomic fit. RHAKOSS is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets. We initiated pre-clinical studies for our RHAKOSS spinal implants in December 2000 and our goal is to initiate human clinical studies in Europe in 2002.

We have assembled a network of independent stocking distributors in Europe, Australia and Israel and commissioned sales agencies in the U.S. in order to market VITOSS, and we are utilizing this network for CORTOSS in Europe, Australia and Israel. If MDM is successful in obtaining approval to market VITOSS, it will distribute, sell and market VITOSS in Japan. We plan to seek a similar arrangement for CORTOSS in Japan.

Critical Accounting Policies

Our discussions and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses and disclosures of contingent assets and liabilities as of the date of the financial statements. On an on-going basis, we evaluate our estimates, including, but not limited to, those related to accounts receivable and inventories. We use authoritative

pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue

Revenue from product sales is recognized upon the receipt of a valid order and shipment to our distributor customers in Europe, Australia and Israel. In the U.S., product sales revenue is recognized upon the receipt of a valid order and shipment of the product to the end user hospital. We do not allow product returns or exchanges. In addition, collection of the customers' receivable balance must be deemed probable. We maintain an accounts receivable allowance for an estimated amount of losses that may result from customers' inability to pay for product purchased. 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.

Inventory

Inventory is stated at the lower of cost or market value using the first-in first-out basis, or FIFO, method. If market value declined, we would write down our inventory, if necessary, by estimating the potential for future loss based on a variety of factors, including the quantity of particular items, their prospect for replacement or obsolescence and the remaining shelf life. If actual market conditions were to be less favorable than those projected by management and demand decreased, inventory write-downs would be required. As of December 31, 2001, we have not needed to write down our inventory.

Revenue Interest Obligation

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Capital Royalty Acquisition Fund, L.P. ("Paul Royalty") in which we sold a revenue interest and 2,582,645 shares of our Common Stock.

The net proceeds of the financing were first allocated to the fair value of the Common Stock on the date of the transaction, and the $5,222,107 remainder of the net proceeds was allocated to the revenue interest obligation. Given that the products subject to the revenue interest have only recently been approved and marketed or are still under development, we, as of December 31, 2001 and for the foreseeable future, cannot make a reasonable estimate of their future sales levels and the related revenue interest obligation. Accordingly, in 2002 and the forseeable future, we will charge revenue interest expense payments due under the revenue interest obligation as incurred.

On March 22, 2002, the agreement with Paul Royalty was modified whereby they exchanged 860,882 shares of our Common Stock for elimination of certain potential credits allowable to us against our revenue interest obligation, as well as, a reduction in the repurchase price (described below in the Certain Risks Related to Our Business). This modification will be accounted for as a treasury stock transaction with a decrease to shareholders' equity and an increase to the revenue interest obligation based upon the fair market value of the Common Stock on the date of the modification to the transaction, or $2.26 per share or $1,946,454 in the aggregate.

Income Taxes

We account for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected tax consequences of events that have been recognized in the financial statements or tax returns. SFAS No. 109 requires that deferred tax assets and liabilities be recorded without consideration as to their realizability. The deferred tax asset includes the cumulative temporary difference related to certain research, patent and organizational costs, which have been charged to expense in our Statements of Operations contained in this Form 10-K but have been recorded as assets for federal tax return purposes. These tax assets are amortized over periods generally ranging from 5 to 20 years for federal tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance against the asset. A valuation allowance has been established against all of our deferred tax assets since the realization of the deferred tax asset is not assured given our history of operating losses.

Stock Options

We apply Accounting Principal Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and the related interpretations in accounting for our stock option plans. Under APB 25, compensation cost related to stock options is computed based on the intrinsic value of the stock option at the date of grant, reflected by the difference between the exercise price and the fair value of our Common Stock. Under SFAS No. 123, "Accounting for Stock-Based Compensation," compensation cost related to stock options is computed based on the value of the stock options at the date of grant using an option valuation methodology, typically the Black-Scholes model. SFAS No. 123 can be applied either by recording the Black-Scholes model value of the options or by continuing to record the APB 25 value and by disclosing SFAS No. 123. We have applied the pro forma disclosure requirement of SFAS No. 123, "Accounting for Stock-Based Compensation".

Research & Development Costs

In accordance with SFAS No. 2 "Accounting for Research and Development Costs," we expense all research and development expenses as incurred.

Certain Risks Related to Our Business

We are dependent on the commercial success of CORTOSS and VITOSS.

We are highly dependent on successfully selling our products which have received regulatory approval as we expect approvals for our products under development, if obtained at all, to take several years. To date, we have received regulatory approval to market VITOSS and CORTOSS for specified uses in the European Union and Australia, and countries adhering to the regulatory standards of the European Union. We have also received regulatory clearance to market VITOSS in the United States. Certain factors that could affect sales of VITOSS and CORTOSS include the following:

We may be unable to increase sales of our approved products.

Because our products have only recently been approved and the markets for our products are evolving, we cannot accurately predict either the future growth rate of sales, if any, or the ultimate size of these markets. Surgeons will not use our products unless they determine, based on experience, clinical data and recommendations from prominent surgeons and mentors, that our products are safe and effective. In addition, surgeons may be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third party reimbursement for our products.

Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use. Our products are based on new technologies that have not been previously used and must compete with more established treatments currently accepted as the standards of care. The attributes of some of our products may require some changes in surgical techniques that have become standard within the medical community, and there may be resistance to change. Therefore, for these products, we must be able to convince surgeons who currently favor existing techniques to switch to new procedures that would use our products. Many surgeons will not purchase our products until there is sufficient, long-term clinical evidence to convince them to alter their existing treatment methods. We believe our initial product sales have been made to a group of early adopting surgeons.

We have generated minimal revenues from product sales into the orthopaedic spine and trauma markets since we launched VITOSS and CORTOSS, our first orthopaedic products to be approved. Certain factors which may limit our ability to increase sales include:

- our dependence on the efforts of independent agents and distributors to promote the use of our products, over which we have limited control and our dependence on the continued publication of independent pre-clinical and clinical data to support the use of our products;
- our need to train a sufficient number of surgeons to create demand for our products; and
- the need of payors to authorize insurance reimbursement for procedures using our products.

We may not be able to operate an effective sales and distribution network.

We have assembled a network of independent stocking distributors in Europe, Australia and Israel and commissioned sales agencies in the U.S. in order to market VITOSS, and we are utilizing this network for CORTOSS in Europe, Australia and Israel. We also intend to distribute VITOSS and CORTOSS through a third party strategic alliance in Japan if they are approved there. Any failure to maintain and manage our distribution network will impair our ability to generate sales and become profitable.

We are dependent upon these distributors and agencies for the sale of our products. There can be no assurance that the distributors and agencies will perform their obligations in their respective territories as expected, or that we will continue to derive any revenue from these arrangements. We cannot assure that our interests will continue to coincide with those of our distributors and agencies. In addition, we cannot assure that that they will not develop, independently or with alternative companies, other products that could compete with our products.

The independent U.S. agencies selling VITOSS generally sell products from other orthopaedic companies. A single agency may sell to end user hospitals VITOSS, as well as, metal plates and screws and titanium spinal cages. Should any of these other orthopaedic companies add a bone graft material to their product line, our independent agencies could decide to eliminate VITOSS and terminate their arrangement with us. Our sales could be adversely affected if one or more of our successful agencies eliminated VITOSS from their product line and terminated their arrangement with us.

In addition, our ability to penetrate the markets that we intend to serve is highly dependent upon the quality and breadth of the other product lines which our distribution network carries, the components of which may change from time to time, and over which we have little or no control. The complete product line represented by the distributors and agencies, including our products, is an important factor in the distributors' and agencies' ability to penetrate the market.

We may not train a sufficient number of surgeons to create demand for our products.

It is critical to the commercial success of our products that our independent distributors and agents succeed in training a sufficient number of surgeons and in providing them adequate instruction in the use of our products. This training requires a commitment of time and money by surgeons, which they may be unwilling to give. Even if surgeons are willing, if they are not properly trained, they may misuse or ineffectively use our products. This may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could damage our business and reduce product sales.

If health care providers cannot obtain third-party reimbursement for procedures using our products, or if such reimbursement is inadequate, we may never become profitable.

Successful sales of our products in the United States and other markets will depend on the availability of adequate reimbursement from third-party payors. In the United States, healthcare providers, such as hospitals and surgeons that purchase medical devices for treatment of their patients, generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Both public and

private insurance reimbursement plans are central to new product acceptance. The Health Care Financing Administration Centers for Medicare and Medicaid Services ("CMS," formerly the Health Care Financing Administration or "HCFA") administers the policies and guidelines for coverage and reimbursement of health care providers treating Medicare beneficiaries in the United States through local fiscal intermediaries and carriers. Medicaid, designed to pay providers for care given to medically needy persons, is dually funded by federal and state appropriations and is administered by each state in the United States. If a procedure or service is deemed "medically necessary" under applicable Medicare or Medicaid rules, providers may be reimbursed under Medicare or Medicaid for the service. The United States Medicare inpatient reimbursement system is a prospective reimbursement system whereby rates are set in advance, fixed for a specific fiscal period, constitute full institutional payment for the designated health service and generally do not vary with hospital treatment costs. Medicare also reimburses outpatient services based on a predetermined fee schedule. Similarly, some states reimburse certain healthcare providers for inpatient services under their Medicaid programs by using prospective rates for diagnosis-related groups of illnesses. Therefore, healthcare providers may refuse to use our products if reimbursement is inadequate.

Inadequate reimbursement by private insurance companies and government programs could significantly reduce usage of our products. In addition, an increasing emphasis on managed care in the U.S. has placed, and we believe will continue to place, greater pressure on medical device pricing. Such pressures could have a material adverse effect on our ability to sell our products. Failure by hospitals and other users of our products to obtain coverage or reimbursement from third-party payors or changes in governmental and private third-party payors' policies toward reimbursement for procedures employing our products would reduce demand for our products.

Member countries of the European Union operate various combinations of centrally financed health care systems and private health insurance systems. The relative importance of government and private systems varies from country to country. The choice of devices is subject to constraints imposed by the availability of funds within the purchasing institution. Medical devices are most commonly sold to hospitals or health care facilities at a price set by negotiation between the buyer and the seller. A contract to purchase products may result from an individual initiative or as a result of a competitive bidding process. In either case, the purchaser pays the supplier, and payment terms vary widely throughout the EU. Failure to obtain favorable negotiated prices with hospitals or health care facilities could adversely affect sales of our products.

In Japan, at the end of the regulatory approval process, the Ministry of Health, Labor and Welfare ("MHW") makes a determination of the reimbursement level of the product. The MHW can set the reimbursement level for our products at their discretion, and we may not be able to obtain

regulatory approval in Japan or if such approval is granted, we may not obtain a favorable per unit reimbursement level.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our Common Stock.

We do not expect sales to generate cash flow in excess of operating expenses for at least the next several years, if at all. We expect to continue to use cash, cash equivalents and short-term investments to fund operating and investing activities. We believe that our existing cash of approximately $12,907,000 as of December 31, 2001 will be sufficient to meet our currently estimated operating and investing requirements into early 2003; however, if we do not raise additional cash during 2002, we may be required to curtail or limit certain marketing support and research and development activities in order to remain compliant with our Paul Royalty financial covenants. A curtailment of certain activities would delay development of certain of our products. We will need to raise additional funds by the fourth quarter of 2002 to meet the Nasdaq National Market's continuing listing requirements if the bid price per share of our Common Stock remains below $3.00 per share. We may seek to obtain additional funds through equity or debt financings, or strategic alliances with third parties either alone or in combination with equity. These financings could result in substantial dilution to the holders of our Common Stock or require debt service and/or royalty payment arrangements. Any such required financing may not be available in amounts or on terms acceptable to us.

Factors that may cause our future capital requirements to be greater than anticipated include:

- unforeseen developments during our preclinical and clinical trials;
- timing of receipt of required regulatory approvals;
- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of our products;
- unanticipated expenditures in the acquisition and defense of intellectual property rights; or
- the failure to develop strategic alliances for the marketing of some of our products.

If adequate financing is not available, we may be required to delay, scale back or eliminate certain operations. In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line via acquisitions or joint ventures. Any such acquisitions or joint ventures may increase our capital requirements.

If we fail to obtain and maintain the regulatory approvals necessary to sell our products, sales could be delayed or never realized.

The jurisdictions in which we will seek to market our products will regulate these products as medical devices. In most circumstances, we and our distributors and agents must obtain regulatory approvals and otherwise comply with extensive regulations regarding safety, quality and efficacy standards. These regulations vary from country to country, and the regulatory review can be lengthy, expensive and uncertain. We may not obtain or maintain the

regulatory approvals necessary to market our products in our targeted markets. Moreover, regulatory approvals that are obtained may involve significant restrictions on the anatomic sites and types of procedures for which our products can be used. In addition, we may be required to incur significant costs in obtaining or maintaining our regulatory approvals. If we do not obtain or maintain regulatory approvals to enable us to market our products in the U.S. or elsewhere, or if the approvals are subject to significant restrictions, we may never generate significant revenues. The regulatory requirements in some of the jurisdictions where we currently market or intend to market our products are outlined below.

United States

Regulation by FDA. The FDA regulates the clinical testing, manu-facturing, labeling, sale, distribution and promotion of medical devices. Before we may market our products in the U.S., we generally must obtain from the FDA either market clearance through a Section 510(k) premarket notification or premarket approval through a premarket approval application. The amount of time and expenses associated with obtaining a clearance under the Section 510(k) notification process is usually less than that under the premarket approval application process. In December 2000, we received notice that the FDA granted Section 510(k) marketing clearance for VITOSS. The FDA granted Section 510(k) marketing clearance for IMBIBE in September 2001.

