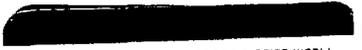


AR/S

# MacroPore Biosurgery, Inc.



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## Annual Report

*For the year ended December 31, 2002*

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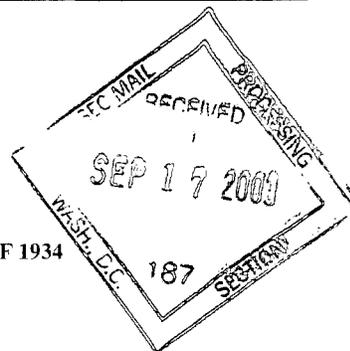
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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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, 2002

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)

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

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

**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 28, 2002 (the last business day of the registrant's most recently completed second fiscal quarter) was \$48,263,520 based on the average of the reported high and low sales price of the registrant's common stock on June 28, 2002 as reported on the Frankfurt Stock Exchange, of 4.25 Euros, or \$4.22 per share, based on the exchange rate in effect as of such date.

As of January 31, 2003, there were 14,522,685 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the 2003 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, 2002, are incorporated by reference in Part III, Items 10, 11, 12 and 13 of this Form 10-K.

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### 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.

## PART I

### Item 1. Business

#### General

We were initially formed as a California general partnership in July 1996, and incorporated in the State of Delaware in May 1997. Our two platform technologies include biomaterials (bioresorbable implants) and biologics (regenerative medicine). Within our biomaterials platform we design, develop, manufacture and market bioresorbable polymer implants for use in the reconstruction, repair and regeneration of hard tissue (bone) and soft tissue throughout the body. Additionally, we design, develop, and manufacture related instruments and accessories used in connection with our implants. Our bioresorbable implants are used in spine, orthopedic, neurosurgical, and other musculoskeletal reconstructive surgical applications, while our bioresorbable thin films are used for soft tissue applications.

In 2002 we sold our craniomaxillofacial “CMF” (skull and face) bone fixation implant and accessory product line to a subsidiary of Medtronic, Inc. “Medtronic”. We will continue to be a backup supplier for the acquired products during a brief transition period.

In November 2002, we acquired StemSource, Inc. “StemSource”, a California company specializing in stem cell bioengineering, research and technology. This has allowed us to begin developing our biologics platform technology of regenerative (stem cell) therapies using adult stem cells derived from a patient’s own adipose (fat) tissue. In addition, this acquisition provides us technology in the field of stem cell preservation and banking, offering the opportunity for people worldwide to bank their stem cells for later personal use.

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.

We believe the benefits of using a bioresorbable material in bone healing and regenerating applications include:

- no long-term growth restrictions such as those related to the use of metallic plates and screws in pediatric patients
- no distortion of diagnostic and therapeutic imaging and no creation of imaging artifacts such as are commonly encountered with metal systems
- no long-term patient palpation
- no interference with x-rays
- virtually eliminates thermal sensitivity from temperature changes
- reduced risk of migration of plates and screws during the bone healing process
- lowered risk of infection
- strength appropriate for specific applications
- predictable resorption rate
- avoids risk of disease transmission associated with human or animal materials
- may eliminate additional surgery to remove non-bioresorbable implants
- encouragement of normal bone growth and increased strength of regenerated bone compared to non-bioresorbable products, particularly metal, that may shield the bone from the stress that facilitates bone growth and bone strength

In addition, because of the thermoplastic properties, bioresorbable products can be easily shaped, sized and applied to varying anatomical structures. We believe this ease-of-use along with the versatility capabilities allows the surgeon to save time in the operating room.

We have received regulatory clearance or approval to market and sell some of our bioresorbable implant products in the United States, Canada, Europe and other countries.

In January 2000, we entered into an exclusive worldwide Distribution Agreement with Medtronic, Inc. for the global marketing and distribution of some of our products for use in CMF applications. We also entered into a Development and Supply Agreement, in January 2000 with Medtronic, to co-develop bioresorbable implants for use in spinal fixation, stabilization and fusion applications and supply any such new implants to Medtronic as the distributor. In September 2002, we entered into an agreement to sell substantially all of the assets related to the CMF line of business to a subsidiary of Medtronic. The sale included a perpetual exclusive license to certain intangible assets to be used in the CMF surgical field, along with use of our bioresorbable implants for repair of the bone harvest site in the iliac crest. We retained all other rights to use the intangible assets in other parts of the body. In another agreement with Medtronic on the same day, we extended the term of our existing co-development and supply agreement for spinal implants to 2012, and obtained a waiver of the right of first offer to market our bioresorbable films in certain fields.

We are continuing development of new products and materials useful for the repair and regeneration of bone. We are currently engaged in a clinical study related to our new faster-resorbing polymer (FRP) which may be particularly useful in treating pediatric patients due to their rapid rate of bone growth, and we are developing additional products for use in spinal fusion procedures, long-bone repair, healing of nonunion fractures and cyst or tumor removal site repair, 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.

Building on our initial biomaterials platform technology, we have developed the SurgiWrap™ and CardioWrap™ families of bioresorbable surgical thin film. These products are constructed from the same polylactide copolymer as our other implants. Our bioresorbable thin films have present and potential clinical applications across multiple surgical specialties in which the primary intended market includes the control of postsurgical adhesions in cardiothoracic, general, spinal and obstetric surgeries. We have not yet obtained clearance for these indications in the United States, although we have in Europe and in other countries. In addition to its soft tissue reinforcement properties, extensive preclinical research has demonstrated that our bioresorbable film also acts as a barrier, controlling the formation of fibrous bands which cause adhesions. Such scarring is historically problematic in almost every kind of operation, often leading to significant pain, and specific anatomic functional impairments, such as bowel obstruction and female infertility. In many cases, additional surgery is required to remove damaging adhesions, but with limited long-term clinical success. Advantages of our bioresorbable thin films include:

- transparent, ultra thin profile to allow simplified intraoperative placement and repositioning without obscuring visualization of underlying tissues
- significant strength retention for up to 8 weeks to maintain support throughout critical healing period
- bioresorbable/biocompatible material provides safe resorption and metabolization with minimal risk of inflammatory reaction
- no human or animal components, avoids the risk of disease transmission

In 2001 we received our first regulatory clearances from the FDA to market our SurgiWrap™ bioresorbable film for reinforcement of soft tissues throughout the body 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. Additional U.S. clearance includes the prevention of postsurgical adhesions in specific ear, nose and throat (“ENT”) procedures. In June 2002, we hired a direct sales force in the U.S. to sell SurgiWrap™ film as an adhesion control product for specified ENT procedures and for soft tissue support. The initial 16-person sales team covered all the major metropolitan areas in the U.S. market.

In 2002 we received the CE Mark (marketing clearance in Europe) to market our bioresorbable film for the prevention of postsurgical adhesions in cardiothoracic, general, spinal and gynecological & obstetric (“OB/GYN”) surgeries. In Canada, Thailand, Korea and Australia we have received clearance to market our surgical film for the prevention of adhesions in the heart, spine, peritoneal cavity (including bowels and organs) and OB/GYN surgeries. To date we have established distribution agreements with a network of 28 independent international distributors to sell our bioresorbable surgical film throughout Europe, South America, the Middle East and the Far East.

In 2002 we received the CE Mark (marketing clearance in Europe) to market our bioresorbable film for the prevention of postsurgical adhesions in cardiothoracic, general, spinal and gynecological & obstetric ("OB/GYN") surgeries. In Canada, Thailand, Korea and Australia we have received clearance to market our surgical film for the prevention of adhesions in the heart, spine, peritoneal cavity (including bowels and organs) and OB/GYN surgeries. To date we have established distribution agreements with a network of 28 independent international distributors to sell our bioresorbable surgical film throughout Europe, South America, the Middle East and the Far East.

Through the acquisition of StemSource, Inc. in November 2002, we are moving to advance stem cell therapies that promote the healing or regeneration of the patient's own tissues with the patient's own stem cells. We believe adult stem cells, harvested from the patient's fat tissue through a liposuction procedure, have the ability to offer replacement cells to treat life-altering or life-threatening disorders. StemSource's approach has significant advantages over many other stem cell technologies. StemSource developed devices and techniques to harvest adult stem cells from fat, and demonstrated the ability of adipose (fat)-derived stem cells to differentiate into a variety of tissues *in vitro*.

A stem cell is an unspecialized cell that can become many of the two-hundred-plus tissues that make up the body. Of the two types of stem cells, adult (found in various tissues after birth), and embryonic (fetal tissue), our efforts are exclusively directed toward adult stem cell autologous transplantation, separating the stem cells from a person's fat and delivering them back to the same person where needed. We believe the prospective benefits of using adult stem cells (derived from fat) for the regeneration of one's own tissue include:

- adult stem cells derived from adipose (fat) tissue have demonstrated the ability to differentiate into a variety of tissues, *in vitro*
- fat 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 California state-licensed tissue bank facility for the preservation of extracted stem cells. Typically arranged through a patient's physician, stem cell banking is the process by which adult stem 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 stem cells, frozen in suspended animation, can be preserved for the life of the individual.

We are required to obtain from the Food and Drug Administration regulatory clearance of our medical device products that we market in the United States. In addition, we must obtain marketing authorization for our products that we market in Europe, Canada, Mexico and certain other non-U.S. jurisdictions. During 2002 and in the first two months of 2003, we received additional regulatory clearance or marketing authorization for our products from various jurisdictions, for the following indications:

- the use of our SurgiWrap™ surgical barrier film to cover orbital implants used in enucleation (eye removal) surgery and to protect the surrounding orbital tissue from the surface of the implant (U.S.)
- the use of our HYDROSORB™ TELAMON™ device to maintain the relative position of bone graft material and to promote fusion in the lumbar spine (in Europe – HYDROSORB™ is a trademark of Medtronic, Inc.)
- the use of our bioresorbable adhesion barrier film to prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane to include the following anatomical regions: pericardium, epicardium, and retrosternal (Canada, Thailand, Korea, Australia)
- the use of our bioresorbable adhesion barrier film (in Europe) 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:

a) Pericardium, epicardium, and retrosternal

- b) Peritoneum, peritoneal cavity, bowels, cecum, organs
- c) Dura, spinal dura, peridural, epidural
- d) OB/GYN (e.g. female pelvic, reproductive organs, ovaries, uterus, uterine tubes, etc.)

- The use of our orthopedic graft containment products (OS Trauma) to support weak bony tissue in orthopedic reconstruction procedures including iliac crest and rib reconstructions

We are also developing additional products for use in spinal fusion procedures, soft tissue repair, adhesion control products and long-bone repair, 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.

We continue to seek patent protection for our new products as evidenced by our recent receipt of a U.S. patent (No. 6,531,146) for our family of bioresorbable thin films (SurgiWrap™/CardioWrap™) for the control of postsurgical adhesions, as well as a new patent in Australia (No. 752357) for our macro-porous mesh.

### Products and Services

We manufacture our bioresorbable implant products solely in the United States at our San Diego facility. We currently market the product lines specified below in the United States, Europe and/or other countries for repair and regeneration of bone, and for soft tissue repair in various locations throughout the body. We anticipate the launch of three additional musculoskeletal reconstructive products in conjunction with our distributor Medtronic in 2003, and one new product to aid in the repair and regeneration of soft tissues. All HYDROSORB™ branded products are manufactured by us and distributed exclusively by Medtronic. HYDROSORB™, CORNERSTONE™, and TELAMON™ are each a trademark of Medtronic. In the case of our thin film products, Medtronic and we both market the products, but only the units which are sold through Medtronic are branded HYDROSORB™. Product lines marked by an asterisk (\*) have been sold to Medtronic PS Medical for all craniomaxillofacial “CMF” (skull and face) bone fixation and iliac crest 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 product lines are:

| Product Lines   | Product Components                             | Use  |
|---|--|--|
| SurgiWrap™<br>HYDROSORB™<br>Shield (U.S.)                         | bioresorbable barrier<br>film                  | for the reinforcement of soft tissues throughout the body 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  |
| SurgiWrap™<br>CardioWrap™<br>HYDROSORB™<br>Shield (International) | bioresorbable adhesion<br>barrier film         | 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. |
| HYDROSORB™ CR<br>(U.S.)   | bioresorbable cement<br>restrictor             | to prevent extrusion of bone cement in hip arthroplasty procedures   |
| HYDROSORB™ Mesh<br>(U.S.)   | bioresorbable mesh/ screws                     | to support weak bony tissue in orthopedic procedures and for iliac crest / rib reconstruction  |
| CORNERSTONE™<br>HSR (U.S.)  | bioresorbable pre-formed<br>cylinders/ sleeves | to support weak bony tissue in orthopedic procedures and for iliac crest / rib reconstruction  |

|   |   |  |
|---|---|--|
| HYDROSORB™<br>TELAMON™<br>HYDROSORB™<br>Mesh<br>(International) | bioresorbable pre-formed cylinders/sleeves  | 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. |
| MacroPore OS Spine™   | bioresorbable macroporous sheets of various shapes and sizes, together with instruments, accessories and bioresorbable screws and tacks                               | for the containment of bone grafts or bone graft substitutes in spinal fusion procedures in conjunction with traditional rigid fixation  |
| MacroPore FX™*  | over 120 bioresorbable components, including specially designed plates, screws, tacks and mesh, as well as instruments and accessories                                | for use in adult and pediatric patients in trauma, reconstructive procedures, and other surgeries for craniomaxillofacial and neurosurgical applications   |
| MacroPore PS*   | bioresorbable macroporous sheets of various shapes and sizes, as well as instruments and accessories  | for use in adult and pediatric patients to facilitate healing and bone regeneration in the skeletal system by, among other things, maintaining the position of bony fragments in trauma and bone graft procedures, and maintaining space beneath soft tissues and allowing bone growth to occur in a protected environment                 |
| MacroPore OS™*  | bioresorbable macroporous sheets of various shapes and sizes, together with instruments, accessories and bioresorbable screws and tacks                               | for the containment of bone grafts other than in the spine, and for reconstruction of the iliac crest, or hip, bone graft donor site   |
| MacroPore NS™*  | specially designed bioresorbable plates   | in cranial reconstruction or cranial closure following neurosurgical applications  |
| MacroPore LP™*  | specially designed bioresorbable macroporous sheets of various shapes and sizes, with related instruments, accessories and low profile bioresorbable screws and tacks | in pediatric and adult patients in plastic, reconstructive, and neurosurgical procedures, as well as other specialized surgical applications   |
| MacroPore MX™*  | specially designed bioresorbable plates and screws with templates and various specialized instrumentation   | for mandibular fracture fixation   |
| MacroPore DX*   | fully and partially bioresorbable craniofacial distraction device, together with specialty instruments and accessories  | to gradually lengthen the midface cranial skeleton to correct cranial skeleton growth disorders  |

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

Revenues realized from the sale of our musculoskeletal bone fixation products in the years ended December 31, 2002, 2001 and 2000 accounted for 58%, 27% and 0% respectively, of our total revenues. Revenues realized from the sale of our CMF bone fixation products in the years ended December 31, 2002, 2001 and 2000 accounted for 31%, 67% and 95% respectively, of our total revenues. Since all of our products are developed and sold for use in the medical device industry and have similar purposes, production processes, markets and regulatory requirements, we report them as a single industry segment.

