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MACROPORE BIOSURGERY  
The Practice of Regenerative Medicine

Annual Report 2003



MacroPore Biosurgery, Inc. (NASDAQ: MPO) is focused on the discovery and development of regenerative medicine technologies. We have two technology platforms, bioresorbable technology and regenerative cell technology. Our surgical implants, derived from our bioresorbable technology, represent one of the latest advancements in spine and orthopedic medicine. They are manufactured by us and distributed exclusively through Medtronic Sofamor Danek. Within our regenerative cell technology program, we are developing a system to isolate autologous, homologous-use regenerative cells. Simultaneously, we are generating scientific knowledge through internal research to support the clinical use of these cells. Our most advanced research and development program is in the repair of cardiovascular tissues that are damaged after a heart attack. We are also researching applications in bone repair, spinal disc regeneration, and cosmetic and reconstructive surgery.

Regenerative Medicine is based on the human body's remarkable ability to partially repair itself after injury, disease, or trauma by directing a symphony of cells, proteins and growth factors at the point of injury. However, this ability diminishes with age and can result in scarred or incompletely healed tissue with reduced function. At MacroPore Biosurgery, we believe we can harness the body's own regenerative ability by designing novel products and systems that will facilitate and encourage healing by the body's natural repair components: cells, growth factors and scaffolds.

## 2003 Highlights

- CE Mark for HYDROSORB™ Telamon® and HYDROSORB™ Mesh resorbable lumbar spine cages in Europe
  - Expanded HYDROSORB™ spine and orthopedic product line with two new products
  - Initiated regenerative cell technology pre-clinical study to examine the effect of regenerative cells on damaged muscle tissue resulting from heart attack
  - CardioWrap™ Bioresorbable Film cleared by the FDA for the repair of the pericardium
  - SurgiWrap™ MAST Bioresorbable Sheet cleared by the FDA for minimizing tissue attachment to the device
  - Awarded a U.S. patent (No. 6,531,146) for the Company's bioresorbable thin film for preventing formation of scar tissue at a postsurgical site
  - Entered into an agreement to sell bioresorbable thin film product line
  - Appointed E. Carmack Holmes, MD, Professor, Division of Thoracic Surgery, David Geffen School of Medicine, UCLA, to the board of directors
- 

## 2004 Expected Milestones

### First Half

- Receive \$5 million payment from Medtronic for the completion of the Faster Resorbing Polymers evaluation
- Announce pre-clinical study results using adipose-derived regenerative cell technology for repair of cardiac muscle
- Receive award of \$750,000 for Phase II of an NIH SBIR grant
- Finalize the sale of bioresorbable thin film product line
- Announce publication of 12 scientific papers citing HYDROSORB™ products in *Neurosurgical Focus* demonstrating up to 32 months of clinical follow-up
- Receive CE Mark approval for HYDROSORB™ Boomerang® for interbody fusion

### Second Half

- Receive \$1.0 - \$2.0 million milestone payment from Medtronic on the transfer of know-how related to the CMF product line sale
- Enter into a commercialization agreement for SurgiWrap™ in Japan
- Launch bioresorbable cervical graft containment plate
- Expand HYDROSORB™ family of bioresorbable spine and orthopedic products in Europe
- Finalize the engineering design of autologous tissue harvesting and processing system for regenerative cells

## **Dear Shareholders,**

Regenerative medicine is coming! Significant financial and human resources are being invested in regenerative medicine at many academic and research institutions around the world. In fact, for 2003, there was a dramatic increase in the number of peer-reviewed journal articles and medical conference abstracts demonstrating the promise and progress of regenerative medicine therapies. We see this trend only accelerating as regenerative medicine becomes a clinical reality. In the midst of this excitement, we continued to execute on our goal to become the leader in regenerative medicine.

We continued to successfully execute our strategy as demonstrated by our financial performance, regulatory track record and product development success over the past three years. Key financial metrics, including revenues and gross margins, continue to strengthen. To build for the future, we are investing in both of our technology platforms to aggressively expand our product pipeline. Most importantly, we are continuing to help doctors treat patients. By year end 2003, physicians had implanted more than 500,000 of our bioresorbable products into patients.

Financially, it was our strongest year to date. Since 2001, we have increased revenues at an average annual rate of 58% and, in 2003, we achieved record product revenues and 70% gross margins. Importantly, during this period, net loss as a percentage of sales declined from nearly 198% in 2001 to 66% in 2003. We expect to continue these trends in 2004 based on the growing demand for our bioresorbable spine and orthopedic implants buoyed by the demographics of an aging population.

To capitalize on the opportunity in regenerative medicine, we have adopted a product design and development philosophy that is as practical as it is innovative. For example, our spine and orthopedic products provide a framework for bone regeneration and, in the European market, have unique synergies with Medtronic Sofamor Danek's bone growth protein, INFUSE®. Furthermore, our regenerative cell technology is an attempt to harness the body's own specialized cells to repair damaged organs and tissues. We are engineering and



developing a regenerative cell technology system to facilitate this process in a point-of-care setting. Simultaneously, our scientists are performing pre-clinical studies examining the potential of regenerative cells to treat a variety of serious diseases.

Strategically, we have married this technology development philosophy to a commercialization approach that targets the high growth and demographically advantaged markets of orthopedics, spine and cardiovascular disorders. In addition, we intend to form partnerships related to our two platform technologies to accelerate and broaden clinical development.

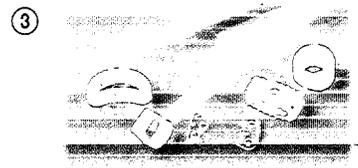
Looking forward to 2004, we expect to advance the development of our regenerative cell technology system to support its future use in cardiovascular disease, spine and disc regeneration and cosmetic and reconstructive surgery. Additionally, we plan to strengthen our bioresorbable-based product offerings as our technology continues to bring products from the development stage to the market.

MacroPore Biosurgery is in a unique position. By virtue of two exciting technology platforms and a growing revenue base, we offer physicians and their patients promising new medical technologies and our investors an opportunity to participate in the promise of regenerative medicine.

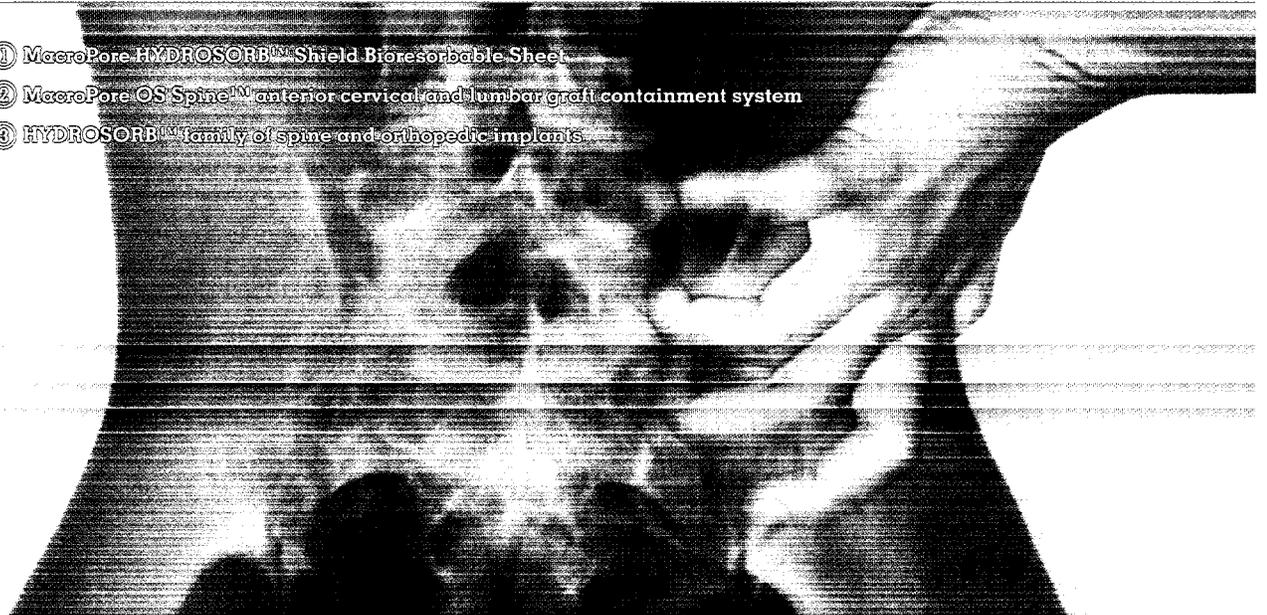
Christopher J. Calhoun

Chief Executive Officer

Vice Chairman of the Board of Directors



- ① MacroPore-HYDROSORB<sup>™</sup> Shield Bioresorbable Sheet
- ② MacroPore OS Spine<sup>™</sup> anterior cervical and lumbar graft containment system
- ③ HYDROSORB<sup>™</sup> family of spine and orthopedic implants



## Bioresorbable Technology

MacroPore Biosurgery understands that regenerating damaged tissue and restoring function often requires devices that are both biologically and biomechanically active. This belief has led to the development of our platform of bioresorbable containment devices, which represent some of the latest innovations in the \$20 billion spine and orthopedic industry. In Europe, for example, these products provide the biomechanical stability required in spinal fusion procedures during the early healing phase and then later transfer the loading force to the newly regenerated bone. These devices ultimately disappear, leaving no artificial implant or foreign material behind, resulting in true bone regeneration.

Our flagship product line is the HYDROSORB™ family of spine and orthopedic implants. They are manufactured at our San Diego facility and marketed exclusively through Medtronic Sofamor Danek, the dominant company in the spinal implant industry. In 2003, the first full year of commercialization, HYDROSORB™ products became the major contributor to our revenue growth. This success is attributed to a significant increase in physician demand coupled with the strength of Medtronic Sofamor Danek's distribution network.

The HYDROSORB™ implants have FDA clearance in the United States for graft containment when used with rigid fixation. In addition, MacroPore Biosurgery holds the first CE Mark for lumbar

**"We have developed three bioresorbable product lines consisting of over 600 products with 44 regulatory clearances and approvals for spinal surgery, orthopedic trauma, and other musculoskeletal applications in the United States and abroad. Two of the product lines have been divested to raise money and advance our R&D. The clinical experience with our products has been extremely favorable, and there are now more than 20 medical journal publications documenting extensive pre-clinical research studies, as well as long term clinical evidence of safety and effectiveness."**

*Sharon Schulzki, Chief Operating Officer, MacroPore Biosurgery, Inc.*



spinal interbody fusion procedures using a resorbable cage. HYDROSORB™ implants provide the early and intermediate stability required for healing, but without the potential long-term complications of metal, such as stress shielding or migration. They are also the first bioresorbable alternative to allograft cadaver bone implants, offering safe and predictable performance, while eliminating the disadvantages of disease transmission and unreliable supply issues.

Growth of our spine and orthopedic products in 2004 will be driven by our dynamic working relationship with Medtronic Sofamor Danek. We will be particularly focused on expanding and communicating the clinical evidence supporting the potential benefits of using HYDROSORB™ in combination with Medtronic Sofamor Danek's bone growth protein, INFUSE®, to the European medical community. Our long-term growth strategy is to identify clinical synergies that benefit from the combined use of regenerative cells and bioresorbable mechanical support.

## Regenerative Cell Technology

MacroPore Biosurgery is actively developing regenerative cell technologies. Our approach is unique in that we use adipose (fat) tissue as the source of regenerative cells. This proprietary technology platform presents an important opportunity for us to provide comprehensive regenerative medicine technologies to doctors to treat their patients when and where regenerative cells are needed. MacroPore Biosurgery has a distinct ability to provide this level of technology and service to the medical community.

Cells capable of regenerating organs and tissues are the cornerstone of regenerative medicine. The scientific and medical communities have now accepted that there are regenerative cells in each of us that can be used therapeutically. Through the use of the body's own regenerative cells, we can avoid the use of controversial sources of regenerative cells such as embryonic stem cells.

Parallel development programs are underway in order to make this therapeutic technology available as soon as possible to the medical community. First, we are engineering systems to make a patient's own adipose-derived regenerative cells available to them at the point-of-care. Second, through research performed both internally and by academic groups around the world, we are gathering the scientific and pre-clinical knowledge to support the use of these cells to treat many serious diseases. Finally, we are developing and beginning the commercialization of adipose-derived regenerative cell preservation services to support the broad adoption of regenerative cell technologies.



**"Our strategy in regenerating damaged tissues, though seemingly simple, is based on a sophisticated knowledge of cell biology and clinical medicine. We now know that the body contains the raw materials to heal and repair itself. Our job is to remove the barriers preventing regeneration and identify ways to facilitate the process that will ultimately be embraced by doctors and patients."**

*Marc H. Hedrick, MD, President, MacroPore Biosurgery, Inc.*

Bringing regenerative cell technologies to the market begins with a sophisticated system to automate and simplify the technically complex process of isolating regenerative cells from adipose tissue. We intend to offer these systems to hospitals and clinics, providing physicians the ability to access the patient's own adipose-derived regenerative cells.

The first system in our pipeline is being designed specifically for use in cardiovascular disease. Subsequently, we intend to develop systems for other opportunities including bone and spinal disc regeneration, and cosmetic and reconstructive surgery.

In the future, cell preservation will be an important part of providing comprehensive regenerative medicine treatments to patients. We are a leader in this area, having developed the world's first commercially licensed program for banking adipose-derived regenerative cells. We are now in the process of building on this expertise and working toward expanding this service into new markets.



Macropore Biosurgery envisions a three-step process for the homologous use of autologous, adipose-derived cells:

- ① Harvesting of adipose tissue;
- ② Isolation of regenerative cells from the adipose tissue; and
- ③ Delivery of regenerative cells to the injured tissue to facilitate regeneration.

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-32501

### MACROPORE BIOSURGERY, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE  
(State or Other Jurisdiction  
of Incorporation or Organization)

33-0827593  
(I.R.S. Employer  
Identification No.)

6740 TOP GUN STREET, SAN DIEGO, CALIFORNIA  
(Address of principal executive offices)

92121  
(Zip Code)

Registrant's telephone number, including area code: (858) 458-0900

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

Securities registered pursuant to Section 12(g) of the Act:  
Common stock, par value \$0.001

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

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

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2003, the last business day of the registrant's most recently completed second fiscal quarter was \$43,281,045 based on the average of the reported high and low sales price of the registrant's common stock on June 30, 2003 as reported on the Frankfurt Stock Exchange, of 3.22 Euros, or \$3.68 per share, based on the exchange rate in effect as of such date.

As of January 31, 2004, there were 13,932,460 shares of the registrant's common stock outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2004 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the year ended December 31, 2003, are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14 of this Form 10-K.

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**Item 1. Business****General**

MacroPore Biosurgery, Inc., (MacroPore) was initially formed as a California general partnership in July 1996, and incorporated in the State of Delaware in May 1997.

We are focused on research, development and commercialization of regenerative medicine technologies. We have two principal technology platforms: bioresorbable technology and regenerative cell technology, with which we currently target two of the largest markets in medicine, spine and orthopedic bone repair and cardiovascular tissue repair.

To date, we have introduced three bioresorbable product lines that are marketed in the United States, Canada, Europe and other countries. These product lines include:

1. Spine and orthopedics surgical implants (includes HYDROSORB™ bioresorbable product families), which address surgical procedures including graft containment for spinal and other musculoskeletal applications and are marketed by Medtronic Sofamor Danek, a division of Medtronic, Inc. (Medtronic);
2. Thin films surgical implants (includes SurgiWrap™ bioresorbable products), which are used for soft tissue indications and;
3. Craniomaxillofacial “CMF” surgical implants, which consists of bioresorbable bone fixation implants for the face and skull, and associated instruments and accessories.

The CMF product line was sold to Medtronic Neurologic Technologies, a division of Medtronic, Inc., (Medtronic), in 2002; and we have agreed to sell our bioresorbable thin film product line (with certain exclusions) to Medicis Ventures Management GmbH in 2004.

Additionally, we are conducting research and development for an autologous cell-based technology for the regeneration and repair of damaged tissues. We are currently targeting the repair of heart and vascular tissues that are damaged after a myocardial infarction (heart attack) and other diseases.

*Bioresorbable Technology*

Our bioresorbable implants are made from a polylactide copolymer composed of lactic acid similar to that which occurs naturally in the human body. The polymer implant maintains its strength during the healing process, while slowly breaking down in the body through hydrolysis. The polymer fragments into single lactic acid molecules, and the lactic acid molecules are then metabolized by the liver into carbon dioxide and water, and released from the body through the lungs.

By polymerizing lactic acid and taking advantage of thermoplastic properties, we can create bioresorbable products that can be easily shaped, sized and applied to varying anatomical structures. We believe the benefits of using a bioresorbable material in bone healing and regenerative applications include:

- Provides initial and intermediate stability during healing
- Eliminates long-term complications with metal implants related to stress shielding or migration
- Avoids the disadvantages of radiographic interference typically encountered with metallic implants
- Provides a bone / implant interface without an intervening fibrous tissue layer
- Eliminates the disadvantages of unpredictable bone remodeling in comparison to allograft (cadaver) bone
- Eliminates issues related to risk of disease transmission and limited supply, as well as the public perception issues associated with the use of allograft tissue

The spine and orthopedic bioresorbable implant product line, which includes HYDROSORB™, was introduced in 2002 by our distribution partner Medtronic Sofamor Danek and became our leading product line that same year. It consists of five unique surgical implants, which accounted for a majority of our product revenues in 2003. The products have

received FDA clearance in the United States for certain graft containment applications, and have received the CE Mark in Europe for spinal interbody fusion procedures. The products are manufactured by us and distributed exclusively through Medtronic Sofamor Danek.

The spine and orthopedic product line resulted from a Development and Supply Agreement that we entered into with Medtronic in January 2000. The agreement was to co-develop bioresorbable implants for use in spinal fixation, stabilization and fusion applications and supply any such new implants to Medtronic Sofamor Danek as the distributor. We amended the agreement in 2002 extending the term to 2012.

We have also developed and brought to market the thin films product line, which includes the SurgiWrap™ and CardioWrap™ families of bioresorbable surgical thin films. In 2001 we received our first regulatory clearances from the FDA to market our SurgiWrap™ bioresorbable film for reinforcement of soft tissues and as a bridging material where indicated. Some of the uses include, but are not limited to, repair of fascial defects including vaginal prolapse repair, colon and rectal prolapse repair, and reconstruction of the pelvic floor.

In 2003, we started to shift our strategy for the commercialization of bioresorbable thin films away from a direct sales force toward a distributor sales representative model in the United States. 2003 also saw expansion of regulatory claims, which included:

- MacroPore SurgiWrap™ MAST Bioresorbable Sheet to support and reinforce soft tissues and to minimize tissue attachment to the device in case of contact with the viscera (organs of the body)
- MacroPore CardioWrap™ Surgical Bioresorbable Film to repair the pericardium in patients that may require reoperation within 6 months

On December 13, 2003 we entered into an agreement with Medicis Ventures Management GmbH to sell substantially all the assets of our bioresorbable thin film product line for \$7,000,000 cash at closing, a secured one-year note for \$5,000,000, and a \$200,000 milestone payment for a specific regulatory approval. In addition, we would receive a nonexclusive, perpetual, worldwide, royalty-free license to the thin film technology for the regenerative-medicine field of use, and a worldwide exclusive, royalty-free license to thin-polymeric-film implants for spinal surgery, and the parties would enter into a temporary business development and revenue sharing agreement for the territory of Japan. We also agreed to act as Medicis' back-up supplier of the thin film bioresorbable implant products for one year after the closing of the sale of the product line.

In September 2002 we sold substantially all of the assets of our CMF product line to Medtronic, and granted them an exclusive license to certain related intangible assets, along with exclusive rights to the use of our bioresorbable implants for repair of the bone harvest site in the iliac crest. In addition, we provided them the right to use our new faster-resorbing polymer (FRP) bioresorbable implant system when development is complete, and granted them access to relevant improvements in the technology for a period of five years. In February 2004, we completed and received payment on a successful 20-patient, 12-month study related to the FRP system entitling us to a \$5,000,000 milestone payment related to the sale of the CMF business unit to Medtronic in 2002.

In February of 2004 we received a \$5,000,000 payment for successfully completing a 12-month, 20-patient analysis of new faster-resorbing polymer (FRP) CMF products, which brings the total amount received under the agreement to \$19,000,000. Of this, \$4,000,000 was used to purchase a waiver of the right of first offer to market our bioresorbable films in certain fields from Medtronic. We expect to receive the last remaining milestone payment between \$1,000,000 and \$2,000,000 in 2004 upon the successful transfer of manufacturing know-how to Medtronic Neurologic Technologies. We do not expect to receive significant back-up supplier-related revenues from Medtronic Neurologic Technologies after the second quarter of 2004.

We are also developing additional products for use in spinal fusion / reconstruction procedures among other things. These future products may require further development and regulatory clearance or approval, potentially including clinical trials, prior to marketing and commercial use.

In 2003 we began development of a medical system to process autologous adipose (fat) tissue. This system could potentially allow physicians to isolate, concentrate and deliver regenerative cells at the point-of-care for multiple tissue-specific medical applications. These research applications include, peripheral vascular disease, cardiovascular tissue repair, bone regeneration, wound healing, and soft tissue augmentation. Our primary research focus is the repair of cardiovascular tissues that are damaged after a myocardial infarction.

Our approach is based on research findings which indicate that adipose (fat) tissue is a rich source of regenerative cells. These cells have demonstrated in preclinical research that they have the ability to repair injured tissues. Regenerative cells from adipose tissue are of three primary kinds: adult stem cells, endothelial progenitor cells and growth factor producing cells. We acquired access to this technology and the underlying intellectual property in 2002, when we purchased StemSource, Inc. (StemSource), a company that specialized in bioengineering research and technology.

Adipose-derived regenerative cells possess many advantages over other cell therapy and stem cell technologies. We believe the prospective benefits of using cells derived from adipose tissue for the regeneration of one's own tissue include:

- A demonstrated ability to differentiate into a variety of tissues, *in vitro*
- Adipose tissue is expendable and accessible
- Potential benefits could encompass a variety of medical applications
- By using one's own cells, the recipient can avoid the problems of disease transmission and rejection associated with donor tissue

The acquisition of StemSource has also provided us a California state-licensed tissue bank facility for the preservation of extracted regenerative cells. Typically arranged through a patient's physician, cell banking is the process by which regenerative cells, taken from a liposuction or other procedure, are stored (cryopreserved) in a liquid nitrogen freezer at -320°F (-196°C) exclusively for the particular patient who banked them. The banked cells, frozen in suspended animation, can be preserved for the life of the individual.

## **Products and Services**

We manufacture our bioresorbable implant products solely in the United States at our San Diego facility. We have not yet developed regenerative cell related products or services for commercial use except for our cell banking service, which is being offered on a limited basis, to surgical patients undergoing liposuction procedures.

We currently market our bioresorbable technology product lines in the United States, Europe and/or other countries for the repair and regeneration of tissue. All HYDROSORB™ branded products are manufactured by us and distributed exclusively by Medtronic Sofamor Danek. HYDROSORB™ is a trademark of Medtronic. We provide a range of support services to our customers, to distributors and to surgeons including:

- Producing promotional, educational and instructional materials and literature
- Producing scientific publications
- Demonstrating our products
- Training at our San Diego headquarters
- Teaching regional and on-site training seminars and symposia
- Providing support personnel to advise surgeons during surgery on the use of our products

## Plan of Operation

During 2004, we intend to focus our efforts on:

- Expanding the portfolio of MacroPore Biosurgery products sold by Medtronic Sofamor Danek,
- Driving technology adoption through increased clinical evidence demonstrating the advantages of bioresorbable products over metal and allograft
- Achieving revenue gains in Europe from potential synergistic use of HYDROSORB™ in combination with Medtronic's bone growth protein, INFUSE®
- Determining the optimal methods for separating and handling regenerative cells derived from adipose tissue
- Determining the optimal methods of delivery and dosages of our adipose-derived regenerative cells
- Expanding collaborations and agreements with academic and corporate researchers engaged in regenerative medicine research
- Applying for additional research grants through the National Institutes of Health (NIH) through the Small Business Innovation Research (SBIR) program
- Developing strategic partnerships with companies in markets that would benefit from our regenerative cell platform
- Continuing preclinical research to advance toward clinical studies
- Developing a commercial system for therapeutic application of adipose derived regenerative cells

## Research and Development

Our bioresorbable research and development team is focused on developing bioresorbable devices, processes, and technologies that facilitate the repair and regeneration of bone and other tissues. Additional biomaterials research will target differing resorption rates, strength profiles, designs, and handling characteristics for various soft tissues, spinal, orthopedic, and other musculoskeletal applications.

In 2003, our biomaterials research and development efforts resulted in expanded applications of our bioresorbable thin film products, as well as several new spine and reconstructive products in conjunction with our distributor Medtronic Sofamor Danek. Much of our ongoing biomaterials research and testing is focused on mechanical property and polymer characterization for better understanding of the performance of our new and existing products.

Through the acquisition of StemSource, in 2002, we began our focus on regenerative cell research and technology including ongoing development of proprietary methods for using adipose-derived regenerative cells clinically. Potential clinical applications for these adipose-derived regenerative cells include cardiac and vascular healing, bone healing and regeneration, and plastic and reconstructive surgery, and many others. In addition to our ongoing regenerative cell research, we are developing an integrated system for extracting, concentrating, and delivering therapeutic regenerative cells to patients. These have been the primary focus areas of our Regenerative Cell Technology (formerly "Biologics") research group in 2003. We have also developed and established a licensed tissue bank that is being used for the long-term storage and preservation of regenerative cells, a service we offer through a network of participating surgeons in the U.S.

Notable research and development accomplishments of our Regenerative Cell Technology group in 2003 include:

- Significant advances in our understanding of the functionality of regenerative cells in myocardial (heart) injury applications
- Development of a quantitative assay test for adipose tissue-derived regenerative cells
- Optimization of Regenerative Cell Processing

- Significant progress in the development of an integrated cell extraction and processing system
- Applied for and awarded a \$100,000 research grant for our regenerative cell research from the National Institutes of Health (NIH) through the Small Business Innovation Research (SBIR) program. We have additional applications pending through the SBIR program
- Participation in sponsored research programs with University of California, Los Angeles (UCLA) and Cedars-Sinai Medical Center, both in Los Angeles, California
- Addition of a histology research and cell analytics group to support preclinical programs

In 2003 we relocated our StemSource laboratory, staff and equipment to San Diego. We have made considerable investments in new facilities, equipment and personnel during the year as well. We have added full time scientists, laboratory assistants, and engineers to the research and development team. In early 2004 we added additional support personnel including an in-house patent attorney to the group.