During 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the U.S. for the use of CORTOSS for vertebral augmentation. In addition, during 2002, we received approval from the FDA to conduct a pivotal clinical study in the U.S. for the use of CORTOSS for long bone screw augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

We are currently manufacturing VITOSS and CORTOSS in the United States and distributing VITOSS in the United States, Europe, Australia and Israel, and CORTOSS in Europe and Australia. We are manufacturing IMBIBE and ALIQUOT through outside third-party contract manufacturers. VITOSS, as well as any other products that we manufacture or distribute following the approval thereof by the FDA, will be subject to extensive regulation by the FDA. If safety or efficacy problems occur after the product reaches the market, the FDA may impose severe limitations on the use of any approved product. Moreover, modifications to the approved or cleared product may require the submission of a new premarket approval application or a premarket approval application supplement, or a new 510(k) notification. We may not be successful in obtaining the approval or clearance of any new premarket approval applications, necessary premarket approval application supplements, or new 510(k) notifications in a timely manner, if at all. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing approvals and criminal prosecution.

European Union and Other International Markets

General. International sales of medical devices are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our products in markets outside the U.S. will be subject to regulatory clearances in those jurisdictions. The

regulatory review process varies from country to country. Many countries also impose product standards, packaging and labeling requirements and import restrictions on devices. In addition, each country has its own tariff regulations, duties and tax requirements. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. Our ability to market our products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

Requirement of CE marking in the European Union. To market a product in the European Union, we must be entitled to affix a CE marking, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. A CE marking allows us to market a product in all of the countries of the European Union, as well as in other countries, such as Switzerland and Israel, that have adopted the European Union's regulatory standards. To date, we have received a CE marking for the use of VITOSS as a bone void filler and for the use of CORTOSS in screw augmentation. Additionally, we are completing clinical trials with CORTOSS for vertebral augmentation. There can be no assurance that we will receive CE markings for CORTOSS for any other indications for use or any of our other products.

Requirement of approval in Japan. In order to market our products in Japan, we must obtain the approval of the Japanese Ministry of Health, Labor and Welfare. We will need to conduct clinical trials for VITOSS and CORTOSS in Japan to obtain approval there for those two products. Accordingly, we entered into a third party strategic alliance to conduct clinical trials, obtain the necessary regulatory approvals and market our VITOSS product in Japan. There can be no assurance that we will ultimately obtain the approvals necessary to market our products in Japan. While we intend to seek a similar strategic alliance for CORTOSS in Japan, we cannot assure that we will succeed in achieving such an alliance.

If we do not manage commercial scale manufacturing capability and capacity for our products, our product sales may suffer.

We have completed construction of our VITOSS and CORTOSS manufacturing facilities and have successfully produced commercial product. Our VITOSS and CORTOSS manufacturing facilities are certified as meeting the requirements of ISO 9001 and European Norm 46001, for the period July 1, 2000 through July 1, 2003, and are subject to inspection by the FDA for compliance with FDA device manufacture requirements. We are manufacturing IMBIBE and ALIQUOT through outside third-party contract manufacturers. In order to commercialize CORTOSS in the United States, its manufacturing facility is subject to inspection by the FDA.

Our product sales depend upon, among other things, our ability to manufacture our products in commercial quantities, in compliance with regulatory requirements and in a cost-effective manner. The manufacture of our products is subject to regulation and periodic inspection by various regulatory bodies for compliance with quality standards. There can be no assurance that the regulatory authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in meeting the applicable standards and request or seek remedial action.

Failure to comply with such regulations or a delay in attaining compliance may result in:

- warning letters;
- injunctions suspending our manufacture of products;
- civil and criminal penalties;
- refusal to grant premarket approvals, CE Marks or clearances to products that are subject to future or pending submissions;
- product recalls or seizures of products; and
- total or partial suspensions of production.

Our ability to manufacture VITOSS and CORTOSS is dependent on a limited number of specialty suppliers of certain raw materials. The failure of a supplier to continue to provide us with these materials at a price or quality acceptable to us, or at all, would have a material adverse effect on our ability to manufacture these products. Moreover, our failure to maintain strategic reserve supplies of each significant single-sourced material used to manufacture VITOSS, CORTOSS and certain products that we may develop in the future may result in a breach of our material financing agreements. Although we believe that we maintain good relationships with our suppliers, there can be no guarantee that such supplies and services will continue to be available with respect to our current and future commercialized products.

It may be difficult to operate in international markets.

We operate in international markets and a number of risks are inherent in international operations. For example, international sales and operations may be limited or disrupted by the imposition of governmental controls, difficulties in managing international operations, and fluctuations in foreign currency exchange rates. The international nature of our business subjects us and our representatives, agents and distributors to the laws and regulations of the jurisdictions in which they operate, and in which our products are sold.

If losses continue in the long term, it could limit our growth and slow our generation of revenues.

To date, we have not been profitable. We have incurred substantial operating losses since our inception and, at December 31, 2001, had an accumulated deficit of approximately $61,600,000. These losses have resulted principally from:

- the development and patenting of our technologies;
- preclinical and clinical studies;
- preparation of submissions to the FDA and foreign regulatory bodies;
- the development of manufacturing, sales and marketing capabilities; and
- unforeseen competitor developments which adversely effect our distribution channels.

We expect to continue to incur significant operating losses in the future as we continue our product development efforts, expand our marketing and sales activities and further develop our manufacturing capabilities. We may not ever successfully commercialize our products in development. We may never be able to achieve or maintain profitability in the future and our products may never be commercially accepted or generate sufficient revenues.

If we fail to meet our obligations under a revenue sharing agreement, we may be required to repurchase from an investor its right to receive revenues on certain of our product sales, and the investor could foreclose on certain assets that are essential to our operations.

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Royalty. We will use the proceeds realized from this financing for clinical development, marketing programs, and working capital relating to VITOSS, CORTOSS and RHAKOSS products. In this financing, we sold Paul Royalty a revenue interest and sold 2,582,645 shares of our Common Stock, for aggregate gross proceeds of $10,000,000. The Common Stock was recorded at its market value of $4,777,893 and a revenue interest obligation related to the revenue interest of $5,222,107 was recorded.

The net proceeds of the financing were first allocated to the fair value of the Common Stock on the date of the transaction, and the $5,222,107 remainder of the net proceeds was allocated to the revenue interest obligation. Given that the products subject to the revenue interest have only recently been approved and marketed or are still under development, we, as of December 31, 2001 and for the foreseeable future, cannot make a reasonable estimate of their future sales levels and the related revenue interest obligation. Accordingly, in 2002 and the foreseeable future, we will charge revenue interest expense as payments due under the revenue interest obligation are incurred.

On March 22, 2002, the agreement with Paul Royalty was modified whereby they exchanged 860,882 shares of our Common Stock for elimination of certain potential credits allowable to us against our revenue interest obligation, as well as, a reduction in the repurchase price. This modification will be accounted for as a treasury stock transaction with a decrease to shareholders' equity and an increase to the revenue interest obligation based upon the fair market value of the Common Stock on the date of the transaction, or $2.26 per share or $1,946,454 in the aggregate.

The revenue interest provides for Paul Royalty to receive 3.5% on the first $100,000,000 of annual sales plus 1.75% of annual sales in excess of $100,000,000 of our VITOSS, CORTOSS and RHAKOSS products in North America and Europe through 2016, subject to certain adjustments. Our obligation to pay the revenue interest is secured by our licenses, patents and trademarks relating to certain of our products, including VITOSS, CORTOSS and RHAKOSS, in North America and Europe, and the 12% royalty interest we pay to Vita Licensing, Inc., our wholly-owned subsidiary, on the sales of our products (collectively, the "Pledged Assets"). We are also required to maintain:

- cash and cash equivalent balances equal to or greater than the product of (i) 1.5 and (ii) total operating losses, net of non-cash charges, for the preceding fiscal quarter; and
- total shareholders' equity of at least $8,664,374; provided, however, that under the provisions of the agreement with Paul Royalty when calculating shareholders' equity for the purposes of the financial covenants, the revenue interest is included in shareholders' equity.

As of December 31 2001, we were in compliance with all financial covenants. However, if we fail to maintain such balances and shareholders' equity, Paul Royalty can demand that we repurchase its revenue interest.

In addition to the financial covenants described above, Paul Royalty has the right to cause us to repurchase their revenue interest upon the occurrence of certain events, including:

- a judicial decision that has a material adverse effect on our business, operations, assets or financial condition;
- the acceleration of our obligations or the exercise of default remedies by a secured lender under certain debt instruments;
- a voluntary or involuntary bankruptcy that involves us or our wholly owned subsidiary, Vita Special Purpose Corp.;
- our insolvency;
- a change in control of our company;
- the breach of a representation, warranty or certification made by us in the agreements with Paul Royalty that, individually or in the aggregate, would reasonably be expected to have a material adverse effect on our business, operations, assets or financial condition, and such breach is not cured within 30 days after notice thereof from Paul Royalty.

We may not have sufficient cash funds to repurchase the revenue interest upon a repurchase event. The exact amount of the repurchase price is dependent upon certain factors, including when the repurchase event occurs. The repurchase price targets an internal rate of return for Paul Royalty's $10,000,000 investment ranging up to 45% net of revenue interest amounts paid by us to Paul Royalty during the term of the revenue sharing agreement. If we were unable to repurchase the revenue interest upon a repurchase event, Paul Royalty could foreclose on the Pledged Assets, and we could be forced into bankruptcy. Paul Royalty could also foreclose on the pledged assets if we are insolvent or are involved in a voluntary or involuntary bankruptcy. No repurchase events or foreclosures have occurred as of December 31, 2001. As of December 31, 2001, if the repurchase event had been triggered and Paul Royalty exercised their right to require us to repurchase their revenue interest, we would have owed Paul Royalty $10,871,750.

The March 2002 amendment reduced by $3,333,333 the amount that would be due to Paul Royalty should certain repurchase events occur in the future and which resulted in Paul Royalty requiring us to repurchase the revenue interest obligation. Had the amendment to the arrangement been executed prior to December 31, 2001 and had a repurchase event been triggered, as of December 31, 2001, we would have owed Paul Royalty $7,538,417 rather than $10,871,750. If we know that we will not be in compliance, we will be required to accrete the revenue interest obligation to the repurchase amount. As of December 31, 2001, we believe that we will remain in compliance for the forseeable future with all covenants and terms of the revenue interest obligation.

Our results of operations may fluctuate due to factors out of our control.

VITOSS, IMBIBE and CORTOSS are currently our only products which have received regulatory approvals for sale. VITOSS is cleared for sale under a CE Mark in the European Union and under a 510(k) marketing clearance in the United States. IMBIBE is cleared for sale under a 510(k) in the United States. CORTOSS is cleared for sale under a CE Mark in the European Union. We began selling VITOSS in Europe in the fourth quarter of 2000 and began selling VITOSS in the U.S. late in the first quarter of 2001. Orthovita began

sales of CORTOSS in Europe and IMBIBE in the United States at the end of 2001. Future levels of CORTOSS and IMBIBE product sales are difficult to predict. VITOSS product sales are difficult to predict at this early stage of the product launch process and VITOSS sales to-date may not be indicative of future sales levels. VITOSS and CORTOSS sales levels in Europe may fluctuate due to the timing of any distributor stocking orders and VITOSS and IMBIBE sales levels may fluctuate in the U.S. due to the timing of orders from hospitals. Our results of operations may fluctuate significantly in the future as a result of a number of factors, many of which are outside of our control. These factors include, but are not limited to:

- the timing of governmental approvals for our products;
- unanticipated events associated with clinical and pre-clinical trials of our products;
- the medical community's acceptance of our products;
- the timing in obtaining adequate third party reimbursement of our products;
- the success of products competitive with ours;
- our ability to enter into strategic alliances with other companies;
- expenses associated with development and protection of intellectual property matters;
- establishment of commercial scale manufacturing capabilities;
- world events effecting logistics and elective surgery trends;
- the timing of expenses related to commercialization of new products; and
- competitive disruptions to our distribution channels from business development arrangements.

The results of our operations may fluctuate significantly from quarter to quarter and may not meet expectations of securities analysts and investors. This may cause our stock price to be volatile.

Our business will be damaged if we are unable to protect our proprietary rights to the technologies used in our products, and we may be subject to intellectual property infringement claims by others.

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, nondisclosure and confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these measures afford only limited protection and may not adequately protect our rights. For example, our patents may be challenged, invalidated or circumvented by third parties. As of March 22, 2002, we own or control four issued U.S. patents, two allowed patents and ten pending patent applications in the United States, and several counterparts of certain of these patents and pending patent applications in Europe, Canada, Mexico and Japan. There can be no assurance that patents will issue from any of the pending patent applications. Since patent applications filed prior to December 2000 in the United States are maintained in secrecy until issued and patent applications filed in the United States after November 2000 are maintained in secrecy for 18 months, and since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries, we cannot be certain that we or any of our licensors were the first creator of inventions covered by pending patent applications or that we or any of our licensors were the first to file patent applications for the relevant inventions. If we do receive a patent, it may not be

broad enough to protect our proprietary position in the technology or to be commercially useful to us. In addition, if we lose any key personnel, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by those former employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. Finally, even if our intellectual property rights are adequately protected, litigation may be necessary to enforce our intellectual property rights, which could result in substantial costs to us and result in a diversion of management attention. If our intellectual property is not adequately protected, our competitors could use the intellectual property that we have developed to enhance their products and compete more directly with us, which could damage our business.

In addition, to determine the priority of inventions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or in opposition, nullity or other proceedings before foreign agencies with respect to any of our existing patents or patent applications or any future patents or applications, which could result in substantial cost to us. Further, we may have to participate at substantial cost in International Trade Commission proceedings to abate importation of goods that would compete unfairly with our products. In addition to the risk of failing to adequately protect our proprietary rights, there is a risk that we may become subject to a claim that we infringe upon the proprietary rights of others. Although we do not believe that we are infringing the rights of others, third parties may claim that we are doing so. In addition, because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that our products infringe. There is a substantial amount of litigation over patent and other intellectual property rights in the medical device industry generally, and in the spinal market segments particularly. If the holder of patents brought an infringement action against us, the cost of litigating the claim could be substantial and divert management attention. In addition, if a court determined that one of our products infringed a patent, we could be prevented from selling that product unless we could obtain a license from the owner of the patent. A license may not be available on terms acceptable to us, or at all. Modification of our products or development of new products to avoid infringement may require us to conduct additional clinical trials for these new or modified products and to revise our filings with the FDA, which is time consuming and expensive. If we were not successful in obtaining a license or redesigning our product, our business could suffer.