We provide a range of support services to our customers, to distributors and to surgeons interested in, and who are currently using our products, 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 2003, we intend to focus our efforts on:

- streamlining our business operations and implementing new cost controls to reduce spending to increase value for our shareholders
- enhancing production planning and manufacturing processes to reduce costs and increase efficiency of our high volume spinal / reconstructive products
- further expanding of our international distribution network for sales of our bioresorbable surgical film products
- obtaining further regulatory clearances and/or approvals for the use of our bioresorbable surgical film products
- continuing our development and testing of spinal and reconstructive implants to expand the portfolio of HYDROSORB™ devices sold through Medtronic
- collecting further clinical and pre-clinical data in support of our bioresorbable surgical film products
- continuing development of implant systems and instrumentation to deliver biologics such as adult stem cells, and biological molecules such as bone morphogenetic proteins that may improve healing time and the quality of tissue regeneration
- determining the optimal methods for separating and handling stem cells derived from adipose tissue
- determining the optimal methods of delivery and dosages of our adipose derived stem cells
- expanding existing and developing new collaborations with academic and corporate researchers engaged in stem cell research
- continuing basic research related to the clinical use of adult stem cells

- developing a commercial system for the harvesting and therapeutic application of adipose derived stem cells
- marketing our stem cell banking services
- developing strategic partnerships with companies in markets that would benefit from our unique stem cell platform

## Research and Development

Our biomaterials research and development team is focused on developing bioresorbable devices, processes and technologies that facilitate the repair and regeneration of bone and soft tissues. We are conducting research to further our development of new polymers designed to enhance performance of our bioresorbable barrier films for control of post surgical soft tissue adhesions in cardiovascular surgery, tendon and nerve repair, plastic surgery, ear nose and throat, OB/GYN, abdominal and general surgery applications. Additional biomaterials research will target differing resorption rates, strength profiles and handling characteristics for various spinal, orthopedic, and other musculoskeletal applications.

In 2002, our biomaterials research and development efforts resulted in the final commercial development and market launches of our bioresorbable barrier film products, as well as several new musculoskeletal products in conjunction with our distributor Medtronic Sofamor Danek. In 2002 we also completed initial development of our new faster-resorbing polymer which is currently under clinical evaluation for use in pediatric patients, as well as the redesign of our PowerBath products. Much of the other biomaterial research and testing is directed to assessment of the mechanical design and performance of our new and existing products.

Through the acquisition of StemSource, Inc., in 2002, we acquired completed and in-process adult stem cell research and development including ongoing development of proprietary methods for differentiating adipose derived stem cells into a number of different tissues such as bone, muscle and cartilage *in vitro*. This is the primary focus of our new biologics research group. Our initial focus areas are cardiovascular disease, cosmetic surgery, and bone healing and regeneration. We plan to launch human clinical studies in two of these areas this year. Our goal is to develop a therapeutic system for extracting, concentrating, and delivering adult stem cells to patients. We have also completed the development of a licensed tissue bank that is being used for the long-term storage and preservation of adipose derived stem cells, a service we will offer through a network of participating surgeons in the U.S. in 2003.

## Customers

Medtronic is our primary distributor and our principal customer, directly accounting for \$8,605,000, or 93.9%, \$5,547,000, or 98.2% and \$6,092,000 or 97.5% of our revenues for the years ended December 31, 2002, 2001 and 2000, respectively. We also sell some of our products directly to end users, hospitals and international 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 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 accordance with the terms of our September 2002 agreement to sell substantially all of the assets of our CMF product line to Medtronic, we also granted them an exclusive license to certain related intangible assets, along with exclusive rights to 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 faster-resorbing polymer product when development is complete, and granted them access to relevant improvements in the technology for a period of five years.

Also in September 2002, Medtronic agreed to amend our existing distribution agreement to remove the contractual right of first offer for distributorship of our bioresorbable thin film products in various types of surgery. Medtronic continues to retain its right of

first offer for distributorship to our other products in all fields and to our bioresorbable thin film products in the spinal field. In addition, we agreed to extend the term of our existing global co-development and supply agreement with Medtronic for spinal implants to 2012.

Medtronic owns approximately 6.8% of our outstanding stock.

## **Market and Competition**

We compete with many other companies in developing and marketing our technology and products. In the musculoskeletal fixation 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 Leibinger GmbH & Co. KG and Synthes-Stratec are two companies that we are aware of who produce both bioresorbable and titanium implants. It has historically proved difficult for providers of new medical device technologies to change surgeons' habits of using long-established, well-marketed devices, e.g. metallic bone fixation methods.

We believe our SurgiWrap™ barrier film can be used to control postsurgical adhesions and scarring and we intend to obtain further clearances and approvals necessary to market our bioresorbable surgical film for use in cardiothoracic surgery, obstetrics and gynecology, tendon surgery and general surgery applications. We have received these clearances in Europe and other countries, but not yet in the United States. We are aware of two other companies that have entered these markets with products designed to prevent or control postoperative adhesions. We believe that our bioresorbable surgical film has advantages over competitive products because it is noninflammatory, it maintains its strength during the critical healing period, it creates a clear surgical dissection plane, and it is bioresorbable, where some of our competitors' products are not. Genzyme Corporation and Gore, Inc. are two companies we are aware of that produce products which are competitive in markets in which we sell our bioresorbable surgical films.

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

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

We believe that adipose (fat) tissue is the optimal source of stem cells for therapeutic use due to the expendability and accessibility of adipose tissue, as well as the high yield and high quality of stem cells obtainable from this source. Many of the other sources of stem cells are difficult to harvest and/or do not yield a high number of cells. These sources also may require the cells to be expanded in culture before clinical application. We are only aware of one other company, Artecél Sciences, that is focusing on adipose derived stem cells. The status of Artecél's research and development is largely unknown to us at this time.

We are aware that Genzyme Biosurgery, Diacrin and BioHeart are currently involved in stem cell related clinical trials focused on myocardial infarction and congestive heart failure. Osiris Therapeutics is involved in a clinical trial to provide blood and bone marrow transplantation support using human mesenchymal stem cells. There are several other companies currently doing pre-clinical research on potential stem cell therapies. We cannot with any accuracy forecast when or if these companies are likely to bring stem 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 assure you 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 in the United States and 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 in the currency of the countries in which the products are sold.

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. For the year ended December 31, 2000, we recorded \$6,251,000 in revenues, including \$6,200,000 of product sales in the United States and \$51,000 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 \$1,000,000 on capital equipment purchases in 2003.

## **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, 2004, 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 U.S. patents relating to four of our primary bioresorbable implant products and technology. We also have two Australian patents relating to our bioresorbable mesh. 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 two Australian patents issued August 2000 and January 2003. Each of our patents will expire 20 years from the date of the original patent application.

We have filed applications for 28 additional U.S. patents, as well as 33 corresponding patent applications outside the United States, relating to our technology. As part of the StemSource acquisition we were assigned a perpetual non-exclusive license rights to three additional U.S. patent applications and two 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 approved, 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 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 United States laws. 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 United States. 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 United States. 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 to specific controls such as performance standards, postmarket surveillance and patient registries. 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 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, or to a Class III medical device for which the FDA has not called for PMAs. 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 I or 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.

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, reconstructive and bone augmentation procedures of the mandible  | March 1999                |
| MacroPore DX*        | treatment of cranial or midface conditions in reconstructive osteotomy and segment advancement   | June 2000                 |
| MacroPore OS™*       | protecting 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  | October 2000              |
| MacroPore NS™*       | fixation of bone flaps after a craniotomy  | May 2001                  |
| MacroPore OS Spine™  | with traditional rigid fixation in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts, autografts or bone graft substitutes cleared for spinal use                                     | July 2001                 |
| MacroPore IB         | a cement restrictor in the femur, tibia, and humerus   | September 2001            |

| <u>Product Lines</u>                       | <u>Clearance received for, among other things, the following uses:</u>  | <u>Clearance received</u> |
|--|---|---------------------------|
| MacroPore FX™*, PS™*, NS™* and LPT™*       | specific pediatric and adult plastic, reconstructive and neurosurgical applications in the craniofacial skeleton  | September 2001            |
| HYDROSORB™ CR                              | to prevent migration of cement in hip and knee arthroplasty procedures  | 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                       | protecting 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 support weak bony tissue in orthopedic procedures and for iliac crest / rib reconstruction   | July 2002                 |
| CORNERSTONE™ HSR                           | to support weak bony tissue in orthopedic procedures and for iliac crest / rib reconstruction   | July 2002                 |
| HYDROSORB™ TELAMON™                        | support weak bony tissue in orthopedic procedures 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              |

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:

| <u>Country</u>     | <u>Indications received for, among other things, the following uses:</u>   | <u>Received Clearance</u> |
|--------------------|--|---------------------------|
| European Community | MacroPore FX™, MacroPore PS, MacroPore NS™, MacroPore DX, MacroPore OS™ and MacroPore OS Spine™ 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 in adult and pediatric populations. | March 2002                |

| Country | Indications received for, among other things, the following uses:   | Received Clearance |
|---------|---|--------------------|
|         | <p>MacroPore SurgiWrap™ products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system.</p>  | March 2002         |
|         | <p>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:</p> | May 2002           |
|         | <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>   |                    |
|         | <p>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</p>  |                    |
|         | <p>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.</p>   | January 2003       |
| Canada  | <p>MacroPore FX™ and MacroPore PS products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system</p>   | December 1999      |
|         | <p>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:</p> | 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>   |                    |
|         | <p>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</p>  |                    |

| <u>Country</u> | <u>Indications received for, among other things, the following uses:</u>  | <u>Received Clearance</u> |
|----------------|---|---------------------------|
| Malaysia       | Same as Canada for MacroPore FX™ and PS only                              | June 2000                 |
| Singapore      | Same as Canada for MacroPore FX™ and PS only                              | November 2000             |
| South Korea    | Same as Canada for MacroPore FX™ and PS                                   | January 2001              |
|                | Same as Canada for SurgiWrap <sub>i</sub> ™ and CardioWrap <sub>i</sub> ™ | December 2002             |
| Australia      | Same as Canada for MacroPore FX™ and PS                                   | March 2001                |
|                | Same as Canada for SurgiWrap <sub>i</sub> ™ and CardioWrap <sub>i</sub> ™ | November 2002             |
| Thailand       | Same as Canada for SurgiWrap <sub>i</sub> ™ and CardioWrap <sub>i</sub> ™ | January 2003              |

In addition, we have submitted applications for authorizations to market our products in 15 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, 2002, we had 94 full-time employees, comprised of 28 employees in research and development, 21 employees in manufacturing, 17 employees in management and finance and administration, and 28 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). We make available free of charge through our Internet website 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.

## Item 2. Properties

Our main facility which we use for 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 of additional research and technology facility 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.

- 15,000 square feet of which all is used for research and development, located at 1125 Business Center Circle, Thousand Oaks, California for a five-year term, expiring in 2006. This space will become excess in April/May of this year.

We pay an aggregate of approximately \$64,000 in rent per month for our properties located in the United States and approximately €11,000 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

None.