## **Customers**

Medtronic is our primary distributor and our principal customer, directly accounting for \$12,893,000 or 91.5%, \$8,605,000, or 93.9% and \$5,547,000, or 98.2% of our revenues for the years ended December 31, 2003, 2002 and 2001, respectively. We also sell some of our products directly to end users, hospitals and internationally through distributors.

We entered into a five-year distribution agreement and a five-year development and supply agreement with Medtronic in January 2000. Under the distribution agreement, Medtronic agreed to purchase all of its bioresorbable implant products for use in the reconstruction or fixation of the craniomaxillofacial (skull and face) bones, exclusively from us. In turn, we granted Medtronic exclusive rights in the United States and exclusive rights worldwide, except for rights granted under our then-existing distribution agreements with other distributors, to market, distribute and sell all of our bioresorbable implant products, devices, systems and instruments solely for use in the reconstruction or fixation of the cranial or facial skeleton. Under this distribution agreement with Medtronic, we were allowed to enter into a distribution agreement with another distributor for distribution rights to any of our products other than those used in the cranial or facial skeleton, as long as we first presented Medtronic with the right to distribute these other products. If we failed to come to terms with Medtronic, or if Medtronic did not wish to distribute these other products, we were allowed to enter into a distribution agreement with a third party distributor on the same or more favorable terms than those we offered to Medtronic.

Under our development and supply agreement, we co-develop bioresorbable implants with Medtronic for spinal or reconstructive fixation, stabilization and fusion. Medtronic has exclusive worldwide rights to market and sell all of the products that we co-develop. We and Medtronic will each own an undivided, one-half interest in any inventions we jointly develop.

In September 2002 we sold substantially all of the assets of our CMF product line to Medtronic, and granted them an exclusive license to certain related intangible assets, along with exclusive rights to the use of our bioresorbable implants for repair of the bone harvest site in the iliac crest. In addition, we provided them the right to use our new faster-resorbing polymer (FRP) bioresorbable implant system when development is complete, and granted them access to relevant improvements in the technology for a period of five years. In February 2004, we completed and received payment on a successful 20-patient, 12-month study related to the FRP system entitling us to a \$5,000,000 milestone payment related to the sale of the CMF business unit to Medtronic in 2002.

Also in September 2002, Medtronic agreed to remove the contractual right of first offer for distributorship of our bioresorbable thin film products in various types of surgery outside of the spinal field. Medtronic continues to retain its right of first offer for distributorship to our other products in all fields until January 5, 2005, and our bioresorbable plates and mesh for orthopedic applications until January, 2006. In addition, we agreed to extend the term of our existing global co-development and supply agreement with Medtronic for spinal implants to 2012.

## **Thin Film**

During the summer of 2002, a direct sales force was recruited, trained, and placed in the field throughout the United States with a focus on introducing the SurgiWrap™ bioresorbable thin film products to the marketplace. Through their efforts, sales of the bioresorbable thin film products in the U.S. reached \$806,000 in 2003. A parallel effort was coordinated from Europe to organize a network of independent distributors to represent the bioresorbable thin film products outside of the

U.S. This distributor sales model generated \$361,000 sales in 2003.

In 2003, we started to shift our strategy for the commercialization of bioresorbable thin films away from a direct sales force toward a distributor sales representative model in the United States.

## **Market and Competition**

We compete with many other companies in developing and marketing our technology and products. In the spine and orthopedic market, we compete primarily with titanium products, although we believe that an increasing number of other companies are developing, or are offering, bioresorbable bone fixation systems. Stryker Inc. and Synthes are two companies that we are aware of who produce both bioresorbable and titanium implants. Additionally, surgeons have historically been slow to adopt the use of new medical device technologies as alternatives for long-established, well-marketed devices, such as metallic bone fixation methods.

We have not yet developed regenerative cell related products or services for commercial use except for our cell banking service, which is being offered on a limited basis, to surgical patients undergoing liposuction procedures. While we are not currently aware of any other provider of cell banking comparable to our own, there are various companies engaged in umbilical cord blood banking and bone marrow banking.

The field of regenerative cell technology and services is rapidly progressing, with many corporations and universities exploring the clinical potential. Most of these organizations are involved in stem cell research using sources other than adipose (fat) tissue such as: embryonic and fetal derived stem cells, and blood, bone marrow, muscle and skin derived adult stem cells.

We believe that adipose tissue is an ideal source of regenerative cells for therapeutic use due to the expendability and accessibility of adipose tissue, as well as the high yield and high quality of stem and other regenerative cells obtainable from this source. Many other cell sources are difficult to harvest and/or do not yield a high number. These sources also generally require the cells to be expanded in culture before clinical application. We are only aware of one other company, Cognate Therapeutics, that has any commercial program in adipose derived stem cells.

We are aware that several companies including Genzyme, Baxter, and BioHeart are currently involved in stem cell related clinical trials focused on myocardial infarction and congestive heart failure. Osiris Therapeutics and Aastrom are involved in clinical trials using cultured human mesenchymal stem cells. Baxter, Inc. is involved in a pilot clinical trial using blood-derived stem and progenitor cells. There are several other companies currently conducting preclinical research on potential stem cell therapies. We cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals, and manufacturing and marketing such products. Some of these competitors may obtain patent protection, approval or clearance by the FDA or from foreign countries, or may achieve product commercialization earlier than us, any of which could materially adversely affect our business or results of operations. We cannot be assured that our competitors will not succeed in developing alternative technologies and products that are more effective, easier to use or more economical than those which have been or are being developed by us or that would render our technology and products obsolete and noncompetitive in these fields. In addition, even if our products are technologically superior, it is possible that competitors' superior marketing power could defeat us in the marketplace. Furthermore, under the terms of our marketing agreement with Medtronic, Medtronic may pursue parallel development of other technologies or products, which may result in Medtronic developing additional products that will compete with our products.

## **Sales by Geographic Region**

We sell our products predominantly in the United States and to a lesser extent internationally through independent distributors. International sales may be limited or disrupted by political instability, price controls, acts of war, trade restrictions and changes in tariffs. Our existing distribution agreements all provide for payment in U.S. dollars and we intend to include similar payment provisions in future distribution agreements. Fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products relative to the currency of the countries in which the products are sold.

For the year ended December 31, 2003, we recorded \$14,088,000 in revenues, including \$13,727,000 of product sales in the United States and \$361,000 of product sales outside the United States. For the year ending December 31, 2002, we recorded \$9,166,000 in revenues, including \$8,854,000 of product sales in the United States and \$312,000 of product sales outside the United States. For the year ending December 31, 2001, we recorded \$5,648,000 in revenues, including \$4,954,000 of product sales in the United States and \$694,000 of product sales outside the United States.

### **Working Capital**

We generally build products to order although for selected products we may from time to time maintain an inventory of approximately six to twelve months. Although capital expenditures may vary significantly depending on a variety of factors, including sales, we presently intend to spend approximately \$1,300,000 on capital equipment purchases in 2004 of which a portion may be paid with our current cash reserve.

### **Raw Materials**

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our products, from a single qualified source, B.I. Chemicals, Inc. Although we have a contract with B.I. Chemicals, which guarantees continuation of supply through August 15, 2005, we cannot guarantee that they will elect to continue the contract beyond that date, or that they will not elect to discontinue the manufacture of the material. They have agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide us with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Also, despite this agreement, they might fail to fulfill their obligations. Under the terms of the contract, B.I. Chemicals, Inc. may choose to raise their prices upon nine months prior notice which may also result in a substantially increased material cost. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates. Lack of adequate commercial quantities or inability to develop alternative sources meeting regulatory requirements at similar prices and terms within a reasonable time or any interruptions in supply in the future could have a significant negative effect on our ability to manufacture products, and, consequently, could have a material adverse effect on the results of our operations and financial condition.

### **Intellectual Property**

Our success depends in large part on our ability to protect our proprietary technology and information, and operate without infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends on our ability to obtain patents on our technology.

We have eight United States patents relating to four of our primary bioresorbable implant products and technology. We also have two Australian patents relating to our bioresorbable mesh, one Australian patent for the design of our high torque bioresorbable screws and another Australian patent related to our membrane with tissue guiding surface corrugations. Our three U.S. patents for the design of our macro-porous bioresorbable sheets were issued in July 1999 and August 2001. Our three U.S. patents for the design of our high torque bioresorbable screws were issued in August 2001, February 2002 and November 2002. Our U.S. patent related to our membrane with tissue guiding surface corrugations was issued May 2002. Our most recent U.S. patent issued on March 2003 and is related to our bioresorbable barrier film for the control of postsurgical adhesions. Our four Australian patents issued in August 2000, January 2003 and September 2003. Each of our patents will expire 20 years from the filing date of the original patent application.

We have filed applications for 37 additional United States patents, as well as 43 corresponding international patent applications, relating to our technology. As part of the StemSource acquisition we were granted certain exclusive and non-exclusive perpetual license rights to four U.S. patent applications and fourteen international patent applications through a license agreement with the Regents of the University of California. We cannot assure you that any of the pending patent applications will be issued, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, we cannot assure you that others will not independently develop similar products, duplicate any of our products or design around our patents.

Litigation may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark

Office to determine priority of invention. Any such litigation and/or interference proceedings, could result in substantial costs to us and divert our management's attention from our business operations, even if the eventual outcome is favorable to us. Litigation could subject us to significant liabilities to third parties and require disputed rights to be licensed from third parties or require us to cease using certain technology.

Patent law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries may not protect our proprietary rights to the same extent as the laws of the U.S. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the U.S. It may be necessary or useful for us to participate in proceedings to determine the validity of our, or our competitors' patents that have been issued in countries other than the U.S. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. We cannot assure you that others will not independently develop or otherwise acquire substantially equivalent techniques, or otherwise gain access to our trade secrets and proprietary technological expertise or disclose such trade secrets, or that we can ultimately protect our rights to such unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors. Our failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on our results of operations and financial condition.

### **Government Regulation**

Most medical devices for use in humans, including our bioresorbable protective sheets, plates, screws and tacks, are subject to stringent government regulation in the United States by the Food and Drug Administration, or "FDA," under the federal Food, Drug and Cosmetic Act, or "FDC" Act. The FDA regulates the clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices. Included among these regulations are premarket clearance, premarket approval, and Quality System Regulation, or "QSR," requirements. Other statutory and regulatory requirements govern, among other things, registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and postmarket reporting. The regulatory process may be lengthy, expensive and uncertain. Securing FDA approvals and clearances may require us to submit extensive clinical data and supporting information to the FDA. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusal to approve or clear new applications or notifications, and criminal prosecution.

Under the FDC Act, medical devices are classified into Class I, Class II or Class III devices, based on their risks and the control necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls such as labeling, premarket notification and adherence to QSR requirements. Class II devices are subject to general controls, and may be subject to specific controls such as performance standards, postmarket surveillance and patient registries. Class II devices require premarket notification to the FDA in the form of a 510(k) application that demonstrates the new device to be "substantially equivalent" to an existing FDA 510(k) cleared device. Generally, Class III devices, which include certain life-sustaining, life-supporting and implantable devices or new devices which have been found not to be substantially equivalent to certain legally marketed devices, must receive premarket approval from the FDA. All of our implant products to date are Class II medical devices.

Before any new Class II or III medical device may be introduced to the market, the manufacturer generally must obtain either premarket clearance through the 510(k) premarket notification process or premarket approval through the lengthier Premarket Approval Application, or "PMA," process. The FDA will grant a 510(k) premarket notification if the submitted data establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device. The FDA may request data, including clinical studies, before it can make a determination of substantial equivalence. It generally takes from three to 12 months from submission to obtain 510(k) premarket clearance, although it may take longer. There is no assurance that clearance will be granted. We must file a PMA if one of our products is found not to be substantially equivalent to a legally marketed Class II device or if it is a Class III device for which the FDA requires PMAs. A PMA must be supported by extensive data to demonstrate the safety and effectiveness of the device, including laboratory, preclinical and clinical trial data, as well as extensive manufacturing information. Before initiating human clinical trials on

devices that present a significant risk, we must first obtain an Investigational Device Exemption, or IDE, for the proposed medical device. Obtaining FDA approval of the Investigational Device Exemption allows the sponsor to begin the collection of clinical data according to a protocol that must be approved by the FDA. Several factors influence the overall time frame of the IDE process. These include: the number of patients required for statistical significance, the requirement for a pilot (safety) study in advance of initiating a pivotal study, and the duration of follow-up required before the IDE can be closed and the PMA prepared for submission to FDA. This follow-up period typically ranges from 12-24 months on the last patient to be enrolled in the study. Toward the end of the PMA review process, the FDA will generally conduct an inspection of our manufacturing facilities to ensure compliance with QSRs. Approval of a PMA could take up to one or more years from the date of submission of the application or petition, however, the entire process of IDE submission /approval, clinical data collection, patient follow-up, PMA preparation and approval typically requires 4 years or more. The PMA process can also be expensive and uncertain, and there is no guarantee of ultimate approval.

Modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

As a medical device manufacturer, we are subject to periodic inspections by the FDA to ensure that devices continue to be manufactured in accordance with QSR requirements. We are also subject to postmarket reporting requirements for deaths or serious injuries when a device may have caused or contributed to 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. Postmarket reporting also may be required for certain corrective actions undertaken for distributed devices. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing of devices for indications or uses that have not been cleared or approved by the FDA.

Under the terms of our development and supply agreement with Medtronic, Medtronic is responsible for preparing and filing applications for, and obtaining regulatory approval of the products we co-develop for use in spinal fixation, stabilization or fusion applications. We or our marketing partners may not be able to obtain necessary 510(k) clearances or PMA approvals to market the products we are developing in the United States for their intended use on a timely basis, if at all.

Product lines marked by an asterisk (\*) have been sold to Medtronic PS Medical for all craniomaxillofacial (skull and face) bone fixation and iliac crest (hip bone) reconstruction purposes. We temporarily serve as a back-up supplier of these products to Medtronic. We retain the rights to these products for all other purposes, though many of these products will not have any significant application for us outside of the field of use for which they were sold.

Our current medical devices are at different stages of FDA review. We have received 510(k) clearance for the following:

<u>Product Lines</u>	<u>Clearance received for, among other things, the following uses:</u>	<u>Clearance received</u>
MacroPore FX™*	trauma and reconstructive procedures in the midface and craniofacial skeleton	July 1998
MacroPore PS*	trauma and reconstructive procedures in the midface and craniofacial skeleton	July 1998
MacroPore PS*	trauma, and reconstructive procedures of the mandible and maxilla when used in conjunction with rigid fixation	March 1999
MacroPore DX*	for temporary stabilization and gradual lengthening of cranial and midface bones	June 2000
MacroPore OS™*	bone graft containment in the iliac crest, or hip bone, graft donor sites, tumor resections where bone strength is not compromised and throughout the skeleton, other than in spinal applications, when used in conjunction with traditional rigid fixation devices	July 2000
MacroPore MX™*	stabilizing fractured bones in the mandible when used in conjunction with maxillomandibular fixation	October 2000

MacroPore NS™*	fixation of bone flaps after a craniotomy	May 2001
MacroPore OS Spine™	when used in conjunction with traditional rigid fixation; utilized in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts	July 2001
MacroPore IB	a cement restrictor in the femur, tibia, and humerus	September 2001
MacroPore FX™*, PS*, NSTM* and LPTM*	general and specific pediatric and adult trauma and reconstructive bone fixation and bone graft containment procedures of the midface and craniofacial skeleton	September 2001
HYDROSORB™ CR	a cement restrictor in the femur, tibia and humerus	September 2001
MacroPore ENT Reconstruction Film	adhesion prevention between the septum and the nasal cavity; tympanic membrane repair; tympanoplasty in the middle ear; nasal splinting and surgical repair of nasal septum; guided tissue regeneration of the external ear	October 2001
MacroPore SurgiWrap™	for temporary wound support, to reinforce soft tissues where weakness exists, for the repair of hernia or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result, including but not limited to vaginal prolapse repair, colon and rectal prolapse repair, and reconstruction of the pelvic floor	December 2001
MacroPore OS™ Trauma	bone graft containment in the iliac crest, or hip bone, ribs, graft donor sites, tumor resections where bone strength is not compromised and throughout the skeleton, other than in spinal applications, when used in conjunction with traditional rigid fixation devices	July 2002
HYDROSORB™ Mesh	to maintain the relative position of weak bony tissue in orthopedic procedures when used in conjunction with rigid fixation and for iliac crest / rib reconstruction	July 2002
CORNERSTONE™ HSR	to maintain the relative position of weak bony tissue in orthopedic procedures when used in conjunction with rigid fixation and for iliac crest / rib reconstruction	July 2002
HYDROSORB™ TELAMON®	to maintain the relative position of weak bony tissue in orthopedic procedures when used in conjunction with rigid fixation and for iliac crest / rib reconstruction	July 2002
MacroPore SurgiWrap™ surgical barrier film	to cover orbital implants used in enucleation surgery and to protect the surrounding orbital tissue from the surface of the implant	January 2003
MacroPore SurgiWrap™ MAST Bioresorbable Sheet	to support and reinforce soft tissues. To minimize tissue attachment to the device in case of contact with the viscera (organs of the body)	September 2003
MacroPore CardioWrap™ Surgical Bioresorbable Film	To repair the pericardium in patients that may require reoperation within 6 months	September 2003

CORNERSTONE, HYDROSORB and TELAMON are trademarks of Medtronic, Inc. All other trademarks are owned by us.

In addition, we must obtain marketing authorization for our products that we market in Europe, Canada and certain other non-U.S. jurisdictions. We have received marketing authorization for the sale of our products in the following countries:

Country	Indications received for, among other things, the following uses:	Clearance received
European Community	MacroPore FX™, MacroPore PS, MacroPore NS™, and MacroPore DX products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system.	December 1999
	MacroPore FX™, MacroPore PS, MacroPore NS™, MacroPore DX, and MacroPore LP™ products indicated to fixate non-load bearing fractures in the midface and /or craniofacial skeleton with specific indications for Le Fort procedures along with craniosynostosis, congenital malformation, tumor reconstructions, bone grafting procedures, and midface distraction indications.	March 2002
	MacroPore SurgiWrap™ products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system.	March 2002
	<p>MacroPore SurgiWrap™, CardioWrap™ bioresorbable adhesion barrier film as a temporary physical barrier to separate opposing tissues and prevent the in growth of scar tissues and the formation or reformation of adhesions immediately adjacent to the barrier film; aid in reoperation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the barrier film; prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane to include the following anatomical regions:</p> <ol style="list-style-type: none"> <li>a) Pericardium, epicardium, and retrosternal</li> <li>b) Peritoneum, peritoneal cavity, bowels, cecum, organs</li> <li>c) Dura, spinal dura, peridural, epidural</li> <li>d) OB/GYN (e.g. female pelvic, reproductive organs, ovaries, uterus, uterine tubes, etc.)</li> </ol>	May 2002
	for temporary wound support, to reinforce soft tissues where weakness exists, for the repair of hernia or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result, including but not limited to vaginal prolapse repair, colon and rectal prolapse repair, and reconstruction of the pelvic floor	
	MacroPore HYDROSORB™ TELAMON® and MacroPore HYDROSORB™ Mesh to promote spinal fusion in the lumbar spine by maintaining the relative position of bone graft material and/or growth factors by assisting in maintaining the space between adjacent vertebral bodies in the treatment of spinal disorders such as degenerative disc disease, disc herniation, scoliosis, failed previous surgeries, etc.	January 2003
MacroPore OS™ is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPore OS Protective sheet is also indicated for cement restriction in total joint arthroplasty procedures. Only when used in conjunction with traditional rigid fixation, the MacroPore OS System is intended to maintain the relative position weak bony tissue in trauma and reconstructive orthopedic procedures involving:	July 2003	
<ul style="list-style-type: none"> <li>• Long bones</li> <li>• Flat bones</li> <li>• Short bones</li> <li>• Irregular bones</li> <li>• Appendicular skeleton</li> <li>• Thorax</li> </ul>		
When used alone (without traditional rigid fixation), the MacroPore OS System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving:		

- Tumor resections where bone strength has not been compromised
- Iliac crest harvests
- Ribs

This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

Canada	MacroPore FX™ and MacroPore PS products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system	December 1999
	MacroPore SurgiWrapi™, CardioWrapi™ bioresorbable adhesion barrier film as a temporary physical barrier to separate opposing tissues and prevent the in growth of scar tissues and the formation or reformation of adhesions immediately adjacent to the barrier film; aid in reoperation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the barrier film; prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane to include the following anatomical regions:	February 2003
	<ul style="list-style-type: none"> <li>a) Pericardium, epicardium, and retrosternal</li> <li>b) Peritoneum, peritoneal cavity, bowels, cecum, organs</li> <li>c) Dura, spinal dura, peridural, epidural</li> <li>d) OB/GYN (e.g. female pelvic, reproductive organs, ovaries, uterus, uterine tubes, etc.)</li> </ul>	
	and for temporary wound support, to reinforce soft tissues where weakness exists, for the repair of hernia or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result, including but not limited to vaginal prolapse repair, colon and rectal prolapse repair, and reconstruction of the pelvic floor	
Malaysia	Same as Canada for MacroPore FX™ and PS only	June 2000
Singapore	Same as Canada for MacroPore FX™ and PS Same as Canada for SurgiWrap™ and CardioWrap™	November 2000 December 2003
South Korea	Same as USA for MacroPore FX™ and PS	January 2001
	Same as USA for SurgiWrapi™	December 2002
Australia	Same as Canada for MacroPore FX™ and PS	March 2001
	Same as Canada for SurgiWrapi™ and CardioWrapi™	November 2002
Thailand	Same as Canada for SurgiWrapi™ and CardioWrapi™	January 2003
China	Same as USA for FX™ and PS	June 2002

CORNERSTONE, HYDROSORB and TELAMON are trademarks of Medtronic, Inc. All other trademarks are owned by us.

In addition, we have submitted applications for authorizations to market our products in several other countries.

We must comply with extensive regulations from foreign jurisdictions regarding safety, manufacturing processes and quality. These regulations, including the requirements for marketing authorization, may differ from the United States FDA regulatory scheme. Under the terms of our distribution agreements, our distributors are generally responsible for obtaining the necessary approvals.

We may not be able to obtain marketing authorization in all of the countries where we intend to market our products, may incur significant costs in obtaining or maintaining our foreign marketing authorizations, or may not be able to successfully commercialize our current or future products in any foreign markets. Delays in receipt of marketing authorizations for our products in foreign countries, failure to receive such marketing authorizations or the future loss of previously received marketing authorizations could have a material adverse effect on our results of operations and financial condition.

## Staff

As of December 31, 2003, we had 93 full-time employees, comprised of 39 employees in research and development, 19 employees in manufacturing, 17 employees in management and finance and administration, and 18 employees in sales and marketing. From time to time, we also employ independent contractors to support our administrative organizations. Our employees are not represented by any collective bargaining unit and we have never experienced a work stoppage.

## Web Site Access to SEC Filings

We maintain an Internet website at [www.macropore.com](http://www.macropore.com). Through this site, we make available free of charge our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, we publish on our website all reports filed under Section 16(a) of the Exchange Act by our directors, officers and 10% stockholders.

These materials are accessible via the Investor Relations section of our website within the "Filings & Reports" link. Some of the information is stored directly on our website, while other information can be accessed by selecting the provided link to the section on the SEC website, which contains our filings.

## Item 2. Properties

Our main facility which we use as our corporate headquarters and for manufacturing is located at 6740 Top Gun Street, San Diego, California. We currently lease approximately 27,000 square feet of space at this location of which approximately 6,000 square feet is laboratory space, 12,000 square feet is office space and 9,000 square feet is manufacturing space. Our lease has a five-year term, expiring in 2008. We also lease:

- 14,000 square feet, of which approximately 4,000 square feet is for research and development and 10,000 square feet is office space at 6749 Top Gun Street, San Diego, California for a five-year term expiring in 2006.
- 16,000 square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five year term expiring 2007.
- 5,800 square feet, of office space located at Ömühlweg 33, Königstein, Germany for use in marketing and administration for a five-year term, expiring in 2006. We ceased business operations at this location in September 2003, but continue to remain obligated under the terms of the lease agreement.

We pay an aggregate of approximately \$71,000 in rent per month for our properties located in the United States and approximately €10,000 (\$12,500) in rent per month for our property in Germany.

## Item 3. Legal Matters

None.

## Item 4. Submission of Matters to a Vote of Security Holders

We provided the information with regard to our October 23, 2003 annual meeting of stockholders in Part II, Item 4 of our Form 10-Q filed on November 12, 2003.

## PART II

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

#### Market Prices

Our common stock is quoted on the Frankfurt Stock Exchange under the symbol "XMP." There is no established public trading market in the United States for our common stock. The following table shows the high and low sales prices for our common stock for the periods indicated, as reported on Xetra, the Frankfurt Stock Exchange's Exchange Electronic Trading System. These prices do not include retail markups, markdowns or commissions.

	High Euro		High US		Low Euro		Low US	
<b>2002</b>								
Quarter ended March 31, 2002 .....	€	4.10	\$	3.57	€	3.10	\$	2.75
Quarter ended June 30, 2002 .....	€	5.00	\$	4.59	€	3.10	\$	2.77
Quarter ended September 30, 2002 .....	€	4.55	\$	4.45	€	3.45	\$	3.40
Quarter ended December 31, 2002 .....	€	4.84	\$	4.93	€	3.90	\$	4.03
<b>2003</b>								
Quarter ended March 31, 2003 .....	€	4.63	\$	4.90	€	2.66	\$	2.95
Quarter ended June 30, 2003 .....	€	3.40	\$	4.00	€	2.56	\$	3.07
Quarter ended September 30, 2003 .....	€	3.79	\$	4.36	€	2.67	\$	2.96
Quarter ended December 31, 2003 .....	€	3.74	\$	4.31	€	2.15	\$	2.68

All of our shares are represented by global stock certificates issued in the name of Concord Effekten AG and deposited with Clearstream Banking AG, Frankfurt, Germany, the German securities depository. As of January 31, 2004, based on information provided by Clearstream, we believe that the number of beneficial owners of our common stock held through the global stock certificates is approximately 11,000.