Enforceability of Patents. Under Title 35 of the United States Code as amended by the General Agreement on Tariffs and Trade implementing the Uruguay Round Agreement Act of 1994, ("Title 35"), patents that issue from patent applications filed prior to June 8, 1995 will enjoy a 17-year period of enforceability as measured from the date of patent issue, or a 20-year period of enforceability as measured from the earliest effective date of filing, whichever is longer. Patents that issue from applications filed on or after June 8, 1995 will enjoy a 20-year period of enforceability as measured from the date the patent application was filed or the first claimed priority date, whichever is earlier. Patents that issue from applications filed on or after June 8, 1995 may be extended under the term extension provisions of Title 35 for a period of up to five years to compensate for any period of enforceability lost due to interference proceedings, government secrecy orders or successful appeals to the Board of Patent Appeals and Interferences or the Federal courts. Under the Drug Price Competition and Patent Term Restoration Act of

1984, including amendments implemented under Title 35, the period of enforceability of the first patent for a product or use may be extended for up to five years to compensate the patent holder for the time required for FDA regulatory review of the product. Any extension under the Patent Term Restoration Act and any extension under Title 35 are cumulative. We may not be able to take advantage of all of the patent term extension provisions of these laws, and these extensions may not adequately restore the time lost to the FDA approval process. If the current law is changed to shorten the duration of patent protection, our ability to protect our proprietary information and sustain the commercial viability of our products will decrease. The possibility of shorter terms of patent protection, combined with the lengthy FDA review process and possibility of extensive delays in such process, could effectively reduce the term during which a marketed product could be protected by patents.

FBFC Patent Challenge. In July 1992, we obtained a license from FBFC International, Belgian company, that allowed us to manufacture and sell our BIOGRAN dental grafting products. We sold the rights to sell the BIOGRAN product line in March 2000 to a company called Implant Innovations, Inc., or 3i. In July, 1994, U.S. Biomaterials Corporation filed with the U.S. Patent and Trademark Office a Request for Reexamination of a patent held by FBFC for BIOGRAN, of which we were the exclusive licensee. FBFC filed a response in this proceeding, establishing that the claims of the FBFC patent were properly allowed. As a result, a Certificate of Reexamination was issued by the U.S. Patent and Trademark Office confirming the patentability of all claims of the FBFC patent without amendment. However, U.S. Biomaterials Corporation also instituted a nullification proceeding against the European counterpart to the FBFC's U.S. patent. The opposition division of the European Patent Office tentatively decided in FBFC's favor, but the matter is still proceeding under an appeal. In connection with the BIOGRAN sale to 3i, 3i assumed control of this matter and we agreed to reimburse 3i for the associated legal costs and to provide a limited indemnity with respect to the matter. We do not believe there are any material liabilities with respect to the indemnification for this matter.

We may lack the financial resources needed to respond to technological changes and other actions by competitors, obtain regulatory approvals for our products and efficiently market our products.

Extensive research efforts and rapid technological change characterize the market for products in the orthopaedic market. We anticipate that we will face intense competition from medical device, medical products and pharmaceutical companies. Our products could be rendered noncompetitive or obsolete by competitors' technological advances. We may be unable to respond to technological advances through the development and introduction of new products. Moreover, many of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources than us. These competitors may be in the process of seeking FDA or other regulatory approvals, or patent protection, for their respective products. Our competitors could, therefore, commercialize competing products in advance of our products. They may also enjoy substantial advantages over us in terms of:

- research and development expertise;
- experience in conducting clinical trials;
- experience in regulatory matters;
- manufacturing efficiency;

- name recognition;
- sales and marketing expertise;
- established distribution channels; and
- established relationships with health care providers and payors.

As a result of the above, our plans for market acceptance of our products may be adversely impacted.

We may acquire technologies or companies in the future, and these acquisitions could result in dilution to our shareholders and disruption of our business.

Entering into an acquisition could divert management attention. We also could fail to assimilate the acquired company, which could lead to higher operating expenses. Finally, our shareholders could be diluted if we issue shares of our stock to acquire another company or technology.

Provisions of Pennsylvania law or our Articles of Incorporation may deter a third party from seeking to obtain control of us or may affect your rights as a common stock holder.

Certain provisions of Pennsylvania law could make it more difficult for a third party to acquire us, or could discourage a third party from attempting to acquire us. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, our Articles of Incorporation enable our board of directors to issue shares of preferred stock having rights, privileges and preferences as are determined by the board of directors. This provision may discourage, delay or prevent a merger or acquisition that a shareholder may consider favorable. The rights of the holders of any preferred stock that may be issued in the future may adversely affect your rights as a holder of common stock. We have no current plans to issue any shares of preferred stock.

Our executive officers and directors own a large percentage of our voting stock and could exert significant influence over matters requiring stockholder approval, including takeover attempts.

Our executive officers and directors, and their respective affiliates, own as of March 22, 2002, approximately 15.2% of our outstanding Common Stock. Accordingly, these shareholders may, as a practical matter, be able to exert significant influence over matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combinations. This concentration could have the effect of delaying or preventing a change in control.

We do not intend to pay any cash dividends.

We have never declared nor paid dividends on our Common stock. We currently intend to retain any future earnings for funding growth and, therefore, do not intend to pay any cash dividends in the foreseeable future.

Our stock price may be volatile.

Our stock price, like that of many early stage medical technology companies, may be volatile. In general, equity markets, including Nasdaq, have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies or existing economic conditions. These broad market fluctuations may

adversely affect the market price of our common stock. The following factors could also cause our stock price to be volatile or decrease:

- fluctuations in our results of operations;
- under-performance in relation to analysts' estimates or financial guidance provided by us;
- changes in the financial guidance we provide to the investment community;
- changes in stock market analyst recommendations regarding our stock;
- announcements of technological innovations or new products by us or our competitors;
- issues in establishing commercial scale manufacturing capabilities;
- unanticipated events associated with clinical and pre-clinical trials;
- FDA and international regulatory actions regarding us or our competitors;
- determinations by governments and insurance companies regarding reimbursement for medical procedures using our or our competitors' products;
- the medical community's acceptance of our products;
- product sales growth rates;
- product recalls;
- disruptions to our distribution channels as a result of competitive market changes;
- developments with respect to patents or proprietary rights;
- public concern as to the safety of products developed by us or by others;
- changes in health care policy in the United States and internationally;
- acquisitions or strategic alliances by us or our competitors;
- business conditions affecting other medical device companies or the medical device industry generally; and
- general market conditions, particularly for companies with small market capitalizations.

If our shares are delisted from the Nasdaq National Market, it may be difficult to sell your investment in our company.

From June 1998 until August 1, 2000, our Common Stock traded exclusively on the Nasdaq Europe Exchange (formerly known as EASDAQ). Since August 1, 2000, our Common Stock has traded on both the Nasdaq Europe Exchange and the Nasdaq National Market. The trading volume of our Common Stock is, and may continue to be, limited. To continue to be listed on the Nasdaq National Market, we must continue to meet, with certain exceptions, one of two separate continued listing standards with specified maintenance criteria, including:

- specified levels for total assets;
- market value of the public float;
- a minimum bid price per share; and
- total market capitalization.

We believe that we satisfy the current requisite Nasdaq National Market listing requirements. However, if the minimum bid price of our common stock fell below $1.00, we

could face delisting from the Nasdaq National Market. In addition, there are amendments to the Nasdaq marketplace rules scheduled to take effect on November 1, 2002 that will replace the net tangible assets standard with an equity standard. These amendments may require us to raise more capital than what is necessary to fund our operations should the bid price per share for our Common Stock remain below $3.00 per share. The additional capital may be not be available on satisfactory terms, if at all. Any additional equity capital raised could result in substantial dilution to our shareholders. Should we fail to meet the Nasdaq National Market listing requirements in the future, our stock could then list on the over-the-counter exchange, which would further limit the trading volume and liquidity of our stock and adversely impact the stock price per share.

If we are sued in a product liability action, we could be forced to pay substantial damages and the attention of our management team may be diverted from operating our business.

We manufacture medical devices that are used on patients in surgery, and we may be subject to a product liability lawsuit. In particular, the market for spine products has a history of product liability litigation. Under certain of our agreements with our distributors, we indemnify the distributor from product liability claims. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we would have to pay any amount awarded by a court in excess of policy limits. We maintain product liability insurance in the annual aggregate amount of up to $10 million, although our insurance policies have various exclusions. Thus, we may be subject to a product liability claim for which we have no insurance coverage, in which case we may have to pay the entire amount of any award. Even in the absence of a claim, our insurance rates may rise in the future to a point where we decide not to carry this insurance. A meritless or unsuccessful product liability claim would be time-consuming and expensive to defend and could result in the diversion of management's attention from our core business. A successful product liability claim or series of claims brought against us in excess of our coverage could have a material adverse effect on our business, financial condition and results of operations.

Our business could suffer if we cannot attract and retain the services of key employees.

We depend substantially upon the continued service and performance of our existing executive officers. We rely on key personnel in formulating and implementing our product research, development and commercialization strategies. Our success will depend in large part on our ability to attract and retain highly skilled employees. We compete for such personnel with other companies, academic institutions, government entities and other organizations. We may not be successful in hiring or retaining qualified personnel. If one or more of our key employees resigns, the loss of that employee could harm our business. If we lose any key personnel, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by those former employees. We have employment agreements with David S. Joseph, our Chairman, Bruce A. Peacock, our Chief Executive Officer and President, and each of our Vice Presidents.

Liquidity and Capital Resources

We have experienced negative operating cash flows since our inception, and we have funded our operations primarily from the proceeds received from sales of our Common Stock. Cash, cash equivalents and short-investments increased $9,091,565 from December 31, 2000 to 2001 due primarily to proceeds received from the sale of Common Stock. As of December 31, 2001 and 2000, cash, cash equivalents and short-term investments consisted of the following:

	Original Cost	Gross Unrealized Gross	Gross Losses	Unrealized Fair Market Value
December 31, 2001:				
Cash and cash equivalents	$12,906,557	$ —	$ —	$12,906,557
	$12,906,557	$ —	$ —	$12,906,557
Percentage of total assets				60.8%
December 31, 2000:				
Cash and cash equivalents	$ 3,614,626	$ —	$ —	$ 3,614,626
Short-term investments	199,886	480	—	200,366
	$ 3,814,512	$ 480	$ —	$ 3,814,992
Percentage of total assets				37.4%

We invest excess cash in highly liquid investment-grade marketable securities including corporate commercial paper and U.S. government agency bonds.

The following is a summary of selected cash flow information:

	Year Ended December 31,		
	2001	2000	1999
Net cash used in operating activities	$ (14,785,792)	$ (13,066,702)	$ (7,460,789)
Net cash (used in) provided by investing activities	(895,523)	6,440,248	7,614,063
Net cash provided by financing activities	24,950,020	7,842,251	1,472,122
Effects of exchange rate changes on cash and cash equivalents	23,226	(88,514)	19,883
Net increase in cash and cash equivalents	$ 9,291,931	$ 1,127,283	$ 1,645,279

Net Cash Used in Operating Activities

Operating Cash Inflows —

Operating cash inflows for 2001 have been derived from VITOSS product sales. We have also received cash inflows from interest income on cash equivalents and short-term investments. Operating cash inflows also included BIOGRAN product sales realized prior to the close of the sale of all rights to our BIOGRAN dental grafting product line in March 2000 and from interest income on cash equivalents and short-term investments.

Operating Cash Outflows —

Our operating cash outflows have continued to be primarily used for development, manufacturing scale-up qualification, pre-clinical and clinical activities in preparation for regulatory filings of our products in development. In addition, funds have been used for the production of

inventory, increase in sales and marketing staffing, development of marketing materials and payment of sales commissions related to the commercialization of VITOSS and CORTOSS products.

Operating Cash Flow Requirements Outlook —

We do not expect sales to generate cash flow in excess of operating expenses for at least the next several years, if at all. We expect to continue to use cash, cash equivalents and short-term investments to fund operating activities. We began selling VITOSS in Europe in the fourth quarter of 2000 and began selling VITOSS in the United States late in the first quarter of 2001. During the third quarter of 2001, we received a 510(k) FDA regulatory clearance to market the IMBIBE Bone Marrow Aspirate Syringe in the United States. Late in the fourth quarter of 2001, we began selling CORTOSS in Europe for the fixation of bone screws under a CE Mark. Future cash flow levels from VITOSS, CORTOSS and IMBIBE product sales are difficult to predict at this early stage of the products' launches. VITOSS sales to date may not be indicative of future sales levels. VITOSS and CORTOSS sales levels in Europe may fluctuate due to the timing of any distributor stocking orders and may experience seasonal slowdowns during the summer months. Sales of VITOSS and IMBIBE in the U.S. may fluctuate due to the timing of orders from hospitals. Any future cash flows from CORTOSS are dependent upon the successful launch of the product in Europe during 2002. We initiated a controlled launch of CORTOSS on a country-by-country basis in Europe which began during December 2001. We expect to have CORTOSS available in most of the major markets in Europe by the middle of 2002.

There may be future quarterly fluctuations in spending. We expect sales commission expense may increase at a higher rate than any increase in VITOSS product sales in the United States. In addition, we expect increases in the use of cash to build inventory and fund receivables. We also expect to continue to use cash in operating activities associated with research and development, including clinical trials for CORTOSS and RHAKOSS, manufacturing scale-up qualification, and pre-launch marketing activities in support of our other products under development as well as to the associated marketing and sales activities with VITOSS in the United States, and with VITOSS and CORTOSS in Europe, Australia and Israel.