## PART II

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

#### Market Prices

Our common stock has been quoted on the Frankfurt Stock Exchange under the symbol "XMP" since our initial public offering on August 8, 2000. Prior to this time, there was no public market for our stock. Our common stock is not currently traded on any United States exchange. 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.

|                                  | <u>High Euro</u> |       | <u>High US</u> |       | <u>Low Euro</u> |      | <u>Low US</u> |      |
|----------------------------------|------------------|-------|----------------|-------|-----------------|------|---------------|------|
| <b>2001</b>                      |                  |       |                |       |                 |      |               |      |
| Quarter ended March 31, 2001     | €                | 14.04 | \$             | 13.08 | €               | 6.00 | \$            | 5.71 |
| Quarter ended June 30, 2001      | €                | 12.08 | \$             | 10.44 | €               | 4.20 | \$            | 3.80 |
| Quarter ended September 30, 2001 | €                | 8.45  | \$             | 7.20  | €               | 2.60 | \$            | 2.39 |
| Quarter ended December 31, 2001  | €                | 5.54  | \$             | 4.98  | €               | 3.50 | \$            | 3.18 |
| <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 |

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, 2003, 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 12,000.

#### 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 restrict the export or import of capital, except for investments in Iraq and Libya in accordance with applicable resolutions adopted by the United Nations and the European Union. 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 2,550 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 the aggregate, exceed Euro 1.53 million or the equivalent in a foreign currency, during any one month. Residents must also report any direct investment outside Germany if such investment exceeds Euro 51,000 or the equivalent in a foreign currency.

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

### Recent Sales of Unregistered Securities

On November 13, 2002 we issued 1,447,755 shares of unregistered common stock in exchange for all outstanding shares of StemSource not already owned by us. The closing price per share of our securities that day on the Frankfurt Stock Exchange was \$4.15. We did not use an underwriter, and we relied on the Section 4(2) exemption from the Securities Acts' registration requirement.

On November 29, 2002 we sold 200,000 shares of unregistered common stock to DWS, a German investment bank, at \$4.18 per share. On December 17, 2002, we sold 10,000 shares of unregistered common stock to DWS, a German investment bank, at \$4.08 per share. We did not use an underwriter, and we relied on the Section 4(2) exemption from the Securities Acts' registration requirement.

### Equity Compensation Plan Information

| Plan Category  | Number of securities to be issued upon exercise of outstanding options, warrants and rights<br>(a) | Weighted-average exercise price of outstanding options, warrants and rights<br>(b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))<br>(c) |
|--|--|--|--|
| Equity compensation plans approved by security holders     | 4,263,000  | \$ 3.85  | 1,377,000  |
| Equity compensation plans not approved by security holders | None   | None   | None   |
| Total  |  |  |  |

### Item 6. Selected Consolidated Financial Data

The following selected historical consolidated financial data are derived from our consolidated financial statements and the related notes thereto. We were founded as a partnership in July 1996, commenced operations in January 1997 and incorporated in May 1997. Our financial statements as of December 31, 1998 and, 1999 and for the years then ended have been audited by PricewaterhouseCoopers LLP, independent accountants. Our financial statements as of December 31, 2000 and, 2001 and for the years then ended have been audited by Arthur Andersen LLP, independent public accountants. Our consolidated financial statements as of December 31, 2002, and for the year then ended, have been audited by KPMG LLP, independent public accountants. Some of our financial statements are included elsewhere in this report.

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,

|  | 2002   | 2001               | 2000              | 1999              | 1998              |
|--|--|--------------------|-------------------|-------------------|-------------------|
|  | (dollars in thousands, except shares and per share data) |                    |                   |                   |                   |
| <b>Statement of Operations Data:</b>                                   |  |                    |                   |                   |                   |
| Revenues:  |  |                    |                   |                   |                   |
| Sales to related party   | \$ 8,605   | \$ 5,547           | \$ 6,092          | \$ —              | \$ —              |
| Sales to third parties   | 561  | 101                | 159               | 1,513             | —                 |
|  | <u>9,166</u>   | <u>5,648</u>       | <u>6,251</u>      | <u>1,513</u>      | <u>—</u>          |
| Cost of revenues   | 3,169  | 2,401              | 2,394             | 486               | —                 |
| Inventory provision  | 1,395  | 1,750              | —                 | —                 | —                 |
| Gross profit   | <u>4,602</u>   | <u>1,497</u>       | <u>3,857</u>      | <u>1,027</u>      | <u>—</u>          |
| Operating expenses:  |  |                    |                   |                   |                   |
| Research and development   | 5,605  | 5,487              | 2,584             | 1,172             | 1,175             |
| Sales and marketing  | 3,987  | 4,493              | 2,629             | 2,356             | 202               |
| General and administrative   | 3,952  | 3,578              | 2,555             | 1,313             | 604               |
| Stock based compensation   | 1,287  | 1,123              | 5,698             | 661               | 76                |
| In-process research and development                                    | 2,296  | —                  | —                 | —                 | —                 |
| Equipment impairment charge  | 370  | —                  | —                 | —                 | —                 |
| Total operating expenses   | <u>17,497</u>  | <u>14,681</u>      | <u>13,466</u>     | <u>5,502</u>      | <u>2,057</u>      |
| Other income (expenses):   |  |                    |                   |                   |                   |
| Interest income  | 1,037  | 2,249              | 1,315             | 68                | 10                |
| Interest and other expenses  | (263)  | (168)              | (351)             | (164)             | (43)              |
| Equity loss in investment  | (882)  | (104)              | —                 | —                 | —                 |
| Net loss   | <u>\$ (13,003)</u>                                       | <u>\$ (11,207)</u> | <u>\$ (8,645)</u> | <u>\$ (4,571)</u> | <u>\$ (2,090)</u> |
| Basic and diluted net loss per share                                   | <u>\$ (.89)</u>  | <u>\$ (.75)</u>    | <u>\$ (1.05)</u>  | <u>\$ (1.32)</u>  | <u>\$ (0.64)</u>  |
| Shares used in calculating basic and diluted net loss per share        | <u>14,630,374</u>  | <u>14,926,107</u>  | <u>8,201,739</u>  | <u>3,458,292</u>  | <u>3,250,000</u>  |
| <b>Statement of Cash Flows Data:</b>                                   |  |                    |                   |                   |                   |
| Net cash used in operating activities                                  | \$ (6,886)   | \$ (8,322)         | \$ (2,982)        | \$ (5,107)        | \$ (1,523)        |
| Net cash provided by (used in) investing activities                    | 17,265   | 2,263              | (39,450)          | (381)             | (598)             |
| Net cash (used in) provided by financing activities                    | (7,971)  | 1,283              | 47,437            | 7,924             | 1,837             |
| Net increase (decrease) in cash  | <u>2,408</u>   | <u>(4,776)</u>     | <u>5,005</u>      | <u>2,436</u>      | <u>(284)</u>      |
| Cash and cash equivalents at beginning of year                         | 2,700  | 7,476              | 2,471             | 35                | 319               |
| Cash and cash equivalents at end of year                               | <u>\$ 5,108</u>  | <u>\$ 2,700</u>    | <u>\$ 7,476</u>   | <u>\$ 2,471</u>   | <u>\$ 35</u>      |
| <b>Balance Sheet Data:</b>   |  |                    |                   |                   |                   |
| Cash, cash equivalents and short-term investments                      | \$ 24,983  | \$ 33,951          | \$ 44,484         | \$ 2,581          | \$ 140            |
| Working capital  | 25,302   | 35,119             | 46,858            | 3,510             | (493)             |
| Total assets   | 39,319   | 43,143             | 52,269            | 5,575             | 1,020             |
| Capital lease obligations, less current portion                        | —  | 135                | 255               | 304               | 209               |
| Long-term obligation, less current portion                             | 770  | 1,791              | —                 | —                 | —                 |
| Convertible redeemable preferred stock, net of offering costs of \$197 | —  | —                  | —                 | 10,689            | 2,696             |
| Total stockholders' equity (deficit)                                   | <u>\$ 25,995</u>   | <u>\$ 38,486</u>   | <u>\$ 49,335</u>  | <u>\$ (6,147)</u> | <u>\$ 108</u>     |

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

### Overview

We have a limited operating history. Our prospects are subject to the risk and uncertainties frequently encountered by companies in the early stages of development and commercialization, and particularly by companies in rapidly evolving and technologically advanced fields such as the medical device industry.

Because we saw more upside in musculoskeletal and thin film product lines we decided to sell the craniomaxillofacial (skull and face) product line for a favorable cash price. In September 2002, we entered into an Asset Purchase Agreement (the "Agreement") to sell assets related to our craniomaxillofacial bone fixation implant and accessory product line to Medtronic PS Medical, Inc. (a subsidiary of Medtronic, Inc.) for a total consideration of up to \$16,000,000. Medtronic PS Medical agreed to pay us an initial payment of \$13,000,000 and additional payments totaling \$3,000,000 upon the successful transfer of technology and know how, including training, related to the manufacture of the craniomaxillofacial 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 2003. The Agreement also requires us not to market, in the craniomaxillofacial field, for 5 years any products that compete with the acquired product line.

Additionally, we will continue to be a backup supplier of the acquired products to Medtronic at a price equal to our cost of manufacture during the transition technology transfer period. Discounts from the previously agreed price have been recorded as a reduction to the deferred gain and totaled \$267,000 for the year ended December 31, 2002. The Agreement also allows us to receive up to \$5,000,000 if and when we complete successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement.

In a separate, but simultaneous transaction we paid Medtronic \$4,000,000 in cash to amend an existing Development and Supply Agreement (the "Amended Development Agreement") to remove a preexisting contractual right of first offer for distributorship by Medtronic of our 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 our other products in all fields, as well as to our 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.

We are accounting for the net proceeds of the Agreements as a deferred gain on sale of assets, related party, until such a time as the technology and know how transfer is completed pursuant to the terms of the Agreement. Upon successfully completing our requirements under these provisions of the Agreement, we will recognize the net gain on the sale in the statement of operations.

For the year ended December 31, 2002, 2001 and 2000, revenues related to the product line sold in September 2002 were \$2,875,000, \$3,775,000 and \$5,237,000, respectively.

Medtronic continues to be a significant stockholder of MacroPore and our largest customer, as the primary distributor of our bioresorbable implant products for use in musculoskeletal applications. Under the Amended Development Agreement, we sell these products to Medtronic at fixed selling prices which are subject to adjustment upon biannual reviews. Therefore, our revenues, operating results and cash flow will be affected by fluctuations in the cost of sales, sales volumes and operating expenses. Although the Amended Development Agreement provides that direct selling costs are borne by the distributor, our cash flow may be adversely affected if our fixed costs increase and we are unable to negotiate or otherwise obtain an increase in product pricing with Medtronic.

On November 13, 2002, we completed the acquisition of the remaining shares of StemSource, a company engaged in research toward the development of therapies based on adult stem cells. We acquired the remaining stock, not already owned by us, in order to broaden our base in the biosurgery marketplace and to enter the therapeutic marketplace using Adult Stem Cells. StemSource has an advanced position in Adult Stem Cell research and numerous patents and other intellectual property position, which we believe should provide a first mover advantage for us. Upon the closing of the merger, we delivered to the StemSource stockholders 1,447,785 shares of our common stock at an aggregate value of \$5,951,000, based on \$4.11 per 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 common stock and underlying options that were not already owned by us.

We incurred net losses of \$13,003,000, \$11,207,000 and \$8,645,000 for the years ended December 31, 2002, 2001, and 2000, respectively. As of December 31, 2002, we had an accumulated deficit of \$40,102,000. These net losses resulted to a large extent from expenses associated with developing bioresorbable implant designs, performing preclinical studies, preparing submissions to the FDA and foreign regulatory agencies, expanding marketing and distribution channels, further developing our manufacturing capabilities, securing intellectual property rights and trademarks and supporting our status as a public company. We expect to expend

substantial financial resources to expand marketing, training and customer support needed to generate and support higher sales, obtain additional regulatory clearances and to develop new products. This investment is likely to result in continued operating losses for the foreseeable future until operational efficiencies are reached.

For the year ended December 31, 2002, our \$9,166,000 in revenue was composed of \$8,473,000 or 92.4% from sales of our bioresorbable implant products for use in musculoskeletal, craniomaxillofacial and soft tissue applications. The other \$693,000 in revenue was composed of \$318,000 or 3.5% from sales of instruments and accessories used by surgeons to form, mold and manipulate our bioresorbable products during surgical procedures, \$150,000 or 1.6% from a special project for Medtronic and \$225,000 or 2.5% from a license agreement with Medtronic. The \$8,473,000 in revenue from bioresorbable implant products was composed of \$2,557,000 or 30.2% of craniomaxillofacial sales which were included in the September 2002 product line sale to Medtronic, \$5,394,000 or 63.7% of musculoskeletal sales and \$522,000 or 6.1% from our recently introduced thin film products for soft tissue applications.

## **Results of Operations**

*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 \$3,893,000 increase in the sales of bioresorbable implant products and instrumentation for use in musculoskeletal applications, \$525,000 in bioresorbable thin film sales and a \$900,000 decrease in craniomaxillofacial product sales. The increase in musculoskeletal products 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 craniomaxillofacial product decreased because of the decrease in replenishment product orders from Medtronic. Revenues attributable to Medtronic, which owns approximately 6.8% of our outstanding common stock, represented 93.9% of our revenues for the year ended December 31, 2002, compared to 98.2% for the year ended December 31, 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, excluding 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 craniomaxillofacial product line could negatively impact our margins until 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 the year ended December 31, 2002, was a result of a reduction in the expected sales of our craniomaxillofacial bone fixation implants and accessories product line inventory due to the asset sale to Medtronic. The inventory provision for the year ended December 31, 2001 was a result from potential excess and obsolete inventory due to an anticipated reduction in future revenues of our craniofacial implant and instrument products.