We have never paid cash dividends and do not intend to do so in the foreseeable future.

#### Dividends

We have never declared or paid any dividends and currently intend to retain all available earnings generated by our operations for the development and growth of our business. We do not currently anticipate paying any cash dividends on our outstanding shares of common stock in the foreseeable future.

#### German Securities Laws

As a United States company with securities trading on a German stock exchange, we are subject to various laws and regulations in both jurisdictions. Some of these laws and regulations, in turn, can affect the ability of holders of our securities to transfer or sell those securities.

At present, Germany does not essentially restrict the export or import of capital, but exceptions can apply to certain states subject to UN or EU embargoes or to persons and organizations suspects of terrorism. However, for statistical purposes only, every individual or corporation residing in Germany must report to the German Central Bank, subject only to immaterial exceptions, any payment received from or made to an individual or a corporation not a resident of Germany if such payment exceeds Euro 12,500.00 or the equivalent in a foreign currency. In addition, residents of Germany must report any claims against or any liabilities payable to non-residents if such claims or liabilities, in aggregate, exceed Euro 5 million, during any one month. Residents holding 10% or more of the shares or voting rights in a non-resident undertaking must give an annual report of the assets and liabilities of the undertaking invested in, provided that the balance sheet total of this undertaking exceeds Euro 3 million.

There are no limitations imposed by German law or our certificate of incorporation or bylaws on the right of owners to hold or vote the shares.

## Recent Sales of Unregistered Securities

Previously reported.

## Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders.....	4,848,000 \$	4.00	709,000
Equity compensation plans not approved by security holders.....	None	None	None
Total			

## Item 6. Selected Consolidated Financial Data

The selected data presented below under the captions "Statement of Operations Data", "Statement of Cash Flows Data" and "Balance Sheet Data" for, and as of the end of, each of the years in the five-year period ended December 31, 2003, are derived from the consolidated financial statements of MacroPore Biosurgery, Inc. The consolidated financial statements as of December 31, 2003 and 2002, and for each of the years in the two-year period ended December 31, 2003, which have been audited by KPMG LLP, independent auditors, and their report thereon, are included elsewhere in this annual report. *The consolidated financial statements as of December 31, 2001 and 2000 and for each of the years for the two year period ended December 31, 2001, which have been audited by Arthur Andersen LLP, independent auditors, and their report thereon, is included elsewhere in this annual report. The consolidated financial statements as of and for the year ended December 31, 1999, have been audited by PricewaterhouseCoopers, whose report thereon is not included herein.*

The information contained in this table should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto included elsewhere in this report.

	Years Ended December 31,				
	2003	2002	2001	2000	1999
	(dollars in thousands, except shares and per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
Sales to related party .....	\$ 12,893	\$ 8,605	\$ 5,547	\$ 6,092	\$ —
Sales to third parties .....	1,195	561	101	159	1,513
	<u>14,088</u>	<u>9,166</u>	<u>5,648</u>	<u>6,251</u>	<u>1,513</u>
Cost of revenues:					
Cost of revenues .....	4,244	3,169	2,401	2,394	486
Inventory provision .....	—	1,395	1,750	—	—
Gross profit .....	<u>9,844</u>	<u>4,602</u>	<u>1,497</u>	<u>3,857</u>	<u>1,027</u>
Operating expenses:					
Research and development .....	9,071	5,605	5,487	2,584	1,172
Sales and marketing .....	4,417	3,987	4,493	2,629	2,356
General and administrative .....	4,581	3,952	3,578	2,555	1,313
Stock based compensation .....	985	1,287	1,123	5,698	661
In-process research and development .....	—	2,296	—	—	—
Restructuring charge .....	451	—	—	—	—
Equipment impairment charge .....	—	370	—	—	—
Total operating expenses .....	<u>19,505</u>	<u>17,497</u>	<u>14,681</u>	<u>13,466</u>	<u>5,502</u>
Other income (expense):					
Interest income .....	417	1,037	2,249	1,315	68
Interest and other expenses, net .....	(39)	(263)	(168)	(351)	(164)
Equity loss in investment .....	—	(882)	(104)	—	—
Net loss .....	<u>\$ (9,283)</u>	<u>\$ (13,003)</u>	<u>\$ (11,207)</u>	<u>\$ (8,645)</u>	<u>\$ (4,571)</u>
Basic and diluted net loss per share .....	<u>\$ (0.64)</u>	<u>\$ (0.91)</u>	<u>\$ (0.75)</u>	<u>\$ (1.05)</u>	<u>\$ (1.32)</u>
Shares used in calculating basic and diluted net loss per share .....	<u>14,555,047</u>	<u>14,274,254</u>	<u>14,926,107</u>	<u>8,201,739</u>	<u>3,458,292</u>
<b>Statement of Cash Flows Data:</b>					
Net cash used in operating activities .....	\$ (7,245)	\$ (6,886)	\$ (8,322)	\$ (2,982)	\$ (5,107)
Net cash provided by (used in) investing activities .....	5,954	17,265	2,263	(39,450)	(381)
Net cash (used in) provided by financing activities .....	(997)	(7,971)	1,283	47,437	7,924
Net (decrease) increase in cash .....	<u>(2,288)</u>	<u>2,408</u>	<u>(4,776)</u>	<u>5,005</u>	<u>2,436</u>
Cash and cash equivalents at beginning of year .....	5,108	2,700	7,476	2,471	35
Cash and cash equivalents at end of year .....	<u>\$ 2,820</u>	<u>\$ 5,108</u>	<u>\$ 2,700</u>	<u>\$ 7,476</u>	<u>\$ 2,471</u>
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments .....	\$ 14,268	\$ 24,983	\$ 33,951	\$ 44,484	\$ 2,581
Working capital .....	12,432	25,283	35,119	46,858	3,510
Total assets .....	28,089	39,319	43,143	52,269	5,575
Deferred gain on sale of assets, related party .....	7,539	9,623	—	—	—
Long-term obligations, less current portion .....	1,157	770	1,791	—	—
Convertible redeemable preferred stock .....	—	—	—	—	10,689
Total stockholders' equity (deficit) .....	<u>\$ 14,909</u>	<u>\$ 25,995</u>	<u>\$ 38,486</u>	<u>\$ 49,335</u>	<u>\$ (6,147)</u>

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

*This report contains certain statements that may be deemed "forward-looking statements" within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. The forward-looking statements included in this report are also subject to a number of material risks and uncertainties, including but not limited to the risks described under "Risk Factors" in the Management's Discussion and Analysis of Financial Conditions and Results of Operations. We encourage you to read those descriptions carefully. We caution investors not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.*

### Overview

We are focused on the research, development and commercialization of regenerative medicine technologies. We have two principal technology platforms: bioresorbable technology and regenerative cell technology, with which we currently target two of the largest markets in medicine, spine and orthopedic bone repair and cardiovascular tissue repair. Because our technologies can potentially be applied across a broad spectrum of medical applications, we may seek to expand our revenue stream opportunities through divestitures, licensing or other development and marketing agreements with corporate and academic partners or by applying for government sponsored research grants.

In 2003, we generated \$14,088,000 in revenues with a net loss of \$9,283,000. Most of these revenues were from the spine and orthopedic products sold through Medtronic Sofamor Danek, our exclusive worldwide distributor. Revenues from our spine and orthopedic implants, which includes the HYDROSORB™ family of products, accounted for \$9,882,000. Revenues from bioresorbable thin films, which includes SurgiWrap™, accounted for \$1,167,000. Revenues from craniomaxillofacial "CMF" products accounted for \$3,030,000. Revenues from the spine and orthopedic products came from a development and supply agreement with Medtronic. Revenues from the bioresorbable thin films are attributable to our direct sales force and our international distributors. Revenues from CMF, which was sold to Medtronic as of October 2002, related entirely to a back-up supply agreement established at the time we disposed of this product line. Revenues attributable to Medtronic represented 91.5% of our revenues in 2003.

Between 2001 and 2003, we have increased revenues and gross profits each year, trends we expect will continue in 2004. The increase in revenues is primarily the result of increased market penetration by the spine and orthopedic products and stocking orders that were placed by Medtronic. The increase in gross profits and decrease in net losses are primarily due to economics of scale. In 2004, revenue growth from the spine and orthopedic products will depend largely on the following: (1) Medtronic increasing market penetration; (2) Physicians becoming more comfortable with bioresorbable materials and more aware of the products' advantages over metal and allograft and; (3) European acceptance of the use of bioresorbable materials in combination with Medtronic's bone growth protein INFUSE®. We expect that the spine and orthopedic product revenues will grow in 2004 to offset the loss of revenues that will not be realized as a result of product line divestitures.

As part of our growth strategy, we are using the cash flow from our bioresorbable product line, plus the proceeds from bioresorbable product line dispositions, to support our research and development programs, particularly the regenerative cell technology program. Because of the potential value of the regenerative cell technology, we have made a strategic decision to commit a significant percentage of research and development spending to this program. For 2004, we anticipate committing \$12,000,000 to \$14,000,000 toward research and development of which \$7,800,000 to \$8,800,000 will be associated with regenerative cell technology.

We ended 2003 with \$14,300,000 in cash and short term equivalents. In the first quarter of 2004 we received a \$5,000,000 milestone payment from Medtronic and were awarded a research grant for \$100,000 from the National Institutes of Health (NIH). Additionally, we anticipate receiving a payment between \$1,000,000 and \$2,000,000 from Medtronic for satisfying the transfer of manufacturing know-how related to the CMF product line sale. Based on our anticipated research and development expenses and selling, general and administrative expenses, we believe that our current cash and cash equivalents, short term investments and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through December 31, 2004. In December 2003 we agreed to sell our bioresorbable thin film product line,

completion of this sale would also augment our 2004 cash position.

#### *Bioresorbable Technology: Developments*

In November 2002, we sold our CMF product line to Medtronic for up to \$21,000,000 because of the potential value we believe the cash inflow would provide to the shareholders. We are accounting for the net proceeds of the sale as a deferred gain on sale of assets, related party. This gain will not be fully recognized until certain events occur. For instance, we are recognizing a portion of the deferred gain upon the sale of the CMF products to Medtronic under our back-up supply arrangement, which provides for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized correlates to the gross margin normally charged by us on similar products. The remainder of the deferred gain will be recognized when the technology and know-how transfer is completed pursuant to the contract terms. This is expected to occur in 2004. We expect an additional \$1,000,000 to \$2,000,000 payment from Medtronic for satisfying the transfer of manufacturing know-how relate to the CMF business sale. In addition, we received in the first quarter of 2004 a \$5,000,000 milestone payment from Medtronic for the 2002 sale of our CMF product line. Also, we continue to be a back-up supplier for the acquired CMF products during a transition period, which we expect to be complete in 2004.

In December 2003 we agreed to sell our bioresorbable thin film implant product line to Medicis Ventures Management GmbH. We remain focused on completing the deal, however, the close of the transaction has been delayed and we can provide no assurances that the sale will be consummated..

#### *Regenerative Cell Technology: Developments*

Our regenerative cell technology research consists of two primary and concurrent programs; medical system engineering and medical applications research.

One program involves the engineering of a tissue processing medical system. This system could potentially allow physicians to isolate, concentrate and deliver adipose-derived regenerative cells for multiple tissue-specific, medical applications. Engineering and design advancements made in 2003 will allow us to have a prototype of a manual system in 2004. This would allow researchers, including those at our own company, to explore potential medical applications for adipose-derived regenerative cells.

Another research program involves the identification of specific medical applications for the use of adipose-derived regenerative cells. Currently, the most advanced program is studying the repair of cardiovascular muscle tissue that is damaged after a myocardial infarction (heart attack). We are currently conducting preclinical studies at the University of California, Los Angeles (UCLA) and Cedars-Sinai Medical Center, both in Los Angeles, California, through our own funding and with an NIH Small Business Innovations Research (SBIR) phase one grant worth \$100,000 awarded to us in January 2004. We also have earlier stage programs exploring the use adipose-derived regenerative cells for vascular disease, bone and cartilage repair, wound healing, and soft tissue augmentation.

Anticipated milestones for the regenerative cell technology program in 2004 include a first generation manual system for cell processing, resulting from preclinical animal studies that we expect to make available in 2004, and possibly the receipt of the second phase of the NIH SBIR grant.

We believe that in order for any regenerative cell technology products we develop to be successful commercially, we need to overcome certain scientific obstacles in addition to marketing challenges, which probably will require conducting and publishing the results of influential studies.

### **Results of Operations**

#### *Year ended December 31, 2003 compared to year ended December 31, 2002*

*Revenues.* For the year ended December 31, 2003, revenues were \$14,088,000 compared to \$9,166,000 for the year ended December 31, 2002, an increase of \$4,922,000 or 53.7%. The revenue for 2003 was comprised of \$9,882,000 in spine and orthopedics products, \$1,167,000 in bioresorbable thin film products, \$3,030,000 in CMF products of which \$2,046,000 resulted in the amortization of deferred gain on sale of assets, related party and \$9,000 in regenerative cell storage services. The revenue for 2002 was comprised of \$5,544,000 in spine and orthopedics of which \$150,000 related to an engineering project that involved spine and orthopedics, \$523,000 in bioresorbable thin film, \$2,874,000 in CMF of which \$267,000 related to the amortization of gain on the sale of assets and \$225,000 that related to CMF license fees. Excluding the spine and orthopedics engineering project of \$150,000 in 2002, the \$4,488,000 increase in spine and orthopedics revenue in 2003 resulted primarily from stocking orders of three newly developed spine and orthopedics products. Our revenue from spine and orthopedics products will depend largely on Medtronic's (our sole distributor of spine and orthopedics products) ability to maintain and/or increase its market share in the bioresorbable spine and orthopedics arena. In addition, we sell these

products to Medtronic at fixed selling prices which are subject to adjustment upon biannual reviews. Therefore, our future revenue streams are affected by fluctuations in sales volumes and our ability to negotiate and obtain product pricing increases. The \$644,000 increase in bioresorbable thin film revenue in 2003 was attributable to a full year of sales of the product line in 2003 as compared to sales only in the last two quarters of 2002. We sold our CMF product line to Medtronic in September 2002, but agreed to remain as a back-up supplier for a short time. The \$156,000 increase in CMF product sales and the \$225,000 decrease in license fee revenue in 2003 related to Medtronic transitioning the manufacturing of CMF products to their own facilities. We expect CMF product sales to decrease significantly through the first six months of 2004 and cease thereafter. Revenue in regenerative cell storage services is expected to remain insignificant throughout 2004. Revenues attributable to Medtronic, which owns approximately 7.0% of our outstanding common stock, represented 91.5% of our revenues for 2003, compared to 93.9% for 2002. The decrease in the revenue percentage attributable to Medtronic relates to the distribution of bioresorbable thin film products by our own direct sales force and other third party distributors in 2003.

*Cost of revenues.* For the year ended December 31, 2003, cost of revenues was \$4,244,000 or 30.1% of revenues, compared to \$3,169,000 or 34.6% of revenues excluding the inventory provision for the year ended December 31, 2002. Cost of revenues includes material, manufacturing labor and overhead costs. The decrease of 4.5% in cost as a percentage of revenues in 2003 was primarily attributable to increased sales revenue that allowed us to absorb more of our manufacturing labor and overhead costs. Included in the cost of revenue for 2003 with no comparable charges in 2002, was a warranty charge of \$267,000 related to a warranty claim on certain products sold to Medtronic. In August 2003, as part of our ongoing product monitoring process, we determined that some of the products sold to Medtronic did not meet certain expectations, based on criteria previously communicated by us to Medtronic. We agreed to a "no charge" replacement of the affected inventory in the possession of Medtronic. The replacement product will be provided under the warranty provision in our Development and Supply Agreement. We replaced approximately \$11,000 of products under the warranty provision and wrote-off \$111,000 of our inventory that was related to this warranty claim in 2003. The decrease of 4.5% in cost as a percentage of revenues in 2003 was primarily attributable to increased sales revenue that allowed us to absorb more of our manufacturing labor and overhead costs. In subsequent periods, we will continue to provide for a warranty provision based on our estimates of warranty claims; therefore, we expect cost of revenues as a percentage of sales to slightly increase in the future. In addition, the reduction of revenues as a result of the sale of the CMF product line in September 2002 as well as the anticipated sale of our bioresorbable thin film product line in 2004 could negatively impact our margins unless our other products' sales grow large enough to replace the lost revenue.

*Inventory provision.* For the year ended December 31, 2002, we recorded an inventory provision of \$1,395,000 representing 15.2% of revenues with no comparable charges in the year ended December 31, 2003. The 2002 inventory provision was directly related to the CMF asset sale to Medtronic, meaning that remaining unsold inventory in our CMF bone fixation implants and accessories product line inventory would no longer be recoverable.

*Research and development expenses.* For the year ended December 31, 2003, research and development expenses excluding related stock based compensation expenses were \$9,071,000, compared to \$5,605,000 for the year ended December 31, 2002, an increase of \$3,466,000 or 61.8%. Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and preclinical studies. Our research and development efforts focus on our two core regenerative medicine technology platforms, namely, bioresorbable technology and regenerative cell technology.

We incurred \$4,652,000 of research and development expense in our bioresorbable polymer implants platform technology, mostly in the development of spine and orthopedics products in 2003, as compared to \$5,246,000 on this platform technology in 2002. The \$594,000 decrease in spending on this platform technology during 2003, as compared to 2002, was attributable to the successful development of our bioresorbable thin film product line and the discontinuance of development of the CMF product line which was sold to Medtronic in 2002. We expect to maintain current research and development expenditures in the bioresorbable platform technology because of, among other things, ongoing product development for biomaterial/polymer products and to support our rich pipeline of spine and orthopedic new and next generation products.

We expended \$4,419,000 in 2003 for the development of our regenerative cell technology platform, which relates to using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications. These expenses were primarily composed of labor relating to employing 19 researchers, engineers and support staff, in addition to other significant expenses related to regulatory, consulting, and facilities to develop this technology. Expenditures on this same research totaled \$359,000 in 2002. The \$4,060,000 increase in spending for 2003 was attributable to a full year of operating expenses relating to the acquisition of StemSource that occurred in November 2002. We believe these expenditures in the research and development of our regenerative medicine platform technology have provided us with significant progress in understanding

the potential clinical applications for adipose-derived regenerative cells. We expect to continue to have substantial expenditures in this area of research, estimated at \$7,800,000 to \$8,800,000 in 2004, before we are able to bring products to market and begin generating significant revenues.

Stock based compensation related to research and development was \$78,000 for 2003, and \$211,000 for 2002. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

*Sales and marketing expenses.* For the year ended December 31, 2003, sales and marketing expenses excluding related stock based compensation expenses were \$4,417,000, compared to \$3,987,000 for the year ended December 31, 2002, an increase of \$430,000 or 10.8%. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. We use Medtronic for the distribution, marketing and sales support for our spine and orthopedic devices and formerly for our CMF products. We focused our sales and marketing expenditures on our bioresorbable thin film product line domestically through a dedicated sales force and international through independent distributors. The \$4,417,000 of sales and marketing expenses in 2003 included \$313,000 in general corporate marketing, \$3,145,000 in domestic sales and marketing and \$959,000 in international marketing; As compared to \$3,987,000 in sales and marketing for 2002 of which \$1,892,000 related to general corporate marketing, \$1,483,000 in domestic sales and marketing and \$612,000 in international marketing.

The \$1,579,000 decrease in general corporate marketing expenditures during 2003 was a result of our decision not to continue to supplement Medtronic's marketing of the spine and orthopedics and CMF product lines. We project corporate marketing expenditures to remain constant next year as we focus on maintaining our corporate image and reputation within the research and surgical communities.

The \$1,662,000 increase in spending for domestic sales and marketing expenses in 2003 primarily related to increased salary costs of our bioresorbable thin film sales force and marketing team, who were employed for the full year as compared to 2002 where they were hired in the last six months of the year. To control costs in 2003 we reduced the number of our bioresorbable thin film sales consultants by six and focused the remaining consultants on specific regions in the US domestic market where there is greater market acceptance of our bioresorbable thin film products. The \$347,000 increase in international spending during 2003, as compared to 2002, was attributable to salary and travel expenses relating to developing international distributors and supporting a sales office in Japan for the full year for the bioresorbable thin film products. We project domestic and international sales and marketing expenses to remain constant as we continue to use our existing sales and marketing force to gain wider acceptance of bioresorbable thin product line for surgical procedures.

Stock based compensation related to sales and marketing was \$70,000 for 2003 and \$134,000 for 2002. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

*General and administrative expenses.* For the year ended December 31, 2003, general and administrative expenses excluding related stock based compensation expenses were \$4,581,000, compared to \$3,952,000 for the year ended December 31, 2002, an increase of \$629,000 or 15.9%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The \$629,000 increase in general and administrative expenses for 2003 was primarily attributable to the amortization of intangibles, consulting and professional services. We expect general and administrative expenses to remain at current levels for the next twelve months. In addition, stock based compensation related to general and administrative expenses was \$837,000 for 2003, compared to \$942,000 for 2002. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

*Stock based compensation expenses.* For the year ended December 31, 2003, total non-cash stock based compensation expenses classified in operating expenses were \$985,000, compared to \$1,287,000 for the year ended December 31, 2002, a decrease of \$302,000 or 23.5%. Stock based compensation results from options issued to employees, directors and non-employees. The stock based compensation relating to employees and directors represents the difference between the exercise price of the stock based awards and the deemed market value of the underlying common stock on the date of the grant. The stock based compensation relating to non-employees represents the fair value of the underlying common stock on the initial date of grant, marked to market over the vesting period until meeting the performance commitment. Unearned stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. The overall decrease in stock based compensation expense for 2003, as compared to 2002, was related to the normal amortization of the stock based compensation expenses over the remaining vesting period and the modification of certain options granted to consultants and officers of the Company.

The decrease of \$133,000 in research and development stock based compensation expense was primarily due to issuing 50,000 fully vested stock options to non-employees in 2002 for consulting services rendered with no comparable expenses in 2003. The decrease of \$64,000 in sales and marketing stock based compensation expense in 2003 was related to the normal amortization of the stock based compensation over the remaining vesting period.

The decrease of \$105,000 in general and administrative stock based compensation expense in 2003 was primarily due to additional expenses of \$241,000 incurred in the modification of certain options granted to our former Chief Financial Officer in his September 2003 separation agreement. This was partially offset by \$92,000 in reduced expense from modifying certain stock options held by our former president and a \$254,000 decrease in expense related to the normal amortization of the stock based compensation expense over the remaining vesting period in 2003.

There was no stock based compensation expense relating to non-employees for 2003.

*In-process research and development.* For the year ended December 31, 2002, we had an in-process research and development charge of \$2,296,000 for which there was no comparable charge in the year ended December 31, 2003. The in-process research and development charge represents the value of StemSource's on-site regenerative cell extraction unit and related technology to process regenerative cells into therapeutic products which had no alternative future uses. The in-process research and development asset was written off at the date of acquisition in accordance with FASB Interpretation No. 4 "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method."

*Restructuring charge.* For the year ended December 31, 2003, we recorded a restructuring charge of \$451,000, for which there was no comparable charge in the year ended December 31, 2002. In an effort to reduce costs and consolidate operations in the United States, we closed our administrative office in Königstein, Germany in September 2003. In connection with the facility closure, we incurred restructuring charges of \$282,000 relating to involuntarily terminating 3 employees including our Chief Financial Officer and \$169,000 relating to a lease termination.

*Equipment impairment charge.* For the year ended December 31, 2002, we had an equipment impairment charge of \$370,000 for which there was no comparable charge in the year ended December 31, 2003. The impairment charge represented the excess of the cost over the estimated net proceeds we estimated we would receive from sale of the assets, which were previously utilized in the manufacturing of implant and accessory products, but not included in the Medtronic sale.

*Interest income.* For the year ended December 31, 2003, interest income was \$417,000, compared to \$1,037,000 for the year ended December 31, 2002, a decrease of \$620,000, or 59.8%. The decrease in interest income resulted from a decrease in the funds we had available for investments and lower interest rates.

*Interest and other expenses.* For the year ended December 31, 2003, interest and other expenses were \$39,000, compared to \$263,000 for the year ended December 31, 2002, a decrease of \$224,000 or 85.2%. The decrease in interest and other expenses for 2003 resulted from increased gains on foreign exchange of \$97,000, less interest expense due to lower average loan outstanding principal balances and a decrease in losses related to the disposal of equipment in 2003 as compared to 2002.

*Equity loss in investment.* For the year ended December 31, 2002, our equity loss in investment was \$882,000, with no comparable loss for the year ended December 31, 2003. The loss related entirely to our former 13.5% equity interest in StemSource, which we accounted for using the equity method until its acquisition by the Company in 2002. Under the equity method of accounting, we recognized a pro rata share of StemSource's operating losses.

*Year ended December 31, 2002 compared to year ended December 31, 2001*

*Revenues.* For the year ended December 31, 2002, revenues were \$9,166,000 compared to \$5,648,000 for the year ended December 31, 2001, an increase of \$3,518,000, or 62.3%. The increase in revenues was attributable to a \$3,895,000 increase in the sales of bioresorbable implant products for use in spine and orthopedics applications, \$523,000 in bioresorbable thin film products sales and a \$900,000 decrease in CMF products sales. The increase in spine and orthopedics product revenue related to the increase in availability of the product from limited clinical evaluations to a full product release. The increase in revenue of bioresorbable thin film product was attributable to the launch of the product during the year, with no comparable sales in the prior year. The CMF product sales decreased because of the decrease in replenishment product orders from Medtronic. Revenues attributable to Medtronic represented 93.9% of our revenues for 2002, compared to 98.2% for 2001. The decrease in the revenue percentage attributable to Medtronic relates to the distribution of our bioresorbable thin film

products by our own direct sales force and other third party distributors in 2002.