Finally, we have entered into and may enter additional financing arrangements where we pay revenue sharing amounts on the sales of certain products. These arrangements can increase expenses related to the sale of our products.

Net Cash (Used In) Provided By Investing Activities

We have invested $1,470,389 and $3,306,335 for the year ended December 31, 2001 and 2000, respectively, primarily for the purchase of leasehold improvements, manufacturing equipment and research and development equipment in order to further expand our product development and manufacturing capabilities.

During the twelve months ended December 31, 2001 and 2000, $199,866 and $6,246,583, respectively, were provided by the net sale of investment grade marketable securities. Additionally, during 2000, we received $3,900,000, of which $400,000 was held in escrow until March 2001, in connection with the sale of the BIOGRAN dental grafting product line to Implant Innovations, Inc. During March 2001, $375,000 of the escrow account was released with the remaining $25,000 held for costs related to certain patent litigation.

Investing Cash Outlook —

Of the approximately $1,470,000 invested in 2001, approximately $581,000 was invested in leasehold improvements associated with the scale-up to the manufacturing facilities for VITOSS and CORTOSS, which is substantially completed. We anticipate capital spending for improvements to manufacturing processes at these facilities. Accordingly, we expect the rate at which we invest funds in 2002 related to improvements to our leased office and manufacturing facilities to be relatively stable compared to 2001. We anticipate new capital spending will be required in support of the RHAKOSS program.

Net Cash Provided By Financing Activities

During December 2001, we sold 1,125,000 shares of our Common Stock to two investors in a private equity financing. The aggregate consideration we received for these shares consisted of $2,700,000 in cash, plus the surrender and cancellation of outstanding warrants to purchase an aggregate of 1,125,000 shares of our Common Stock held by the two investors.

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Royalty. In this financing, we sold Paul Royalty a revenue interest and sold 2,582,645 shares of our Common Stock. The Common Stock was recorded at its market value of $4,777,893 and a revenue interest obligation related to the revenue interest of $5,222,107 was recorded. This arrangement was subsequently modified in March 2002 (see "Certain Risks Related to our Business").

In October 2001, we repaid to our bank our $500,000 capital financing term loan.

During April 2001, we entered into a Development and Distribution Agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"), a Japanese orthopaedic company. In connection with this arrangement, we sold 189,394 shares of Common Stock at $5.28 per share to MDM, raising net proceeds of $1,000,000. Additionally, during April 2001, we sold 740,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $2,692,000.

During March 2001, we sold 1,975,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $7,290,000. In addition, during January 2001, we sold 566,894 shares of our Common Stock and warrants to purchase 566,894 shares of Common Stock at an exercise price of $4.41 per share raising net proceeds of approximately $2,413,000.

During 2001, we received $88,772 from stock option and warrant exercises and purchases of Common Stock under our Employee Stock Purchase Plan. In addition, $628,549 was used to repay capital lease obligations during 2001.

Financing Requirements Outlook

The extent and timing of proceeds from future stock option and warrant exercises, if any, are primarily dependent upon our Common Stock's market price, as well as the exercise prices and expiration dates of the stock options and warrants.

We do not expect sales to generate cash flow in excess of operating expenses for at least the next several years, if at all. We expect to continue to use cash, cash equivalents and short-

term investments to fund operating and investing activities. We believe that our existing cash of approximately $12,907,000 as of December 31, 2001 will be sufficient to meet our currently estimated operating and investing requirements into early 2003; however, if we do not raise additional cash during 2002, we may be required to curtail or limit certain marketing support and research and development activities in order to remain compliant with our Paul Royalty financial covenants. A curtailment of certain activities would delay development of certain of our products. We will need to raise additional funds by the fourth quarter of 2002 to meet the Nasdaq National Market's continuing listing requirements if the bid price per share of our Common Stock remains below $3.00 per share. We may seek to obtain additional funds through equity or debt financings, or strategic alliances with third parties either alone or in combination with equity. These financings could result in substantial dilution to the holders of our Common Stock or require debt service and/or royalty payment arrangements. Any such required financing may not be available in amounts or on terms acceptable to us.

Results of Operations

This section should be read in conjunction with the detailed discussion under "Liquidity and Capital Resources." And as described therein, we expect to continue to incur significant operating losses in the future as we continue our product development efforts.

Comparison of the Year Ended December 31, 2001 to the Year Ended December 31, 2000

Product Sales. Product sales for the year ended December 31, 2001 were approximately $3,940,000 compared to approximately $741,000 for the year ended December 31, 2000. Product sales for 2001 consisted primarily of VITOSS sales in the U.S., Europe, Australia and Israel and initial CORTOSS sales in Europe during the fourth quarter of 2001. Product sales for 2000 consisted of approximately $533,000 from the sales of BIOGRAN product realized prior to the sale of the BIOGRAN product line in March 2000. The remaining $208,000 of product sales occurred during the fourth quarter of 2000 and related to the initiation of sales of VITOSS in Europe.

Gross Profit. Our gross profit for the year ended December 31, 2001 and 2000 was approximately $3,221,000 and $571,000, respectively, or 82% and 77% of product sales, respectively. BIOGRAN cost of sales was approximately $164,000 or a 69% gross profit margin for the year ended December 31, 2000. All of the VITOSS sold in Europe during 2000 was produced prior the receipt of its CE Certification in July 2000. In accordance with SFAS No. 2 "Accounting for Research and Development Costs," the costs of producing that material was recorded as research and development expense prior to July 2000 and, accordingly, are not reflected in cost of sales. Accordingly, VITOSS cost of sales for the year ended December 31, 2000 of $6,000 is not indicative of margins to be realized in future periods.

Operating Expenses. Operating expenses for the year ended December 31, 2001 were approximately $17,475,000 compared to approximately $15,191,000 for 2000. General & administrative expenses for twelve months ended December 31, 2001, were comparable to the same period in 2000. Selling and marketing expenses for same twelve-month periods from 2000 to 2001 increased as a result of commission expense paid to the independent commissioned sales agencies in the U.S. on VITOSS product sales, increased staffing and other spending related to the support of product sales. Research and development expenses decreased for the twelve months ended December 31, 2001, as compared to the same period in 2000 primarily as a result

of the completion of certain process development activities primarily related to CORTOSS and the initiation of commercial scale manufacturing.

Other Income (Expense). Net other income includes interest income, interest expense and revenue interest expense. We recorded approximately $88,000 of net other income for the year ended December 31, 2001 compared to approximately $214,000 of net other income for the year ended December 31, 2000. The decrease in net other income between 2001 and 2000 is attributed to lower average interest rates earned on invested cash and, in 2001, revenue interest expense as a result of the arrangement with Paul Royalty.

Net Gain On Sale of Product Line. In connection with the sale of the BIOGRAN dental grafting product line to 3i in March 2000, we received $3,900,000, of which $400,000 was held in escrow until March 2001. We realized a net gain on the transaction of approximately $375,000 and $3,071,000 for the years ended December 31, 2001 and 2000, respectively.

Net Loss. As a result of the foregoing factors, our net loss for the year ended December 31, 2001 was approximately $13,790,000 compared to a net loss of approximately $11,335,000 for 2000.

Comparison of the Year Ended December 31, 2000 to the Year Ended December 31, 1999

Product Sales. Product sales for the year ended December 31, 2000 were approximately $741,000 compared to approximately $1,054,000 for the year ended December 31, 1999. Product sales for 2000 consisted of $533,000 from the sales of BIOGRAN product realized prior to the sale of the BIOGRAN product line in March 2000. The remaining $208,000 of product sales occurred during the fourth quarter of 2000 and relate to the initiation of sales of VITOSS in Europe. Sales in Europe during 2000 were to distributors.

Gross Profit. Our gross profit for the year ended December 31, 2000 was $571,000, or 77% of net revenues, compared to $730,000, or 69% of net revenues, for 1999. BIOGRAN cost of sales was approximately $164,000 or a 69% gross profit margin for the year ended December 31, 2000. All of the VITOSS sold in Europe during 2000 was produced prior the receipt of its CE Certification in July 2000. In accordance with SFAS No. 2 "Accounting for Research and Development Costs," the costs of producing that material was recorded as research and development expense prior to July 2000 and, accordingly, are not reflected in cost of sales. Accordingly, VITOSS cost of sales for the year ended December 31, 2000 of $6,000 is not indicative of margins to be realized in future periods.

Operating Expenses. Operating expenses for the year ended December 31, 2000 were approximately $15,191,000 compared to approximately $10,755,000 for 1999. The increase in general and administrative expenses year-over-year is primarily a result of an increase in the number of employees during 2000. Selling and marketing expenses increased year-over-year as a result of the development and printing of marketing and sales literature in support of VITOSS product launch. The increase from 1999 to 2000 in research and development expenses is attributable to the expanded development of our product pipelines and pre-clinical and clinical activities of CORTOSS and RHAKOSS.

Other Income (Expense). Net other income includes interest income and interest expense. We recorded $214,000 of net other income for the year ended December 31, 2000 compared to

$529,000 of net other income for the year ended December 31, 1999. The decrease in net other income between 1999 and 2000 is attributed to lower average cash balances year over year.

Net Gain On Sale of Product Line. We received $3,900,000, of which $400,000 was being held in escrow until March 23, 2001, in connection with the sale of the BIOGRAN dental grafting product line to 3i in March 2000. We realized a net gain on the transaction of approximately $3,071,000.

Net Loss. As a result of the foregoing factors, our net loss for the year ended December 31, 2000 was approximately $11,335,000 compared to a net loss of approximately $9,497,000 for 1999.

Commitments and Contingencies

We lease office space and equipment under non-cancelable operating leases. For the years ended December 31, 2001, 2000 and 1999, lease expense was approximately $422,000, $321,000 and $305,000, respectively. As of December 31, 2001, future minimum rent payments through the expiration of these leases are approximately $373,000 in 2002, $362,000 in 2003, $357,000 in 2004, $357,000 in 2005, $357,000 in 2006, and $1,477,000 in 2007 and thereafter.

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Royalty. In this financing, we sold Paul Royalty a revenue interest and sold 2,582,645 shares of our Common Stock, for gross proceeds of $10,000,000. The Common Stock was recorded at its market value of $4,777,893 and a revenue interest obligation related to the revenue interest of $5,222,107 was recorded. The revenue interest provides for Paul Royalty to receive 3.5% on the first $100,000,000 of annual sales plus 1.75% of annual sales in excess of $100,000,000 of our VITOSS, CORTOSS and RHAKOSS products in North America and Europe through 2016, subject to certain adjustments.

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

Foreign Currency Risk

The functional currency for our European branch operation is the Euro. Accordingly, in accordance with SFAS No. 52 "Foreign Currency Translations", all assets and liabilities related to this operation are translated at the current exchange rates at the end of each period. The resulting translation adjustments are accumulated in a separate component of shareholders' equity. Revenues and expenses are translated at average exchange rates in effect during the period with foreign currency transaction gains and losses, if any, included in results of operations.

Market Risk

We may be exposed to market risk through changes in market interest rates that could affect the value of our short-term investments. Interest rate changes would result in unrealized gains or losses in the market value of the short-term investments due to differences between the market interest rates and rates at the inception of the short-term investment.

We held no investments as of December 31, 2001. As of December 31, 2000, our investments consisted primarily of commercial paper, United States government agency bonds and high credit quality corporate bonds. The impact on our future interest income and future changes in investment yields will depend on the gross amount of our investments and various external economic factors.

ITEM 8. ***Financial Statements and Supplemental Data***

The consolidated financial statements of the Company and its subsidiaries and supplementary data required by this item are attached to this annual statement on Form 10-K beginning on page F-1.

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

None.

PART III

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

The information concerning directors and compliance with Section 16(a) of the Securities Exchange Act of 1934 called for by Item 10 of Form 10-K will be set forth under the captions "Nominees for the Board of Directors" and "Section 16(a) Reports" in our definitive proxy statement, to be filed within 120 days after the end of the fiscal year covered by this annual report on Form 10-K, and is incorporated herein by reference.

ITEM 11. ***Executive Compensation***

See Item 12.

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

The information called for by Items 11 and 12 of Form 10-K will be set forth under the captions "Executive Compensation: Report of the Compensation Committee," "Summary Compensation Table," and "Holders of 5% or More of Orthovita's Stock and Directors' and Officers' Ownership of Orthovita's Stock," respectively, in our definitive proxy statement, to be filed within 120 days after the end of the fiscal year covered by this annual report on Form 10-K, and is incorporated herein by reference.

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

To compensate Randal Betz, M.D. for serving as the leader of our Surgeon Clinical Panel, we paid Dr. Betz $40,000 during each of our 2001, 2000 and 1999 fiscal years. In addition, Dr. Betz was granted stock options in May 2001, which have an estimated value of approximately $30,000, for serving as a member of our Board of Directors.

PART IV

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

(a) Documents filed as part of this Report

1. *Financial Statements* The following financial statements and notes thereto which are attached hereto beginning on page F-1 have been incorporated by reference into Item 8 of this part of the annual report on Form 10-K:

2. *Financial Statement Schedules.* All schedules are omitted because they are inapplicable, or not required, or the information is shown in the Financial Statements or notes thereto.

3. *Exhibits.* (see (c) below).

(b) Reports on Form 8-K.

The Company filed a Current Report on Form 8-K on November 13, 2001, which it amended by filing a Current Report on Form 8-K/A on November 27, 2001, announcing the October 16, 2001 agreement for product sales revenue interest and a sale of shares of common stock to Paul Capital Royalty Acquisition Fund, L.P. for aggregate proceeds of $10 million.

(c) Exhibits

The following is a list of exhibits filed as part of this annual report on Form 10-K. Where so indicated, exhibits which were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated in parentheses.