*Gross profit.* For the year ended December 31, 2002, gross profit was \$4,602,000 or 50.2% of revenues, compared to \$1,497,000 or 26.5% of revenues for the year ended December 31, 2001. Excluding the inventory provisions, the gross profit would have been \$5,997,000 or 65.4% of revenues in the year ended December 31, 2002, compared to \$3,247,000 or 57.5% of revenues in the year ended December 31, 2001. The increase in gross profit, excluding the inventory provisions, as a percentage of revenues was attributable to increased revenue and the ability to absorb more fixed manufacturing labor and overhead costs, as discussed above.

*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%. 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 clinical trials. The increase in research and development expenses in the year ended December 31, 2002 was primarily attributable to an increase of \$118,000 of expenses associated with the development of new products and applications for musculoskeletal and thin film product lines. In addition, stock based compensation related to research and development was \$211,000 for the year ended December 31, 2002 and \$111,000 for the year ended December 31, 2001. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect research and development spending to increase approximately \$3,000,000 for the next twelve months as we continue to support the research and development of therapies based on adult stem cells

we acquired with the purchase of StemSource. We also plan to continue to fund the product development efforts and seek further regulatory approvals for our current bioresorbable product lines related to musculoskeletal and thin film.

*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%. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. Medtronic is responsible for the sales and marketing of our musculoskeletal product lines; therefore, we are focusing our sales and marketing efforts on our thin film product line domestically through a dedicated sales force and internationally through independent distributors. The decrease in sales and marketing expenses in the year ended December 31, 2002 was primarily attributable to a \$197,000 decrease in labor and associated expenses relating to our sales force labor mix, \$130,000 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 musculoskeletal product line. In addition, stock based compensation related to sales and marketing was \$134,000 for the year ended December 31, 2002 and \$176,000 for the year ended December 31, 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." We expect sales and marketing expenses to increase for the next twelve months as we continue our promotional efforts related to the thin film product line with a dedicated sales force. We do not expect to make significant marketing expenditures related to the StemSource purchase until our research and development efforts realize commercialization of new products.

*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%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The \$374,000 increase in general and administrative expenses for the year ended December 31, 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 the year ended December 31, 2002, compared to \$836,000 for the year ended December 31, 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." We expect general and administrative expenses to remain at current levels for the next twelve months.

*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. 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 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 the year ended December 31, 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 Stem Cell extraction unit and related technology to process Adult Stem 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."

*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 craniomaxillofacial 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 lower interest rates and from a decrease in the funds we had available for investments.

*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 relate 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 recognize a pro rata share of StemSource's operating losses.

*Year ended December 31, 2001 compared to year ended December 31, 2000*

*Revenues.* For the year ended December 31, 2001, revenues were \$5,648,000 compared to \$6,251,000 for the year ended December 31, 2000, a decrease of \$603,000, or 9.6%. The decrease in revenues was primarily attributable to Medtronic's initial inventory purchase of \$1,162,000 in the three months ended June 30, 2000. Excluding the initial inventory purchase, our revenues in the year ended December 31, 2001 increased by \$559,000 compared to the year ended December 31, 2000, which increase was attributable to revenues generated from new product introductions during the three months ended September 30, 2000. Revenues attributable to Medtronic, which owns approximately 6.6% of our outstanding common stock, represented 98.2% of our revenues for the year ended December 31, 2001, compared to 97.5% for the year ended December 31, 2000.

*Cost of revenues.* For the year ended December 31, 2001, cost of revenues, excluding the inventory provision discussed below, was \$2,401,000 or 42.5% of revenues, compared to \$2,394,000 or 38.3% of revenues for the year ended December 31, 2000. Cost of revenues includes material, manufacturing labor and overhead costs. The increase in cost as a percentage of revenues was primarily attributable to an inability to absorb some of our fixed manufacturing overhead costs due to lower sales volumes and excess capacity.

*Inventory provision.* For the year ended December 31, 2001, we recorded an inventory provision of \$1,750,000, representing 31.0% of revenues, for which there was no comparable charge in the year ended December 31, 2000. The inventory provision resulted from potential excess and obsolete inventory due to an anticipated reduction in future revenues of our craniomaxillofacial implant and instrument products.

*Gross profit.* For the year ended December 31, 2001, gross profit was \$1,497,000 or 26.5% of revenues, compared to \$3,857,000 or 61.7% of revenues for the year ended December 31, 2000. Excluding the inventory provision, the gross profit would have been \$3,247,000 or 57.5% of revenues in the year ended December 31, 2001. The decrease in gross profit as a percentage of revenues was primarily attributable to an inability to absorb some of our fixed manufacturing overhead costs due to lower sales volume and excess capacity.

*Research and development expenses.* For the year ended December 31, 2001, research and development expenses excluding related stock based compensation expenses were \$5,487,000, compared to \$2,584,000 for the year ended December 31, 2000. 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 clinical trials. The increase in research and development expenses in the year ended December 31, 2001 was primarily attributable to a \$1,465,000 increase in additional personnel costs related to the hiring of employees, and other costs of \$1,438,000 associated with the research into the development of new product lines. In addition, stock based compensation related to research and development was \$111,000 for the year ended December 31, 2001 and \$2,239,000 for the year ended December 31, 2000. For further information regarding fluctuations in research and development inclusive of 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, 2001, sales and marketing expenses excluding related stock based compensation expenses were \$4,493,000, compared to \$2,629,000 for the year ended December 31, 2000. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. The increase in sales and marketing expenses in the year ended December 31, 2001 was primarily attributable to a \$1,507,000 increase in additional personnel costs related to the hiring of employees, and other costs of \$357,000 for tradeshow expenses, promotional activities and materials expenses related to the promotion of product lines. In addition, stock based compensation related to sales and marketing was \$176,000 for the year ended December 31, 2001 and \$1,852,000 for the year ended December 31, 2000. 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, 2001, general and administrative expenses excluding related stock based compensation expenses were \$3,578,000, compared to \$2,555,000 for the year ended December 31, 2000. General

and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The increase in general and administrative expenses in the year ended December 31, 2001 was primarily attributable to increased personnel costs of \$554,000, increased administrative costs of \$469,000 for professional services, increased other general corporate expenditures related to all areas of our operations and costs to support our status as a public company. In addition, stock based compensation related to general and administrative expenses was \$836,000 for the year ended December 31, 2001, compared to \$1,607,000 for the year ended December 31, 2000. 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, 2001, total non-cash stock based compensation expenses classified in operating expenses were \$1,123,000, compared to \$5,698,000 for the year ended December 31, 2000. Stock based compensation results from options issued to employees and non-employees. Stock based compensation expenses are 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 was related to the acceleration of vesting and other modifications to compensatory stock options granted to employees and consultants in the year ended December 31, 2000. The decrease of \$2,128,000 in research and development stock based compensation was primarily due to our decision on August 9, 2000 to accelerate options granted to doctors who performed consulting services, as the services for which these options were granted were deemed complete, and the recognition of the compensation expense related to all of the accelerated options. The decrease of \$1,676,000 in sales and marketing stock based compensation was due primarily to \$1,775,000 in additional expense recorded in the three months ended March 31, 2000 as a result of the extension of the expiration date of some stock options granted to members of our sales force upon the termination of their employment. The decrease of \$771,000 in general and administrative stock based compensation was primarily due to \$636,000 in additional expense recorded in the year ended December 31, 2000 as a result of significant options granted to senior management with immediate vesting and at exercise prices below fair market value.

*Interest income.* For the year ended December 31, 2001, interest income was \$2,249,000, compared to \$1,315,000 for the year ended December 31, 2000, an increase of \$934,000, or 71.0%. The increase in interest income resulted from cash equivalents and short-term investments being invested for twelve months in the year ended December 31, 2001, compared to an investment period of four and one-half months in the year ended December 31, 2000.

*Interest and other expenses.* For the year ended December 31, 2001, interest and other expenses were \$168,000, compared to \$351,000 for the year ended December 31, 2000. The decrease in interest and other expenses was primarily related to the conversion loss of the Euro to the U.S. dollar in connection with the net proceeds we realized from the sale of equity in our initial public offering in August 2000.

*Equity loss in investment.* For the year ended December 31, 2001, our equity loss in our investment in StemSource was \$104,000, for which there was no comparable charge in the year ended December 31, 2000 since the investment was made in May 2001.

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

We have not yet recognized any gain on the September 2002 asset sale to Medtronic, and will not do so until we successfully transfer the technology and know how, including training, related to the manufacture of the craniomaxillofacial product line, which we expect to occur in 2003. Until then, we have deferred a gain of \$9,623,000, which is reflected as "Deferred gain on sale of assets, related party" on our balance sheet.

### **Liquidity and Capital Resources**

As of December 31, 2002, we had cash and cash equivalents, and short-term investments, available-for-sale, of \$24,983,000 and working capital of \$25,302,000. Since inception, we have financed our operations primarily through sales of stock and from the September 2002 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, at which time the outstanding shares of our preferred stock were converted into 6,831,398 shares of common stock. 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 market acceptance of our products and regulatory approvals, the

resources we devote to developing and supporting our products and other factors. We expect to devote substantial capital resources to continue our research and development efforts, to expand our support and product development activities and for other general corporate activities. We believe that our current cash and investment balances and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through December 31, 2003. Due to the acquisition of StemSource, we will also have to commit substantial cash resources to fund StemSource's development activities in 2003 which is estimated at approximately \$4,000,000. Our strategic concept is to use the cash from the Medtronic asset sale to enable us to undertake the StemSource opportunity without affecting our remaining bioresorbable product lines of capital which would otherwise have been available to them. Nonetheless, until we begin to generate sufficient revenues from our bioresorbable products operations to cover our operating costs, we may need to seek additional sources of financing in the future. We cannot assure that we will generate sufficient revenues to cover our bioresorbable products operating costs or that we will be able to obtain additional financing on terms satisfactory to us, if at all.

Net cash used in operating activities was \$6,886,000, \$8,322,000 and \$2,982,000 for the years ended December 31, 2002, 2001 and 2000, 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, 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 the year ended December 31, 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 thin film sales in the fourth quarter of 2002, increase in inventory of \$860,000 related to increased stock of musculoskeletal and thin film product lines, offset by 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, an asset impairment of \$370,000 and stock based compensation of \$1,238,000. In the year ended December 31, 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, offset by non-cash charges for inventory provision, stock based compensation, and depreciation and amortization. In the year ended December 31, 2000, net cash used in operating activities resulted primarily from our net loss of \$8,645,000 and an increase in inventory of \$1,143,000, offset by stock based compensation of \$5,716,000 and deferred revenue related to an up-front license fee of \$1,200,000 paid to us by Medtronic. 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 and will offset the associated costs.

Net cash provided by investing activities was \$17,265,000 and \$2,263,000 for the years ended December 31, 2002 and 2001, respectively. Net cash used in investing activities was \$39,450,000 for the year ended December 31, 2000. Net cash provided by investing activities for the year ended December 31, 2002 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), and cash received upon the sale of craniomaxillofacial product line to Medtronic which was offset by cash paid in the acquisition of StemSource. Net cash provided by investing activities for the year ended December 31, 2001 consisted of net proceeds from the purchase and sale of short-term investments, capital expenditures and our investment in StemSource. Net cash used in investing activities for the year ended December 31, 2000 included net purchases of short-term investments related to the use of proceeds from our initial public offering in August 2000 as well as capital expenditures. We expect to continue to have cash provided by 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 \$7,971,000 for the year ended December 31, 2002. Net cash provided by financing activities was \$1,283,000 and \$47,437,000 for the years ended December 31, 2001 and 2000, respectively. Net cash used in financing activities for the year ended December 31, 2002 was primarily related to our repurchase of 1,972,863 shares of common stock on the open market at an average price of \$3.77 per share, and payments toward capital leases and long term obligations, offset by the proceeds from the sale of 210,000 treasury stock at an average price of \$4.18. Net cash provided by financing activities for the year ended December 31, 2001 was primarily related to proceeds from long-term debt financing, partially offset by our repurchase of 356,120 shares of our common stock at an average price of \$3.02. Net cash provided by financing activities for the year ended December 31, 2000 was primarily attributable to our sale of shares of Series D preferred stock and our sale of common stock in our initial public offering. We do not expect to use cash in financing activities in 2003 at the same level as we did for the year ended December 31, 2002, except for the cash required for payments on our long term obligations.

In October 2000, we obtained \$2,433,000 of equipment financing promissory notes that mature in October 2005 at an interest rate of 9.3%. In 2002 we prepaid \$621,000 relating to a 48 month promissory note and the lender changed the terms of this promissory note to bear 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.

As of December 31, 2002, we had property and equipment of \$6,146,000, less accumulated depreciation of \$2,520,000 to support our clinical, research, development, manufacturing and administrative activities. The net carrying cost of the property and equipment sold to Medtronic in the September 2002 asset sale was \$476,000. Our capital expenditures were \$909,000, \$2,664,000 and \$2,732,000 for the year ended 2002, 2001 and 2000, respectively. We expect capital expenditures for the next twelve months to be approximately \$1,000,000 as we acquire additional equipment and expand our facilities that include capital expenditures at StemSource. We intend to pay for future capital expenditures with available working capital.

### **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 from our estimates, we will make adjustments to our financial statements as we become aware of the necessity for an adjustment. Specifically, we make estimates in the following areas:

*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 Stem Cell rich adipose tissue. In our StemBank operations, we recognize revenue when the collection procedure is performed and the adipose tissue is received by MacroPore; fees from the procedure are fixed and determinable, and 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 Stem 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 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 reasonable commensurate with the effort expended and collection of the payment is reasonably assured. Income earned under development agreements are 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.