*Cost of revenues.* For the year ended December 31, 2002, cost of revenues, which does not include the inventory provision discussed below, was \$3,169,000 or 34.6% of revenues, compared to \$2,401,000 or 42.5% of revenues for the year ended December 31, 2001. Cost of revenues includes material, manufacturing labor and overhead costs. The decrease in cost as a percentage of revenues was primarily attributable to increased sales revenue that allowed us to absorb more of our fixed manufacturing labor and overhead costs. The sale of the CMF product line should negatively impact our margins unless our other products' sales grow enough to replace the lost revenue.

*Inventory provision.* For the year ended December 31, 2002, we recorded an inventory provision of \$1,395,000, representing 15.2% of revenues. In the year ended December 31, 2001, we recorded an inventory provision of \$1,750,000, representing 31.0% of revenues. The inventory provision for 2002 was a result of a reduction in the expected sales of our CMF bone fixation implants and accessories product line inventory due to the asset sale to Medtronic. The inventory provision for 2001 was a result of potential excess and obsolete inventory due to an anticipated reduction in future revenues of our CMF implant and instrument products.

*Research and development expenses.* For the year ended December 31, 2002, research and development expenses excluding related stock based compensation expenses were \$5,605,000, compared to \$5,487,000 for the year ended December 31, 2001, an increase of \$118,000 or 2.2%. The increase in research and development expenses in 2002 was primarily attributable to an increase of \$118,000 of expenses associated with the development of new products and applications for spine and orthopedics and bioresorbable thin film product lines. In addition, stock based compensation related to research and development was \$211,000 for 2002 and \$111,000 for 2001. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

*Sales and marketing expenses.* For the year ended December 31, 2002, sales and marketing expenses excluding related stock based compensation expenses were \$3,987,000, compared to \$4,493,000 for the year ended December 31, 2001, a decrease of \$506,000 or 11.3%. Medtronic is responsible for the sales and marketing of our spine and orthopedics product lines; therefore, in 2002 we focused our sales and marketing efforts on our bioresorbable thin film product line domestically through a dedicated sales force and internationally through independent distributors. The decrease in sales and marketing expenses in 2002 was primarily attributable to a \$197,000 decrease in labor and associated expenses relating to our sales force labor mix, \$130,000 of severance payments made to certain members of the sales force terminated during 2001 and other expense reductions of \$179,000 in promotional activities which related to the decision to rely on Medtronic to market the spine and orthopedics product line. In addition, stock based compensation related to sales and marketing was \$134,000 for 2002 and \$176,000 for 2001. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

*General and administrative expenses.* For the year ended December 31, 2002, general and administrative expenses excluding related stock based compensation expenses were \$3,952,000, compared to \$3,578,000 for the year ended December 31, 2001, an increase of \$374,000 or 10.5%. The \$374,000 increase in general and administrative expenses for 2002 was primarily attributable to a \$180,000 retirement package we extended to our former president and a \$194,000 increase in the overall general corporate expenditures due to the increasing complexity and expense of managing our domestic and international operations and facilities. In addition, stock based compensation related to general and administrative expenses was \$942,000 for 2002, compared to \$836,000 for 2001. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

*Stock based compensation expenses.* For the year ended December 31, 2002, total non-cash stock based compensation expenses classified in operating expenses were \$1,287,000, compared to \$1,123,000 for the year ended December 31, 2001, an increase of \$164,000, or 14.6%. Stock based compensation results from options issued to employees and non-employees. The overall increase in stock based compensation expense was related to the acceleration of vesting and other modifications to compensatory stock options granted to our former president and stock options granted to consultants for services rendered in 2002. The increase of \$100,000 in research and development stock based compensation expense was primarily due to issuing 50,000 fully vested stock options to non-employees for consulting services rendered in 2002. The decrease of \$42,000 in sales and marketing stock based compensation expense was due primarily to a reduction in accrued compensation costs recorded in 2001 as a result of the forfeiture and cancellation of certain stock options that had been granted to members of our sales force upon the termination of their employment. The increase of \$106,000 in general and administrative stock based compensation expense was primarily due to additional expense recorded in 2002 as a result of accelerating vesting and modifying the exercise period of certain stock options held by our former president.

*In-process research and development.* For the year ended December 31, 2002, we had an in-process research and development charge of \$2,296,000 for which there was no comparable charge in the year ended December 31, 2001. The in-process research and development charge represents the value of StemSource's on-site regenerative cell extraction unit and related technology to process regenerative cells into therapeutic products which had no alternative future uses. The in-process research and development asset was written off at the date of acquisition in accordance with FASB Interpretation No. 4 "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method."

*Equipment impairment charge.* For the year ended December 31, 2002, we had an equipment impairment charge of \$370,000 for which there was no comparable charge in the year ended December 31, 2001. The impairment charge represents the excess of the cost over the estimated net proceeds we estimate we will receive from sale of the assets, which were previously utilized in the manufacturing of CMF implant and accessory products, but not included in the Medtronic sale.

*Interest income.* For the year ended December 31, 2002, interest income was \$1,037,000, compared to \$2,249,000 for the year ended December 31, 2001, a decrease of \$1,212,000, or 53.9%. The decrease in interest income resulted from a decrease in the funds we had available for investments and lower interest rates.

*Interest and other expenses.* For the year ended December 31, 2002, interest and other expenses were \$263,000, compared to \$168,000 for the year ended December 31, 2001, an increase of \$95,000 or 56.5%. The increase in interest and other expense related to \$141,000 of additional interest expense on our long-term debt obligations because loan balances were outstanding for the full year and \$59,000 relating to additional losses recorded on disposal of assets as compared to the prior year, which was off set by foreign currency gains and other income of \$105,000.

*Equity loss in investment.* For the year ended December 31, 2002, our equity loss in investment was \$882,000, compared to \$104,000 for the year ended December 31, 2001, an increase of \$778,000. Both losses related entirely to our minority interest in StemSource, which we purchased our initial minority interest of 13.5% in May 2001. Under the equity method of accounting, we recognized a pro rata share of StemSource's operating losses.

#### **Gain on Asset Sale to Medtronic**

We have not yet recognized the full gain on the September 2002 asset sale to Medtronic, and will not do so until we successfully transfer to Medtronic the technology and know-how, including training, related to the manufacture of the CMF product line, which we expect to occur in 2004. However, to date we have recognized approximately \$2,313,000 of the gain as revenue related to the sale of CMF product line to Medtronic under our back-up supply arrangement, which provides for sales of CMF products to Medtronic at cost. Discounts from contractual sales prices in effect prior to the sale of the CMF product line have been recorded as a reduction to the deferred gain. We have recorded \$7,539,000 of unamortized "Deferred gain on sale of assets, related party" on our balance sheet at December 31, 2003.

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

As of December 31, 2003, we had cash and cash equivalents, and short-term investments, available-for-sale, of \$14,268,000 and working capital of \$12,432,000. Since inception, we have financed our operations primarily through sales of stock and from the September 2002 CMF product line sale. Our sales of preferred stock in 1999, 1998 and 1997 yielded net proceeds of \$14,679,000. On August 8, 2000, we completed our public offering in Germany and listed our common stock for trading on the Frankfurt Stock Exchange in Frankfurt, Germany. We received net proceeds of \$43,244,000 from the sale of 3,500,000 shares of our common stock in our initial public offering. A portion of those net proceeds have been used for research and development, to expand our manufacturing operations, to promote our brand and to pursue regulatory approvals for our products. In addition, some of the proceeds have been used for working capital and general corporate purposes. We have invested some of the proceeds from the offering in short-term investments, pending other uses of the proceeds in our business.

Our capital requirements depend on numerous factors, including the resources we devote to developing and supporting our products, market acceptance of our developed products, regulatory approvals and other factors. We expect to devote substantial capital resources to continue our research and development efforts focusing on our two core regenerative medicine technology platforms, namely, bioresorbable technology and regenerative cell technology and for other general corporate activities. We have positioned ourselves to expand our cash position through actively pursuing grants, licensing, co-development and marketing agreements related to our technology platforms. In the near-term, we are committed to increasing revenues from our bioresorbable products and reinvesting the profits into our regenerative cell therapy research. The revenue generated from our bioresorbable products will depend on Medtronic's (our sole distributor of spine and orthopedics implants) efforts in the bioresorbable spine and orthopedics arena. We believe that our current cash and cash equivalents, short term investments and revenue to be derived from the sale of our products will be sufficient to fund our operations at least beyond December 31, 2004. In addition, we received in the first quarter of 2004 a \$5,000,000 milestone

payment from Medtronic for the 2002 sale of our CMF product line. Nonetheless, if we continue research and development expenses at or beyond our current level, in our regenerative cell platform for an extended time, we may need to seek partnerships or additional sources of financing in the future.

Net cash used in operating activities was \$7,245,000, \$6,886,000 and \$8,322,000 for the years ended December 31, 2003, 2002 and 2001, respectively. For each period, net cash used in operating activities resulted primarily from net losses and working capital requirements. Net losses for each period resulted to a large extent from expenses associated with the development of our bioresorbable designs, regenerative medicine research, preclinical studies, preparation of submissions to the FDA and foreign regulatory agencies, the establishment of marketing and distribution channels, and the improvement of our manufacturing capabilities. In 2003, net cash used in operating activities primarily resulted from our net loss of \$9,283,000 as adjusted for \$2,046,000 of non-cash amortization of gain on the sale of assets to a related party. The "non-cash amortization of gain on the sale of assets to a related party" was a result of CMF products purchased by Medtronic under a back-up supplier agreement at discounts and the revenue being recognized at the previously agreed prices with the difference reducing the deferred gain in sale of assets on the balance sheet. The cash used in these operating activities was primarily adjusted for non-cash charges for depreciation and amortization of \$1,657,000 and stock based compensation of \$997,000. In 2002, net cash used in operating activities primarily related to our net loss of \$13,003,000, increase in accounts receivable of \$775,000 related to the increase in sales to Medtronic and bioresorbable thin film sales in the fourth quarter of 2002 and an increase in inventory of \$860,000 related to increased stock of spine and orthopedics and bioresorbable thin film product lines. The cash used in these operating activities was adjusted for non-cash charges for depreciation and amortization of \$1,471,000, an inventory provision related to the sale of the CMF product line of \$1,395,000, acquired in-process research and development of \$2,296,000 related to purchase of StemSource, an asset impairment of \$370,000 related to the manufacture of CMF product line, stock based compensation of \$1,301,000 and an equity loss of \$882,000 in our investment in StemSource. In 2001, net cash used in operating activities primarily related to our net loss of \$11,207,000 and an increase in inventory of \$1,157,000, adjusted for non-cash charges for inventory provision of \$1,750,000, stock based compensation of \$1,137,000 and depreciation and amortization of \$1,184,000. Our working capital requirements fluctuate with changes in our operating activities that include such items as sales and manufacturing costs, which affect the levels of accounts receivable, inventories and current liabilities. We expect to use less cash in operating activities as our product lines become more profitable.

Net cash provided by investing activities was \$5,954,000, \$17,265,000 and \$2,263,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Net cash provided by investing activities for 2003, 2002 and 2001 consisted of net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e. we cashed in short-term investments to fund our operations and our stock buybacks). In 2003 we purchased \$1,743,000 in property and equipment primarily to support bioresorbable polymer implant manufacturing and research and development of the regenerative cell technology platform. We also paid \$654,000 of costs associated with the acquisition of StemSource related to professional services and the settlement of the remaining lease payments on a lease assumed in the StemSource acquisition. In 2002 we received \$9,689,000 upon the sale of the CMF product line to Medtronic which was offset by the \$2,896,000 in cash paid in the acquisition of StemSource. Our investing activities for 2001 consisted of outlays for capital expenditures and our investment in StemSource. We expect to continue to generate cash from investing activities as we sell our short-term investments to provide cash for our operating activities and property and equipment purchases.

Net cash used in financing activities was \$997,000 and \$7,971,000 for the years ended December 31, 2003 and 2002, respectively. Net cash provided by financing activities was \$1,283,000 for the year ended December 31, 2001. Net cash used by financing activities for 2003, resulted primarily from our purchase of 614,099 shares of our common stock for \$2,266,000 at an average price of \$3.69 per share and \$426,000 for payments of long term obligations. This was offset by proceeds from the sale of 150,500 shares of our common stock held in treasury for \$542,000 at a price of \$3.60 per share and \$1,120,000 from the issuance of three promissory notes under an Amended Master Security Agreement to finance our equipment purchases. Net cash used in financing activities for 2002 was primarily related to \$7,442,000 for the repurchase of 1,972,863 shares of our common stock at an average price of \$3.77, \$1,166,000 for payments toward long term obligations and \$256,000 for principal payments on capital lease obligations. This was offset by the proceeds from the sale of 210,000 shares of our common stock held in treasury for \$877,000 at a price of \$4.18 per share. Net cash provided by financing activities for 2001 was primarily related to \$2,433,000 of proceeds from long-term debt financing, partially offset by our repurchase of 356,120 shares of our common stock for \$1,077,000 at an average price of \$3.02.

Our Board of Directors has authorized the repurchase of up to 3,000,000 shares of the Company's common stock in the open market, from time to time until August 10, 2004, subject to the Company's assessment of market conditions and buying opportunities, and at a purchase price per share not to exceed €15.00, based on the exchange rate in effect on August 11, 2003. Of these 3,000,000 shares, our repurchases under this authorization have totaled 2,943,082 shares through December 31, 2003. We do not expect to use more cash in financing activities in 2004 than we did in 2003. However, we will use cash for payments on our long term obligations and the repurchase of \$976,000 of our stock from a former StemSource

shareholder (see note 18 to the consolidated financial statements).

In 2001 we entered into a Master Security Agreement to provide financing for equipment purchases. In connection with the agreement, we originally issued two promissory notes to the lender for a total of approximately \$2,433,000. Currently, one note bears interest at 9.3% per annum with principal and interest due in monthly payments of approximately \$7,000, maturing over 36 months and is secured by equipment with a cost of \$227,000. The other promissory note bears interest at 8.8% per annum with principal and interest due in monthly payments of approximately \$34,000, maturing over 35 months and secured by equipment with a cost of \$1,442,000.

In 2003 we entered into an Amended Master Security Agreement to provide financing for equipment purchases. In connection with the agreement, we issued three promissory notes to the lender in an aggregate principal amount of approximately \$1,120,000. These notes bear interest at 8.6%, 8.6% and 8.7% per annum with principal and interest due in monthly payments of approximately \$6,000, \$8,000 and \$17,000, respectively and mature over 48, 36 and 48 month periods, respectively and are secured by equipment with a cost of \$1,120,000.

As of December 31, 2003, we had property and equipment of \$7,512,000, less accumulated depreciation of \$3,690,000 to support our clinical, research, development, manufacturing and administrative activities. Our capital expenditures were \$1,743,000, \$909,000 and \$2,664,000 for the years ended 2003, 2002 and 2001, respectively. We expect capital expenditures for the next twelve months to be approximately \$1,200,000 as we acquire additional equipment and expand our facilities. We intend to pay for future capital expenditures with available working capital or financing under our amended master security agreement.

The following summarizes our contractual obligations and other commitments at December 31, 2003, and the effect such obligations could have on our liquidity and cash flow in future periods:

Contractual Obligations	Total	Payments due by period			More than 5 years
		Less than 1 year	1 - 3 years	3 - 5 years	
Long-term debt obligations .....	1,874,000	717,000	1,157,000	—	—
Operating lease obligations .....	3,317,000	884,000	2,219,000	214,000	—
Share repurchase payable .....	976,000	976,000	—	—	—
Total .....	6,167,000	2,577,000	3,376,000	214,000	—

The following summarizes the Company's warranty reserve at December 31, 2003 and 2002:

	Balance at January 1	Additions (charges to expenses)	Claims	Balance at December 31
2003:				
Warranty reserve .....	\$ —	\$ 278,000	\$ (11,000)	\$ 267,000
2002:				
Warranty reserve .....	\$ —	\$ —	\$ —	\$ —

### Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and that affect our disclosure of contingent assets and liabilities. While our estimates are based on assumptions we consider reasonable at the time they were made, our actual results may differ from our estimates, perhaps significantly. If results differ materially from our estimates, we will make adjustments to our financial statements prospectively, as we become aware of the necessity for an adjustment.

*Revenue Recognition.* We sell our products to hospitals and distributors. Revenue from sales to hospitals is recognized upon delivery of the product. We have agreements with our distributors that title and risk of loss pass upon shipment of the products to the distributor. We warrant that our products are free from manufacturing defects at the time of shipment to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order.

Revenue from license agreements is recognized ratably over the term of the agreement, provided no significant obligations remain.

We recognize revenue from the collection and storage of regenerative cells rich adipose tissue. In our cell banking operations, we recognize revenue when (i) the collection procedure is performed, (ii) the adipose tissue is received by us, (iii) fees from the procedure are fixed and determinable and (iv) payment is probable. We use the residual method to recognize revenue when a procedure includes elements to be delivered at a future date if evidence of the fair value of all undelivered elements exists. If evidence of the fair value of the undelivered elements does not exist, revenue is deferred on all elements and recognized when all elements are delivered.

We recognize revenue from regenerative cell storage services as the services are performed.

We earn revenue for performing services under development agreements. Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when (i) the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, (ii) the amount of the milestone payments appears reasonably commensurate with the effort expended and (iii) collection of the payment is reasonably assured. Income earned under development agreements is classified under revenues in our statement of operations. The costs associated with development agreements are recorded as research and development expense.

Additionally, we earn revenue from contracted development arrangements. These arrangements are generally time and material arrangements and accordingly any revenue is recognized as services are performed. Any costs related to these arrangements are recognized as cost of revenue as these costs are incurred.

A majority of our revenues are from Medtronic, under our Development and Supply Agreement with Medtronic dated January 5, 2000 and amended December 22, 2000 and September 30, 2002, as well as our Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002.

*Allowance for doubtful accounts.* We provide a reserve against our receivables for estimated losses that may result from our customers' inability to pay. These reserves are based on known uncollectible accounts, aged receivables, historical losses and our estimate of our customers' credit-worthiness. Should a customer's account become past due, we generally place a hold on the account and discontinue further shipments to that customer, minimizing further risk of loss. The likelihood of our recognition of a material loss on an uncollectible account mainly depends on deterioration in the economic financial strength of the customer and the general business environment. Medtronic is our single largest customer, directly accounting for 91.5% and 93.9% of our revenues in the year ended December 31, 2003 and 2002, respectively.

*Inventory.* We state inventories at the lower of average cost, determined on the first-in first-out method, or fair market value. We review the components of our inventory on a regular basis for excess, obsolete and impaired inventory, based on estimated future usage. The likelihood of any material adjustment of our stated inventory depends on whether there are significant changes in the competitive conditions in which we operate, new product introductions by us or our competitors, or fluctuations in customer demand.

We estimate our labor and overhead costs based on the estimated utilization of our labor force and manufacturing facilities. We periodically evaluate these costs in order to determine that any excess capacity is treated as a period expense rather than capitalized. The likelihood of a material change in our estimates of labor and overhead costs is directly related to manufacturing volume, which can vary significantly between reporting periods.

*Warranty Provision.* The vast majority of our revenues are derived from the sale of medical devices.

At the time of sale, we grant customers the right to a full refund if (and only if) the purchased medical device does not meet all of the agreed upon specifications and expectations. Accordingly, we established a liability for the estimated cost of honoring this warranty at the same time we record revenues from the sale of the related medical device.

We believe the accounting estimate related to our warranty liability is a "critical accounting estimate" because changes in the related warranty provision can materially affect net loss. Moreover, because of our limited history and our continual development of new products, estimating our expected warranty costs requires significant judgment.

In the past, our warranty provision was based primarily on actual history of warranty claims submitted by our customers. Prior to the third quarter of 2003, we had de minimis warranty claims despite recognizing approximately \$27 million in cumulative sales of medical devices. Accordingly, we had no warranty reserves as of June 30, 2003.

In the third quarter of 2003, we determined that some of the products we sold did not meet certain customer

expectations, based on criteria previously communicated to our customer. After detecting this matter, we elected to replace all lots of effected inventory that were on hand at the customer, and we subsequently modified our procedures to alleviate similar occurrences in the future.

As a result, we recorded a warranty charge of \$243,000 in the third quarter of 2003. We have incorporated this new historical warranty data into our determination of appropriate warranty reserves to record prospectively and will continue to evaluate the adequacy and accuracy of our warranty obligations on a quarterly basis.

*Accounting for income taxes:* As part of preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items, such as deferred revenue, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We establish valuation allowances, when necessary, to reduce deferred tax assets to the amount we expect to realize, using a "more likely than not" standard.

We have established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding the realization of such assets, which consist mostly of net operating loss carryforwards. We periodically evaluate the recoverability of the deferred tax asset. The likelihood of a material change in our expected realization of these assets depends on our generation of future taxable income, our ability to deduct tax loss carryforwards against future taxable income and the effectiveness of our tax planning strategies in the various tax jurisdictions that we operate in. At such time as it is determined that it is more likely than not that the deferred assets are realizable, the valuation allowance will be reduced.

### **Net Operating Loss and Tax Credit Carryforwards**

We have established a valuation allowance against our deferred tax asset due to the uncertainty surrounding the realization of such assets. We periodically evaluate the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. We have recorded a valuation allowance of \$18,734,000 as of December 31, 2003 to reflect the estimated amount of deferred tax assets that may not be realized. We increased our valuation allowance by approximately \$3,697,000 during the year ended December 31, 2003. The valuation allowance includes approximately \$621,000 related to stock option deductions, the benefit of which will eventually be credited to equity and not to income.

At December 31, 2003, we had federal and state tax loss carryforwards of approximately \$29,700,000 and \$19,300,000 respectively. The federal and state net operating loss carryforwards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2003, we had federal and state tax credit carryforwards of approximately \$653,000 and \$766,000 respectively. The federal credits will begin to expire in 2017, if unused, and the state credits will begin to expire in 2009 if unused.

The Internal Revenue Code limits the future availability of net operating loss and tax credit carryforwards that arose prior to certain cumulative changes in a corporation's ownership resulting in a change of control of Macropore. Due to prior ownership changes as defined in IRC Section 382, a portion of our net operating loss and tax credit carryforwards are limited in their annual utilization. In September 1999, we experienced an ownership change for purposes of the IRC Section 382 limitation. At December 31, 2003, the remaining pre-change federal net operating loss carryforward of \$2,100,000 is subject to an annual limitation of approximately \$570,000. It is estimated that these pre-change net operating losses and credits will be fully available by 2008.

Additionally, in 2002 we acquired federal and state net operating loss carryforwards of approximately \$2,700,000 and \$2,700,000 respectively. This event triggered an ownership change for purposes of IRC Section 382. As of December 31, 2003, the remaining pre-change federal and state net operating loss carryforward of \$1,900,000 is subject to an annual limitation of approximately \$460,000. It is estimated that the pre-change net operating losses and credits will be fully available by 2008.

The Company does not expect that an ownership change for purposes of IRC Section 382 occurred during 2003. However, if the Company did experience an ownership change in 2003, the net operating losses would be subject to IRC Section 382 and may be further limited in their use. The extent of any additional limitations resulting from an ownership change in 2003 has not been determined at this time.

### **Unearned Compensation**

We record unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair market value of our common stock on the date of grant. Unearned compensation is amortized to stock based compensation expense and is reflected as such in the Statement of Operations and Comprehensive Income (Loss). The remaining unearned compensation of \$109,000 as of December 31, 2003 will be amortized using the straight-line method over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. We expect to record amortization expense for unearned compensation of \$109,000 in 2004. The amount of unearned compensation expense recorded in future periods may decrease if unvested options for which unearned compensation has been recorded are subsequently forfeited.

### **Recent Accounting Pronouncements**

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of FASB Statement No. 123 (SFAS 148)." This Statement provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and requires prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We have elected not to adopt the recognition and measurement provisions of SFAS No. 123 and continue to account for our stock-based employee compensation plan under APB Opinion No. 25 and related interpretations. We have adopted the interim and annual disclosure provisions required by SFAS 148 beginning with our March 31, 2003 financial statements.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." This pronouncement was amended by the FASB in December 2003 and renamed FASB Interpretation No. 46-R (FIN 46-R). FIN 46 and FIN 46-R clarify the application of Accounting Research Bulletin No. 51 - Consolidated Financial Statements to those entities defined as "Variable Interest Entities" (sometimes colloquially referred to as special purpose entities) in which equity investors do not have the characteristics of a "controlling financial interest" or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to all Variable Interest Entities created after January 31, 2003, and by the beginning of the first interim or annual reporting period commencing after December 15, 2003 for Variable Interest Entities created prior to February 1, 2003. FIN 46-R further delays the effective date of certain provisions of the revised interpretation until the quarter ended March 31, 2004. The adoption of FIN 46 did not have any effect on our consolidated financial position or consolidated results of operations as we currently do not have any variable interest entities falling within the scope of FIN 46. Moreover, we do not expect that FIN 46-R will have a material effect on our financial position, results of operations, or cash flows.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS 133. In particular, SFAS No. 149 clarifies under what circumstances a contract within an initial net investment meets the characteristic of a derivative and when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is generally effective for contracts entered into or modified after June 30, 2003. The adoption of SFAS No. 149 did not have a material effect on our consolidated financial position or consolidated results of operations as we currently do not have any derivative instruments and hedging activities falling within the scope of SFAS No. 149.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material effect on our consolidated financial position or consolidated results of operations.

### **Risk Factors**

*In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this annual report on Form 10-K. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this annual report on Form 10-K and in any other documents incorporated by reference into this report. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.*

We are subject to the following significant risks, among others:

***We have a limited operating history; our operating results can be volatile***

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced fields such as the medical device field. Due to our limited operating history, comparisons of our year-to-year operating results are not necessarily meaningful and the results for any periods should not be relied upon as an indication for future performance. Since our limited operating history makes the prediction of future results difficult or impossible, our recent revenue growth should not be taken as an indication of any future growth or of a sustainable level of revenue.

Moreover, our operating results can vary substantially from analyst expectations and from previous periodic results for many reasons, including the timing of product introductions and distributor purchase orders. Also, the sale of our craniomaxillofacial "CMF" bone fixation implant and accessory product line, which had represented a large portion of our revenues, will distort quarterly and annual earning comparisons through 2003 and 2004. The sale of our thin film product line would also distort 2004 earnings comparisons. Earnings surprises can have a disproportionate effect on the stock prices of emerging companies such as ours. Also, our stock price is likely to be disproportionately affected by changes which generally affect the economy, the stock market or the medical device industry.