3.1 Amended and Restated Articles of Incorporation of the Company (3)

3.2 Amended and Restated Bylaws of the Company (3)

4.1 Specimen of Common Stock Certificate of the Company (10)

4.2 Registration Rights Agreement dated August 22, 2000 among the Company, Brown Simpson Partners I, Ltd., Janney Montgomery Scott LLC, Emerging Growth Equities, Ltd. and VFT Special Ventures Ltd. (4)

4.3 Form of Registration Rights Agreement among the Company, Emerging Growth Equities, Ltd. and each of the investors named therein (6)

Registration Rights Agreement dated March 29, 2001 between the Company and Japan Medical Dynamic Marketing, Inc. (6)

4.4 Registration Rights Agreement dated December 20, 2001 among the Company, SDS Merchant Fund, L.P. and S.A.C. Capital Associates, LLC (8)

4.5 Warrant to Purchase Shares of Common Stock dated as of November 3, 1999 in favor of Progress Capital, Inc. (10)

4.6 Warrant to Purchase 31,779 Shares of Common Stock dated August 22, 2000 in favor of Janney Montgomery Scott LLC (4)

4.7 Warrant to Purchase 31,780 Shares of Common Stock dated August 22, 2000 in favor of VFT Special Ventures Ltd. (4)

4.8 Warrant to Purchase 566,894 Shares of Common Stock dated January 18, 2001 in favor of Rennes Foundation (10)

4.9 Warrant to Purchase 59,250 Shares of Common Stock dated March 19, 2001 in favor of Emerging Growth Equities, Ltd. (5)

4.10 Warrant to Purchase 22,200 Shares of Common Stock dated March 19, 2001 in favor of Emerging Growth Equities, Ltd. (6)

4.11 Form of Warrant to Purchase Shares of Common Stock dated May 18, 2001 granted to S.A.C. Capital Associates, LLC and SDS Merchant Fund, L.P. (7)

4.12 Warrant to Purchase 50,000 Shares of Common Stock dated October 23, 2001 in favor of Tucker Anthony Incorporated (1)

10.1 Employment Agreement dated as of December 31, 1999 between the Company and Bruce A. Peacock (10)

10.2 Addendum to Employment Agreement dated January 1, 2001 between the Company and Bruce A. Peacock (10)

10.3 Addendum to Employment Agreement dated January 1, 2002 between the Company and Bruce A. Peacock (1)

10.4 Employment Agreement dated as of December 31, 1999 between the Company and David S. Joseph (10)

10.5 Addendum to Employment Agreement dated January 1, 2001 between the Company and David S. Joseph (10)

10.6 Addendum to Employment Agreement dated January 1, 2002 between the Company and David S. Joseph (1)

10.7 Employment Agreement dated as of July 1, 2000 between the Company and Dr. Erik M. Erbe (10)

10.8 Addendum to Employment Agreement dated as of January 1, 2002 between the Company and Dr. Erik M. Erbe (1)

10.9 Master Equipment Lease Agreement dated as of July 11, 1997 between the Company and Finova Technology Finance, Inc. (2)

10.10 Amendment to the Master Equipment Lease Agreement dated as of April 15, 1999 between the Company and Finova Technology Finance, Inc. (9)

10.11 1993 Stock Option Plan (3)

10.12 Amended and Restated 1997 Equity Compensation Plan (3)

10.13 Amended and Restated Employee Stock Purchase Plan (3)

10.14 Revenue Interests Assignment Agreement dated as of October 16, 2001 among Vita Special Purpose Corp., the Company and Paul Capital Royalty Acquisition Fund, L.P. (12)

10.15 Assignment dated as of October 16, 2001 between Vita Special Purpose Corp. and Paul Capital Royalty Acquisition Fund, L.P. (11)

10.16 Security Agreement dated as of October 16, 2001 between Vita Special Purpose Corp. and Paul Capital Royalty Acquisition Fund, L.P. (11)

10.17 Pledge Agreement dated as of October 16, 2001 between Vita Licensing, Inc. and Paul Capital Royalty Acquisition Fund, L.P. (11)

10.18 Stock Purchase Agreement dated as of October 16, 2001 between the Company and Paul Capital Royalty Acquisition Fund, L.P. (11)

10.19 Third Amended and Restated Line of Credit dated October 25, 2000 between the Company and Progress Bank (10)

10.20 Capital Expenditure Loan Note dated October 25, 2000 between the Company and Progress Bank (10)

10.21 Asset Sale Agreement dated as of February 10, 2000 between the Company and Implant Innovations, Inc. (9)

10.22 Development and Distribution Agreement dated March 29, 2001 between the Company and Japan Medical Dynamic Marketing, Inc. (1)

10.23 Subscription Agreement dated July 10, 2000 between the Company and Rennes Foundation (10)

10.24 Subscription Agreement dated August 22, 2000 between the Company and Brown Simpson Partners I, Ltd. (4)

10.25 Subscription Agreement dated as of October 4, 2000 between the Company and Raimund Gabriel (10)

10.26 Subscription Agreement dated as of January 18, 2001 between the Company and Rennes Foundation (10)

10.27 Form of Subscription Agreement between the Company and each of the purchasers named therein (6)

10.28 Subscription Agreement dated March 29, 2001 between the Company and Japan Medical Dynamic Marketing, Inc. (6)

10.29 Subscription Agreement dated as of December 20, 2001 between the Company and S.A.C. Capital Associates, LLC (8)

10.30 Subscription Agreement dated as of December 20, 2001 between the Company and SDS Merchant Fund, L.P. (8)

10.31 Amendment to Revenue Interests Assignment Agreement and Stock Purchase Agreement dated March 22, 2002 among the Company, Paul Capital Royalty Acquisition Fund, L.P. and Vita Special Purpose Corp. (1)

21.1 Subsidiaries (1)

23.1 Consent of Arthur Andersen LLP (1)

24.1 Power of Attorney (1) (included in the signature page)

99.1 Letter to the Commission Regarding Arthur Andersen

(1) Filed herewith.

(2) Filed as an Exhibit to the Company's Registration Statement on Form S-1 (File No. 333 51689) filed on May 1, 1998 and incorporated herein by reference.

(3) Filed as an Exhibit to Amendment No. 3 to the Company's Registration Statement on Form S-1 (File No. 333-51689) filed on June 15, 1998 and incorporated herein by reference.

(4) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (File No. 333-47386) filed on October 5, 2000 and incorporated herein by reference.

(5) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (File No. 333-59288) filed on April 20, 2001 and incorporated herein by reference.

(6) Filed as an Exhibit to Amendment No. 1 to the Company's Registration Statement on Form S-3 (File No. 333-59288) filed on May 4, 2001 and incorporated herein by reference.

(7) Filed as an Exhibit to Amendment No. 2 to the Company's Registration Statement on Form S-3 (File No. 333-59288) filed on May 24, 2001 and incorporated herein by reference.

(8) Filed as an Exhibit to the Company's Registration Statement on Form S-3 (File No. 333-84622) filed on March 20, 2002 and incorporated herein by reference.

(9) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 1999 and incorporated herein by reference.

(10) Filed as an Exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.

(11) Filed as an Exhibit to the Company's Current Report on Form 8-K filed on November 13, 2001 and incorporated herein by reference.

(12) Filed as an Exhibit to the Company's Current Report on Form 8-K/A filed on November 27, 2001 and incorporated herein by reference.

Copies of the exhibits are available to shareholders (upon payment of a $.20 per page fee to cover the Company's expenses in furnishing the exhibits) from Investor Relations, Orthovita, Inc., 45 Great Valley Parkway, Malvern, Pennsylvania 19355.

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.

ORTHOVITA, INC.

Date: April 1, 2002

/s/ BRUCE A. PEACOCK
By: Bruce A. Peacock
Chief Executive Officer and President

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

Each person in so signing also makes, constitutes and appoints Bruce A. Peacock, Chief Executive Officer of Orthovita, Inc. and subsidiaries and Joseph M. Paiva, Vice President and Chief Financial Officer of Orthovita, Inc. and subsidiaries, and each of them acting alone, as his true and lawful attorneys-in-fact, in his name, place and stead, to execute and cause to be filed with the Securities and Exchange Commission any or all amendments to this report.

Signature	Capacity	Date
/s/ BRUCE A. PEACOCK **Bruce A. Peacock**	Chief Executive Officer and President (principal executive officer)	April 1, 2002
/s/ DAVID S. JOSEPH **David S. Joseph**	Chairman	April 1, 2002
/s/ JOSEPH M. PAIVA **Joseph M. Paiva**	Vice President and Chief Financial Officer (principal financial and accounting officer)	April 1, 2002
/s/ RANDAL R. BETZ, M.D. **Randal R. Betz, M.D.**	Director	April 1, 2002
/s/ MORRIS CHESTON, JR. **Morris Cheston, Jr.**	Director	April 1, 2002
/s/ PAUL DUCHEYNE, PH.D. **Paul Ducheyne, Ph.D.**	Director	April 1, 2002
/s/ JAMES M. GARVEY **James M. Garvey**	Director	April 1, 2002
/s/ ROBERT M. LEVANDE **Robert M. Levande**	Director	April 1, 2002
/s/ JOS B. PEETERS, PH.D. **Jos B. Peeters, Ph.D.**	Director	April 1, 2002

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Orthovita, Inc.:

We have audited the accompanying consolidated balance sheets of Orthovita, Inc. (a Pennsylvania corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, and shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Orthovita, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

Philadelphia, Pennsylvania
January 22, 2002
(except with respect to the matter discussed in
Note 7, as to which the date is March 29, 2002)

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31	
	2001	2000
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents (Notes 3, 6 and 7)	$ 12,906,557	$ 3,614,626
Short-term investments (Notes 3 and 6)	—	200,366
Restricted cash (Note 11)	—	400,000
Accounts receivable	983,467	80,050
Inventories (Note 4)	1,606,333	182,399
Other current assets	125,022	21,721
Total current assets	15,621,379	4,499,162
PROPERTY AND EQUIPMENT, net (Note 5)	5,433,353	5,321,228
OTHER ASSETS (Note 6)	158,111	367,977
	$ 21,212,843	$ 10,188,367
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term capital lease obligations (Note 8)	$ 482,420	$ 654,063
Accounts payable	1,010,423	1,156,533
Accrued compensation and related expenses	624,168	734,820
Deferred gain (Note 11)	—	400,000
Other accrued expenses	790,765	805,911
Total current liabilities	2,907,776	3,751,327
LONG-TERM LIABILITIES:		
Other long term liabilities	62,000	—
Capital lease obligations (Note 8)	350,519	807,425
Bank term loan (Note 6)	—	500,000
Revenue interest obligation (Note 7)	5,222,107	—
Total long-term liabilities	5,634,626	1,307,425
COMMITMENTS AND CONTINGENCIES (Notes 13 and 14)		
SHAREHOLDERS' EQUITY (Note 10):		
Preferred Stock, $.01 par value, 20,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $.01 par value, 50,000,000 shares authorized, 20,874,536 and 13,426,988 shares issued and outstanding	208,745	134,270
Additional paid-in capital	74,066,082	52,929,538
Deferred compensation	—	(97,500)
Accumulated deficit	(61,599,522)	(47,809,103)
Accumulated other comprehensive loss	(4,864)	(27,590)
Total shareholders' equity	12,670,441	5,129,615
	$ 21,212,843	$ 10,188,367

The accompanying notes are an integral part of these statements.

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31		
	2001	**2000**	**1999**
PRODUCT SALES (Note 11)	$ 3,940,395	$ 740,660	$ 1,054,120
COST OF SALES (Note 4)	719,373	170,041	324,590
Gross profit	3,221,022	570,619	729,530
OPERATING EXPENSES:			
General and administrative	4,361,183	4,333,094	3,674,515
Selling and marketing	5,910,505	3,357,903	1,807,212
Research and development	7,202,942	7,500,165	5,273,590
Total operating expenses	17,474,630	15,191,162	10,755,317
Operating loss	(14,253,608)	(14,620,543)	(10,025,787)
INTEREST EXPENSE	(154,074)	(151,161)	(110,601)
REVENUE INTEREST EXPENSE (Note 7).	(65,750)	—	—
INTEREST INCOME	308,013	365,434	639,794
NET GAIN ON SALE OF PRODUCT LINE (Note 11)	375,000	3,070,921	—
NET LOSS APPLICABLE TO COMMON SHAREHOLDERS	$ (13,790,419)	$ (11,335,349)	$ (9,496,594)
NET LOSS PER COMMON SHARE, BASIC AND DILUTED	$ (.82)	$ (.92)	$ (.83)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	16,841,970	12,281,117	11,411,896

The accompanying notes are an integral part of these statements.