Substantially all of our revenues are from Medtronic, under its Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002, as well as its Development and Supply Agreement dated January 5, 2000 and amended December 22, 2000 and September 30, 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 93.9% and 98.2% of our revenues in the year ending December 31, 2002 and 2001, respectively. We believe that our allowance for doubtful accounts as of December 31, 2002 with respect to Medtronic's account is sufficient, given Medtronic's collection history and overall financial strength.

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

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 reserves.* We estimate our potential warranty reserve based on historical claims by our customers. The likelihood of a material change in our estimated warranty reserve depends on a significant change in actual product failures and increased customer claims from those incurred historically.

*Valuation of deferred income taxes.* 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 taken a 100% valuation allowance against our deferred tax assets, which consist mostly of net operating loss carryforwards. 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.

*Principles of consolidation.* We determine whether the equity method of consolidation is appropriate to account for our investments based on our ability to exercise control through decision-making, our ability to exercise significant influence over management of the company in which we have invested and our equity ownership interest in that company. If our ability to exercise significant influence or our decision-making abilities change materially from our evaluation, or our ownership interest in an investment increases or decreases, our operating results could be impacted, either positively or negatively.

## **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 reflected as such in the Statement of Operations and Comprehensive Income (Loss). Unearned compensation recorded through December 31, 2002 was \$6,665,000 with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of \$5,608,000. The remaining \$1,057,000 as of December 31, 2002 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 \$844,000 in 2003 and \$213,000 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.

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

We have 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. We have recorded a valuation allowance of \$15,037,000 as of December 31, 2002 to reflect the estimated amount of deferred tax assets that may not be realized. We increased our valuation allowance by approximately \$4,831,000 for the year ended December 31, 2002. The valuation allowance includes approximately \$505,000 related to stock option deductions, the benefit of which will eventually be credited to equity.

At December 31, 2002, we had federal and state tax loss carryforwards of approximately \$17,200,000 and \$10,500,000 respectively. The federal and state net operating loss carryforwards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2002, we had federal and state tax credit carryforwards of approximately \$390,000 and \$396,000 respectively. The federal credits will begin to expire in 2017, if unused, and the state credits will begin to expire in 2012 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, 2002, the remaining pre-change federal net operating loss carryforward of \$2,700,000 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 \$1,600,000 respectively. These losses are subject to IRC Section 382 and may be limited in their use. The extent of such limitation has not been determined at this time.

### **Recent Accounting Pronouncements**

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to all entities and to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal operation of long-lived assets, except for some lessee obligations. SFAS No. 143 is effective for financial statements issued for fiscal years beginning after June 15, 2002. We do not expect the adoption of SFAS No. 143 to have a material impact on our consolidated financial position or consolidated results of operations.

In April 2002, the FASB issued SFAS No. 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS No. 145 updates, clarifies and simplifies existing accounting pronouncements including: rescinding Statement No. 4, which required all gains and losses from extinguishment of debt to be aggregated and, if material, classified as an extraordinary item, net of related income tax effect and amending Statement No. 13 to require that certain lease modifications that have economic effects similar to sale-leaseback transactions be accounted for in the same manner as sale-leaseback transactions. SFAS No. 145 is effective for fiscal years beginning after May 15, 2002, with early adoption of the provisions related to the rescission of Statement No. 4 encouraged. We do not expect this standard to have a material effect on our consolidated financial statements or consolidated results of operations as it currently does not have any guarantees falling within the scope of FIN 45.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. We do not expect this standard to have a material effect on our consolidated financial position or consolidated results of operations.

In December 2002, the FASB issued FASB Interpretation No. 45 (FIN 45). FIN 45 provides guidance on how companies should record and disclose "guarantees." The primary principle of FIN 45 is that guarantees must be recorded as a liability, regardless of the probability of occurrence. The amount of the liability to be accrued depends on the likelihood of the liability to occur. The liability recognition provisions of FIN 45 shall be applied on a prospective basis to guarantees issued or modified after December 31, 2002. Additionally, FIN 45 requires certain disclosures about guarantees in our December 31, 2002 consolidated financial statements. We do not expect this standard to have a material effect on our consolidated financial position or consolidated results of operations as it currently does not have any guarantees falling within the scope of FIN 45.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of FASB Statement No. 123." 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. Therefore, the transition provisions will not apply, but the annual and interim disclosure provisions will apply to us beginning with our financial statements for the year ended December 31, 2002 and interim periods thereafter.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities". FIN 46 clarifies the application of Accounting Research Bulletin No. 51 - Consolidated Financial Statements to those entities defined as "Variable Interest Entities" (more commonly 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 June 15, 2003 for Variable Interest Entities created prior to February 1, 2003. We do not expect this interpretation to have a material 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.

## **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 \$19,875,000 as of December 31, 2002, 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, 2002, 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. We believe that we 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. 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, 2002, 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).

### **Risk Factors**

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

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

We commenced operations in May 1997 and therefore 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 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. 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 \$13,003,000 for the year ended December 31, 2002. These losses have resulted primarily from expenses associated with our research and development activities, including extensive in-vitro testing and numerous preclinical studies and general and administrative expenses, as well as. 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 losses through the end of 2003, and the amount of future net losses and time necessary to reach profitability are somewhat uncertain. Even if our bone fixation and thin film medical device product lines achieve profitability, development-stage losses related to our development of stem cell regenerative technology could keep us in a loss position on a consolidated basis for several years.

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

In the second half of 2002 we sold our craniomaxillofacial bone fixation implant and accessories product line to Medtronic, and announced an agreement to acquire StemSource, which is a development-stage adult stem cell company. Our craniomaxillofacial product line was relatively stable and slower-growth, compared to our retained musculoskeletal bone fixation implant and accessories product line and our thin film for soft-tissue repair and regeneration. By focusing on these less-mature and more volatile product areas, we accept more risk. In addition, we intend to use the cash we received from the sale of the craniomaxillofacial product line to finance the newly acquired StemSource and its development-stage cash needs. This is a high-risk strategy because there can be no assurance that our StemSource 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 stem cells where needed in the body (strategic risk), or that our cash resources will be adequate to develop the StemSource 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 received from selling that product line to reinvest in our core business, we are using it in one of the riskiest industries in the entire 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 and expanding our sales and marketing for our SurgiWrap™ bioresorbable barrier film and other new products resulting from our research and development activities. We are presently pursuing product opportunities in musculoskeletal 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 stem cell related products and /or services are years away.

Moreover, the various applications and uses of our resorbable 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 experience in sales, marketing and distribution. Therefore, our strategy for sales and marketing of our resorbable products has included entering into agreements with other companies to market many of our current and certain future products incorporating our technology. We have derived the vast majority of our 2001 and 2002 revenues from the sale of products to our distribution partner Medtronic Inc. (Medtronic). Our direct sales force markets the SurgiWrap™ product line throughout geographic territories in the United States and we have signed international distributor agreements in 28 countries. We cannot guarantee that this sales force or international distributors will adequately penetrate the markets to generate significant revenues in the near future, if at all.

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 6.8% 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 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 craniomaxillofacial 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, 2004, 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 stem cell technology license agreement with the University of California Regents 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 stem 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 QSRs. 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. 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, 2002, we had \$24,983,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. Our 2002 sale of the craniomaxillofacial product line to Medtronic has buttressed that cash position, but our acquisition of StemSource will result in a substantial cash burn. 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, Ari Bizimis, our Chief Financial Officer and Marc Hedrick, MD, our Chief Scientific Officer and Medical Director. 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, Inc., as well as 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, Inc., 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***

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 the 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.

***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.

|   |             |
|---|-------------|
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| <u>Consolidated Balance Sheets as of December 31, 2002 and 2001</u>   | 47          |
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Independent Auditors' Report

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

We have audited the accompanying consolidated balance sheet of MacroPore Biosurgery, Inc. (the Company) as of December 31, 2002, the related consolidated statements of operation and comprehensive income (loss), stockholders' equity and cash flows for the year then ended. In connection with our audit of the consolidated financial statements, we also have audited the financial statement schedule for the year ended December 31, 2002. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audit. The December 31, 2001 and 2000 financial statements and financial statement schedules 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 schedules in their report dated February 15, 2002.

We conducted our audit 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 audit provides a reasonable basis for our opinion.

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

/s/ KPMG LLP

San Diego, CA  
March 7, 2003

**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 sheet as of December 31, 2000, referred to in this report has not been included in the accompanying financial statements.**

Report of Independent Public Accountants

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, |               |
|---|--------------------|---------------|
|   | 2002               | 2001          |
| <b>Assets</b>   |                    |               |
| Current assets:   |                    |               |
| Cash and cash equivalents   | \$ 5,108,000       | \$ 2,700,000  |
| Short-term investments, available-for-sale  | 19,875,000         | 31,251,000    |
| Accounts receivable, net of allowance for doubtful accounts of \$50,000 and \$35,000 in 2002 and 2001, respectively                                   | 1,238,000          | 463,000       |
| Inventories   | 1,150,000          | 1,685,000     |
| Other current assets  | 843,000            | 851,000       |
| Total current assets  | 28,214,000         | 36,950,000    |
| Property and equipment, net   | 3,626,000          | 5,171,000     |
| Other assets  | 562,000            | 1,022,000     |
| Goodwill and intangibles, net   | 6,917,000          | —             |
| Total assets  | \$ 39,319,000      | \$ 43,143,000 |
| <b>Liabilities and Stockholders' Equity</b>   |                    |               |
| Current liabilities:  |                    |               |
| Accounts payable and accrued expenses   | \$ 2,502,000       | \$ 1,155,000  |
| Current portion of capital lease obligations  | —                  | 121,000       |
| Current portion of long-term obligations  | 410,000            | 555,000       |
| Total current liabilities   | 2,912,000          | 1,831,000     |
| Deferred revenue from license agreement, related party  | —                  | 900,000       |
| Deferred gain on sale of assets, related party  | 9,623,000          | —             |
| Deferred revenue  | 19,000             | —             |
| Capital lease obligations, less current portion   | —                  | 135,000       |
| Long-term obligations, less current portion   | 770,000            | 1,791,000     |
| Total liabilities   | 13,324,000         | 4,657,000     |
| <b>Commitments</b>  |                    |               |
| Stockholders' equity:   |                    |               |
| Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2002 and 2001                                   | —                  | —             |
| Common stock, \$0.001 par value; 95,000,000 shares authorized; 16,646,664 and 15,106,623 shares issued and outstanding in 2002 and 2001, respectively | 17,000             | 15,000        |
| Additional paid-in capital  | 74,730,000         | 68,402,000    |
| Unearned compensation   | (1,057,000)        | (2,105,000)   |
| Accumulated deficit   | (40,102,000)       | (27,099,000)  |
| Treasury stock, at cost; 2,118,983 and 356,120 shares in 2002 and 2001, respectively  | (7,752,000)        | (1,077,000)   |
| Accumulated other comprehensive income  | 159,000            | 350,000       |
| Total stockholders' equity  | 25,995,000         | 38,486,000    |
| Total liabilities and stockholders' equity  | \$ 39,319,000      | \$ 43,143,000 |

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, |                 |                |
|--|----------------------------------|-----------------|----------------|
|  | 2002                             | 2001            | 2000           |
| Revenues:  |                                  |                 |                |
| Sales to related party (Note 14)   | \$ 8,605,000                     | \$ 5,547,000    | \$ 6,092,000   |
| Sales to third parties   | 561,000                          | 101,000         | 159,000        |
|  | 9,166,000                        | 5,648,000       | 6,251,000      |
| Cost of revenues:  |                                  |                 |                |
| Cost of revenues (including stock based compensation expense of \$14,000, \$14,000, and \$18,000 for the years ended December 31, 2002, 2001, and 2000, respectively)              | 3,169,000                        | 2,401,000       | 2,394,000      |
| Inventory provision  | 1,395,000                        | 1,750,000       | —              |
| Gross profit   | 4,602,000                        | 1,497,000       | 3,857,000      |
| Operating expenses:  |                                  |                 |                |
| Research and development, excluding stock based compensation expense of \$211,000, \$111,000 and \$2,239,000 for the years ended December 31, 2002, 2001, and 2000, respectively   | 5,605,000                        | 5,487,000       | 2,584,000      |
| Sales and marketing, excluding stock based compensation expense of \$134,000, \$176,000 and \$1,852,000 for the years ended December 31, 2002, 2001, and 2000, respectively        | 3,987,000                        | 4,493,000       | 2,629,000      |
| General and administrative, excluding stock based compensation expense of \$942,000, \$836,000 and \$1,607,000 for the years ended December 31, 2002, 2001, and 2000, respectively | 3,952,000                        | 3,578,000       | 2,555,000      |
| Stock based compensation (excluding cost of revenues stock based compensation)   | 1,287,000                        | 1,123,000       | 5,698,000      |
| In-process research and development  | 2,296,000                        | —               | —              |
| Equipment impairment charge  | 370,000                          | —               | —              |
| Total operating expenses   | 17,497,000                       | 14,681,000      | 13,466,000     |
| Other income (expense):  |                                  |                 |                |
| Interest income  | 1,037,000                        | 2,249,000       | 1,315,000      |
| Interest and other expenses  | (263,000)                        | (168,000)       | (351,000)      |
| Equity loss in investment  | (882,000)                        | (104,000)       | —              |
| Net loss   | (13,003,000)                     | (11,207,000)    | (8,645,000)    |
| Other comprehensive income (loss): unrealized holding (loss) gain  | (191,000)                        | 170,000         | 180,000        |
| Comprehensive loss   | \$ (13,194,000)                  | \$ (11,037,000) | \$ (8,465,000) |
| Basic and diluted net loss per share   | \$ (0.89)                        | \$ (0.75)       | \$ (1.05)      |
| Shares used in calculating basic and diluted net loss per share  | 14,630,374                       | 14,926,107      | 8,201,739      |