***We have never been profitable***

We have incurred net losses in each year since we started doing business, including net losses of \$9,283,000 for the year ended December 31, 2003. These losses have resulted primarily from expenses associated with our research and development activities, and general and administrative expenses. We anticipate that our recurring operating expenses will increase for the next several years, as our research and development expenses may increase in order to develop and market new products and fund additional preclinical research and possibly clinical trials. We expect to continue to incur operational losses at least through the end of 2004, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Even though our bone fixation product line achieved profitability, development-stage losses related to our development of regenerative cell technology could keep us in a loss position on a consolidated basis for several years.

***We are adopting a high-risk strategy***

We intend to use the cash we received from the profits of the spine products and the proceeds of the sale of the CMF product lines to finance the regenerative cell technology and its development-stage cash needs. This is a high-risk strategy because there can be no assurance that our regenerative cell technology will ever be developed into commercially viable products (scientific risk), that we will be able successfully to manage a company in a different business than we have operated in the past (operational risk), that we will be able to use our medical device products to deliver regenerative cells where needed in the body (strategic risk), or that our cash resources will be adequate to develop the regenerative cell technology until it becomes profitable (if ever) while still serving the cash needs of our medical device product lines (financial risk). Instead of using the cash to reinvest in our core business, we are using it in one of the riskiest industries in the economy. This fundamentally changes our risk/reward profile and may make our stock an unsuitable investment for some investors.

***We depend on recently introduced products and anticipated new products, which subject us to development and marketing risks***

We are in the early stage of commercialization with many of our products although we have derived revenue from sales of certain products to our distributors, particularly Medtronic, Inc. We believe that our long-term viability and growth will depend in large part on receiving additional regulatory clearances or approvals for our products and expanding our sales and marketing for our spine and orthopedics bone fixation implants and other new products that may result from our research and development activities. We are presently pursuing product opportunities in spine and orthopedics bone fixation and soft tissue repair and regeneration throughout the body that will require extensive additional capital investment, research, development, clinical testing and regulatory clearances or approvals prior to commercialization. There can be no assurance that our product development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all. Most of our cell related products and/or services are at least 3-5 years away.

Moreover, the various applications and uses of our bioresorbable surgical implants are relatively new and evolving. The successful development and market acceptance of our products are subject to inherent developmental risks, including

ineffectiveness or lack of safety, unreliability, failure to receive necessary regulatory clearances or approvals, high commercial cost and preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, as well as general economic conditions affecting purchasing patterns. There can be no assurance that we or our distribution partners will be able to successfully commercialize or achieve market acceptance of our technologies or products, or that our competitors will not develop competing technologies that are less expensive or otherwise superior to ours. The failure to successfully develop and market our new products or receive the required regulatory clearances or approvals could have a substantial negative effect on the results of our operations and financial condition.

***We rely on Medtronic to distribute our products***

We have limited control over sales, marketing and distribution. Our strategy for sales and marketing of our bioresorbable products has included entering into agreements with other companies having large distribution networks to market many of our current and certain future products incorporating our technology. We have derived the vast majority of our 2003, 2002 and 2001 revenues from the sale of products to our distribution partner Medtronic, Inc. (Medtronic).

We remain significantly dependent on Medtronic to generate sales revenues for many of our products. The amount and timing of resources which may be devoted to the performance of Medtronic's contractual responsibilities are not within our control. There can be no guarantee that Medtronic will perform its obligations as expected, pay us any additional option or license fees or market any new products under the distribution agreements, or that we will derive any significant revenue from such arrangements.

The prices which Medtronic pays us are fixed, pending biannual price reviews, based on a percentage of Medtronic's historic selling prices to its customers. If our costs increase but our selling prices remain fixed, our profit margin will suffer.

Medtronic owns more than 7.0% of our stock, which may limit our ability to negotiate commercial arrangements optimally with Medtronic.

Although Medtronic has exclusive distribution rights to our co-developed spinal implants, Medtronic is not constrained in its ability to distribute or develop products competitive to ours, and it is free to pursue existing or alternative technologies in preference to our technology in the spine.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that Medtronic will not develop independently or with third parties products which could compete with ours or that disagreement over rights or technology or other proprietary interests will not occur. To the extent that we choose not to or are unable to enter into future agreements, we would experience increased capital requirements to undertake the marketing or sale of some of our current and future products. There can be no assurance that we will be able to effectively market or sell our current or future products independently in the absence of such agreements. The loss of the marketing services provided by Medtronic, or the loss of revenues generated by Medtronic could have a substantial negative effect on the results of our operations and financial condition.

***We are vulnerable to competition and technological change, and also to physicians' inertia***

We compete with many domestic and foreign companies in developing our technology and products, including medical device, pharmaceutical and biopharmaceutical companies. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than do we. There can be no assurance that our competitors will not succeed in developing alternative technologies and products that are more effective, easier to use or more economical than those which we have developed or are in the process of developing or that would render our technology and products obsolete and non-competitive in these fields. In general, we do not have the legal right to preclude other companies from making products that are similar to ours or perform similar functions.

These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory clearances or approvals, and manufacturing and marketing such products. Certain of these competitors may obtain patent protection, approval or clearance by the U.S. Food and Drug Administration "FDA" or product commercialization earlier than us, any of which could have a substantial negative effect on our business. Finally, under the terms of our distribution agreements, Medtronic and our other partners may pursue parallel development of other technologies or products, which may result in a partner developing additional products that will compete with our products.

We also compete with manufacturers of traditional non-bioresorbable implants, such as titanium implants. Doctors have historically been slow to adopt new technologies such as ours, whatever the merits, when older technologies continue to

be supported by established providers. Overcoming such inertia often requires other very significant marketing expenditures or definitive product superiority.

***We do not have much manufacturing experience***

We have a limited manufacturing history and limited experience in manufacturing some of our products. Our future success is dependent in significant part on our ability to manufacture products in commercial quantities, in compliance with regulatory requirements and in a cost-effective manner. Production of some of our products in commercial-scale quantities may involve unforeseen technical challenges and may require significant scale-up expenses for additions to facilities and personnel. There can be no guarantee that we will be able to achieve large-scale manufacturing capabilities for some of our products or that we will be able to manufacture these products in a cost-effective manner or in quantities necessary to allow us to achieve profitability. Our 2002 sale of CMF production assets to Medtronic deprives us of some economies of scale in manufacturing. If we are unable to sufficiently meet Medtronic's requirements for certain products as set forth under their agreement, Medtronic may itself then manufacture and sell such product and only pay us royalties on the sales. The resulting loss of payments from Medtronic for the purchase of these products would have a substantial negative effect on the results of our operations and financial condition.

***We have to maintain quality assurance certification and manufacturing approvals***

The manufacture of our products is subject to periodic inspection by regulatory authorities and distribution partners, and our manufacture of products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's Quality System Regulation "QSR" requirements, as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no guarantee that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek, remedial action.

Failure to comply with such regulations or delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant premarket approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances or the loss of previously received approvals or clearances could have a substantial negative effect on the results of our operations and financial condition.

***We depend on a sole source supplier for our crucial raw material***

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our products, from a single qualified source. Although we have a contract with B.I. Chemicals, Inc., which guarantees continuation of supply through August 15, 2005, we cannot guarantee that they will elect to continue the contract beyond that date, or that they will not elect to discontinue the manufacture of the material. They have agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide us with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Also, despite this agreement they might fail to do these things for us. Under the terms of the contract, B.I. Chemicals, Inc. may choose to raise their prices upon nine months prior notice which may also result in a substantially increased material cost. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates. Lack of adequate commercial quantities or inability to develop alternative sources meeting regulatory requirements at similar prices and terms within a reasonable time or any interruptions in supply in the future could have a significant negative effect on our ability to manufacture products, and, consequently, could have a material adverse effect on the results of our operations and financial condition.

***We may not be able to protect our proprietary rights***

Our success depends in part on whether we can obtain additional patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. We have several U.S. patents for the design of our bioresorbable plates and high torque screws and one for our SurgiWrap™ bioresorbable film, and we have filed applications for various additional U.S. patents, as well as certain corresponding patent applications outside the United States, relating to our technology. However, we believe we cannot patent the use of our lactic acid copolymer for surgical implants, nor are our particular implants generally patentable. There can be no assurance that any of the pending patent applications will be

approved, or that we will develop additional proprietary products that are patentable, or that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products or design around our patents.

Our regenerative cell technology license agreement with the Regents of the University of California contains certain developmental milestones, which if not achieved could result in the loss of exclusivity or loss of the license rights. The loss of such rights could significantly impact our ability to continue the development of the regenerative cell technology and/or commercialize related products.

Our commercial success will also depend, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. Patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us.

Any such litigation or interference proceeding, regardless of outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties and require disputed rights to be licensed from third parties or require us to cease using certain technology.

In addition to patents, which as noted cannot protect the fundamentals of our technology and our business, we also rely on unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our distribution partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Failure to obtain or maintain patent or trade secret protection, for any reason, third party claims against our patents, trade secrets or proprietary rights, or our involvement in disputes over our patents, trade secrets or proprietary rights, including involvement in litigation, could have a substantial negative effect on the results of our operations and financial condition.

***We may not be able to protect our intellectual property in countries outside the United States***

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. We currently have pending patent applications in the European Patent Office, Australia, Japan, Canada, China, Korea, and Mexico and we have published other international patent applications.

***We are subject to intensive FDA regulation***

As newly developed medical devices, our bioresorbable surgical implants must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments, prior to their sale. Our current and future bioresorbable surgical implants for humans are subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices and drugs. Included among these regulations are premarket clearance and premarket approval requirements, design control requirements, and the Quality System Regulations / Good Manufacturing Practices. Other statutory and regulatory requirements govern, among other things, establishment registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and postmarket reporting.

The regulatory process can be lengthy, expensive and uncertain. Before any new medical device may be introduced to

the market, the manufacturer generally must obtain FDA clearance or approval through either the 510(k) premarket notification process or the lengthier premarket approval application "PMA" process. It generally takes from three to 12 months from submission to obtain 510(k) premarket clearance although it may take longer. Approval of a PMA could take four or more years from the time the process is initiated. The 510(k) and PMA processes can be expensive, uncertain and lengthy, and there is no guarantee of ultimate clearance or approval. We expect that some of our future products under development will be subject to the lengthier PMA process. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA, and there can be no guarantee of ultimate clearance or approval. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications and criminal prosecution.

Medical devices also are 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 effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA.

Our current medical implants are at different stages of FDA review. We currently have 510(k) clearances for a wide variety of products and we are constantly engaged in the process of obtaining additional clearances for new and existing products. There can be no guarantee that we will be able to maintain our existing 510(k) clearances or that it will be able to obtain the necessary 510(k) clearances or PMA approvals to market and manufacture our other products in the United States for their intended use on a timely basis, if at all. The FDA approval process may be particularly problematic for our regenerative cell technology products in view of the novel nature of the technology. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a substantial negative effect on the results of our operations and financial condition.

#### ***To sell in international markets will subject us to intensive regulation in foreign countries***

In cooperation with our distribution partners, particularly Medtronic, we intend to market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order for us to market our products in Europe, Canada and certain other non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining its foreign regulatory approvals or clearances, or that we will be able to successfully commercialize its current or future products in any foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on the results of our operations and financial condition.

#### ***We may need to raise more cash in the future***

If we do not increase our sales quickly enough or if we choose to invest additional cash in areas of promise, we may be required to seek additional capital to finance our operations in the future. As of December 31, 2003, we had \$14,268,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. The acquisition of StemSource, Inc. (StemSource) has and will continue to result in a substantial requirement for research and development expenses. Other than our current equipment financing lines of credit, we currently have no commitments for any additional debt or equity financing, and there can be no guarantee that adequate funds for our operations from any additional debt or equity financing, our operating revenues, arrangements with distribution partners or from other sources will be available when needed or on terms attractive to us. The inability to obtain sufficient funds may require us to delay, scale back or eliminate some or all of our research or product development programs, manufacturing operations, clinical studies or regulatory activities or to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, and could have a substantial negative effect on the results of our operations and financial condition.

### ***We depend on a few key officers***

Our performance is substantially dependent on the performance of our executive officers and other key scientific staff, including Christopher J. Calhoun, our President and Chief Executive Officer and Marc Hedrick, MD, our Chief Scientific Officer and Medical Director. We rely upon them for strategic business decisions and guidance. We do not currently have “key person” life insurance policies on any of our employees. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

### ***We recently acquired StemSource and may undertake additional business acquisitions which will present risks associated with integrating new businesses***

Mergers and acquisitions, especially in our industry, are inherently risky, and no assurance can be given that our current or future acquisitions will be successful and will not materially adversely affect our business, operating results, or financial condition. Our recent acquisition of StemSource, as would be the same with any future acquisitions, involved numerous risks including, among others:

- Difficulties and expenses incurred in the consummation of acquisitions and integration of the operations, technologies, personnel and services or products of the acquired companies
- The risk of diverting management’s attention from normal daily operations
- Potential difficulties in completing projects associated with in-process research and development
- Risks of entering markets in which we have no or limited direct prior experience and where competitors in such markets have stronger market positions
- Initial dependence on unfamiliar supply chains or relatively small supply partners
- Insufficient revenues to offset increased expenses associated with acquisitions
- The potential loss of key employees of the acquired companies

We plan to continue to review potential acquisition candidates in the ordinary course of our business. As with the acquisition of StemSource, any future acquisitions would involve numerous business and integration risks.

### ***We may not have enough product liability insurance***

The testing, manufacturing, marketing and sale of our surgical implant products involve an inherent risk that product liability claims will be asserted against us, our distribution partners or licensees. There can be no guarantee that our current clinical trial and commercial product liability insurance is adequate or will continue to be available in sufficient amounts or at an acceptable cost, if at all. A product liability claim, product recall or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a substantial negative effect on the results of our operations and financial condition. Also, well publicized claims could cause our stock to fall sharply, even before the merits of the claims are decided by a court.

### ***Our charter documents contain anti-takeover provisions and we have adopted a Stockholder Rights Plan to prevent hostile takeovers***

Our Amended and Restated Certificate of Incorporation and Bylaws contain certain provisions that could prevent or delay the acquisition of the Company by means of a tender offer, proxy contest or otherwise, or could discourage a third party from attempting to acquire control of us, even if such events would be beneficial to the interests of our stockholders. Such provisions may have the effect of delaying, deferring or preventing a change of control of us and consequently could adversely affect the market price of our shares. Also, in 2003 we adopted a Stockholder Rights Plan, of the kind often referred to as a poison pill. The purpose of the Stockholder Rights Plan is to prevent coercive takeover tactics that may otherwise be utilized in takeover attempts. The existence of such a rights plan may also prevent or delay the change in control of the Company which could adversely affect the market price of our shares.

***The trading market for our stock in the United States is not liquid and our European stock exchange listing recently changed***

In the United States, our stock is traded through the Pink Sheets, which results in an illiquid market. Investors trading in this market may be disadvantaged in comparison to investors trading in our stock in Europe. Our stock had been traded on the Neuer Markt segment of the Frankfurt Stock Exchange, but the Neuer Markt closed in 2002. Our shares have since been listed on the "Prime Standard" segment of the Frankfurt Stock Exchange, but we cannot assure that this will result in a satisfactory trading market.

***We pay no dividends***

We currently intend not to pay any cash dividends for the foreseeable future.

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

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

**Interest Rate Exposure**

Our exposure to market risk due to fluctuations in interest rates relates primarily to short-term investments. These short-term investments, reported at an aggregate fair market value of \$11,448,000 as of December 31, 2003, consist primarily of investments in debt instruments of financial institutions, corporations with strong credit ratings and United States government obligations. These securities are subject to interest rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at December 31, 2003, for example, and assuming average investment duration of nine months, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. While we do not always have the intent, we do currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows. Changes in interest rates would, of course, affect the interest income which we earn on our cash balances after re-investment.

**Foreign Currency Exchange Rate Exposure**

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our cash balances in Europe and Japan. Although we transact business in various foreign countries, settlement amounts are usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the year ended December 31, 2003, a hypothetical 10% adverse change in the Euro against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

Notwithstanding the foregoing, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business, financial condition and results of operations. For example, foreign currency exchange rate fluctuations may affect international demand for our products. In addition, interest rate fluctuations may affect our customers' buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations.

Foreign currency exchange rates can be obtained from the website at [www.oanda.com](http://www.oanda.com).

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

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Independent Auditors' Report

The Board of Directors and Stockholders of  
MacroPore Biosurgery, Inc.:

We have audited the accompanying consolidated balance sheets of MacroPore Biosurgery, Inc. (the Company) as of December 31, 2003 and 2002, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the years then ended. In connection with our audits of the consolidated financial statements, we also have audited the financial statement schedule for the years ended December 31, 2003 and 2002. These consolidated financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedules based on our audits. The December 31, 2001 financial statements and financial statement schedule of the Company were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements and financial statement schedule in their report dated February 15, 2002.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated 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.

As discussed in Note 1 to the consolidated financial statements, the Company derives a substantial portion of its revenues from a related party.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of MacroPore Biosurgery, Inc. as of December 31, 2003 and 2002 and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related December 31, 2003 and 2002 financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Diego, California  
February 20, 2004

**This is a copy of the audit report previously issued by Arthur Andersen LLP in connection with the filing by MacroPore Biosurgery, Inc. (then known as MacroPore, Inc.) on Form 10-K for the year ended December 31, 2001. This audit report has not been reissued by Arthur Andersen LLP in connection with this filing on Form 10-K. See Exhibit 23.2 for further discussion. The balance sheets as of December 31, 2001 and 2000, and statement of operations and comprehensive income (loss), stockholders' equity and cashflows for the year ended December 31, 2000 referred to in this report have not been included in the accompanying financial statements.**

Report of Independent Auditors'

To the Board of Directors and Stockholders of  
MacroPore, Inc.

We have audited the accompanying balance sheets of MacroPore, Inc. as of December 31, 2001 and 2000 and the related statements of operations and comprehensive income, stockholders' equity and cash flows for the years then ended. 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 MacroPore, Inc. as of December 31, 2001 and 2000, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States.

Our audits were made for the purpose of forming an opinion of the basic financial statements taken as a whole. The schedule presented in Item 14(a) (2) of the Company's Report on Form 10-K for the period ended December 31, 2001 is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This schedule, for the years ended December 31, 2001 and 2000, has been subjected to the auditing procedures applied in our audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

/s/ Arthur Andersen LLP

San Diego, California

February 15, 2002 (except with respect to the matter discussed in Note 13, as to which the date is February 26, 2002)

**MACROPORE BIOSURGERY, INC.  
CONSOLIDATED BALANCE SHEETS**

	As of December 31,	
	2003	2002
<b>Assets</b>		
Current assets:		
Cash and cash equivalents.....	\$ 2,820,000	\$ 5,108,000
Short-term investments, available-for-sale.....	11,448,000	19,875,000
Accounts receivable, net of allowance for doubtful accounts of \$62,000 and \$50,000 in 2003 and 2002, respectively.....	1,291,000	1,238,000
Inventories.....	831,000	1,150,000
Other current assets.....	526,000	843,000
Total current assets.....	16,916,000	28,214,000
Property and equipment, net.....	3,822,000	3,626,000
Other assets.....	332,000	562,000
Intangibles, net.....	2,392,000	2,661,000
Goodwill.....	4,627,000	4,256,000
Total assets.....	\$ 28,089,000	\$ 39,319,000
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses.....	\$ 3,767,000	\$ 2,521,000
Current portion of long-term obligations.....	717,000	410,000
Total current liabilities.....	4,484,000	2,931,000
Deferred gain on sale of assets, related party.....	7,539,000	9,623,000
Long-term obligations, less current portion.....	1,157,000	770,000
Total liabilities.....	13,180,000	13,324,000
Commitments		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2003 and 2002.....	—	—
Common stock, \$0.001 par value; 95,000,000 shares authorized; 16,777,644 and 16,646,664 shares issued and 14,195,062 and 14,527,681 shares outstanding in 2003 and 2002, respectively.....	17,000	17,000
Additional paid-in capital.....	74,698,000	74,730,000
Unearned compensation.....	(109,000)	(1,057,000)
Accumulated deficit.....	(49,385,000)	(40,102,000)
Treasury stock, at cost.....	(9,362,000)	(7,752,000)
Treasury stock receivable.....	(976,000)	—
Accumulated other comprehensive income.....	26,000	159,000
Total stockholders' equity.....	14,909,000	25,995,000
Total liabilities and stockholders' equity.....	\$ 28,089,000	\$ 39,319,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL  
STATEMENTS

**MACROPORE BIOSURGERY, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**

	For the Years Ended December 31,		
	2003	2002	2001
Revenues:			
Sales to related party (note 17) .....	\$ 12,893,000	\$ 8,605,000	\$ 5,547,000
Sales to third parties .....	1,195,000	561,000	101,000
	14,088,000	9,166,000	5,648,000
Cost of revenues:			
Cost of revenues (including stock based compensation expense of \$12,000, \$14,000, and \$14,000 for the years ended December 31, 2003, 2002, and 2001, respectively) .....	4,244,000	3,169,000	2,401,000
Inventory provision .....	—	1,395,000	1,750,000
Gross profit.....	9,844,000	4,602,000	1,497,000
Operating expenses:			
Research and development, excluding stock based compensation expense of \$78,000, \$211,000 and \$111,000 for the years ended December 31, 2003, 2002, and 2001, respectively.....	9,071,000	5,605,000	5,487,000
Sales and marketing, excluding stock based compensation expense of \$70,000, \$134,000 and \$176,000 for the years ended December 31, 2003, 2002, and 2001, respectively .....	4,417,000	3,987,000	4,493,000
General and administrative, excluding stock based compensation expense of \$837,000, \$942,000 and \$836,000 for the years ended December 31, 2003, 2002, and 2001, respectively.....	4,581,000	3,952,000	3,578,000
Stock based compensation (excluding cost of revenues stock based compensation).....	985,000	1,287,000	1,123,000
In-process research and development .....	—	2,296,000	—
Restructuring charge.....	451,000	—	—
Equipment impairment charge .....	—	370,000	—
Total operating expenses.....	19,505,000	17,497,000	14,681,000
Other income (expense):			
Interest income .....	417,000	1,037,000	2,249,000
Interest and other expenses, net .....	(39,000)	(263,000)	(168,000)
Equity loss in investment .....	—	(882,000)	(104,000)
Net loss .....	(9,283,000)	(13,003,000)	(11,207,000)
Other comprehensive income (loss) - unrealized holding (loss) gain...	(133,000)	(191,000)	170,000
Comprehensive loss .....	\$ (9,416,000)	\$ (13,194,000)	\$ (11,037,000)
Basic and diluted net loss per share .....	\$ (0.64)	\$ (0.91)	\$ (0.75)
Shares used in calculating basic and diluted net loss per share.....	14,555,047	14,274,254	14,926,107

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001

	Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Treasury Stock		Treasury Stock Receivable	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				Shares	Amount			
Balance at December 31, 2000	14,814,346	\$ 15,000	\$ 68,126,000	\$ (3,094,000)	\$ (15,892,000)	—	\$ —	\$ —	180,000	\$ 49,335,000
Issuance of common stock under stock option plan.....	292,277	—	128,000							128,000
Compensatory stock options			148,000	989,000						1,137,000
Purchase of treasury stock...						356,120	(1,077,000)			(1,077,000)
Unrealized income on investments .....									170,000	170,000
Net loss for the year ended December 31, 2001					(11,207,000)					(11,207,000)
Balance at December 31, 2001	15,106,623	15,000	68,402,000	(2,105,000)	(27,099,000)	356,120	(1,077,000)	—	350,000	38,486,000
Issuance of common stock under stock option plan.....	92,286	—	16,000							16,000
Issuance of common stock in acquisition .....	1,447,755	2,000	5,949,000							5,951,000
Compensatory stock options			253,000	1,048,000						1,301,000
Purchase of treasury stock...						1,972,863	(7,442,000)			(7,442,000)
Sale of treasury stock...			110,000			(210,000)	767,000			877,000
Unrealized loss on investments .....									(191,000)	(191,000)
Net loss for the year ended December 31, 2002					(13,003,000)					(13,003,000)
Balance at December 31, 2002	16,646,664	17,000	74,730,000	(1,057,000)	(40,102,000)	2,118,983	(7,752,000)	—	159,000	25,995,000
Issuance of common stock under stock option plan.....	130,980	—	33,000							33,000
Compensatory stock options			49,000	948,000						997,000
Purchase of treasury stock...						614,099	(2,266,000)			(2,266,000)
Sale of treasury stock...			(10,000)			(150,500)	552,000			542,000
Treasury stock receivable .....								(976,000)		(976,000)
Exchange of unlisted common stock for common stock held in treasury			(104,000)				104,000			—
Unrealized loss on investments .....									(133,000)	(133,000)
Net loss for the year ended December 31, 2003					(9,283,000)					(9,283,000)
Balance at December 31, 2003	16,777,644	\$ 17,000	\$ 74,698,000	\$ (109,000)	\$ (49,385,000)	2,582,582	\$ (9,362,000)	\$ (976,000)	\$ 26,000	\$ 14,909,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL  
STATEMENTS