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Comprehensive Income (Loss)	Comprehensive (Loss) Income	Total
BALANCE, DECEMBER 31, 1998	$113,727	$42,289,024	$ —	$(6,977,160)	$102,984		$15,528,575
Exercise of Common Stock options and warrants to purchase Common Stock and Common Stock purchased under the Employee Stock Purchase Plan	1,088	363,123	—	—	—	—	364,211
Issuance of Common Stock options and warrants for services	—	185,664	—	—	—	—	185,664
Repurchase of Common Stock	(720)	(348,920)	—	—	—	—	(349,640)
Receipt of Common Stock in repayment of loan	(779)	(486,096)	—	—	—	—	(486,875)
Comprehensive loss:							
Net loss	—	—	—	(9,496,594)	—	$ (9,496,594)	(9,496,594)
Other comprehensive loss:							
Unrealized loss on short-term investments, net	—	—	—	—	(60,267)	(60,267)	(60,267)
Currency translation adjustment	—	—	—	—	(38,405)	(38,405)	(38,405)
Comprehensive loss	—	—	—	—	—	$ (9,595,266)	—
BALANCE, DECEMBER 31, 1999	113,316	42,002,795	—	(36,473,754)	4,312		5,646,669
Exercise of Common Stock options and warrants to purchase Common Stock and Common Stock purchased under the Employee Stock Purchase Plan	3,347	1,112,145	—	—	—	—	1,115,492
Issuance of Common Stock options and warrants for services	—	510,431	—	—	—	—	510,431
Sale of 1,715,679 shares of Common Stock and warrants	17,157	9,034,292	—	—	—	—	9,051,449
Amortization of deferred compensation	—	—	172,825	—	—	—	172,825
Issuance of Common Stock under restricted stock award	450	269,875	(270,325)	—	—	—	—
Comprehensive loss:							
Net loss	—	—	—	(11,335,349)	—	$ (11,335,349)	(11,335,349)
Other comprehensive loss:							
Unrealized gain on short-term investments, net	—	—	—	—	480	480	480
Currency translation adjustment	—	—	—	—	(32,382)	(32,382)	(32,382)
Comprehensive loss	—	—	—	—	—	$(11,367,251)	—
BALANCE, DECEMBER 31, 2000	134,270	52,929,538	(97,500)	(47,809,103)	(27,590)		5,129,615
Exercise of Common Stock options and warrants to purchase Common Stock and Common Stock purchased under the Employee Stock Purchase Plan	455	88,317	—	—	—	—	88,772
Issuance of Common Stock options and warrants for services	—	354,557	—	—	—	—	354,557
Sale of 7,402,013 shares of Common Stock and warrants	74,020	20,693,670	—	—	—	—	20,767,690
Amortization of deferred compensation	—	—	97,500	—	—	—	97,500
Comprehensive loss:							
Net loss	—	—	—	(13,790,419)	—	$(13,790,419)	(13,790,419)
Other comprehensive loss:							
Unrealized gain on short-term investments, net	—	—	—	—	500	500	500
Currency translation adjustment	—	—	—	—	22,226	22,226	22,226
Comprehensive loss	—	—	—	—	—	$(13,767,693)	—
BALANCE, DECEMBER 31, 2001	$208,745	$74,066,082	$ —	$(61,599,522)	$(4,864)		$12,670,441

The accompanying notes are an integral part of these statements.

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31		
	2001	**2000**	**1999**
OPERATING ACTIVITIES:			
Net loss	$ (13,790,419)	$ (11,335,349)	$ (9,496,594)
Adjustments to reconcile net loss to net cash used in operating activities—			
Depreciation and amortization	1,345,572	953,683	631,696
Amortization of deferred compensation	97,500	172,825	—
Common Stock options and warrants issued for services rendered	354,557	510,431	185,664
Net gain on sale of product line	(375,000)	(3,070,921)	—
Loss on disposal of property and equipment	12,692	—	—
Net cash used in operations	(12,355,098)	(12,769,331)	(8,679,234)
(Increase) decrease in-			
Accounts receivable	(903,417)	(20,539)	(36,791)
Other receivables	—	—	744,959
Inventories	(1,423,934)	(35,129)	181,981
Other current assets	(103,301)	58,948	57,664
Other assets	209,866	(264,836)	(17,747)
Increase (decrease) in-			
Accounts payable	(146,110)	(171,292)	946,681
Accrued patent defense costs	—	—	(402,977)
Other liabilities	(48,652)	(202,043)	(128,865)
Other accrued expenses	(15,146)	337,520	(126,460)
Net cash used in operating activities	(14,785,792)	(13,066,702)	(7,460,789)
INVESTING ACTIVITIES:			
Purchase of investments	—	(199,886)	(10,346,255)
Proceeds from sale of investments	199,866	6,446,469	18,314,180
Proceeds from sale of product line	—	3,900,000	—
Decrease (increase) in restricted cash	375,000	(400,000)	—
Purchases of property and equipment	(1,470,389)	(3,306,335)	(353,862)
Net cash (used in) provided by investing activities	(895,523)	6,440,248	7,614,063
FINANCING ACTIVITIES:			
(Repayments) proceeds of short-term bank borrowings	—	(2,000,000)	2,000,000
Proceeds from debt	—	500,000	—
Repayment of debt	(500,000)	(141,837)	(108,649)
Proceeds from royalty note	5,222,107	—	—
Repayments of capital lease obligations	(628,549)	(682,853)	(433,800)
Proceeds from exercise of common stock options and warrants and common stock purchased under the Employee Stock Purchase Plan	88,772	1,115,492	364,211
Repurchase of common stock	—	—	(349,640)
Proceeds from sale of common stock and warrants	20,767,690	9,051,449	—
Net cash provided by financing activities	24,950,020	7,842,251	1,472,122
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	23,226	(88,514)	19,883
NET INCREASE IN CASH AND CASH EQUIVALENTS	9,291,931	1,127,283	1,645,279
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,614,626	2,487,343	842,064
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 12,906,557	$ 3,614,626	$ 2,487,343

The accompanying notes are an integral part of these statements.

1. The Company:

Orthovita, Inc. ("Orthovita" or the "Company") is a Pennsylvania corporation with proprietary technologies applied to the development of biostructures, which are synthetic, biologically active tissue engineering products for restoration of the human skeleton. Our focus is on developing products for use in spine surgery and in the repair of osteoporotic fractures. We are also addressing a broad range of clinical needs in the trauma market. We have developed several products to date:

- VITOSS™ Scaffold Synthetic Cancellous Bone Void Filler;
  - IMBIBE™ Bone Marrow Aspirate Syringe to be used with VITOSS;
- CORTOSS™ Synthetic Cortical Bone Void Filler;
  - ALIQUOT™ Microdelivery System to be used with CORTOSS.

In addition, we are developing RHAKOSS™ Synthetic Bone Spinal Implants.

VITOSS is a resorbable, beta-tricalcium, phosphate scaffold used as a bone void filler in trauma and spinal procedures. CORTOSS is a high-strength, bone-bonding, self-setting composite intended for use in the augmentation of screws used in a variety of orthopaedic procedures and in vertebral augmentation. RHAKOSS is under development as a high-strength, bone-bonding preformed composite. RHAKOSS is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets.

We received regulatory clearance for VITOSS in the U.S. from the United States Food and Drug Administration ("FDA") in December 2000 and the CE Mark in the European Union from our notified body in July 2000. The CE Mark permits us to sell VITOSS in all of the countries of the European Union, as well as in other countries, such as Switzerland and Israel, that have adopted the European Union's regulatory standards. These regulatory approvals allow us to market VITOSS for use as a cancellous bone void filler for bony voids or gaps of the skeletal system, including the extremities, spine and pelvis. We also received regulatory approval, in March 2001, to sell VITOSS for this use in Australia. We launched VITOSS in Europe in October 2000 and in the United States in February 2001. In April 2001, we entered into a agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"), an orthopaedic company in Japan, under which MDM will initiate clinical studies necessary to apply for regulatory approval to market VITOSS in Japan. In September 2001, we received regulatory clearance in the United States from the FDA to market IMBIBE for use as a bone marrow aspiration syringe. IMBIBE provides spine and trauma surgeons with a simple method for harvesting a patient's own bone marrow, mixing it with VITOSS and delivering the mixture to the bone graft site.

We received the CE Mark for CORTOSS in October 2001 in the European Union and regulatory approval in March 2001 in Australia which allows us to sell CORTOSS in these territories for use in screw augmentation procedures. Screw augmentation is a procedure for the fixation of bone screws used in patients with weak bone caused by osteoporosis. We initiated a limited launch of CORTOSS in Europe in December 2001. In addition, we are conducting post-

marketing human clinical studies in Europe for the use of CORTOSS in hip compression screw augmentation. We are also pursuing clinical studies of CORTOSS in Europe seeking to expand its label to include its use in vertebral augmentation. During 2001, we received conditional approval from the FDA to conduct a pilot clinical study in the U.S. for the use of CORTOSS for vertebral augmentation. In addition, during 2002, we received approval from the FDA to conduct a pivotal clinical study in the U.S. for the use of CORTOSS for long bone screw augmentation. There can be no assurance that the data from any such clinical trials will support FDA clearance or approval to market this product for these uses.

Our ALIQUOT Microdelivery System facilitates effective delivery of our CORTOSS product directly to the surgical site. A two-part system of catheter and dispenser is designed to assure effective delivery of CORTOSS in screw augmentation procedures.

RHAKOSS is designed to mimic the strength and flexibility characteristics of bone, as well as its radiolucency, which means its degree of transparency to x-rays and other radiation. RHAKOSS can be manufactured into any size or shape to optimize anatomic fit. RHAKOSS is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets. We initiated pre-clinical studies for our RHAKOSS spinal implants in December 2000 and our goal is to initiate human clinical studies in 2002 in Europe.

We have assembled a network of independent stocking distributors in Europe, Australia and Israel and commissioned sales agencies in the U.S. in order to market VITOSS, and we are utilizing this network for CORTOSS in Europe, Australia and Israel. If MDM is successful in obtaining clearance to market VITOSS, it will distribute, sell and market VITOSS in Japan. We plan to seek a similar arrangement for CORTOSS in Japan.

We incorporated in Pennsylvania in 1992 and began operations in 1993. Our principal offices are located at 45 Great Valley Parkway, Malvern, Pennsylvania 19355.

Our operations are subject to certain risks including but not limited to the need to successfully commercialize both VITOSS in the U.S., Europe, Australia and Israel, and CORTOSS in Europe and Australia. We also need to successfully develop, obtain regulatory approval for, and commercialize CORTOSS in the U.S. and RHAKOSS in the U.S. and Europe. We have incurred losses each year since our inception in 1993 and we expect to continue to incur losses for at least the next several years. As of December 31, 2001, we had an accumulated deficit of $61,599,522. Our products under development may never be commercialized or if commercialized, may never generate substantial revenue. We do not expect sales to generate cash flow in excess of operating expenses for at least the next several years, if at all. We expect to continue to use cash, cash equivalents and short-term investments to fund operating and investing activities. We believe that our existing cash of $12,906,557 as of December 31, 2001 will be sufficient to meet our currently estimated operating and investing requirements into early 2003; however, if we do not raise additional cash during 2002, we may be required to curtail or limit certain marketing support and research and development activities in order to remain compliant with certain financial covenants (see Note 7). A curtailment of certain activities would delay

development of certain of our products. We will need to raise additional funds by the fourth quarter of 2002 to meet the Nasdaq National Markets continuing listing requirements if the bid price per share of our Common Stock remains below $3.00 per share. We may seek to obtain additional funds through equity or debt financings, or strategic alliances with third parties either alone or in combination with equity. These financings could result in substantial dilution to the holders of our Common Stock or require debt service and/or royalty payment arrangements. Any such required financing may not be available in amounts or on terms acceptable to us.

2. Summary of Significant Accounting Policies:

Preparation of Financial Statements and Use of Estimates

Our consolidated financial statements have been prepared using United States generally accepted accounting principles. This preparation requires that we make assumptions and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. We believe our more significant estimates and judgments involve accounting policies affecting the areas of revenue recognition inventories, revenue interest obligation accounting, income taxes and accounting for certain equity transactions.

Basis of Consolidation

The consolidated financial statements include the accounts of Orthovita, Inc., our European branch operations, and our wholly owned subsidiaries including, Vita Licensing, Inc., which was established to hold all intellectual property. We have eliminated all intercompany balances in consolidation.

Net Loss Per Common Share

We have presented net loss per common share pursuant to Statement of Financial Accounting Standards ("SFAS") No. 128, "Earnings per Share." Basic net loss per share excludes potentially dilutive securities and is computed by dividing net loss applicable to common shareholders by the weighted average number of shares of Common Stock outstanding for the period. Diluted net loss per common share data is generally computed assuming the conversion or exercise of all dilutive securities such as Common Stock options and warrants; however, Common Stock options and warrants were excluded from our computation of diluted net loss per common share for the years ended December 31, 2001, 2000 and 1999 because they were anti-dilutive due to our losses.

Revenue Recognition

Revenue from product sales is recognized upon the receipt of a valid order and shipment to our distributor customers in Europe, Australia and Israel. In the U.S., product sales revenue is recognized upon the receipt of a valid order and shipment of the product to the end user

hospital. We do not allow product returns or exchanges. In addition, collection of the customers' receivable balance must be deemed probable. We maintain an accounts receivable allowance for an estimated amount of losses that may result from customers' inability to pay for product purchased. 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.

Inventory

Inventory is stated at the lower of cost or market value using the first-in first-out basis, or FIFO, method. We would write down our inventory, if necessary, by estimating the potential for future loss based on a variety of factors, including the quantity of particular items, their prospect for replacement or obsolescence and the remaining shelf life. If actual market conditions were to be less favorable than those projected by management and demand decreased, inventory write-downs would be required. As of December 31, 2001, we have not needed to write down our inventory.

Revenue Interest Obligation

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Capital Royalty Acquisition Fund, L.P. ("Paul Royalty") in which we sold a revenue interest and 2,582,645 shares of our Common Stock.

The net proceeds of the financing were first allocated to the fair value of the Common Stock on the date of the transaction, and the $5,222,107 remainder of the net proceeds was allocated to the revenue interest obligation. Given that the products subject to the revenue interest have only recently been approved and marketed or are still under development, we, as of December 31, 2001 and for the foreseeable future, cannot make a reasonable estimate of their future sales levels and the related revenue interest obligation. Accordingly, in 2002 and the forseeable future, we will charge revenue interest expense as payments due under the revenue interest obligation are incurred.

On March 22, 2002, the agreement with Paul Royalty was modified whereby they exchanged 860,882 shares of our Common Stock for elimination of certain potential credits allowable to us against our revenue interest obligation, as well as, a reduction in the repurchase price (see Note 7). This modification will be accounted for as a treasury stock transaction with a decrease to shareholders' equity and an increase to the revenue interest obligation based upon the fair market value of the Common Stock on the date of the transaction, or $2.26 per share or $1,946,454 in the aggregate.