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

**MACROPORE BIOSURGERY, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000**

|   | Preferred A |            | Preferred B |              | Preferred C |              | Preferred D |              |
|---|-------------|------------|-------------|--------------|-------------|--------------|-------------|--------------|
|   | Shares      | Amount     | Shares      | Amount       | Shares      | Amount       | Shares      | Amount       |
| Balance at December 31, 1999  | 1,267,000   | \$ 630,000 | 1,032,583   | \$ 1,547,000 | 2,574,989   | \$ 5,657,000 | 832,226     | \$ 2,855,000 |
| Issuance of common stock under stock option plan  |             |            |             |              |             |              |             |              |
| Conversion of Series C Preferred shares to common stock                                   |             |            |             |              | (45,951)    | (103,000)    |             |              |
| Issuance of Series C Preferred shares for cash, at \$2.25 per share                       |             |            |             |              | 2,777       | 6,000        |             |              |
| Issuance of Series D Preferred shares for cash, at \$3.50 per share                       |             |            |             |              |             |              | 1,167,774   | 4,087,000    |
| Issuance of common stock for services rendered  |             |            |             |              |             |              |             |              |
| Issuance of common stock in initial public offering, net of issuance costs of \$3,957,000 |             |            |             |              |             |              |             |              |
| Conversion of preferred stock in connection with initial public offering                  | (1,267,000) | (630,000)  | (1,032,583) | (1,547,000)  | (2,531,815) | (5,560,000)  | (2,000,000) | (6,942,000)  |
| Compensatory stock options  |             |            |             |              |             |              |             |              |
| Unrealized income on investments  |             |            |             |              |             |              |             |              |
| Net loss for the year ended December 31, 2000   |             |            |             |              |             |              |             |              |
| Balance at December 31, 2000  | —           | —          | —           | —            | —           | —            | —           | —            |
| Issuance of common stock under stock option plan  |             |            |             |              |             |              |             |              |
| Compensatory stock options  |             |            |             |              |             |              |             |              |
| Purchase of treasury stock  |             |            |             |              |             |              |             |              |
| Unrealized income on investments  |             |            |             |              |             |              |             |              |
| Net loss for the year ended December 31, 2001   |             |            |             |              |             |              |             |              |
| Balance at December 31, 2001  | —           | —          | —           | —            | —           | —            | —           | —            |
| Issuance of common stock under stock option plan  |             |            |             |              |             |              |             |              |
| Issuance of common stock in acquisition   |             |            |             |              |             |              |             |              |
| Compensatory stock options  |             |            |             |              |             |              |             |              |
| Purchase of treasury stock  |             |            |             |              |             |              |             |              |
| Sale of treasury stock  |             |            |             |              |             |              |             |              |
| Unrealized loss on investment   |             |            |             |              |             |              |             |              |
| Net loss for the year ended December 31, 2002   |             |            |             |              |             |              |             |              |
| Balance at December 31, 2002  | —           | \$ —       | —           | \$ —         | —           | \$ —         | —           | \$ —         |

|  | Common Stock |           | Additional<br>Paid-In<br>Capital | Unearned<br>Compensation | Accumulated<br>Deficit | Treasury<br>Stock | Accumulated<br>Other<br>Comprehensive<br>Income | Total         |
|--|--------------|-----------|----------------------------------|--------------------------|------------------------|-------------------|---|---------------|
|  | Shares       | Amount    |                                  |                          |                        |                   |   |               |
| Balance at December 31,<br>1999  | 3,639,505    | \$ 4,000  | \$ 2,381,000                     | \$ (1,285,000)           | \$ (7,247,000)         | —                 | —   | \$ 4,542,000  |
| Issuance of common stock<br>under stock option plan  | 784,124      |           | 156,000                          |                          |                        |                   |   | 156,000       |
| Conversion of Series C<br>Preferred shares to<br>common stock                                      | 45,951       |           | 103,000                          |                          |                        |                   |   | —             |
| Issuance of Series C<br>Preferred shares for cash,<br>at \$2.25 per share                          |              |           |                                  |                          |                        |                   |   | 6,000         |
| Issuance of Series D<br>Preferred shares for cash,<br>at \$3.50 per share                          |              |           |                                  |                          |                        |                   |   | 4,087,000     |
| Issuance of common stock<br>for services rendered  | 13,368       |           | 161,000                          |                          |                        |                   |   | 161,000       |
| Issuance of common stock in<br>initial public offering,<br>net of issuance costs of<br>\$3,957,000 | 3,500,000    | 4,000     | 43,240,000                       |                          |                        |                   |   | 43,244,000    |
| Conversion of preferred<br>stock in connection with<br>initial public offering                     | 6,831,398    | 7,000     | 14,672,000                       |                          |                        |                   |   | —             |
| Compensatory stock options   |              |           | 7,413,000                        | (1,809,000)              |                        |                   |   | 5,604,000     |
| Unrealized income on<br>investments  |              |           |                                  |                          |                        |                   | 180,000   | 180,000       |
| Net loss for the year ended<br>December 31, 2000   |              |           |                                  |                          | (8,645,000)            |                   |   | (8,645,000)   |
| Balance at December 31,<br>2000  | 14,814,346   | 15,000    | 68,126,000                       | (3,094,000)              | (15,892,000)           | —                 | 180,000   | 49,335,000    |
| Issuance of common stock<br>under stock option plan  | 292,277      |           | 128,000                          |                          |                        |                   |   | 128,000       |
| Compensatory stock options   |              |           | 148,000                          | 989,000                  |                        |                   |   | 1,137,000     |
| Purchase of treasury stock   |              |           |                                  |                          |                        | (1,077,000)       |   | (1,077,000)   |
| Unrealized income on<br>investments  |              |           |                                  |                          |                        |                   | 170,000   | 170,000       |
| Net loss for the year ended<br>December 31, 2001   |              |           |                                  |                          | (11,207,000)           |                   |   | (11,207,000)  |
| Balance at December 31,<br>2001  | 15,106,623   | 15,000    | 68,402,000                       | (2,105,000)              | (27,099,000)           | (1,077,000)       | 350,000   | 38,486,000    |
| Issuance of common stock<br>under stock option plan  | 92,286       |           | 16,000                           |                          |                        |                   |   | 16,000        |
| Issuance of common stock in<br>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   |              |           |                                  |                          |                        | (7,442,000)       |   | (7,442,000)   |
| Sale of treasury stock   |              |           | 110,000                          |                          |                        | 767,000           |   | 877,000       |
| Unrealized loss on<br>investment   |              |           |                                  |                          |                        |                   | (191,000)                                       | (191,000)     |
| Net loss for the year ended<br>December 31, 2002   |              |           |                                  |                          | (13,003,000)           |                   |   | (13,003,000)  |
| Balance at December 31,<br>2002  | 16,646,664   | \$ 17,000 | \$ 74,730,000                    | \$ (1,057,000)           | \$ (40,102,000)        | \$ (7,752,000)    | \$ 159,000                                      | \$ 25,995,000 |

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, |                     |                     |
|--|----------------------------------|---------------------|---------------------|
|  | 2002                             | 2001                | 2000                |
| <b>Cash flows from operating activities:</b>   |                                  |                     |                     |
| Net loss   | \$ (13,003,000)                  | \$ (11,207,000)     | \$ (8,645,000)      |
| Adjustments to reconcile net loss to net cash used in operating activities:  |                                  |                     |                     |
| Depreciation and amortization  | 1,471,000                        | 1,184,000           | 441,000             |
| Loss on disposal of assets   | 91,000                           | —                   | —                   |
| Equipment impairment charge  | 370,000                          | —                   | —                   |
| Inventory provision  | 1,395,000                        | 1,750,000           | —                   |
| Gain on sale of assets, related party  | (267,000)                        | —                   | —                   |
| Acquired in-process research and development   | 2,296,000                        | —                   | —                   |
| Stock based compensation   | 1,301,000                        | 1,137,000           | 5,716,000           |
| 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  | (775,000)                        | 230,000             | (201,000)           |
| Inventories  | (860,000)                        | (1,157,000)         | (1,143,000)         |
| Other current assets   | 284,000                          | 31,000              | (851,000)           |
| Other assets   | (304,000)                        | 115,000             | (223,000)           |
| Accounts payable and accrued expenses  | 458,000                          | (209,000)           | 724,000             |
| Deferred revenue from license agreement, related party   | (225,000)                        | (300,000)           | 1,200,000           |
| Net cash used in operating activities  | <u>(6,886,000)</u>               | <u>(8,322,000)</u>  | <u>(2,982,000)</u>  |
| <b>Cash flows from investing activities:</b>   |                                  |                     |                     |
| Proceeds from the sale and maturity of short-term investments  | 68,151,000                       | 90,065,000          | 85,610,000          |
| Purchases of short-term investments  | (56,966,000)                     | (84,138,000)        | (122,328,000)       |
| Purchases of property and equipment  | (909,000)                        | (2,664,000)         | (2,732,000)         |
| Equity investment  | —                                | (1,000,000)         | —                   |
| Acquisition, net of cash acquired  | (2,896,000)                      | —                   | —                   |
| Proceeds from sale of assets, related party, net   | 9,689,000                        | —                   | —                   |
| Proceeds from the sale of impaired assets  | 196,000                          | —                   | —                   |
| Net cash provided by (used in) investing activities  | <u>17,265,000</u>                | <u>2,263,000</u>    | <u>(39,450,000)</u> |
| <b>Cash flows from financing activities:</b>   |                                  |                     |                     |
| Principal payments on capital leases   | (256,000)                        | (114,000)           | (105,000)           |
| Principal payments on long-term obligations  | (1,166,000)                      | (87,000)            | —                   |
| Proceeds from long-term debt   | —                                | 2,433,000           | —                   |
| Proceeds from sale of common stock   | 16,000                           | 128,000             | 205,000             |
| Purchase of treasury stock   | (7,442,000)                      | (1,077,000)         | —                   |
| Proceeds from sale of treasury stock   | 877,000                          | —                   | —                   |
| Proceeds from sale of series C and series D preferred stock, net of issuance costs                                     | —                                | —                   | 4,093,000           |
| Proceeds from initial public offering, net of offering costs   | —                                | —                   | 43,244,000          |
| Net cash (used in) provided by financing activities  | <u>(7,971,000)</u>               | <u>1,283,000</u>    | <u>47,437,000</u>   |
| Net increase (decrease) in cash  | 2,408,000                        | (4,776,000)         | 5,005,000           |
| Cash and cash equivalents at beginning of year   | <u>2,700,000</u>                 | <u>7,476,000</u>    | <u>2,471,000</u>    |
| Cash and cash equivalents at end of year   | <u>\$ 5,108,000</u>              | <u>\$ 2,700,000</u> | <u>\$ 7,476,000</u> |

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, |              |              |
|--|----------------------------------|--------------|--------------|
|  | 2002                             | 2001         | 2000         |
| <b>Supplemental disclosure of cash flows information:</b>                                    |                                  |              |              |
| Cash paid during period for:   |                                  |              |              |
| Interest   | \$ 182,000                       | \$ 100,000   | \$ 82,000    |
| Taxes  | 800                              | 800          | 800          |
| <br><b>Supplemental schedule of non-cash operating, investing, and financing activities:</b> |                                  |              |              |
| Unearned stock based compensation  | \$ 1,301,000                     | \$ 1,137,000 | \$ 5,716,000 |
| Equipment acquired under capital leases  | —                                | —            | 82,000       |
| Conversion of bridge loan to Series C preferred stock  | —                                | —            | 112,000      |
| <br><b>Supplemental schedule of investing activities:</b>                                    |                                  |              |              |
| 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  | \$ 2,896,000                     | —            | —            |

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, 2002, 2001 AND 2000**

**1. Organization and Operations**

**The Company**

The Company develops, commercializes and manufactures bioresorbable surgical implants to aid in the reconstruction, repair and regeneration of bone. The Company's bioresorbable products are made from a lactic acid copolymer which is composed of a lactic acid similar to that which occurs naturally in the human body.

**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 the absence of instances where the Company retains control through decision-making ability and generally a greater than 50% ownership interest, the Company generally accounts for these investments under the cost or equity method, depending upon management's evaluation of the Company's ability to exercise and retain control.

On November 13, 2002, the Company consummated a merger with StemSource, Inc. (StemSource) for cash and stock accounted for as a purchase (see Note 4). Previously, the Company's earlier investment in StemSource was accounted for under the equity method. Accordingly, the 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.

**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; in particular by such companies in rapidly evolving and technologically advanced fields 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 biotechnology 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.

**Capital Availability**

The Company has a limited operating history and recorded the first sale of its products in 1999. The Company incurred losses of \$13,003,000, \$11,207,000 and \$8,645,000 for the years ended December 31, 2002, 2001 and 2000, respectively, and has an accumulated deficit of \$40,102,000 as of December 31, 2002. Additionally, the Company has experienced net cash used in operations of \$6,886,000, \$8,322,000 and \$2,982,000 for the years ended December 31, 2002, 2001 and 2000, 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, 2003. 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.