**MACROPORE BIOSURGERY, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Years Ended December 31,		
	2003	2002	2001
<b>Cash flows from operating activities:</b>			
Net loss .....	\$ (9,283,000)	\$ (13,003,000)	\$ (11,207,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	1,657,000	1,471,000	1,184,000
Loss on disposal of assets.....	14,000	91,000	—
Equipment impairment charge .....	—	370,000	—
Inventory provision .....	—	1,395,000	1,750,000
Warranty charge .....	267,000	—	—
Restructuring charge .....	153,000	—	—
Amortization of gain on sale of assets, related party .....	(2,046,000)	(267,000)	—
Stock based compensation.....	997,000	1,301,000	1,137,000
Acquired in-process research and development .....	—	2,296,000	—
Equity loss in investment .....	—	882,000	104,000
Increases (decreases) in cash caused by changes in operating assets and liabilities, excluding effects of acquisition:			
Accounts receivable .....	(53,000)	(775,000)	230,000
Inventories.....	319,000	(860,000)	(1,157,000)
Other current assets .....	317,000	284,000	31,000
Other assets .....	76,000	(304,000)	115,000
Accounts payable and accrued expenses.....	337,000	458,000	(209,000)
Deferred revenue from license agreement, related party.....	—	(225,000)	(300,000)
Net cash used in operating activities .....	<u>(7,245,000)</u>	<u>(6,886,000)</u>	<u>(8,322,000)</u>
<b>Cash flows from investing activities:</b>			
Proceeds from the sale and maturity of short-term investments .....	49,561,000	68,151,000	90,065,000
Purchases of short-term investments .....	(41,267,000)	(56,966,000)	(84,138,000)
Purchases of property and equipment .....	(1,743,000)	(909,000)	(2,664,000)
Equity investment.....	—	—	(1,000,000)
Cost of sale of assets, related party.....	(38,000)	—	—
Acquisition costs, net of cash acquired.....	(654,000)	(2,896,000)	—
Proceeds from sale of assets, related party, net.....	—	9,689,000	—
Proceeds from the sale of impaired assets .....	95,000	196,000	—
Net cash provided by investing activities.....	<u>5,954,000</u>	<u>17,265,000</u>	<u>2,263,000</u>
<b>Cash flows from financing activities:</b>			
Principal payments on capital leases .....	—	(256,000)	(114,000)
Principal payments on long-term obligations .....	(426,000)	(1,166,000)	(87,000)
Proceeds from long-term obligations.....	1,120,000	—	2,433,000
Proceeds from the exercise of employee stock options .....	33,000	16,000	128,000
Purchase of treasury stock .....	(2,266,000)	(7,442,000)	(1,077,000)
Proceeds from sale of treasury stock .....	542,000	877,000	—
Net cash (used in) provided by financing activities .....	<u>(997,000)</u>	<u>(7,971,000)</u>	<u>1,283,000</u>
Net (decrease) increase in cash .....	(2,288,000)	2,408,000	(4,776,000)
Cash and cash equivalents at beginning of year.....	<u>5,108,000</u>	<u>2,700,000</u>	<u>7,476,000</u>
Cash and cash equivalents at end of year.....	<u>\$ 2,820,000</u>	<u>\$ 5,108,000</u>	<u>\$ 2,700,000</u>

For the Years Ended December 31,		
2003	2002	2001

**Supplemental disclosure of cash flows information:**

Cash paid during period for:

Interest .....	\$ 127,000	\$ 182,000	\$ 82,000
Taxes.....	12,000	800	800

**Supplemental schedule of investing activities:**

Increase in cost of acquisition (goodwill).....	\$ 371,000	\$ —	—
Share repurchase payable.....	976,000	—	—
Tangible assets acquired .....	—	691,000	—
Goodwill acquired .....	—	4,256,000	—
In-process research and development acquired .....	—	2,296,000	—
Technology acquired.....	—	2,695,000	—
Total assets acquired .....	—	9,938,000	—
Cash acquired .....	—	(169,000)	—
Common stock issued.....	—	(5,951,000)	—
Accrued costs associated with acquisition.....	—	(530,000)	—
Initial investment, net.....	—	(14,000)	—
Liabilities assumed.....	—	(378,000)	—
Cash paid, net of cash acquired.....	—	<u>\$ 2,896,000</u>	—

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

**MACROPORE BIOSURGERY, INC.,**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001**

**1. Organization and Operations**

**The Company**

The Company is focused on research, development and commercialization of regenerative medicine technologies. The Company has two principal technology platforms: bioresorbable technology and regenerative cell technology, which target two of the largest markets in medicine, spine and orthopedic bone repair and cardiovascular tissue repair. The Company's surgical implants, which represent one of the latest advancements in spine and orthopedic medicine, are manufactured by the Company and distributed exclusively through Medtronic Sofamor Danek. Additionally, the Company is conducting research and development for an autologous cell-based technology for the regeneration and repair of damaged tissues. The Company is initially targeting the repair of heart and vascular tissues that are damaged after a myocardial infarction (heart attack).

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany transactions and balances have been eliminated. Management evaluates its investments on an individual basis for purposes of determining whether or not consolidation is appropriate. In instances where the Company does not demonstrate control through decision-making ability and/or a greater than 50% ownership interest, the Company generally accounts for the related investments under the cost or equity method, depending upon management's evaluation of the Company's ability to exercise and retain significant influence over the investee.

On November 13, 2002, the Company consummated a merger with StemSource, Inc. (StemSource) for cash and stock accounted for as a purchase (note 4). Accordingly, the acquired assets and liabilities of StemSource were recorded based on their fair values at the date of acquisition and the results of operations have been included in the financial statements for the period subsequent to the acquisition date. Previously, the Company's earlier investment in StemSource was accounted for under the equity method.

**Certain Risks and Uncertainties**

The Company has a limited operating history and its prospects are subject to the risks and uncertainties frequently encountered by companies in the early stages of development and commercialization, especially those companies in rapidly evolving and technologically advanced industries such as the medical device field. The future viability of the Company largely depends on the Company completing development of new products and receiving regulatory approvals for those products. No assurance can be given that the Company's new products will be successfully developed, regulatory approvals will be granted, or acceptance of these products will be achieved. The development of medical devices and therapeutics is subject to a number of risks, including development, regulatory and marketing risks. There can be no assurance the Company's development stage products will overcome these hurdles and become commercially viable products or meet commercial acceptance.

The Company currently purchases the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of its products, from a single qualified source, B.I. Chemicals, Inc. (B.I. Chemicals). Although the Company has a contract with B.I. Chemicals, which guarantees continuation of supply through August 15, 2005, the Company cannot guarantee that B.I. Chemicals will elect to continue the contract beyond that date, or that B.I. Chemicals will not elect to discontinue the manufacture of the material. B.I. Chemicals has agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide the Company with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Although the Company believes that it would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that the Company will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates.

For the years ended December 31, 2003, 2002 and 2001, the Company had bioresorbable product revenue from Medtronic of \$12,893,000, \$8,605,000 and \$5,547,000, respectively, which represented 91.5%, 93.9% and 98.2% of total revenues, respectively. The Company's future revenue generated from its bioresorbable products will depend on Medtronic's (our sole distributor of spine and orthopedics implants) efforts in the bioresorbable spine and orthopedics arena.

### **Capital Availability**

The Company has a limited operating history and recorded the first sale of its products in 1999. The Company incurred losses of \$9,283,000, \$13,003,000 and \$11,207,000 for the years ended December 31, 2003, 2002 and 2001, respectively, and has an accumulated deficit of \$49,385,000 as of December 31, 2003. Additionally, the Company has used net cash of \$7,245,000, \$6,886,000 and \$8,322,000 to fund its operating activities for the years ended December 31, 2003, 2002 and 2001, respectively.

Management recognizes the need to generate positive cash flows in future periods and/or to acquire additional capital from various sources. The Company believes it currently has adequate cash and cash equivalent and investment balances to fund operations at least through December 31, 2004. However, in the continued absence of positive cash flows from operations, no assurance can be given that the Company can generate sufficient revenue to cover operating costs or that additional financing will be available to the Company and, if available, on terms acceptable to the Company in the future.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. The Company's most significant estimates and critical accounting policies involve revenue recognition, as well as determining the allowance for doubtful accounts, inventory provision, warranty provision, valuation of deferred tax assets and product line disposition.

### **Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, short-term investments available-for-sale and accounts receivable substantially all of which is due from Medtronic, Inc. (Medtronic), a related party.

### **Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Investments with original maturities of three months or less that were classified as cash and cash equivalents totaled \$2,820,000 and \$5,108,000 as of December 31, 2003 and 2002, respectively, and consisted primarily of cash and highly liquid investments.

### **Short-term Investments**

The Company invests excess cash in debt instruments of financial institutions and corporations with strong credit ratings and in United States government obligations. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Investments in debt securities are accounted for in accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities," which requires that the Company determine the appropriate classification of investments at the time of purchase based on management's intent. The Company's short-term investments are classified as available-for-sale investments and are stated at fair value, with net unrealized gains or losses, if any, net of tax, reported as a separate component of stockholders' equity. Realized gains or losses from the sale of investments, interest income and dividends are included in interest income in the accompanying statements of operations and comprehensive income (loss).

Management reviews the carrying values of its investments and writes down such investments to estimated fair value by a charge to operations when in management's determination, the decline in value of an investment is considered to be other than temporary. The cost of securities sold is based on the average cost method and are recorded on the settlement date.

### **Fair Value of Financial Instruments**

The carrying amounts of the Company's cash and cash equivalents, accounts receivable and accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances. The carrying amounts of the Company's short-term debt and long-term obligations approximate fair value as the rates of interest for these

instruments approximate market rates of interest currently available to the Company for similar instruments.

### **Inventories**

Inventories include the cost of material, labor and overhead, and are stated at the lower of average cost, determined on the first-in, first-out (FIFO) method, or market. The Company periodically evaluates its on-hand stock and makes appropriate provision for any stock deemed excess or obsolete.

There was no inventory provision recorded during the year ended December 31, 2003.

During the year ended December 31, 2002, the Company recorded an inventory provision of \$1,395,000 for excess and obsolete inventory resulting from the sale of the Company's assets relating to its craniomaxillofacial "CMF" (skull and face) bone fixation implant and accessory product line to a subsidiary of Medtronic, a shareholder of the Company.

During the year ended December 31, 2001, the Company recorded an inventory provision of \$1,750,000 for excess and obsolete inventory related to the Company's CMF implant and accessory product line. The provision for excess and obsolete inventory was due to a reduction in expected future revenues associated with these products.

### **Long-Lived Assets**

In accordance with SFAS No. 144 "Accounting for Impairment or Disposal of Long-Lived Assets" (SFAS No. 144), the Company assesses certain of its long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recovered. An impairment occurs when the undiscounted cash flows expected to be generated by an asset is less than its then carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

During the year ended December 31, 2002, the Company recorded an equipment impairment charge of \$370,000 related to production assets which were used for the CMF bone fixation implant and accessory product line which were not included in the Medtronic sale (note 3). The impairment charge represented the excess of the net book value over the estimated net proceeds the Company expected it would receive upon the sale of these assets. The remaining carrying amount of the assets totaling \$162,000 was reclassified as held for sale and included within Other Assets in the accompanying balance sheet as of December 31, 2002. As of December 31, 2003, these assets have been sold or disposed of and there were no assets held for sale relating to the CMF product line.

At December 31, 2003, the Company has certain other assets held for sale. These assets include certain tangible assets related to the Company's bioresorbable thin film product line (note 19), as well as certain tangible assets associated with a foreign facility whose lease was terminated in September 2003 (note 10).

The carrying values of net assets held for sale at December 31, 2003 are:

Office and computer equipment .....	\$ 119,000
Manufacturing and development equipment.....	93,000
Total .....	<u>\$ 212,000</u>

It is anticipated that these assets will be disposed of during 2004.

The assets have been individually assessed for impairment under SFAS 144, but it is currently anticipated that the fair value of each asset, net of estimated selling costs, will exceed the respective current carrying values. Accordingly, it has not been necessary to record any write-downs to reflect the assets at the lower of carrying value or estimated fair value net of selling costs.

### **Property and Equipment**

Property and equipment is stated at cost. Depreciation expense, which includes the amortization of assets recorded under capital leases, is provided on a straight-line basis over the useful lives of the assets, which range from three to seven years. When assets are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in operations. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. Maintenance and repairs are charged to operations as incurred.

### **Goodwill and Intangibles**

Effective January 1, 2002, the Company adopted SFAS No. 142, "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes Accounting Principles Board Opinion No. 17, "Intangible Assets". Under SFAS No. 142, goodwill and indefinite-lived intangible assets are no longer amortized but are reviewed at least annually for impairment. Separable intangible assets that have finite useful lives will continue to be amortized over their useful lives.

SFAS No. 142 requires that goodwill be tested for impairment at the reporting unit level at adoption and at least annually thereafter, utilizing a two-step methodology. The initial step requires the Company to assess whether indications of impairment exist. If indications of impairment are determined to exist, the second step of measuring impairment is performed, wherein the fair value of the relevant reporting unit is compared to the carrying value, including goodwill, of such unit. If the fair value exceeds the carrying value, no impairment loss is recognized. However, if the carrying value of the reporting unit exceeds its fair value, the goodwill of the reporting unit is impaired. The Company last performed this testing as of November 30, 2003, and upon completion of step one of the SFAS No. 142 analysis concluded that there was not an indication of impairment. Therefore step two was not required.

To test goodwill for impairment, the Company first identified components of its business known as reporting units. A reporting unit is a portion of the company that:

- Has discrete financial information available, which is regularly reviewed by segment management (noting that the Company only operates in one segment – see "Segment Information" section of this note below),
- Meets the accounting definition of a business, and
- Possesses different economic characteristics than other components of the Company.

Based on these criteria, the Company determined that it has three reporting units. The Company allocated company-wide assets and liabilities to these reporting units based on management's judgment as to whether the assets and liabilities would be acquired by a willing buyer in a hypothetical disposal transaction.

All of the Company's goodwill was assigned to each of the Company's three reporting units.

None of the Company's reporting units individually trades in an active market. Pursuant to SFAS No. 142, the Company estimated the fair value of each of its reporting units on November 30, 2003 using accepted valuation methodologies. The fair value of the Company's reporting units was estimated by considering both the income approach and the market approach. Under the income approach, the fair value of a reporting unit is calculated based on the present value of estimated future cash flows. Under the market approach, fair value is estimated based on market multiples of revenue for comparable companies. In all cases, the Company determined that the estimated fair value of each reporting unit exceeded the carrying value of assets and liabilities, including goodwill, allocated to that unit. Accordingly, none of the Company's goodwill was deemed to be impaired during the year ended December 31, 2003.

Intangibles, consisting of core technology and existing technology purchased in the StemSource acquisition, are being amortized on a straight-line basis over their expected lives of ten years.

The changes in the carrying amounts of goodwill and other indefinite and finite-life intangible assets for the years ended December 31, 2003 and 2002 are as follows:

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Goodwill, net:		
Beginning balance .....	\$ 4,256,000	\$ —
Acquisition.....	371,000	4,256,000
Ending balance.....	<u>4,627,000</u>	<u>4,256,000</u>
Other intangibles, net:		
Beginning balance .....	2,661,000	—
Acquisition.....	—	2,695,000
Amortization.....	(269,000)	(34,000)
Ending balance.....	<u>2,392,000</u>	<u>2,661,000</u>
Total goodwill and other intangibles, net.....	<u>\$ 7,019,000</u>	<u>\$ 6,917,000</u>
Aggregate amortization of intangibles expense for the year ended December 31, 2003:.....	<u>\$ 235,000</u>	

Estimated amortization of intangibles for the years ended:

2004.....	\$ 269,000
2005.....	269,000
2006.....	269,000
2007.....	269,000
2008.....	269,000
Thereafter.....	1,047,000
	<u>\$ 2,392,000</u>

### Revenue Recognition

The Company sells its products to hospitals and distributors. Revenue from sales to hospitals is recognized upon delivery of the product. The Company has agreements with its distributors that title and risk of loss pass upon shipment of the products to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order. The Company warrants that its products are free from manufacturing defects at the time of shipment to its customers. The Company has recorded a reserve for the estimated costs it may incur under its warranty program.

Upfront payments received from license agreements are recognized ratably over the term of the agreement, provided no significant obligations remain, into revenues from related party or revenues from third parties depending upon the counterparty to the transaction.

The Company recognizes revenue from the collection and storage of regenerative cell rich adipose tissue. In its cell banking service the Company recognizes revenue when (i) the collection procedure is performed, (ii) the adipose tissue is received by the Company, (iii) fees from the procedure are fixed and determinable and (iv) payment is probable. The Company uses the residual method to recognize revenue when a procedure includes elements to be delivered at a future date if evidence of the fair value of all undelivered elements exists. If evidence of the fair value of the undelivered elements does not exist, revenue is deferred on all elements and recognized when all elements are delivered.

The Company recognizes revenue from regenerative cell banking as the service is performed.

The Company earns revenue for performing services under development agreements. Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, the amount of the milestone payments appears reasonably commensurate with the effort expended and collection of the payment is reasonably assured. Service income earned under development agreements is classified under revenues in

the Company's statements of operations. The costs associated with development agreements are recorded as research and development expense.

Additionally, the Company earns revenue from contracted development arrangements. These arrangements are generally time and material arrangements and accordingly any revenue is recognized as services are performed and recorded in revenues from related party or revenues from third parties based upon the nature of the transaction. Any costs related to these arrangements are recognized as cost of revenue as these costs are incurred.

In September 2002, the Company entered into various agreements with Medtronic and a related subsidiary for the sale of the Company's CMF implants product line. The net proceeds received were recorded as a deferred gain on sale of assets, related party. This gain will not be fully recognized until certain events occur. For instance, the Company has recognized in 2002 and 2003, and will recognize in 2004, a portion of the deferred gain upon the sale of the CMF products to Medtronic under the Company's back-up supply arrangement, which provides for sales of the CMF product to Medtronic at cost. The amount of the deferred gain recognized correlates to the gross margin normally charged by the Company on similar products. The remainder of the deferred gain will be recognized when the technology and know-how transfer is completed pursuant to the contract terms.

The majority of the Company's revenues are from Medtronic, under a Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002, as well as a Development and Supply Agreement dated January 5, 2000 and amended December 22, 2000 and September 30, 2002. These revenues are classified as revenues from related party in the statement of operations.

### Warranty

The Company provides a limited warranty under its agreements with its customers for products that fail to comply with product specifications. The Company has recorded a reserve for estimated costs it may incur under its warranty.

The following summarizes the Company's warranty reserve at December 31, 2003 and 2002:

	<u>Balance at January 1</u>	<u>Additions (charges to expenses)</u>	<u>Claims</u>	<u>Balance at December 31</u>
2003:				
Warranty reserve.....	\$ —	\$ 278,000	\$ (11,000)	\$ 267,000
2002:				
Warranty reserve.....	\$ —	\$ —	\$ —	\$ —

### Research and Development

Research and development expenditures are charged to operations in the period incurred.

### Income Taxes

The Company accounts for income taxes utilizing the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes." Under this method, deferred income taxes are recorded to reflect the tax consequences on future years of temporary differences between the tax bases of assets and liabilities and the corresponding financial reporting amounts at each year end. If it is more likely than not that some portion of any deferred tax asset will not be realized, a valuation allowance is recognized.

### Stock Based Compensation

The Company applies the intrinsic value-based method of accounting as prescribed by Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations including Financial Accounting Standards Board (FASB) Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation an interpretation of APB Opinion No. 25" to account for its stock option plans. Under this method, compensation expense is measured on the date of grant only if the then current market price of the underlying stock exceeded the exercise price and is recorded on a straight-line basis over the applicable vesting period. SFAS No. 123, "Accounting for Stock-Based Compensation," established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting described above, and has adopted the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure."

Under SFAS No. 123, the weighted average fair value of stock options granted during 2003, 2002 and 2001 was \$4.26, \$3.52 and \$6.18 respectively, on the date of grant. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	Years ended December 31,		
	2003	2002	2001
Expected term .....	7 years	7 years	4 years
Interest rate.....	2.8 - 3.96%	3.5 - 5.1%	3.52 - 4.81%
Volatility .....	91%	100%	60%
Dividends .....	—	—	—

Had compensation expense been recognized for stock-based compensation plans in accordance with SFAS No. 123, the Company would have recorded the following net income (loss) and net income (loss) per share amounts (in millions, except per share amounts):

	Years ended December 31,		
	2003	2002	2001
Net loss:			
As reported.....	\$ (9,283,000)	\$ (13,003,000)	\$ (11,207,000)
Add: Stock based employee compensation expense included in reported net loss, net of related tax effects	997,000	1,147,000	1,104,000
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects.....	(4,367,000)	(4,378,000)	(5,367,000)
Pro forma .....	<u>\$ (12,653,000)</u>	<u>\$ (16,234,000)</u>	<u>\$ (15,470,000)</u>
Basic and diluted loss per common share:			
As reported.....	\$ (0.64)	\$ (0.91)	\$ (0.75)
Pro forma .....	\$ (0.87)	\$ (1.14)	\$ (1.04)

The pro forma compensation expense may not be representative of such expense in future years.

#### Other Comprehensive Income (Loss)

The Company has adopted SFAS No. 130, "Reporting Comprehensive Income." This statement establishes standards for reporting and display of comprehensive income and its components in a full set of general purpose consolidated financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners. Comprehensive income is the total of net income and all other non-owner changes in equity.

During the years ended December 31, 2003, 2002 and 2001 the Company's only element of other comprehensive income (loss) resulted from unrealized gains (loss) on investments, which are reflected in the statements of changes in stockholders' equity as accumulated other comprehensive income.

#### Segment Information

The Company runs its business as a single operating segment. Specifically, all of the Company's operations, which comprise sales of medical devices, are managed at the enterprise level. This managerial decision stems from the fact that the Company's operations all share similar purpose, production processes, markets, and regulatory requirements.

The following table provides geographical information regarding the Company's sales to external customers:

For the Years Ended:	U.S. Revenues	Non-U.S. Revenues	Total Revenues
December 31, 2003 .....	\$ 13,969,000	\$ 119,000	\$ 14,088,000
December 31, 2002.....	\$ 8,855,000	\$ 311,000	\$ 9,166,000
December 31, 2001.....	\$ 4,954,000	\$ 694,000	\$ 5,648,000

The Company derives its revenues from the following products and services:

	Years ended December 31,		
	2003	2002	2001
Craniomaxillofacial .....	\$ 3,030,000	\$ 3,099,000	\$ 4,148,000
Spine & Orthopedic .....	9,882,000	5,544,000	1,500,000
Bioresorbable Thin Film.....	1,167,000	523,000	—
Regenerative cell storage.....	9,000	—	—
Totals.....	<u>\$ 14,088,000</u>	<u>\$ 9,166,000</u>	<u>\$ 5,648,000</u>

At December 31, 2003 and 2002, the Company's long-lived assets are located in the following jurisdictions:

	U.S. Domiciled	Non-U.S. Domiciled	Total
December 31, 2003 .....	\$ 4,060,000	\$ 94,000	\$ 4,154,000
December 31, 2002 .....	\$ 3,983,000	\$ 205,000	\$ 4,188,000

### Earnings (Loss) Per Share

The Company computes earnings (loss) per share based on the provision of SFAS No. 128 "Earnings Per Share." Basic per share data is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common share equivalents that would have been outstanding if potential common shares had been issued using the treasury stock method. No common share equivalents were included for periods ended December 31, 2003, 2002 and 2001 as their effect would be anti-dilutive.

The number of potential common shares excluded from the calculations of diluted loss per share for the years ended December 31, 2003, 2002 and 2001 was 4,848,000, 4,311,000 and 3,368,000, respectively, related entirely to outstanding but unexercised option awards and warrants (note 16).

### Recent Accounting Pronouncements

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of FASB Statement No. 123 (SFAS 148)." This Statement provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and requires prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company has elected not to adopt the recognition and measurement provisions of SFAS No. 123 and continue to account for the Company's stock-based employee compensation plan under APB Opinion No. 25 and related interpretations. The Company has adopted the disclosure provisions required by SFAS 148 beginning with the March 31, 2003 financial statements.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities". This pronouncement was amended by the FASB in December 2003 and renamed FASB Interpretation No. 46-R (FIN 46-R). FIN 46 and FIN 46-R clarify the application of Accounting Research Bulletin No. 51 - Consolidated Financial Statements to those entities defined as "Variable Interest Entities" (sometimes colloquially referred to as special purpose entities) in which equity investors do not have the characteristics of a "controlling financial interest" or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to all Variable Interest Entities created after January 31, 2003, and by the beginning of the first interim or annual reporting period commencing after December 15, 2003 for Variable Interest Entities created prior to February 1, 2003. FIN 46-R further delays the effective date of certain provisions of the revised interpretation until the quarter ended March 31, 2004. The adoption of FIN 46 did not have a material effect on the Company's consolidated financial position or consolidated results of operations as the Company currently does not have any variable interest entities falling within the scope of FIN 46. Moreover, the Company does not expect that FIN 46-R will have a material effect on the Company's financial position, results of operations, or cash flows.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative

instruments embedded in other contracts and for hedging activities under SFAS 133. In particular, SFAS No. 149 clarifies under what circumstances a contract within an initial net investment meets the characteristic of a derivative and when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is generally effective for contracts entered into or modified after June 30, 2003. The adoption of SFAS No. 149 did not have a material effect on the Company's consolidated financial position or consolidated results of operations as the Company currently does not have any derivative instruments and hedging activities falling within the scope of SFAS No. 149.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material effect on the Company's consolidated financial position or consolidated results of operations.

### **3. Sale of Craniomaxillofacial "CMF" Bone Fixation Implant and Accessory Product Line**

In September 2002, the Company entered into an Asset Purchase Agreement (the "Agreement") to sell assets related to its craniomaxillofacial (skull and face) bone fixation implant and accessory product line to Medtronic PS Medical, Inc. (a subsidiary of Medtronic) for a total consideration of up to \$16,000,000. In accordance with the terms of the Agreement the Company will receive consideration consisting of an initial payment of \$13,000,000 from Medtronic and additional payments totaling \$3,000,000 upon the successful transfer of technology and know-how, including training, related to the manufacture of the CMF product line. The initial payment of \$13,000,000 and the first milestone payment of \$1,000,000 occurred in the fourth quarter of 2002 and the subsequent milestone payments are expected to occur in 2004. The Agreement also requires the Company not to market, in the craniomaxillofacial field, for 5 years any products that compete with the acquired product line. Additionally, the Company will continue during the technology transfer transition period to be a back-up supplier of the acquired products to Medtronic at a price equal to the Company's cost of manufacture. Discounts from the contractual sales prices in effect prior to the sale of the CMF product line have been recorded as a reduction to the deferred gain and totaled \$2,046,000 and \$267,000 for the years ended December 31, 2003 and 2002, respectively.

The Agreement also allows the Company to receive up to \$5,000,000 if and when the Company completes successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement. The Company received this payment in February of 2004.