Income Taxes

We account for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected tax consequences of events that have been recognized in the financial statements or tax returns. SFAS No. 109 requires that deferred tax

assets and liabilities be recorded without consideration as to their realizability. The deferred tax asset includes the cumulative temporary difference related to certain research, patent and organizational costs, which have been charged to expense in our Statements of Operations contained in this Form 10-K but have been recorded as assets for federal tax return purposes. These tax assets are amortized over periods generally ranging from 5 to 20 years for federal tax purposes. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance against the asset. A valuation allowance has been established against all of our deferred tax assets since the realization of the deferred tax asset is not assured given our history of operating losses.

Accounting for Stock Issued to Employees

We apply Accounting Principal Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and the related interpretations in accounting for our stock option plans.

Research & Development Costs

In accordance with SFAS No. 2 "Accounting for Research and Development Costs," we expense all research and development expenses as incurred.

Foreign Currency Translation

The functional currency for the Company's branch operation in Europe is the Euro. In accordance with SFAS No. 52, "Foreign Currency Translation," assets and liabilities related to this foreign operation are translated at the current exchange rates at the end of each period. The resulting translation adjustments are accumulated as a separate component of shareholders' equity. Revenues and expenses are translated at average exchange rates in effect during the period with foreign currency transaction gains and losses, if any, included in results of operations.

Supplemental Cash Flow Information

During 2001, 2000 and 1999, respectively, we issued options and warrants for the purchase of 203,000, 117,500 and 41,100 shares of Common Stock with various exercise prices to certain vendors in consideration for services valued at $354,557, $510,431 and $185,664, respectively.

In 1999, we received 77,900 shares of our Common Stock valued at $486,875 and, in addition, we received $103,800 in cash for full repayment of a loan.

In 2000 and 1999, we incurred capital lease obligations of $997,489, and $609,851, respectively. We did not incur any capital lease obligations in 2001. In 2001, 2000 and 1999, cash paid for interest was $219,824, $151,161 and $110,601, respectively. The Company paid no income taxes in 2001, 2000 and 1999.

Recent Accounting Pronouncements

The Financial Accounting Standards Board's ("FASB") SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", established accounting for derivative

instruments, including certain derivative instruments embedded in other contracts, and hedging activities. Previously hedging activities relating to changes in foreign exchange rates were addressed in SFAS No. 52, "Foreign Currency Translation". SFAS No. 80, "Accounting for Futures Contracts" addressed the use of futures contracts in other hedging activities. Those two Statements addressed only certain derivative instruments and differed in the criteria required for hedge accounting. We did not have any derivative transactions during 2001.

The FASB's SFAS No. 141, "Business Combinations," established financing accounting and reporting for business combinations which supersedes APB Opinion No. 16, "Business Combinations," and SFAS No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises." SFAS No. 141 requires that all business combinations be accounted for using the purchase method of accounting. The provisions apply to all business combinations initiated after June 30, 2001. We did not have any business combinations during 2001.

The FASB's SFAS No. 142, "Goodwill and Other Intangible Asset," established financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets." SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 31, 2001. We do not have any acquired goodwill or other intangible assets.

The FASB's SFAS No. 143, "Accounting for Asset Retirement Obligations," required that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made, with the associated asset retirement costs capitalized as part of the carrying amount of the long-lived asset. We do not have any asset retirement obligations.

The FASB's SFAS No. 144, "Accounting for the Impairment or Disposal of Long- Lived Assets," is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes FASB Statement No. 121 and parts of APB Opinion No. 30, " Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions Relating to Extraordinary Items," however, SFAS No. 144 retains the requirement of APB Opinion No. 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, abandonment, or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. We have adopted SFAS No. 144 and have evaluated the useful life of our long-lived assets. We do not have any impairment or disposals of long-lived assets.

3. Cash, Cash Equivalents and Short-term Investments:

We invest excess cash in highly liquid investment-grade marketable securities including corporate commercial paper and U.S. government agency bonds. For financial reporting purposes, we consider all highly liquid investment instruments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2000, we invested all excess cash in cash equivalents and short-term investments; however, if long-term investments are held, such investments are considered available-for-sale and, accordingly, unrealized gains and losses are included as a separate component of shareholders' equity. As further discussed in Note 7, our covenants under our revenue agreement require us to maintain specified levels of aggregate cash, cash equivalents and short-term investments.

As of December 31, 2001 and 2000, cash and cash equivalents and short-term investments consisted of the following:

	Original Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
December 31, 2001:				
Cash and cash equivalents . .	$ 12,906,557	$ —	$ —	$ 12,906,557
	$ 12,906,557	$ —	$ —	$ 12,906,557
December 31, 2000:				
Cash and cash equivalents . .	$ 3,614,626	$ —	$ —	$ 3,614,626
Short-term investments	199,886	480	—	200,366
	$ 3,814,512	$ 480	$ —	$ 3,814,992

4. Inventories:

Inventories are stated at the lower of cost or market on a first-in, first-out basis. As of December 31, 2001 and 2000, inventories consisted of the following:

	December 31	
	2001	2000
Raw materials	$ 108,960	$ 2,042
Work-in-process	752,079	180,357
Finished goods	745,294	—
	$ 1,606,333	$ 182,399

All of the approximately $208,000 of VITOSS sold in Europe during 2000 was produced prior the receipt of its CE Certification in July 2000. In accordance with SFAS No. 2 "Accounting for Research and Development Costs," the approximately $77,000 of costs to produce that material was recorded as research and development expense prior to July 2000 and, accordingly, are not reflected in cost of sales. As of December 31, 2000, we maintained inventory on hand of approximately $45,000 that was charged as a research and development expense prior to July 2000. This inventory was sold during 2001.

5. Property and Equipment:

Property and equipment, including assets held under capitalized lease obligations, are recorded at cost. Depreciation is calculated on a straight-line basis over the estimated useful life of each asset, primarily three to five years. The useful life for leasehold improvements is generally the remaining term of the facility lease. Expenditures for major renewals and improvements are capitalized and expenditures for maintenance and repairs are charged to operations as incurred.

Property and equipment consisted of the following:

	December 31	
	2001	**2000**
Machinery and equipment	$ 3,371,746	$ 2,804,893
Furniture, computer, marketing, and office equipment	1,663,060	1,356,970
Leasehold improvements	4,037,637	3,456,526
	9,072,443	7,618,389
Less-Accumulated depreciation	(3,639,090)	(2,297,161)
	$ 5,433,353	$ 5,321,228

In the year ended December 31, 2000, we acquired certain property and equipment under capitalized lease obligations which are reflected in the above table. We did not acquire property and equipment under capitalized lease obligations in 2001. Total assets under capital lease are $2,819,745 and $2,836,080 with related accumulated amortization of $1,651,065 and $1,107,574 at December 31, 2001 and 2000, respectively (see Note 8).

6. Borrowings:

A $1,500,000 bank credit arrangement was due to expire on June 30, 2002 but was terminated, at our request, during October 2001. As of December 31, 2000, no amounts were outstanding under the bank credit arrangement. In addition, as of December 31, 2000, a $500,000 capital expenditure term note ("Term Note") was outstanding and was repaid in full without penalty in October 2001.

The Term Note and line of credit bore interest at an annual rate of the prime rate plus 1.0%. Both the line of credit and Term Note were secured by our general assets and a $250,000 bank certificate of deposit which was included in Other Assets as of December 31, 2000. The bank certificate of deposit, which secured our credit arrangement, was released as collateral during October 2001.

7. Revenue Interest Obligation:

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Royalty. We will use the proceeds realized from this financing for clinical development, marketing programs, and working capital relating to VITOSS, CORTOSS and

RHAKOSS products. In this financing, we sold Paul Royalty a revenue interest and sold 2,582,645 shares of our Common Stock, for aggregate gross proceeds of $10,000,000. The Common Stock was recorded at its market value of $4,777,893 and a revenue interest obligation related to the revenue interest of $5,222,107 was recorded.

The net proceeds of the financing were first allocated to the fair value of the Common Stock on the date of the transaction, and the $5,222,107 remainder of the net proceeds was allocated to the revenue interest obligation. Given that the products subject to the revenue interest have only recently been approved and marketed or are still under development, we, as of December 31, 2001 and for the foreseeable future, cannot make a reasonable estimate of their future sales levels and the related revenue interest obligation. Accordingly, in 2002 and the forseeable future, we will charge revenue interest expense as payments due under the revenue interest obligation are incurred.

On March 22, 2002, the agreement with Paul Royalty was modified whereby they exchanged 860,882 shares of our Common Stock for elimination of certain potential credits allowable to us against our revenue interest obligation, as well as, a reduction in the repurchase price. This modification will be accounted for as a treasury stock transaction with a decrease to shareholders' equity and an increase to the revenue interest obligation ased upon the fair market value of the Common Stock on the date of the transaction, or $2.26 per share or $1,946,454 in the aggregate.

The revenue interest provides for Paul Royalty to receive 3.5% on the first $100,000,000 of annual sales plus 1.75% of annual sales in excess of $100,000,000 of our VITOSS, CORTOSS and RHAKOSS products in North America and Europe through 2016, subject to certain adjustments. Our obligation to pay the revenue interest is secured by our licenses, patents and trademarks relating to certain of our products, including VITOSS, CORTOSS and RHAKOSS, in North America and Europe, and the 12% revenue interest we pay to Vita Licensing, Inc., our wholly-owned subsidiary, on the sales of our products (collectively, the "Pledged Assets"). We are also required to maintain:

- cash and cash equivalent balances equal to or greater than the product of (i) 1.5 and (ii) total operating losses, net of non-cash charges, for the preceding fiscal quarter; and
- total shareholders' equity of at least $8,664,374; provided, however, that under the provisions of the agreement with Paul Royalty when calculating shareholders' equity for the purposes of the financial covenants, the revenue interest obligation is included in shareholders' equity.

As of December 31 2001, we were in compliance with all financial covenants. However, if we fail to maintain such balances and shareholders' equity, Paul Royalty can demand that we repurchase its' royalty interest.

In addition to the financial covenants described above, Paul Royalty has the right to cause us to repurchase their revenue interest upon the occurrence of certain events, including:

- a judicial decision that has a material adverse effect on our business, operations, assets or financial condition;
- the acceleration of our obligations or the exercise of default remedies by a secured lender under certain debt instruments;
- a voluntary or involuntary bankruptcy that involves us or our wholly owned subsidiary, Vita Special Purpose Corp.;
- our insolvency;
- a change in control of our company;
- the breach of a representation, warranty or certification made by us in the agreements with Paul Royalty that, individually or in the aggregate, would reasonably be expected to have a material adverse effect on our business, operations, assets or financial condition, and such breach is not cured within 30 days after notice thereof from Paul Royalty.

We may not have sufficient cash funds to repurchase the revenue interest upon a repurchase event. The exact amount of the repurchase price is dependent upon certain factors, including when the repurchase event occurs. The repurchase price targets an internal rate of return for Paul Royalty's $10,000,000 investment ranging up to 45% net of revenue interest amounts paid by us to Paul Royalty during the term of the revenue sharing agreement. If we were unable to repurchase the revenue interest upon a repurchase event, Paul Royalty could foreclose on the Pledged Assets, and we could be forced into bankruptcy. Paul Royalty could also foreclose on the pledged assets if we are insolvent or involved in a voluntary or involuntary bankruptcy. No repurchase events or foreclosures have occured as of December 31, 2001. As of December 31, 2001, if the repurchase event had been triggered and Paul Royalty exercised their right to require us to repurchase their revenue interest, we would have owed Paul Royalty $10,871,750.

The March 2002 amendment reduced by $3,333,333 the amount that would be due to Paul Royalty should certain repurchase events occur in the future and which resulted in Paul Royalty requiring us to repurchase the revenue interest obligation. Had the amendment to the arrangement been executed prior to December 31, 2001 and had a repurchase event been triggered, as of December 31, 2001, we would have owed Paul Royalty $7,538,417 rather than $10,871,750. If we know that we will not be in compliance, we will be required to accrete the revenue interest obligation to the repurchase amount. As of December 31, 2001, we believe that we will remain in compliance for the forseeable future with all covenants and terms of the revenue interest obligation.

8. Capital Lease Obligations:

In 1997, we secured a $1,200,000 capital asset lease financing arrangement with a lending institution which was increased an additional $1,500,000 in December 1998. The term

of each individual lease is 42 months from each individual lease's inception and annual interest is approximately 10.85% and 9.4% under the 1997 and 1998 arrangements, respectively. As of December 31, 2000, we have utilized all available financing under the capital lease arrangement. The leases are secured by the underlying capital assets. Capital lease obligations consisted of the following:

	December 31	
	2001	**2000**
Capital lease obligations	$ 881,888	$ 1,626,971
Less-amount representing interest	(48,949)	(165,483)
Present value of minimum lease payments	832,939	1,461,488
Less-current portion of minimum lease payments	(482,420)	(654,063)
	$ 50,519	$ 807,425

Capital lease obligation maturities as of December 31, 2001 are as follows:

2002	$ 516,842
2003	319,397
2004	45,649
	$ 881,888

9. Profit Sharing Plan:

The Company has a Section 401(k) plan for all qualified employees, as defined. Company contributions are discretionary and determined annually and were $126,331, $106,415 and $67,541 for the years ended December 31, 2001, 2000 and 1999, respectively.

10. Shareholders' Equity:

Common Stock

During December 2001, we sold 1,125,000 shares of our Common Stock to two investors in a private equity financing. The aggregate consideration we received for these shares consisted of $2,700,000 in cash, plus the surrender and cancellation of outstanding warrants to purchase an aggregate of 1,125,000 shares of our Common Stock held by the two investors.

During October 2001, we completed a $10,000,000 product development and equity financing with Paul Royalty. In this financing, we sold Paul Royalty 2,582,645 shares of Common Stock which was recorded at its market value of $4,777,893. In March 2002, Paul Royalty exchanged 860,882 shares of our Common Stock (see Note 7).