**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 of which substantially all 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 \$5,108,000 and \$2,700,000 as of December 31, 2002 and 2001, respectively, and consisted primarily of cash and highly liquid investments.

### **Short-term Investments**

The Company invests its 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 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 such review results in management's determination that an investment's impairment is considered to be other than temporary. The cost of securities sold is based on the specific identification method.

### **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.

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 (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 2001, the Company recorded an inventory provision of \$1,750,000 for excess and obsolete inventory related to the Company's craniomaxillofacial skeleton implant and accessory product line. The provision for excess and obsolete inventory was due to an anticipated reduction in expected future revenues of these products. This provision includes inventory held on-hand as of December 31, 2001.

### **Long-Lived Assets**

In accordance with SFAS No. 144, the Company assesses potential impairments to its long-lived assets when there is a change in circumstances that indicates carrying values of assets may not be recovered. An impairment loss is recognized when the undiscounted cash flows expected to be generated by an asset is less than its 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 craniomaxillofacial bone fixation implant and accessory product line which were not included in the Medtronic sale (note 3). The impairment charge represents the excess of the net book value over the estimated net proceeds the Company estimates it will receive from the sale of these assets. The remaining carrying amount of the assets totaling \$162,000 has been reclassified as held for sale and is included within Other Assets in the accompanying balance sheet as of December 31, 2002.

## **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 had no goodwill and intangibles as of January 1, 2002 and therefore no impairment test was required upon the adoption of SFAS No. 142.

## **Intangibles**

Intangibles, consisting of core technology and existing technology purchased in the StemSoure acquisition, are being amortized over their expected lives of ten years.

## **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. The Company warrants that its 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. For the years ended December 31, 2002, 2001 and 2000, the Company recognized \$225,000, \$300,000 and \$300,000, respectively, in revenue in each period from a license agreement.

The Company recognizes revenue from the collection and storage of Stem Cell rich adipose tissue. In its StemBank product line, the Company recognizes revenue when the collection procedure is performed and the adipose tissue is received by the Company; fees from the procedure are fixed and determinable, and 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 Stem Cell storage services as the services are 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 reasonable commensurate with the effort expended and collection of the payment is reasonably assured. Income earned under development agreements are 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. Any costs related to these arrangements are recognized as cost of revenue as these costs are incurred.

Substantially all of the Company's revenues are from Medtronic, under its Distribution Agreement dated January 5, 2000 and

amended December 22, 2000 and October 8, 2002, as well as its Development and Supply Agreement dated January 5, 2000 and amended December 22, 2000 and September 30, 2002.

### Warranty

The Company warrants that all of its products will be free from manufactured defects and are manufactured in accordance with all applicable laws and regulations. The Company has not experienced any warranty returns and accordingly carries no 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 their financial reporting amounts at each year end. If it is more likely than not that some portion of the net deferred tax asset will not be realized, a valuation allowance is recognized.

### Stock Based Compensation

The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock Based Compensation." Accordingly, the Company accounts for its stock based compensation plan under the provisions of Accounting Principles Board (APB) opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations under which compensation cost is measured by the excess, if any, of the fair market value of the Company's common stock at the date of grant over the exercise price of the option (intrinsic value method). Compensation cost is amortized using the straight-line method over the related vesting periods. Unearned stock based compensation costs for awards that are forfeited are reversed against compensation expense in the period of forfeiture. Stock based awards issued to non-employees are accounted for using a fair value method and are remeasured to estimated fair value at each period end until the earlier of the date that performance by the counterparty is complete or the awards are fully vested.

As required by SFAS No. 123, the Company has determined the pro forma information as if the Company had accounted for stock options under the fair value method prescribed by SFAS No. 123. The Company used the Black-Scholes option pricing model to determine fair value using the following weighted average assumptions: risk free interest rates ranging from 3.5% to 6.7%, dividend yield of zero, expected market price volatility factor of 60% to 100% and a weighted average expected life of the options ranging from four to seven years. Had compensation cost for stock options granted during the years ended December 31, 2002, 2001 and 2000 been determined consistent with SFAS No. 123, the Company's net loss and related per share amounts on a pro forma basis would be as follows:

|  | Years ended December 31, |                        |                       |
|--|--------------------------|------------------------|-----------------------|
|  | 2002                     | 2001                   | 2000                  |
| Net loss:  |                          |                        |                       |
| As reported  | \$ (13,003,000)          | \$ (11,207,000)        | \$ (8,645,000)        |
| Add: Stock based employee compensation expense included in reported net loss, net of related tax effects                                 | 1,147,000                | 1,104,000              | 3,171,000             |
| Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects | <u>(4,378,000)</u>       | <u>(5,367,000)</u>     | <u>(4,076,000)</u>    |
| Pro forma  | <u>\$ (16,234,000)</u>   | <u>\$ (15,470,000)</u> | <u>\$ (9,550,000)</u> |
| Loss per common share:   |                          |                        |                       |
| As reported  | \$ (.89)                 | \$ (.75)               | \$ (1.05)             |
| Pro forma  | (1.11)                   | (1.04)                 | (1.16)                |

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, 2002, 2001 and 2000 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 follows the provisions of SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information." The Company believes that all of its material operations are managed under the medical device industry, with similar purpose, production processes, markets, and regulatory requirements, and it currently reports as a single industry segment.

For the year ending December 31, 2002, the Company recorded \$9,166,000 in sales. The Company sold \$8,855,000 of product in the United States and \$311,000 of product outside the United States. For the year ending December 31, 2001, the Company recorded \$5,648,000 in sales. The Company sold \$4,954,000 of product in the United States and \$694,000 of product outside the United States. For the year ending December 31, 2000, the Company recorded \$6,251,000 in sales. The Company sold \$6,200,000 of product in the United States and \$51,000 of product outside the United States.

On November 13, 2002, the Company acquired all of the remaining outstanding shares of StemSource. The Company is currently in the process of evaluating its internal reporting structure subsequent to the acquisition of StemSource. Since the date of acquisition the results of StemSource have been immaterial and are not reported as a separate segment. In the future the Company may determine that StemSource is a separate segment under SFAS No. 133, at which time previous disclosures may be restated to reflect StemSource as a separate segment.

### **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, 2002, 2001 and 2000 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, 2002, 2001 and 2000 was 4,314,000, 3,367,000, and 2,797,000, respectively.

### **Recent Accounting Pronouncements**

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to all entities and to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal operation of long-lived assets, except for some lessee obligations. SFAS No. 143 is effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company does not expect the adoption of SFAS No. 143 to have a material impact on the consolidated financial position or consolidated results of operations.

In April 2002, the FASB issued SFAS No. 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS No. 145 updates, clarifies and simplifies existing accounting pronouncements including: rescinding Statement No. 4, which required all gains and losses from extinguishment of debt to be aggregated and, if material, classified as an extraordinary item, net of related income tax effect and amending Statement No. 13 to require that certain lease modifications that have economic effects similar to sale-leaseback transactions be accounted for in the same manner as sale-leaseback transactions. SFAS No. 145 is effective for fiscal years beginning after May 15, 2002, with early adoption of the provisions related to the rescission of Statement No. 4 encouraged. The Company does not expect this standard to have a material effect on its consolidated financial statements or consolidated results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit.

arrangement or an individual deferred-compensation contract. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect this standard to have a material effect on its consolidated financial position or consolidated results of operations.

In December 2002, the FASB issued FASB Interpretation No. 45 (FIN 45). FIN 45 provides guidance on how companies should record and disclose "guarantees." The primary principle of FIN 45 is that guarantees must be recorded as a liability, regardless of the probability of occurrence. The amount of the liability to be accrued depends on the likelihood of the liability to occur. The liability recognition provisions of FIN 45 shall be applied on a prospective basis to guarantees issued or modified after December 31, 2002. Additionally, FIN 45 requires certain disclosures about guarantees in the Company's December 31, 2002 consolidated financial statements. The Company does not expect this standard to have a material effect on its consolidated financial position or consolidated results of operations as it currently does not have any guarantees falling within the scope of FIN 45.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - An Amendment of FASB Statement No. 123." 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 continues to account for its stock-based employee compensation plan under APB Opinion No. 25 and related interpretations. Therefore, the transition provisions will not apply, but the annual and interim disclosure provisions will apply to the Company beginning with the financial statements for the year ended December 31, 2002 and interim periods thereafter.

January 2003, the FASB issued Interpretation FIN 46, "Consolidation of Variable Interest Entities". FIN 46 clarifies the application of Accounting Research Bulletin No. 51 - Consolidated Financial Statements to those entities defined as "Variable Interest Entities" (more commonly 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 June 15, 2003 for Variable Interest Entities created prior to February 1, 2003. The Company does not expect this standard to have a material effect on its consolidated financial position or consolidated results of operations as it currently does not have any variable interest entities falling within the scope of FIN 46.

### **3. Sale of Craniomaxillofacial 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, Inc.) 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 craniomaxillofacial 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 2003. 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 to be a backup supplier of the acquired products to Medtronic at a price equal to the Company's cost of manufacture during the transition technology transfer period. Discounts from the previously agreed price have been recorded as a reduction to the deferred gain and totaled \$267,000 for the year ended December 31, 2002. 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.

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") 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, until such a time as the technology and know how transfer is completed pursuant to the terms of the Agreement. Upon successfully completing its requirements under these provisions of the Agreement, the Company will recognize the net gain on the sale in the statement of operations.

#### 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 adult stem 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 Adult Stem Cells. StemSource has an advanced position in Adult Stem Cell research and numerous patents and other intellectual property position, which provided a first mover advantage for the Company. 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 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, 2001 and 2000, the Company recognized an equity loss in investment of \$882,000, \$104,000 and \$0, 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                          | 4,256,000           |
| 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, the purchase price was allocated as \$4,256,000 to goodwill, \$2,695,000 to intangible assets and \$2,296,000 to in-process research and development projects, principally an on-site Stem Cell extraction unit and related technology to process Adult Stem 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 biotechnology 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 proforma 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.

|                                  | <b>For the Years ended December 31,</b> |                 |
|----------------------------------|---|-----------------|
|                                  | <b>2002</b>                             | <b>2001</b>     |
| (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)       |

## 5. Short-term Investments

As of December 31, 2002 and 2001, all short-term investments were classified as available-for-sale, which consisted of the following:

|                           | <b>December 31, 2002</b>  |                                       |                                     |
|---------------------------|---------------------------|---------------------------------------|-------------------------------------|
|                           | <b>Amortized<br/>Cost</b> | <b>Gross<br/>Unrealized<br/>Gains</b> | <b>Estimated<br/>Fair<br/>Value</b> |
| 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>                |
|                           | <b>December 31, 2001</b>  |                                       |                                     |
|                           | <b>Amortized<br/>Cost</b> | <b>Gross<br/>Unrealized<br/>Gains</b> | <b>Estimated<br/>Fair<br/>Value</b> |
| Corporate notes and bonds | \$ 9,718,000              | \$ 57,000                             | \$ 9,775,000                        |
| Agency securities         | 19,042,000                | 292,000                               | 19,334,000                          |
| Treasury notes            | 2,141,000                 | 1,000                                 | 2,142,000                           |
|                           | <u>\$ 30,901,000</u>      | <u>\$ 350,000</u>                     | <u>\$ 31,251,000</u>                |

As of December 31, 2002 and 2001, investments available-for-sale had the following maturities:

|                                   | <b>December 31, 2002</b>  |                                     | <b>December 31, 2001</b>  |                                     |
|-----------------------------------|---------------------------|-------------------------------------|---------------------------|-------------------------------------|
|                                   | <b>Amortized<br/>Cost</b> | <b>Estimated<br/>Fair<br/>Value</b> | <b>Amortized<br/>Cost</b> | <b>Estimated<br/>Fair<br/>Value</b> |
| Corporate notes and bonds:        |                           |                                     |                           |                                     |
| with maturity of less than 1 year | \$ 6,190,000              | \$ 6,197,000                        | \$ 9,000,000              | \$ 9,057,000                        |
| with maturity of 1 to 2 years     | 313,000                   | 314,000                             | 718,000                   | 718,000                             |
| Agency securities:                |                           |                                     |                           |                                     |
| with maturity of less than 1 year | 5,350,000                 | 5,397,000                           | 8,963,000                 | 9,109,000                           |
| with maturity of 1 to 2 years     | 7,863,000                 | 7,967,000                           | 10,079,000                | 10,225,000                          |
| Treasury notes:                   |                           |                                     |                           |                                     |
| with maturity of less than 1 year | —                         | —                                   | 2,141,000                 | 2,142,000                           |
|                                   | <u>\$ 19,716,000</u>      | <u>\$ 19,875,000</u>                | <u>\$ 30,901,000</u>      | <u>\$ 31,251,000</u>                |

Proceeds from sales of investments for the year ended December 31, 2002, 2001 and 2000 were \$68,151,000, \$90,065,000 and \$85,610,000, respectively. Gross realized gains on such sales for the years ended December 31, 2002, 2001 and 2000 were approximately \$166,000, \$217,000 and \$6,000, respectively.