In a separate, but simultaneous transaction, the Company paid Medtronic \$4,000,000 in cash to amend an existing Development and Supply Agreement (the "Amended Development Agreement", and collectively with the Asset Purchase Agreement, the "Agreements") to remove a preexisting contractual right of first offer for distributorship by Medtronic of the Company's bioresorbable thin film products for use in various types of soft tissue surgical applications. Medtronic will retain its right of first offer for distributorship of the Company's other products in all fields, as well as to the Company's bioresorbable thin film products for use in the spinal application field. In addition, the term of the Amended Development Agreement with Medtronic was extended to September 30, 2012.

The Company is accounting for the net proceeds of the Agreements as a deferred gain on sale of assets, related party. This gain will not be recognized until certain events occur. For instance, the Company will recognize a portion of the deferred gain upon the sale of the CMF products to Medtronic under the Company's back-up supply arrangement, which provides for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized correlates to the gross margin normally charged by the Company on similar products. The remainder of the deferred gain will be recognized when the technology and know-how transfer is completed pursuant to the contract terms.

### **4. Acquisition**

On November 13, 2002, the Company completed the acquisition of the remaining shares of StemSource, a company engaged in research toward the development of therapies based on regenerative cells. The Company acquired the remaining stock, not already owned by the Company, in order to broaden its base in the biosurgery marketplace and to enter the therapeutic marketplace using regenerative cells. Upon the closing of the merger, the Company delivered to the StemSource stockholders 1,447,785 shares of the Company's common stock at an aggregate value of \$5,951,000,

based on \$4.11 per Company share (the average trading price five days before and after the public announcement of the acquisition), in exchange for 759,341 shares of StemSource series A preferred stock and 4,915,334 shares of StemSource common stock and underlying options that were not already owned by the Company.

Previously, on July 12, 2002, in contemplation of the merger, the Company loaned StemSource the amount of \$1,000,000 in cash ("MacroPore Loan"), in exchange for which StemSource issued a convertible promissory note. In connection with the merger, the Company assumed the MacroPore Loan. In addition, on October 4, 2002, in contemplation of the closing of the merger, the Company purchased from five separate StemSource stockholders an aggregate of 2,717,500 shares of StemSource common stock (the "MacroPore Purchases"). The consideration paid by the Company in connection with the MacroPore Purchases was an aggregate of \$1,861,000 in cash.

Before the merger and the MacroPore Purchases, the Company owned approximately 13.5% of the issued and outstanding shares of StemSource capital stock. Immediately before closing of the acquisition and giving effect to the MacroPore Purchases, the Company owned approximately 38% of the issued and outstanding shares of StemSource capital stock. For the years ended December 31, 2002 and 2001 the Company recognized an equity loss in investment of \$882,000 and \$104,000, respectively. The Company's remaining initial investment in StemSource, immediately prior to the merger, after recognizing the equity losses of StemSource, was \$14,000.

The above transaction resulted in aggregate consideration of \$8,826,000. Additionally, the Company incurred approximately \$734,000 in merger related costs and assumed approximately \$378,000 in liabilities.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the date of acquisition.

Current assets .....	\$ 445,000
Property, plant, and equipment .....	246,000
Intangible assets .....	2,695,000
In-Process research & development .....	2,296,000
Goodwill .....	<u>4,256,000</u>
Total assets acquired .....	9,938,000
Current liabilities .....	(378,000)
Net assets acquired .....	<u>\$ 9,560,000</u>

Based upon a valuation by an independent third party, \$4,256,000 of the purchase price was allocated to goodwill, \$2,695,000 to intangible assets and \$2,296,000 to in-process research and development projects, principally an on-site regenerative cell extraction unit and related technology to process regenerative cells into therapeutic products. The in-process research and development asset was written off at the date of acquisition in accordance with FASB Interpretation No. 4 "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method." The allocation of fair value to intangible assets and in-process research and development were adjusted to reflect a 87% step acquisition increase due to the Company's previous 13% equity interest in StemSource. The intangible assets were allocated \$960,000 to existing technology and know-how and \$1,735,000 to patents and core technology. The intangible assets acquired will be amortized over an expected useful life of ten years.

The value of acquired in-process research and development was computed using a discounted cash flow analysis on the anticipated income stream of the related product sales. The value assigned to acquired in-process research and development was determined by estimating the costs to develop the acquired in-process research and development into commercially viable products, estimating the resulting net cash flows from the products and discounting the net cash flows to their present value. With respect to the acquired in-process research and development, the calculations of value were adjusted to reflect the value creation efforts which were made prior to the close of the acquisition.

The development of medical devices and therapeutics is subject to a number of risks, including development, regulatory and marketing risks. There can be no assurance the Company's development stage products will overcome these hurdles and become commercially viable products or meet commercial acceptance.

The following unaudited information presents the pro forma results of operations of the Company, giving effect to certain adjustments including amortization of intangible assets acquired, as if the acquisition had taken place as of January 1 of each year presented. These pro forma results have been prepared for comparative purposes only and do not purport to be indicative of what would have occurred had the acquisition been made on such date, nor are they

necessarily indicative of future results. The pro forma results for each year below include a write-off of \$2,296,000 relating to the in-process research and development acquired in the StemSource acquisition.

	For the Years ended December 31,	
	2002	2001
	(Unaudited) (Pro forma)	
Net revenues .....	\$ 9,180,000	\$ 5,651,000
Net loss.....	\$ (14,507,000)	\$ (14,514,000)
Basic and diluted loss per share .....	\$ (0.91)	\$ (0.89)

In year ended December 31, 2003 the Company incurred and recorded to goodwill an additional \$319,000 in costs associated with exiting a leased facility acquired in the StemSource acquisition and \$52,000 in additional professional services relating to the acquisition.

## 5. Short-term Investments

As of December 31, 2003 and 2002, all short-term investments were classified as available-for-sale, which consisted of the following:

	December 31, 2003		
	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
Corporate notes and bonds .....	\$ 1,569,000	\$ 1,000	\$ 1,570,000
Agency securities.....	9,853,000	25,000	9,878,000
	<u>\$ 11,422,000</u>	<u>\$ 26,000</u>	<u>\$ 11,448,000</u>

	December 31, 2002		
	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
Corporate notes and bonds .....	\$ 6,503,000	\$ 8,000	\$ 6,511,000
Agency securities.....	13,213,000	151,000	13,364,000
	<u>\$ 19,716,000</u>	<u>\$ 159,000</u>	<u>\$ 19,875,000</u>

As of December 31, 2003 and 2002, investments available-for-sale had the following maturities:

	December 31, 2003		December 31, 2002	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Corporate notes and bonds:				
with maturity of less than 1 year .....	\$ 1,365,000	\$ 1,365,000	\$ 6,190,000	\$ 6,197,000
with maturity of 1 to 2 years .....	204,000	205,000	313,000	314,000
Agency securities:				
with maturity of less than 1 year .....	6,503,000	6,519,000	5,350,000	5,397,000
with maturity of 1 to 2 years .....	3,350,000	3,359,000	7,863,000	7,967,000
	<u>\$ 11,422,000</u>	<u>\$ 11,448,000</u>	<u>\$ 19,716,000</u>	<u>\$ 19,875,000</u>

Proceeds from sales and maturity of short term investments for the year ended December 31, 2003, 2002 and 2001 were \$49,561,000, \$68,151,000 and \$90,065,000, respectively. Gross realized gains on such sales for the years ended December 31, 2003, 2002 and 2001 were approximately \$38,000, \$166,000 and \$217,000, respectively.

## 6. Composition of Certain Financial Statement Captions

### Inventories

	December 31,	
	2003	2002
Raw materials.....	\$ 399,000	\$ 602,000
Finished goods.....	432,000	548,000
	<u>\$ 831,000</u>	<u>\$ 1,150,000</u>

### Property and Equipment, net

	December 31,	
	2003	2002
Office and computer equipment.....	\$ 1,922,000	\$ 1,874,000
Manufacturing and development equipment.....	3,685,000	2,721,000
Leasehold improvements.....	1,905,000	1,551,000
	7,512,000	6,146,000
Less accumulated depreciation and amortization.....	(3,690,000)	(2,520,000)
	<u>\$ 3,822,000</u>	<u>\$ 3,626,000</u>

### Other Assets

	December 31,	
	2003	2002
Deposits.....	\$ 120,000	\$ 400,000
Assets held for sale.....	212,000	162,000
	<u>\$ 332,000</u>	<u>\$ 562,000</u>

### Goodwill and Intangibles, net

	December 31,	
	2003	2002
Intangibles.....	\$ 2,695,000	\$ 2,695,000
Less accumulated amortization.....	(303,000)	(34,000)
	<u>\$ 2,392,000</u>	<u>\$ 2,661,000</u>

### Accounts Payable and Accrued Liabilities

	December 31,	
	2003	2002
Accounts payable.....	\$ 520,000	\$ 599,000
Share repurchase payable (note 18).....	976,000	—
Accrued bonus.....	631,000	397,000
Accrued vacation.....	468,000	325,000
Warranty provision (note 2).....	267,000	—
Accrued restructuring costs (note 10).....	153,000	—
Accrued expenses.....	752,000	1,200,000
	<u>\$ 3,767,000</u>	<u>\$ 2,521,000</u>

## 7. Commitments

The Company has contractual obligations on leases of office and manufacturing space as follows:

<u>Years Ending December 31,</u>	<u>Operating Leases</u>
2004.....	884,000
2005.....	916,000
2006.....	683,000
2007.....	620,000
2008.....	214,000
Thereafter.....	—
Total payments.....	<u>\$ 3,317,000</u>

Rent expense for the years ended December 31, 2003, 2002 and 2001 was \$931,000, \$622,000 and \$579,000, respectively.

The Company has entered into a long-term supply agreement for copolymer. The Company has agreed to purchase at least 50 kilograms of copolymer per year, at a cost of between \$2,630 and \$2,655 per kilogram, depending on the volume purchased by the Company. If the Company purchases less than 50 kilograms of the product per year, the purchase price the Company pays for the product will be subject to renegotiation. The Company purchased approximately 542 kilograms of copolymer in 2003.

## 8. License Agreement

On October 16, 2001 StemSource entered into an exclusive worldwide license agreement with the Regents of the University of California (UC), covering certain pending patent applications owned by UC for the life of these patents, with the right of sublicense (subject to certain rights retained by another university). The exclusive license relates to patent applications for isolating adipose (fat) derived regenerative cells and the making and using of such cells. In November of 2002 MacroPore acquired StemSource and UC assigned the license agreement to MacroPore.

The agreement calls for an initial lump sum payment and annual payments until such time as the licensee the Company begins commercial sales of any products utilizing this technology. Upon achieving commercial sales the licensee will pay variable royalties based on the net sales of these products sold. The royalties are further subject to minimum annual royalties increasing annually with a plateau in the fifth year. In addition, the licensee is obligated to pay certain milestone payments upon achieving any of: the filing of an investigational new drug application, applying for marketing approval, and receiving marketing approval. The licensee may also be subject to a substantial change of control payment within sixty days of either the closing of an initial public offering or a change of control transaction.

Additionally, the licensee is obligated to reimburse UC for patent prosecution costs on any patents pending or new foreign applications.

In the year ending December 31, 2003 the Company paid UC \$106,000 under this license agreement. No payments were made in 2002.

## 9. Loss on Unused Office Space

In conjunction with the acquisition of StemSource in 2002, the Company was left with significant unused office space associated with a non-cancelable 45 month operating lease commitment. The initial determination and computation of the initial provision for loss were performed in accordance with EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination."

As of December 31, 2002, the Company had met the criteria of EITF 95-3 with regards to formulating a plan to exit an activity. Additionally, the cost represented an amount to be incurred by the combined company under a contractual obligation of the acquired company that existed prior to the consummation date and continued after the plan was scheduled to be completed with no economic benefit to the combined company.

As such, the initial provision for loss totaling \$210,000 was recorded as a liability at the date of acquisition.

The initial provision for loss on unused office space recorded in 2002 was determined based upon management's analysis, review and assessment as of December 31, 2002, of the expected realization of projected sublease income associated with the expected excess facility capacity, compared to the aggregate scheduled lease payments through the remainder of the lease terms. Also, the Company consulted a national real estate consulting firm to evaluate the current market conditions regarding sublease rates, available commercial real estate capacity in the relevant market and other factors that would be necessary to assess the loss. These factors were used as the basis in estimating the sublease income in order to determine the net loss from unused office space.

During the second quarter of 2003, the estimated timeframe for when the Company would be able to exit the lease was changed. The Company again consulted a national real estate consulting firm to assess the expected range of probable sublease rates giving consideration to the current market for commercial real estate, remaining lease term, property location, and other relevant factors. Based on the expected sublease rates, remaining lease term and the estimated "sublease period," management concluded an additional provision of \$361,000 was required in the second quarter of 2003. This additional provision was recorded as an increase to goodwill.

During the third quarter of 2003, the Company negotiated a settlement of the remaining lease payments with the lessor. Based on the settlement, management reduced the provision by \$42,000 in the third quarter of 2003. This reduction was recorded as a decrease to goodwill.

At December 31, 2003 the accrual for loss on unused office space relating to lease assumed in the StemSource acquisition was zero.

## 10. Restructuring Event

In September 2003, the Company closed an administrative office in Königstein, Germany in an effort to reduce costs and consolidate operations in the U.S.A.

In connection with the facility closure, the Company involuntarily terminated three employees and relocated another employee to the United States. The employee terminations and the employee relocation all occurred on or before September 30, 2003. The Company incurred a liability of approximately \$262,000 related to severance benefits, of which \$259,000 was accrued at the end of the third quarter of 2003. In the fourth quarter of 2003 the Company accrued an additional \$20,000 related to severance benefits and paid all the severance benefits prior to December 31, 2003.

The Königstein, Germany office is rented under an operating lease. As of September 30, 2003, the Company had ceased using the office space, but continued to remain liable for monthly rent payments of approximately \$12,500 per month under a lease agreement that expires in February 2006 (the "Lease Agreement"). The Company currently subleases a small portion of the office space, but intends to exercise contractual provisions that allow the Company to terminate these subleases with 90 days notice. Thereafter, the Company will seek to sublease the entire facility for the remaining term of the Lease Agreement. However, due to the unique nature of the office building and the depressed rental market in and around Frankfurt, Germany, the Company expects that a sublease of the entire facility (if one is successfully negotiated) will yield only approximately 65% of the Company's monthly rental obligation. Accordingly, the Company may consider negotiating a settlement of the remaining lease payments with the lessor if it is unable to enter into a suitable sublease arrangement.

The following outlines the restructuring activity recorded to the liability account during the year ended December 31, 2003:

	Opening Balance	Charged to Expense*	Costs Paid	Adjustments to Liability**	Ending Balance
One-time termination benefits	\$ —	\$ 282,000	\$ (284,000)	\$ 2,000	\$ —
Lease termination .....	—	169,000	(28,000)	12,000	153,000
	<u>\$ —</u>	<u>\$ 451,000</u>	<u>\$ (312,000)</u>	<u>\$ 14,000</u>	<u>\$ 153,000</u>

\* All amounts recorded as "Restructuring charge" in the accompanying statement of operations.

\*\* Revaluation of monetary liability denominated in a foreign currency.

At each subsequent reporting date, the Company will evaluate its restructuring related liabilities to ensure that the liabilities are still appropriate. In certain instances, existing liabilities may be reversed because of efficiencies in carrying out the restructuring plan. In other instances, additional accruals may be recorded to reflect the inability of the Company to obtain previously estimated sublease income.

The restructuring liabilities recorded as of December 31, 2003 do not include accrued brokerage commissions, if any, associated with finding new sublease tenants. Such commissions will be recognized when incurred and are not expected to be material.

## 11. Stockholders Rights Plan

On May 28, 2003, the Board of Directors declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock of the Company. The dividend is payable to the stockholders of record on June 10, 2003 with respect to shares of Common Stock issued thereafter until the Distribution Date (as defined below) and, in certain circumstances, with respect to shares of Common Stock issued after the Distribution Date. Except as set forth below, each Right, when it becomes exercisable, entitles the registered holder to purchase from the Company one one-thousandth (1/1000th) of a share of Series RP Preferred Stock of the Company, \$0.001 par value per share (the "Preferred Stock"), at a price of \$25.00 per one one-thousandth (1/1000th) of a share of Preferred Stock, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement") between the Company and Computershare Trust Company, Inc., as Rights Agent, dated as of May 29, 2003.

Initially, the Rights will be attached to certificates representing shares of Common Stock then outstanding, and no separate certificates representing the Rights ("Right Certificates") will be distributed. The Rights will separate from the Common Stock upon the earlier to occur of (i) a person or group of affiliated or associated persons having acquired, without the prior approval of the Board, beneficial ownership of 15% or more of the outstanding shares of Common Stock or (ii) 10 days, or such later date as the Board may determine, following the commencement of or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in a person or group of affiliated or associated persons becoming an Acquiring Person (as defined in the Rights Agreement) except in certain circumstances (the "Distribution Date"). The Rights are not exercisable until the Distribution Date and will expire at the close of business on May 29, 2013, unless earlier redeemed by the Company.

## 12. Long-term Debt

In 2001 the Company entered into a Master Security Agreement to provide financing for equipment purchases. In connection with the agreement, the Company originally issued two promissory notes to its lender under the agreement for a total of approximately \$2,433,000. Currently, one note bears interest at 9.3% per annum with principal and interest due in monthly payments of approximately \$7,000 maturing over 36 months and is secured by equipment with a cost of \$227,000. The other promissory note bears interest at 8.8% per annum with principal and interest due in monthly payments of approximately \$34,000, maturing over 35 months and secured by equipment with a cost of \$1,442,000.

In 2003 the Company entered into an Amended Master Security Agreement to provide financing for new equipment purchases. In connection with the agreement, the Company issued three additional promissory notes to its lender under the agreement in an aggregate principal amount of approximately \$1,120,000. These notes bear interest at 8.6%, 8.6% and 8.7% per annum with principal and interest due in monthly payments of approximately \$6,000, \$8,000 and \$17,000, respectively and mature over 48, 36 and 48 month periods, respectively and are secured by equipment with a cost of \$1,120,000.

Principal payments on the five promissory notes are as follows:

For the years ended December 31,	
2004 .....	\$ 717,000
2005 .....	664,000
2006 .....	317,000
2007 .....	176,000
	<u>\$ 1,874,000</u>

### 13. Income Taxes

Due to the Company's net loss position for the years ended December 31, 2003, 2002 and 2001, and as the Company recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal or state income tax provisions for the years ended December 31, 2003, 2002, and 2001.

A reconciliation of total income tax provision (benefit) to the amount computed by applying the statutory federal income tax rate of 34% to income (loss) before income tax provision (benefit) for the years ended December 31, 2003, 2002 and 2001 is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Income tax expense (benefit) at federal statutory rate	(34.00)%	(34.00)%	(34.00)%
Stock based compensation.....	3.38%	2.50%	3.00%
Credits.....	(1.99)%	(0.35)%	(3.14)%
Change in federal valuation allowance.....	30.00%	31.50%	40.31%
Other, net.....	2.61%	0.35%	(6.17)%
	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2003 and 2002 are as follows:

	<u>2003</u>	<u>2002</u>
Deferred tax assets:		
Allowances and reserves .....	\$ 139,000	\$ 72,000
Accrued expenses .....	303,000	504,000
Deferred revenue and gain on sale of assets .....	4,025,000	5,892,000
Stock based compensation.....	1,593,000	1,633,000
Net operating loss carryforwards .....	11,866,000	6,757,000
Income tax credit carryforwards .....	1,383,000	770,000
Capitalized assets and other .....	507,000	590,000
	<u>19,816,000</u>	<u>16,218,000</u>
Valuation allowance .....	<u>(18,734,000)</u>	<u>(15,037,000)</u>
Total deferred tax assets, net of allowance .....	<u>1,082,000</u>	<u>1,181,000</u>
Deferred tax liabilities:		
Property and equipment, principally due to differences in depreciation.....	(118,000)	(53,000)
Intangibles.....	(953,000)	(1,060,000)
Other .....	<u>(11,000)</u>	<u>(68,000)</u>
Total deferred tax liability .....	<u>(1,082,000)</u>	<u>(1,181,000)</u>
Net deferred tax assets (liability) .....	<u>\$ —</u>	<u>\$ —</u>

The Company has established a valuation allowance against its deferred tax asset due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a valuation allowance of \$18,734,000 as of December 31, 2003 to reflect the estimated amount of deferred tax assets that may not be realized. The Company increased its valuation allowance by approximately \$3,697,000 for the year ended December 31, 2003. The valuation allowance includes approximately \$621,000 related to stock option deductions, the benefit of which will eventually be credited to equity.

At December 31, 2003, the Company had federal and state tax loss carryforwards of approximately \$29,700,000 and \$19,300,000 respectively. The federal and state net operating loss carryforwards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2003, the Company had federal and state tax credit carryforwards of approximately \$653,000 and \$766,000 respectively. The federal credits will begin to expire in 2017, if unused, and the state credits will begin to expire in 2009 if unused. In addition, the Company has a foreign tax loss carryforward of \$345,000 in Japan.

The Internal Revenue Code limits the future availability of net operating loss and tax credit carryforwards that arose prior to certain cumulative changes in a corporation's ownership resulting in a change of control of the Company. Due to prior ownership changes as defined in IRC Section 382, a portion of the net operating loss and tax credit carryforwards are limited in their annual utilization. In September 1999, the Company experienced an ownership change for purposes of the IRC Section 382 limitation. As of December 31, 2003, the remaining pre-change federal net operating loss carryforward of \$2,100,000 is subject to an annual limitation of approximately \$570,000. It is estimated that the pre-change net operating losses and credits will be fully available by 2008.

Additionally, in 2002 when the Company purchased StemSource, it acquired federal and state net operating loss carryforwards of approximately \$2,700,000 and \$2,700,000, respectively. This event triggered an ownership change for purposes of IRC Section 382. As of December 31, 2003, this remaining pre-change federal and state net operating loss carryforward of \$1,900,000 is subject to an annual limitation of approximately \$460,000. It is estimated that the pre-change net operating losses and credits will be fully available by 2008.

The Company does not expect that an ownership change for purposes of IRC Section 382 occurred during 2003. However, if the Company did experience an ownership change in 2003, the net operating losses may be further limited in their use. The extent of any additional limitations resulting from an ownership change in 2003 has not been determined at this time.

#### **14. Employee Benefit Plan**

The Company implemented a 401(k) retirement savings and profit sharing plan (the "Plan") effective January 1, 1999. The Company may make discretionary annual contributions to the Plan, which is allocated to the profit sharing accounts based on the number of years of employee service and compensation. At the sole discretion of the Board of Directors, the Company may also match the participants' contributions to the Plan. There were no matching contributions made by the Company to the Plan in 2003, 2002 and 2001.

#### **15. Stockholders' Equity**

##### **Preferred Stock**

The Company has authorized 5,000,000 shares of \$.001 par value preferred stock, with no shares outstanding as of December 31, 2003 and 2002. The Board of Directors of the Company is authorized to designate the terms and conditions of any preferred stock issued by the Company without further action by the common stockholders.

##### **Treasury Stock**

On April 3, 2001, the Board of Directors authorized the repurchase of up to 1,000,000 shares of the Company's common stock in the open market, from time to time until March 31, 2002, subject to the Company's assessment of market conditions and buying opportunities, and at a purchase price per share not to exceed €7.50, based on the exchange rate in effect on that date. During 2001 the Company repurchased 356,120 shares of its Common Stock at an average cost of \$3.02 per share for a total of \$1,077,000.

On April 9, 2002 and September 17, 2002, the Board of Directors amended the April 3, 2001 authorization to purchase treasury stock and authorized the repurchase of up to 3,000,000 shares of the Company's common stock in the open market, from time to time until September 16, 2003, subject to the Company's assessment of market conditions and buying opportunities, and at a purchase price per share not to exceed €15.00, based on the exchange rate in effect on September 17, 2002. During 2002 the Company repurchased 1,972,863 shares of its Common Stock at an average cost of \$3.77 per share for a total of \$7,442,000.

In 2002, the Company sold 210,000 shares of treasury stock at \$877,000 at an average price of \$4.18 per share. The basis of the treasury stock sold was the weighted average purchase price or \$3.65 per share with the difference of approximately \$110,000 accounted for as additional paid-in capital.

On August 11, 2003 the Board of Directors amended the April 3, 2001 authorization to purchase treasury stock and authorized the repurchase of up to 3,000,000 shares of the Company's common stock in the open market, from time to time until August 10, 2004 at a purchase price per share not to exceed €15.00, based on the exchange rate in effect on August 11, 2003. During 2003 the Company repurchased 614,099 shares of its Common Stock at an average cost of \$3.69 per share for a total of \$2,266,000.

In 2003, the Company sold 150,500 shares of treasury stock at \$542,000 at an average price of \$3.60 per share. The basis of the treasury stock sold was the weighted average purchase price or \$3.67 per share with the difference of \$10,000 accounted for as a reduction to additional paid-in capital.

On December 6, 2003 the Company exchanged 1,147,755 shares of common stock (all listed on the Frankfurt Stock Exchange) held in its treasury for 1,147,755 of unlisted outstanding Company common stock issued to former StemSource shareholders. The weighted average purchase price of the listed shares held in treasury at the time of the exchange was \$3.57 a share compared to a fair market value of \$3.66 a share. The difference of \$104,000 was accounted for as a charge against additional paid in capital.

The Company's purchases of its common stock are recorded at cost and are included as a component in the accompanying statement of stockholders' equity for the year ended December 31, 2003, 2002 and 2001.

See also the description in note 17 "Related Party Transactions," regarding the repurchase of 375,000 shares from related parties and note 18 "Treasury Stock Receivable, Contra-Equity Account," regarding the repurchase of 262,602 shares from a non affiliate.

## 16. Stock Based Compensation

During 1997, the Company adopted the 1997 Stock Option and Stock Purchase Plan (the "1997 Plan"), which provides for the direct award or sale of shares and for the grant of incentive stock options ("ISO") and non-statutory options to employees, directors or consultants. The 1997 Plan, as amended, provides for the issuance of up to 7,000,000 shares of the Company's common stock.

The exercise price of ISOs cannot be less than the fair market value of the underlying shares on the date of grant. ISOs can be granted only to employees. Option vesting is determined by the Board of Directors and is generally over a four-year period. Options expire no later than ten years from date of grant.