During June 2001, the investor in an August 2000 private placement purchased 206,830 shares of our Common Stock for $.01 per share, and 762,712 warrants exercisable at $5.90 per share were adjusted to 1,125,000 warrants exercisable at $4.00 per share in accordance with the anti-dilution provisions contained in a subscription agreement dated August 22, 2000 due to the equity transactions in January, March and April 2001. No other outstanding warrant shares have material anti-dilution provisions.

During April 2001, we entered into a Development and Distribution Agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"), a Japanese orthopaedic company. In connection with this arrangement, we sold 189,394 shares of Common Stock at $5.28 per share (the fair market value on the date of the transaction) to MDM, raising net proceeds of $1,000,000.

Additionally, during April 2001, we sold 740,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $2,692,000.

During March 2001, we sold 1,975,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $7,290,000.

In addition, during January 2001, we sold 566,894 shares of our Common Stock and warrants to purchase 566,894 shares of Common Stock at an exercise price of $4.41 per share raising net proceeds of approximately $2,413,000.

In August 2000, we listed our Common Stock on the Nasdaq National Market while retaining our listing on the European Association of Securities Dealers Automated Quotation Market which is now under the name of Nasdaq-Europe.

In July and August 2000, we received approximately $9,100,000 in net proceeds through private equity financings under which we sold 1,715,679 shares of our Common Stock at $5.90 per share and warrants to purchase 762,712 shares of Common Stock at an exercise price of $5.90 per share, subject to certain anti-dilution adjustments.

Equity Compensation Plan

We have an Equity Compensation Plan (the "Plan") that provides for incentive and nonqualified stock options, restricted stock awards and other equity incentives to be granted to key employees, consultants and advisors. The Plan is the only Plan under which stock options have been granted and the Plan has been approved by our Shareholders.

Stock Options

Options are granted with exercise prices equal to or greater than the fair market value of the Common Stock on the date of grant. Generally, incentive stock options become exercisable in equal installments over a four-year period and nonqualified stock options to non-employee consultants are issued fully vested. The options remain exercisable for a maximum period of ten years. As of December 31, 2001, there were 468,081 options available for grant under the plan and 1,401,013 exercisable options outstanding with a weighted average exercise price of $3.67 per share. In addition, we issued 373,500 options during January 2002 with a weighted average exercise price of $2.71 per share. For all outstanding options, the weighted average exercise price per share is $4.42 with a weighted average remaining contractual life of approximately seven and three-quarter years. Summary stock option information is as follows:

	Number	Exercise Price Range	Aggregate Exercise Price
Outstanding, December 31, 1998 . . .	982,794	$ 1.00 - 11.63	$ 3,623,660
Granted	739,850	4.35 - 6.60	3,869,778
Exercised	(101,472)	2.75 - 4.25	(332,830)
Canceled	(33,950)	4.25 - 4.75	(147,888)
Outstanding, December 31, 1999 . . .	1,587,222	1.00 -11.63	7,012,720
Granted	421,100	4.13 - 7.95	2,220,783
Exercised	(220,547)	1.00 - 4.25	(763,031)
Canceled	(28,325)	4.25 - 11.12	(195,916)
Outstanding, December 31, 2000 . . .	1,759,450	1.00 - 11.63	8,274,556
Granted	816,600	1.70 - 5.87	3,222,786
Exercised	(13,350)	1.00 - 5.00	(17,925)
Canceled	(91,900)	2.85 - 7.95	(555,905)
Outstanding, December 31, 2001 . . .	2,470,800	$ 1.00 - 11.63	$ 10,923,512

We apply Accounting Principal Board Opinion No. 25, "Accounting for Stock Issued to Employees," ("APB 25") and the related interpretations in accounting for our stock option plans. Under APB 25, compensation cost related to stock options is computed based on the intrinsic value of the stock option at the date of grant, reflected by the difference between the exercise price and the fair value of our Common Stock. Under SFAS No. 123, "Accounting for Stock-Based Compensation," compensation cost related to stock options is computed based on the value of the stock options at the date of grant using an option valuation methodology, typically the Black-Scholes model. SFAS No. 123 can be applied either by recording the Black-Scholes model value of the options or by continuing to record the APB 25 value and by disclosing SFAS No. 123. We have applied the pro forma disclosure requirement of SFAS No. 123, "Accounting for Stock-Based Compensation". Had compensation cost for our common stock option plans been determined under SFAS No. 123, our net loss and net loss per common share would have been adjusted as follows:

	Year Ended December 31		
	2001	2000	1999
Net loss applicable to common shareholders:			
As reported	$ 13,790,419	$ 11,335,349	$ 9,496,594
Pro forma.	14,499,348	11,936,979	11,508,328
Net loss per common share, basic and diluted:			
As reported	$ (.82)	$ (.92)	$ (.83)
Pro forma.	(.86)	(.97)	(1.01)

The weighted average fair value of the options granted during 2001, 2000 and 1999 is estimated as $.87, $1.98 and $2.87 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions: dividend yield of zero, volatility of 50%, risk-free interest rate of 3.3%, 5.0% and 6.4% during 2001, 2000 and 1999, respectively, and an expected life of six years. The resulting pro forma compensation charge presented may not be representative of that to be expected in the future years to the extent that additional stock options are granted and the fair value of the common stock increases or decreases.

Restricted Stock Award

During 2000, a restricted stock award was made to an employee under which an award for 45,000 shares, then valued at $270,325, was granted subject to vesting. As of December 31, 2001 and 2000, 45,000 and 28,750 shares of Common Stock, respectively, were vested under the award.

Employee Stock Purchase Plan

In November 1998, an Employee Stock Purchase Plan (the "ESPP") was established to provide eligible employees an opportunity to purchase our Common Stock. Under the terms of the ESPP, eligible employees may have up to 10% of eligible compensation deducted from their pay to purchase Common Stock. The per share purchase price is 85% of the lower closing price on the first or last trading day of each calender quarter. The amount that may be offered pursuant to the ESPP is 300,000 shares of our Common Stock. There were 32,185, 9,070 and 2,732 shares purchased under the ESPP during 2001, 2000 and 1999, respectively. As of December 31, 2001, there were 256,013 shares available for purchase under the Plan.

Common Stock Purchase Warrants

In December 2001 (see Common Stock above), warrants to purchase 1,125,000 shares of our Common Stock, originally issued in a private placement transaction in August 2000 were surrendered in exchange for the purchase of 1,125,000 shares of our Common Stock.

In connection with the March and April 2001 equity financing (see Common Stock above), we issued warrants to our placement agent to purchase an aggregate of 81,450 shares of our Common Stock at $4.00 per share as a placement agent fee. These warrants were exercisable when issued and expire in March 2003 and April 2003.

In connection with the January 2001 private equity offering (see Common Stock above), we issued warrants to purchase 566,894 shares of Common Stock at an exercise price of $4.41 per share. These warrants were exercisable when issued and expire in January 2003.

During August 2000, in connection with a private equity offering (see Common Stock above), we issued warrants to purchase 762,712 shares of Common Stock at an exercise price of $5.90 per share subject, to certain anti-dilution adjustments. In addition, we paid placement agent fees consisting of warrants to purchase 65,559 shares of our Common Stock at an exercise price of $5.90 per share.

Summary Common Stock warrant information as of December 31, 2001 is as follows:

Year of Expiration	Number of Warrant Shares Outstanding	Exercise Price Range
2002	547,010	$ 4.25
2003	653,405	$ 4.00 - $ 4.41
2003	24,426	$ 8.60
2004	10,000	$ 6.00
2005	113,559	$ 5.26 - $ 5.90
Total	1,348,400	$ 4.00 - $ 8.60

11. Product Sales:

We initiated sales of VITOSS in Europe and the United States in October 2000 and March 2001, respectively. CORTOSS sales were initiated in Europe during December 2001. For the years ended December 31, 2001 and 2000, product sales of VITOSS and CORTOSS by geographic market were as follows:

	Year Ended December 31	
	2001	2000
PRODUCT SALE (excluding BIOGRAN):		
United States	$ 3,305,873	$ —
Outside the United States	634,522	207,693
Total product sales	$ 3,940,395	$ 207,693

Sales of our dental product, BIOGRAN, were $532,967 and $1,054,120 during 2000 and 1999, respectively. In March 2000, we sold our BIOGRAN dental grafting product line for $3,900,000 and received proceeds of $3,500,000 with an additional $400,000 held in a restricted cash escrow account until March 2001.

12. Income Taxes:

We account for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 is an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected tax consequences of events that have been recognized in the financial statements or tax returns.

The components of income taxes are as follows:

	Year Ended December 31		
	2001	2000	1999
Current	$ —	$ —	$ —
Deferred	(3,105,430)	(1,583,490)	(2,116,201)
	(3,105,430)	(1,583,490)	(2,116,201)
Valuation allowance	3,105,430	1,583,490	2,116,201
	$ —	$ —	$ —

The difference between our federal statutory income tax rate and our effective income tax rate is primarily due to state income taxes and the valuation allowance.

Components of our deferred tax asset as of December 31, 2001 and 2000 are as follows:

	December 31	
	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 12,949,311	$ 9,288,321
Accrued expenses not currently deductible	710,023	981,904
Research, patent and organizational costs capitalized for tax purposes	7,139,268	5,614,886
	20,798,602	15,885,111
Valuation allowance	(20,798,602)	(15,885,111)
Net deferred tax asset	$ —	$ —

SFAS No. 109 requires that deferred tax assets and liabilities be recorded without consideration as to their realizability. The portion of any deferred tax asset for which it is more likely than not that a tax benefit will not be realized must then be offset by recording a valuation allowance against the asset. A valuation allowance has been established against all of our deferred tax assets since the realization of the deferred tax asset is not assured given our history of operating losses. The deferred tax asset includes the cumulative temporary difference related to certain research, patent and organizational costs, which have been charged to expense in the accompanying Statements of Operations but have been recorded as assets for federal tax return purposes. These tax assets are amortized over periods generally ranging from 5 to 20 years for federal tax purposes.

As of December 31, 2001, we had $37,645,033 of federal net operating loss carryforwards, which begin to expire in 2008. Our annual utilization of net operating loss carryforwards will be limited pursuant to the Tax Reform Act of 1986, since a cumulative change in ownership over a three-year period of more than 50% occurred as a result of the cumulative issuance of our Common Stock and Common Stock equivalents. We believe, however, that such limitation may not have a material impact on the ultimate utilization of our carryforwards.

The federal net operating loss carryforwards are scheduled to expire approximately as follows:

2008	$ 7,729
2009	490,568
2010	2,976,405
2011	4,342,295
2012	4,574,051
2013	4,219,188
2014	5,874,561
2015	6,114,855
2016	9,045,381
	$ 37,645,033

13. Commitments and Contingencies:

Operating Leases

We lease office space and equipment under noncancelable operating leases. For the years ended December 31, 2001, 2000 and 1999, lease expense was $421,535, $321,039, and $304,732, respectively. At December 31, 2001, future minimum rental payments under operating leases are as follows:

2002	$ 373,418
2003	362,372
2004	356,652
2005	356,652
2006	356,652
2007 and thereafter	1,476,807
	$ 3,282,553

Revenue Interest Expense

We are obligated to pay to Paul Royalty 3.5% on the first $100,000,000 of annual sales plus 1.75% of annual sales in excess of $100,000,000 of our VITOSS, CORTOSS and RHAKOSS products in North America and Europe through 2016, subject to certain adjustments. In addition, Paul Royalty has the right to cause us to repurchase their revenue interest upon the occurrence of certain events (see Note 7).

14. Litigation and Proceedings:

In July 1992, we obtained a license from FBFC International, a Belgian company, that allowed us to manufacture and sell BIOGRAN dental grafting product. We sold the rights to sell BIOGRAN to Implant Innovations ("3i") in 2000. In July 1994, U.S. Biomaterials Corporation filed with the U.S. Patent and Trademark Office ("PTO") a Request for Reexamination of the U.S. patent held by FBFC for BIOGRAN, of which we had been the exclusive licensee. FBFC filed a response in this proceeding, establishing that the claims of the FBFC patent were properly allowed. As a result, a Certificate of Reexamination was issued. The PTO confirmed the patentability of all claims of the FBFC patent without amendment. However, U.S. Biomaterials Corporation instituted a nullification proceeding against the European counterpart to FBFC's U.S. patent. The opposition division of the European Patent Office tentatively decided in FBFC's favor, but the matter is still proceeding under an appeal. In connection with the BIOGRAN sale to 3i, 3i assumed control of this matter and we have agreed to reimburse 3i for the associated legal costs and to provide them with certain indemnification with respect to the matter. We do not believe there are any material liabilities with respect to the indemnification for this matter.

15. Quarterly Financial Data (Unaudited):

	For the Three Months Ended				
2001:	**March 31**	**June 30**	**September 30**	**December 31**	**Total**
Product sales	$ 226,406	$ 953,603	$ 1,134,253	$ 1,626,133	$ 3,940,395
Gross profit	207,006	699,965	963,542	1,350,509	3,221,022
Total operating expenses	3,901,735	4,368,083	4,451,924	4,752,888	17,474,630
Net gain on sale of product line	375,000	—	—	—	375,000
Net loss	(3,290,797)	(3,598,486)	(3,456,448)	(3,444,688)	(13,790,419)
Net loss per common share, basic and diluted	$ (.26)	$ (.22)	$ (.20)	$ (.18)	$ (.82)

	For the Three Months Ended				
2000:	**March 31**	**June 30**	**September 30**	**December 31**	**Total**
Product sales	$ 532,967	$ —	$ —	$ 207,693	$ 740,660
Gross profit	368,926	—	—	201,693	570,619
Total operating expenses	3,180,874	3,682,386	3,612,354	4,715,548	15,191,162
Net gain on sale of product line	3,070,921	—	—	—	3,070,921
Net income (loss)	305,162	(3,635,124)	(3,528,050)	(4,477,337)	(11,335,349)
Net income (loss) per common share, basic and diluted	$ .03	$ (.31)	$ (.28)	$ (.36)	$ (.92)

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