The following summarizes activity with respect to the options granted under the 1997 Plan:

	Years ended December 31,					
	2003		2002		2001	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period.....	4,263,000	\$ 3.85	3,320,000	\$ 4.49	2,750,000	\$ 3.44
Granted.....	896,000	\$ 4.26	1,470,000	\$ 3.52	1,578,000	\$ 6.18
Exercised.....	(131,000)	\$ 0.26	(92,000)	\$ 0.17	(292,000)	\$ 0.44
Forfeited.....	(227,000)	\$ 5.13	(435,000)	\$ 8.44	(716,000)	\$ 5.82
Options outstanding at end of period .....	<u>4,801,000</u>	\$ 3.96	<u>4,263,000</u>	\$ 3.85	<u>3,320,000</u>	\$ 4.49
Options vested at end of period .....	<u>3,130,000</u>	\$ 3.78	<u>2,241,000</u>	\$ 3.28	<u>1,329,000</u>	\$ 2.88

The following table summarizes information about options outstanding under the 1997 Plan as of December 31, 2003:

Range of Exercise Price .....	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Options Vested	Weighted Average Exercise Price
\$ 0.05 - \$1.90 .....	621,000	\$ 0.25	4.9	621,000	\$ 0.25
\$ 2.50 - 3.00 .....	1,098,000	\$ 2.92	6.5	998,000	\$ 2.95
\$ 3.09 - 3.88 .....	892,000	\$ 3.23	8.3	398,000	\$ 3.19
\$ 4.00 - 5.00 .....	1,236,000	\$ 4.30	8.9	374,000	\$ 4.32
\$ 5.50 - 7.50 .....	776,000	\$ 6.93	7.0	590,000	\$ 6.95
\$ 8.00 - 17.26 .....	<u>178,000</u>	\$ 11.82	6.8	<u>149,000</u>	\$ 11.73
\$ 0.05 - \$17.26.....	<u>4,801,000</u>	\$ 3.96	7.3	<u>3,130,000</u>	\$ 3.78

The weighted-average fair value of options granted for the years ended 2003, 2002 and 2001 was \$3.54, \$2.48 and \$3.11, respectively.

#### **Unearned Stock Based Compensation**

In connection with the grant of stock options to employees and directors, the Company recorded unearned stock based compensation within stockholders' equity of \$49,000, \$99,000 and \$115,000 during the years ended December 31, 2003, 2002 and 2001, respectively. This represents the difference between the exercise price of these stock based awards and the deemed market value of the underlying common stock on the date of grant, reduced by any forfeitures during the period. Amortization of unearned stock based compensation, net of any charges reversed during the period for the forfeiture of unvested awards, was \$997,000, \$1,147,000 and \$1,104,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

The remaining unearned stock based compensation of \$109,000 at December 31, 2003 will be expensed in 2004. The amount of stock based compensation expense to be recorded in future periods could decrease if unvested awards are forfeited and previously recorded compensation expense related to those unvested awards is reversed.

#### **Non-Employee Stock Based Compensation**

The Company issued 50,000 stock options to non-employees for consulting services for the year ended December 31, 2002. The weighted-average fair value per share of stock options issued and remeasured to non-employees for the years ended December 31, 2002 and 2001 was \$2.19 and \$3.20, respectively. As a result, the Company recorded stock based compensation expense of \$154,000 and \$33,000 for the years ended December 31 2002 and 2001, respectively. The fair value of the grants was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the years ended December 31, 2002 and 2001 expected dividend yield of 0.0%, risk-free interest rate ranging from 3.87% to 4.72%, expected volatility factor ranging from 60% to 108% and expected life of 4 years.

#### **Warrants**

The Company issued warrants to purchase 25,000 shares of Series C convertible preferred stock with an exercise price of \$2.25 per share, in connection with its convertible bridge loan financing in 1998 and 1999. All of the warrants are currently exercisable and begin to expire in September 2008. As of December 31, 2003, 2,777 of these warrants had been exercised. Upon conversion of the Company's outstanding preferred stock into common stock, which occurred in August 2000, the warrants became immediately exercisable into shares of the Company's common stock.

In connection with a termination of a sales distribution agreement in 2000, the Company issued warrants to purchase 25,000 shares of common stock with an exercise price of \$12.00 per share. All the warrants are exercisable and expire in July 2004. As of December 31, 2002, none of these warrants have been exercised. The Company accounted for the warrants under the Black-Scholes method of SFAS No. 123 and \$33,000 of stock based compensation was recorded in 2000.

### **17. Related Party Transactions**

In January 2000, the Company entered into a five-year distribution agreement with Medtronic. Under the terms of the agreement, the Company granted Medtronic exclusive worldwide rights, except for certain international rights previously granted, to market, distribute and sell all of the Company's products for use in the cranial and facial areas. In consideration for this exclusive right, Medtronic paid a \$1,500,000 up-front license fee to the Company, which will be recognized ratably over the same five-year period. Additionally, Medtronic was required to purchase a minimum amount of product at agreed-upon prices for the first fifteen months of the agreement, as amended. The Company and Medtronic concurrently entered into a five-year development and supply agreement, which provides Medtronic exclusive worldwide rights for products developed as a result of the agreement. The terms of the aforementioned distribution agreement and development and supply agreement are consistent with the terms of MacroPore distribution agreements with unaffiliated third parties. Additionally, in January 2000, Medtronic purchased 1,000,000 shares of

Series D convertible preferred stock for \$3,500,000. The terms of the sale of the Series D convertible preferred stock were equivalent to the terms and price paid by unaffiliated third parties who also purchased shares of Series D convertible preferred stock. Medtronic continues to hold at December 31, 2003, 1,000,000 shares of the Company's common stock, which constitutes 7.0% of the Company's outstanding common stock at December 31, 2003. For the years ended December 31, 2003, 2002 and 2001, the Company had sales to Medtronic of \$12,893,000, \$8,605,000 and \$5,547,000, respectively, which represented 91.5%, 93.9% and 98.2% of total revenues, respectively. At December 31, 2003 and 2002, the Company had amounts due from Medtronic of \$1,136,000 and \$1,073,000, respectively. In connection with the sale of the craniomaxillofacial product line to Medtronic, the terms of this agreement have changed substantially. (See Note 3)

On February 26, 2002, the Company extended loans to two of its directors, who also serve as officers, in the aggregate amount of \$478,000, for the purchase of shares of the Company's common stock from another of the Company's stockholders. The loans carried an annual interest rate of 5.75%, subject to adjustment once a year on the anniversary of the issuance date of the loan based on prime plus one percent. The loans were secured by a pledge of all of the stock purchased with the proceeds of the loan, were full recourse and matured in February 2005. The notes were repaid in full in December 2002.

On December 8, 2003, the Company repurchased from two of its executives (each a senior officer and a director) and from a trust for the benefit of the family of another senior officer and director, a total of 375,000 shares of common stock for \$1,393,000 in cash. The repurchase price was established by the Board of Directors as 100% of the mean average of the closing sale prices of the Company's common stock on the Frankfurt Stock Exchange over the 10 trading days before the repurchase. The Company is holding the 375,000 shares as treasury stock.

#### **18. Treasury Stock Receivable Contra-Equity Account**

On December 17, 2003, the Company agreed to repurchase 262,602 shares of its common stock for \$975,934 in cash from a former director and officer of StemSource, Inc., who was also a stockholder of StemSource when the Company acquired StemSource on November 13, 2002. The Company had issued its common stock to this stockholder (who never became a director, officer or employee of the Company) in exchange for his StemSource shares.

All of the shares issued to acquire StemSource, including the 262,602 shares to be repurchased, were unlisted. Accordingly, these shares were restricted from sale in a public market.

As part of the StemSource acquisition agreement, the Company agreed to list the unlisted shares on a liquid market by December 13, 2003. Although most of the Company's outstanding shares of common stock are listed on the Frankfurt Stock Exchange and the unlisted StemSource acquisition shares would have been eligible for listing on the Frankfurt Stock Exchange, the Company elected not to apply to list them. At the time of the acquisition, and in late 2003, the Company held as treasury stock in excess of 1,500,000 listed shares of its common stock. Accordingly, in lieu of listing the shares issued in the StemSource acquisition, the Company simply swapped listed treasury shares for the unlisted acquisition shares, before thirteen months following the acquisition date.

In December 2003, logistical problems prevented the Company from formally delivering the listed securities into all of the respected holders brokerage accounts. The former director and officer of StemSource, Inc. purported to exercise a contractual right embedded in the StemSource acquisition agreement to put 262,602 shares that he received as part of the StemSource acquisition back to the Company at a calculated price (approximating market value), as the Company had not listed and delivered his shares nor delivered the swapped-in listed shares into his brokerage account by the December 13, 2003 deadline. The other former StemSource shareholders either received Frankfurt Stock Exchange-listed shares before the December 13, 2003 deadline or allowed their put right to lapse.

The Company has recorded its obligation to repurchase the shares of common stock from the former StemSource owner as a liability included in accounts payable and accrued expenses (see note 6). The Company also recorded the shares to be received as "Treasury stock receivable," a contra-equity account. The repurchase was effected in January 2004.

#### **19. Agreement to Sell Bioresorbable Thin Film Product Line**

On December 13, 2003 the Company entered into an agreement with Medicis Ventures Management GmbH to sell substantially all the assets of the Company's bioresorbable thin film product line for \$7,000,000 in cash at closing, a secured one-year note for \$5,000,000 and a \$200,000 milestone payment for a specified regulatory approval. In addition, the Company would receive a nonexclusive, perpetual, worldwide, royalty-free license to the thin film

technology for the regenerative-medicine field of use, and a worldwide exclusive, royalty-free license to thin-polymeric-film implants for spinal surgery, and the parties would enter into a temporary business development and revenue sharing agreement for the territory of Japan. The Company also agreed to act as Medicis' back-up supplier of the thin film bioresorbable implant products for one year after the closing of the sale of the product line. As of December 31, 2003, the product line assets which totals \$212,000 were included in "assets held for sale."

## 20. Quarterly Information (unaudited)

The following unaudited quarterly financial information includes, in management's opinion, all the normal and recurring adjustments necessary to fairly state the results of operations and related information for the periods presented.

	For the three months ended,			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
Revenues.....	\$ 1,929,000	\$ 2,903,000	\$ 4,495,000	\$ 4,761,000
Gross profit.....	1,290,000	2,116,000	3,057,000	3,381,000
Operating expenses, excluding stock based compensation.....	4,494,000	4,062,000	5,491,000	4,473,000
Stock based compensation .....	213,000	212,000	447,000	113,000
Other income (expenses).....	137,000	99,000	82,000	60,000
Net loss .....	<u>(3,280,000)</u>	<u>(2,059,000)</u>	<u>(2,799,000)</u>	<u>(1,145,000)</u>
Basic and diluted net loss per share .....	<u>\$ (0.23)</u>	<u>\$ (0.14)</u>	<u>\$ (0.19)</u>	<u>\$ (0.08)</u>

	For the three months ended,			
	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002
Revenues.....	\$ 1,110,000	\$ 2,707,000	\$ 3,302,000	\$ 2,047,000
Gross profit.....	560,000	1,726,000	956,000	1,360,000
Operating expenses, excluding stock based compensation.....	3,269,000	3,269,000	3,622,000	6,050,000
Stock based compensation .....	469,000	275,000	273,000	270,000
Other expenses.....	244,000	215,000	(27,000)	(540,000)
Net loss .....	<u>(2,934,000)</u>	<u>(1,603,000)</u>	<u>(2,966,000)</u>	<u>(5,500,000)</u>
Basic and diluted net loss per share .....	<u>\$ (0.20)</u>	<u>\$ (0.11)</u>	<u>\$ (0.21)</u>	<u>\$ (0.39)</u>

In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations have been included.

Net loss from continuing operations in the fourth quarter of 2002 includes in-process research and development of \$2,296,000 related to the acquisition of StemSource.

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

Not applicable.

### Item 9a. Controls and Procedures

Within 90 days before the filing of this report, our Chief Executive Officer and Principal Financial Officer, Mr. Calhoun carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, Mr. Calhoun concluded that our disclosure controls and procedures are effective in causing material information to be collected, communicated and analyzed by management of the Company on a timely basis and to ensure that the quality and timeliness of our public disclosures comply with our SEC disclosure obligations.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls after the date of such evaluation.

### **PART III**

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

The information called for by Item 10 with respect to identification of our directors and executive officers is incorporated herein by reference to the material under the captions "Election of Directors" and "Compensation and Other Information Concerning Directors and Executive Officers" in our proxy statement for our 2004 annual stockholders meeting, which will be filed with the Commission before April 29, 2004.

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

The information called for by Item 11 with respect to executive compensation is incorporated herein by reference to the material under the caption "Compensation and Other Information Concerning Directors and Executive Officers" in our proxy statement for our 2004 annual stockholders meeting, which will be filed with the Commission before April 29, 2004.

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

The information called for by Item 12 with respect to security ownership of beneficial owners of more than 10% of our common stock and management is incorporated herein by reference to the material under the caption "Security Ownership of Certain Beneficial Owners and Management" in our proxy statement for our 2004 annual stockholders meeting, which will be filed with the Commission before April 29, 2004.

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

The information called for by Item 13 with respect to certain relationships and related transactions is incorporated herein by reference to the material under the caption "Compensation and Other Information Concerning Directors and Executive Officers – Certain Relationships and Related Transactions" in our proxy statement for our 2004 annual stockholders meeting, which will be filed with the Commission before April 29, 2003.

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

The information called for by Item 14 with respect to Principal Accountant Fees and Services incorporated herein by reference to the material under the caption "Fees Paid to KPMG LLP" in our proxy statement for our 2004 annual stockholders meeting, which will be filed with the Commission before April 29, 2004.

**PART IV**

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

**(a) (1) Financial Statements**

Report of KPMG LLP, Independent Auditors	39
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Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2003, 2002 and 2001	42
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2003, 2002 and 2001	43
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**(a) (2) Financial Statement Schedules**

**SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS**

For the years ended December 31, 2003, 2002 and 2001  
(in thousands of dollars)

	Balance at beginning of year	Additions (charges to expense)	Charged to Other Accounts	Deductions	Balance at end of year
<u>Allowance for doubtful accounts</u>					
Year ended December 31, 2003...	\$ 50	\$ 15	\$ —	\$ 3	\$ 62
Year ended December 31, 2002...	35	15	—	—	50
Year ended December 31, 2001...	\$ 75	\$ 4	\$ —	\$ 44	\$ 35
<u>Purchase accounting reserves</u>					
Year ended December 31, 2003...	\$ 515	\$ —	\$ 371*	\$ 858	\$ 28
Year ended December 31, 2002...	\$ —	\$ —	\$ 735	\$ 220	\$ 515

\* Amount charged to goodwill. As discussed in note 9 to the Consolidated Financial Statements, the Company revised by \$319,000 its estimate of the costs associated with exiting a leased facility acquired in the StemSource acquisition. In addition, the Company incurred \$52,000 in additional professional services relating to the acquisition.

**(a)(3) Exhibits**

Exhibit Number	Description
2.1	Agreement and Plan of Reorganization, dated October 9, 2002, by and between the Company and StemSource, Inc. (filed as Exhibit 2.1 to our Current Report on Form 8-K which was filed with

the Commission on November 27, 2002 and incorporated by reference herein)

- 2.2 Amendment No. 1 to Agreement and Plan of Reorganization, dated November 4, 2002, by and between the Company and StemSource, Inc. (filed as Exhibit 2.2 to our Current Report on Form 8-K which was filed with the Commission on November 27, 2002 and incorporated by reference herein).
- 3.1 Amended and Restated Certificate of Incorporation of MacroPore, Inc. (filed as Exhibit 3.1 to our Form 10 registration statement, as amended, as filed on March 30, 2001 and incorporated by reference herein)
- 3.2 Amended and Restated Bylaws of MacroPore Biosurgery, Inc. (filed as Exhibit 3.2 to our Form 10-Q Quarterly Report, as filed on August 14, 2003 and incorporated by reference herein)
- 4.1 Rights Agreement, dated as of May 19, 2003, between MacroPore Biosurgery, Inc. and Computershare Trust Company, Inc. as Rights Agent, which includes: as Exhibit A thereto, the Form of Certificate of Designation, Preferences and Rights of Series RP Preferred Stock of MacroPore Biosurgery, Inc.; as Exhibit B thereto, the Form of Right Certificate; and, as Exhibit C thereto, the Summary of Rights to Purchase Series RP Preferred Stock (filed as Exhibit 4.1 on Form 8-A which was filed on May 30, 2003 and incorporated by reference herein)
- 10.1 Amended and Restated 1997 Stock Option and Stock Purchase Plan (filed as Exhibit 10.1 to our Form 10 registration statement, as amended, as filed on March 30, 2001 and incorporated by reference herein)
- 10.2+ Distribution Agreement, made and entered into as of January 5, 2000, between MacroPore, Inc. and Medtronic, Inc. (filed as Exhibit 10.2 to our Form 10 registration statement, as amended, as filed on June 1, 2001 and incorporated by reference herein)
- 10.3+ Amendment No. 1 to Distribution Agreement, effective as of December 22, 2000, by and between the Company and Medtronic (filed as Exhibit 10.3 to our Form 10 registration statement, as amended, as filed on June 1, 2001 and incorporated by reference herein)
- 10.4+ Development and Supply Agreement, made and entered into as of January 5, 2000, by and between the Company and Medtronic (filed as Exhibit 10.4 to our Form 10 registration statement, as amended, as filed on June 1, 2001 and incorporated by reference herein)
- 10.5+ Amendment No. 1 to Development and Supply Agreement, effective as of December 22, 2000, by and between the Company and Medtronic (filed as Exhibit 10.5 to our Form 10 registration statement, as amended, as filed on June 1, 2001 and incorporated by reference herein)
- 10.6+ Asset Purchase Agreement, effective as of September 30, 2002, by and between the Company and Medtronic PS Medical, Inc. (filed as Exhibit 2.1 to our Current Report on Form 8-K which was filed on October 23, 2002 and incorporated by reference herein)
- 10.7+ License Agreement, effective as of October 8, 2002, by and between the Company and Medtronic PS Medical, Inc. (filed as Exhibit 2.2 to our Current Report on Form 8-K which was filed on October 23, 2002 and incorporated by reference herein)
- 10.8+ Amended and Restated Distribution Agreement, effective as of October 8, 2002, by and between the Company and Medtronic, Inc. (filed as Exhibit 2.3 to our Current Report on Form 8-K which was filed on October 23, 2002 and incorporated by reference herein)
- 10.9+ Amendment No. 2 to Development and Supply Agreement, effective as of September 30, 2002, by and between the Company and Medtronic, Inc. (filed as Exhibit 2.4 to our Current Report on Form 8-K which was filed on October 23, 2002 and incorporated by reference herein)

- 10.10+ Exclusive License Agreement, effective October 16, 2001, by and between The Regents of the University of California and StemSource, Inc. (the Company was substituted for StemSource in the agreement effective November 8, 2002) (filed as Exhibit 10.10 to our Annual Report on Form 10-K which was filed on March 31, 2002 and incorporated by reference herein)
- 10.11 Retirement Separation Agreement and General Release, effective April 1, 2002, by and between The Company and Michael J. Simpson (filed as Exhibit 10.15 to our Annual Report on Form 10-K which was filed on March 31, 2002 and incorporated by reference herein)
- 10.12 Consulting Services Agreement, effective April 1, 2002, by and between The Company and Michael J. Simpson (filed as Exhibit 10.16 to our Annual Report on Form 10-K which was filed on March 31, 2002 and incorporated by reference herein)
- 10.13 Amended Master Security Agreement between the Company and General Electric Corporation, September, 2003 (filed as Exhibit 10.1 to our Form 10-Q Quarterly Report, as filed on November 12, 2003 and incorporated by reference herein)
- 10.14 Lease Termination Agreement for the Premises Located at 1125 Business Center Circle, Thousand Oaks, California, July, 2003 (filed as Exhibit 10.2 to our Form 10-Q Quarterly Report, as filed on November 12, 2003 and incorporated by reference herein)
- 10.15+ Separation Agreement and General Release between the Company and Ari Bizimis, September, 2003 (filed as Exhibit 10.3 to our Form 10-Q Quarterly Report, as filed on November 12, 2003 and incorporated by reference herein)
- 10.16+ Asset Purchase Agreement, entered into as of December 13, 2002, by and between the Company and Medicis Ventures Management GmbH
- 14.1 Code of Ethics
- 23.1 Consent of KPMG LLP, independent auditors
- 23.2 Notice regarding consent of Arthur Andersen LLP
- 24.1 Power of Attorney (contained in the signature page).
- 31.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes – Oxley Act of 2002

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+ Portions of these exhibits have been omitted pursuant to a request for confidential treatment.

(b) Reports on Form 8-K

On November 3, 2003, we filed a Current Report on Form 8-K with the SEC with regard to a press release announcing financial results for the quarter ended September 30, 2003.

On October 23, 2003, we filed a Current Report on Form 8-K with the SEC regarding an anticipated announcement of revenues for the quarter ended September 30, 2003.

## SIGNATURES

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

MACROPORE BIOSURGERY, INC.

By: /s/ Christopher J. Calhoun  
 Christopher J. Calhoun  
*Chief Executive Officer, and President*  
 March 30, 2004

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

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Marshall G. Cox</u> Marshall G. Cox	<i>Chairman of the Board of Directors</i>	March 30, 2004
<u>/s/ Christopher J. Calhoun</u> Christopher J. Calhoun	<i>Chief Executive Officer, President, and Director (Principal Executive Officer and Principal Financial Officer)</i>	March 30, 2004
<u>/s/ Marc H. Hedrick, MD</u> Marc H. Hedrick, MD	<i>Chief Scientific Officer, Medical Director and Director</i>	March 30, 2003
<u>s/ Charles E. Galetto</u> Charles E. Galetto	<i>Senior Vice President of Finance (Principal Accounting Officer)</i>	March 30, 2004
<u>/s/ David Rickey</u> David Rickey	<i>Director</i>	March 30, 2004
<u>/s/ Ron Henriksen</u> Ron Henriksen	<i>Director</i>	March 30, 2004
<u>/s/ Carmack E. Holmes</u> Carmack E. Holmes	<i>Director</i>	March 30, 2004

**Board of Directors**

**Marshall G. Cox**  
 Chairman of the Board,  
 MacroPore Biosurgery  
 Chairman Emeritus,  
 Western Micro Technology, Inc.

**Christopher J. Calhoun**  
 Chief Executive Officer,  
 Vice Chairman,  
 MacroPore Biosurgery

**Marc H. Hedrick, MD**  
 President,  
 MacroPore Biosurgery

**David Riekey**  
 Chairman Compensation Committee,  
 MacroPore Biosurgery  
 President and Chief Executive Officer,  
 Applied Micro Circuits Corporation

**Ronald D. Henriksen**  
 Chairman Audit Committee,  
 MacroPore Biosurgery  
 Chief Investment Officer,  
 Twilight Ventures, LLC

**E. Carmack Holmes, MD**  
 Professor, Division of Thoracic Surgery,  
 David Geffen School of Medicine  
 at UCLA

**Executive Officers**

**Christopher J. Calhoun**  
 Chief Executive Officer

**Marc H. Hedrick, MD**  
 President

**Sharon Schulzki**  
 Chief Operating Officer

**Mark E. Saad**  
 Chief Financial Officer

**Bruce Reuter**  
 Senior Vice President,  
 Business Development

**Charles E. Galetto**  
 Senior Vice President,  
 Finance and Administration  
 Treasurer

**Matthew Scott**  
 Vice President,  
 Vascular Regenerative Medicine

**John K. Fraser, PhD**  
 Vice President,

Research & Technology

**Elizabeth A. Scarbrough**  
 Vice President,  
 Marketing & Development

**Seijiro Shirahama**  
 Vice President,  
 Asia Pacific

**Stockholder Information**

**Corporate Office**  
 MacroPore Biosurgery  
 6740 Top Gun Street  
 San Diego, California 92121  
 Tel: (858) 458-0900  
 Fax: (858) 458-0994

**SEC Form 10-K**  
 A copy of the Company's Annual  
 Report on Form 10-K for the year  
 ended December 31, 2003, filed  
 with the Securities and Exchange  
 Commission, is available without  
 charge upon written request to  
 Investor Relations, MacroPore  
 Biosurgery, 6740 Top Gun Street,  
 San Diego, California 92121, by  
 calling (877) 470-8000, or by  
 accessing the company's website  
 at [www.macropore.com](http://www.macropore.com).

**Stockholder Inquiries**  
 Tom Baker  
 Director, Investor Relations  
 Tel: (858) 362-0361  
[tbaker@macropore.com](mailto:tbaker@macropore.com)

**Stefanie Bacher**  
 Manager, Investor Relations  
 Tel: (858) 362-0365  
[sbacher@macropore.com](mailto:sbacher@macropore.com)

**Independent Auditors**  
 KPMG LLP  
 San Diego, California

**Legal Counsel**  
 Heller Ehrman White & McAuliffe LLP  
 San Diego, California

**Trading Symbol**  
 MacroPore Biosurgery, Inc. is a  
 publicly held corporation traded on  
 the Frankfurt Stock Exchange in  
 Germany under the symbol XIMP.

**Annual Meeting**  
 The Annual Meeting will be held on  
 Tuesday, August 24, 2004 at 9:00 a.m.  
 (Pacific Daylight Time) at MacroPore  
 Biosurgery, 6740 Top Gun Street,  
 San Diego, CA, 92121.

Spine and orthopedic products are exclusively distributed by Medtronic Sofamor Danek.  
 HYDROSORB™ is a trademark of Medtronic Sofamor Danek.  
 Boomerang® and Telamon® are registered trademarks of Medtronic Sofamor Danek.  
 MacroPore is a registered trademark of MacroPore Biosurgery.  
 MacroPore OS Spine™ is a trademark of MacroPore Biosurgery.  
 CardioWrap™ and SurgiWrap™ are trademarks of MAST Biosurgery AG.

**MACRO**  **PORE**  
**BIO SURGERY**

6740 Top Gun Street  
San Diego, California 92121  
Tel: (858) 458-0900  
Fax: (858) 458-0994

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