**6. Composition of Certain Financial Statement Captions**

**Inventories**

|                | December 31,        |                     |
|----------------|---------------------|---------------------|
|                | 2002                | 2001                |
| Raw materials  | \$ 602,000          | \$ 959,000          |
| Finished goods | 548,000             | 726,000             |
|                | <u>\$ 1,150,000</u> | <u>\$ 1,685,000</u> |

**Property and Equipment, net**

|  | December 31,        |                     |
|--|---------------------|---------------------|
|  | 2002                | 2001                |
| Office and computer equipment                  | \$ 1,874,000        | \$ 1,406,000        |
| Manufacturing and development equipment        | 2,721,000           | 4,235,000           |
| Leasehold improvements                         | 1,551,000           | 1,467,000           |
|  | 6,146,000           | 7,108,000           |
| Less accumulated depreciation and amortization | (2,520,000)         | (1,937,000)         |
|  | <u>\$ 3,626,000</u> | <u>\$ 5,171,000</u> |

**Other Assets**

|                          | December 31,      |                     |
|--------------------------|-------------------|---------------------|
|                          | 2002              | 2001                |
| Investment in StemSource | \$ —              | \$ 896,000          |
| Deposits                 | 400,000           | 126,000             |
| Assets held for sale     | 162,000           | —                   |
|                          | <u>\$ 562,000</u> | <u>\$ 1,022,000</u> |

**Goodwill and Intangibles, net**

|   | December 31,        |             |
|---|---------------------|-------------|
|   | 2002                | 2001        |
| Intangibles (net of accumulated amortization of \$34,000 in 2002) | \$ 2,661,000        | \$ —        |
| Goodwill  | 4,256,000           | —           |
|   | <u>\$ 6,917,000</u> | <u>\$ —</u> |

**Accounts Payable and Accrued Liabilities**

|                  | December 31,        |                     |
|------------------|---------------------|---------------------|
|                  | 2002                | 2001                |
| Accounts payable | \$ 599,000          | \$ 294,000          |
| Accrued bonus    | 397,000             | 398,000             |
| Accrued vacation | 325,000             | 244,000             |
| Accrued expenses | 1,181,000           | 219,000             |
|                  | <u>\$ 2,502,000</u> | <u>\$ 1,155,000</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<br/>Leases</u> |
|----------------------------------|-----------------------------|
| 2003                             | \$ 959,000                  |
| 2004                             | 1,027,000                   |
| 2005                             | 1,062,000                   |
| 2006                             | 783,000                     |
| 2007                             | 621,000                     |
| Thereafter                       | <u>214,000</u>              |
| Total payments                   | <u>\$ 4,666,000</u>         |

Rent expense for the years ended December 31, 2002, 2001 and 2000 was \$622,000, \$579,000 and \$369,000, 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 \$2,480 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.

## 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 patents 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 covers the following fields of use: cell replacement therapy in humans, gene therapy in humans, cosmetic surgery and reconstructive surgery in humans, research and collaboration services; and the development and commercialization of consumables.

The agreement calls for an initial lump sum payment and annual payments until such time as the licensee 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. StemSource obtained a waiver of the change in control provision by UC in connection with the acquisition by the licensee.

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

## 9. 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 issued two promissory notes to its lender under the agreement for a total of approximately \$2,433,000. These notes bear interest at 9.3% per annum with principal and interest due in monthly payments of approximately \$55,000 and \$7,000, respectively and mature over 48 and 36 month periods, respectively and are secured by equipment with a cost of \$2,752,000.

In 2002 the Company prepaid \$621,000 relating to a 48 month promissory note and the lender changed the terms of this promissory note to bear 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.

Principal payments on the promissory notes for the years ending December 31, 2003, 2004 and 2005 will be \$410,000, \$441,000 and \$329,000, respectively.

## 10. Income Taxes

Due to the Company's net loss position for the years ended December 31, 2002, 2001 and 2000, 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, 2002, 2001, and 2000.

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, 2002, 2001 and 2000 is as follows:

|  | <u>2002</u>  | <u>2001</u>  | <u>2000</u>  |
|--|--------------|--------------|--------------|
| Income tax expense (benefit) at federal statutory rate | (34.00)%     | (34.00)%     | (34.00)%     |
| Stock based compensation                               | 2.50%        | 3.00%        | 5.40%        |
| Credits  | (0.35)%      | (3.14)%      | (5.44)%      |
| Change in federal valuation allowance                  | 31.50%       | 40.31%       | 33.90%       |
| Other, net   | 0.35%        | (6.17)%      | 0.14%        |
|  | <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, 2002 and 2001 are as follows:

|  | <u>2002</u>         | <u>2001</u>         |
|--|---------------------|---------------------|
| Deferred tax assets:   |                     |                     |
| Allowances and reserves  | \$ 72,000           | \$ 762,000          |
| Accrued expenses   | 504,000             | 87,000              |
| Deferred revenue and gain on sale of assets                            | 5,892,000           | 359,000             |
| Stock based compensation   | 1,633,000           | 1,429,000           |
| Net operating loss carryforwards                                       | 6,757,000           | 6,592,000           |
| Income tax credit carryforwards  | 770,000             | 1,126,000           |
| Capitalized assets and other   | 590,000             | 83,000              |
|  | <u>16,218,000</u>   | <u>10,438,000</u>   |
| Valuation allowance  | <u>(15,037,000)</u> | <u>(10,206,000)</u> |
| Total deferred tax assets, net of allowance                            | <u>1,181,000</u>    | <u>232,000</u>      |
| Deferred tax liabilities:  |                     |                     |
| Property and equipment, principally due to differences in depreciation | (53,000)            | (232,000)           |
| Intangibles  | (1,060,000)         | —                   |
| Other  | <u>(68,000)</u>     | <u>—</u>            |
| Total deferred tax liability   | <u>(1,181,000)</u>  | <u>(232,000)</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 therecoverability 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 \$15,037,000 as of December 31, 2002 to reflect the estimated amount of deferred tax assets that may not be realized. The Company increased its valuation allowance by approximately \$4,831,000 for the year ended December 31, 2002. The valuation allowance includes approximately \$505,000 related to stock option deductions, the benefit of which will eventually be credited to equity.

At December 31, 2002, the Company had federal and state tax loss carryforwards of approximately \$17,200,000 and \$10,500,000 respectively. The federal and state net operating loss carryforwards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2002, the Company had federal and state tax credit carryforwards of approximately \$390,000 and

\$396,000 respectively. The federal credits will begin to expire in 2017, if unused, and the state credits will begin to expire in 2012 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 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, 2002, the remaining pre-change federal net operating loss carryforward of \$2,700,000 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 the Company has acquired federal and state net operating loss carryforwards of approximately \$2,700,000 and \$1,600,000 respectively. These losses are subject to IRC Section 382 and may be limited in their use. The extent of such limitation has not been determined at this time.

## **11. 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 2002, 2001 and 2000.

## **12. Stockholders' Equity**

### **Convertible Preferred Stock**

In August 1997, the Company issued 1,267,000 shares of Series A non-cumulative convertible preferred stock ("Series A") at \$0.50 per share. Proceeds, net of issuance costs, were \$630,000. In July 1998, the Company issued 1,032,583 shares of Series B non-cumulative convertible preferred stock ("Series B") at \$1.50 per share. Proceeds, net of issuance costs, were \$1,547,000. In September 1999, the Company issued 2,574,989 shares of Series C non-cumulative convertible preferred stock ("Series C") at \$2.25 per share. Proceeds, net of issuance costs, were \$5,657,000. In December 1999, the Company issued 832,226 shares of Series D non-cumulative convertible preferred stock ("Series D") at \$3.50 per share. Proceeds, net of issuance costs, were \$2,855,000.

In March 2000, the Company issued an additional 1,167,774 shares of Series D at \$3.50 per share for \$4,087,000. In May 2000, the Company issued an additional 2,777 shares of Series C at \$2.25 per share for \$6,000 upon the exercise of warrants.

In February 2000, certain stockholders converted 45,951 shares of Series C into 45,951 shares of Common Stock. In August 2000, all outstanding shares of Series A, B, C and D preferred stock were converted into shares of common stock upon the consent of the majority of holders, in connection with the Company's initial public offering.

### **Preferred Stock**

The Company has authorized 5,000,000 shares of \$.001 par value preferred stock, with no shares outstanding as of December 31, 2002 and 2001. 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 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 \$110,000 accounted for as 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, 2002 and 2001.

### 13. 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 Plan, as amended, provides for the issuance of up to 7,000,000 shares of the Company's common stock.

Under the provisions of the 1997 Plan, the exercise price of ISOs is not 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, |                                 |                  |                                 |                  |                                 |
|--|--------------------------|---------------------------------|------------------|---------------------------------|------------------|---------------------------------|
|  | 2002                     |                                 | 2001             |                                 | 2000             |                                 |
|  | Options                  | Weighted Average Exercise Price | Options          | Weighted Average Exercise Price | Options          | Weighted Average Exercise Price |
| Options outstanding at beginning of period | 3,320,000                | \$ 4.49                         | 2,750,000        | \$ 3.44                         | 2,151,000        | \$ 0.19                         |
| Granted                                    | 1,470,000                | \$ 3.52                         | 1,578,000        | \$ 6.18                         | 1,577,000        | \$ 5.92                         |
| Exercised                                  | (92,000)                 | \$ 0.17                         | (292,000)        | \$ 0.44                         | (784,000)        | \$ 0.20                         |
| Forfeited                                  | (435,000)                | \$ 8.44                         | (716,000)        | \$ 5.82                         | (194,000)        | \$ 0.65                         |
| Options outstanding at end of period       | <u>4,263,000</u>         | \$ 3.85                         | <u>3,320,000</u> | \$ 4.49                         | <u>2,750,000</u> | \$ 3.44                         |
| Options vested at end of period            | <u>2,241,000</u>         | \$ 3.28                         | <u>1,329,000</u> | \$ 2.88                         | <u>840,000</u>   | \$ 1.41                         |

The following table summarizes information about options outstanding under the 1997 Plan as of December 31, 2002:

| Exercise Prices     | Options Outstanding | Weighted Average Remaining Contractual Life (in years) | Options Vested   |
|---------------------|---------------------|--|------------------|
| \$ 0.05 - \$ 0.45   | 716,000             | 5.9  | 689,000          |
| \$ 1.90 - \$ 3.51   | 1,892,000           | 8.1  | 994,000          |
| \$ 3.53 - \$ 7.34   | 1,413,000           | 8.8  | 423,000          |
| \$ 7.43 - \$ 10.84  | 105,000             | 7.8  | 63,000           |
| \$ 11.68 - \$ 16.30 | 137,000             | 7.6  | 72,000           |
|                     | <u>4,263,000</u>    |  | <u>2,241,000</u> |

The weighted-average fair value of options granted for the years ended 2002, 2001 and 2000 was \$2.48, \$3.11, and \$6.40, 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 \$(9,000), \$115,000 and \$4,980,000 during the years ended December 31, 2002,

2001 and 2000, 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. Amortization of unearned stock based compensation, net of any charges reversed during the period for the forfeiture of unvested awards, was \$1,147,000, \$1,104,000 and \$3,171,000 for the years ended December 31, 2002, 2001 and 2000, respectively.

The remaining unearned stock based compensation of \$1,057,000 at December 31, 2002 will be amortized as follows: \$844,000 in 2003 and \$213,000 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 and 298,000 stock options to non-employees for consulting services for the years ended December 31, 2002 and 2000, respectively. The weighted-average fair value per share of stock options issued and remeasured to non-employees for the years ended December 31, 2002, 2001 and 2000 was \$2.19, \$4.21 and \$9.42, respectively. As a result, the Company recorded stock based compensation expense of \$154,000, \$33,000, and \$2,545,000 for the years ended December 31, 2002, 2001 and 2000, 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, 2001 and 2000: expected dividend yield of 0.0%, risk-free interest rate ranging from 3.50% to 6.7%, expected volatility factor ranging from 60% to 100% and expected life of 2 to 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, 2002, 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 expensed in 2000.

### **14. Related Party Transactions**

In the year ended December 31, 2000, consulting fees, manufacturing and out-of-pocket expenses paid to various stockholders and employees were included in research and development expenses. These expenses amounted to \$19,000 for the year ended December 31, 2000. There were no similar related party transactions in the year ended December 31, 2002 and 2001, respectively.

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 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, 2002, 1,000,000 shares of the Company's common stock, which constitutes 6.8% of the Company's outstanding common stock. For the years ended December 31, 2002, 2001 and 2000, the Company had sales to Medtronic of \$8,605,000, \$5,547,000 and \$6,092,000, respectively, which represented 93.9%, 98.2% and 97.5% of total revenues, respectively. At December 31, 2002 and 2001, the Company had amounts due from Medtronic of \$1,073,000 and \$463,000, respectively. As a result of the sale of the craniomaxillofacial product line to Medtronic, the terms of this agreement have change substantially. (See Note 3.)

In April 2000, the Company entered into two one year full-recourse notes receivable with one of its directors and officers. At December 31, 2000, the notes totaled approximately \$47,000, with an annual interest rate of 10%. The notes were repaid in full on April 30, 2001.

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 carry 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 are secured by a pledge of all of the stock purchased with the proceeds of the loan, are full recourse and mature in February 2005. The notes were repaid in full in December 2002.

#### 15. 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<br>31, 2002           | June<br>30, 2002 | September<br>30, 2002 | December<br>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<br>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 income (expenses)                                   | 244,000                     | 215,000          | (27,000)              | (540,000)            |
| Net loss  | (2,934,000)                 | (1,603,000)      | (2,966,000)           | (5,500,000)          |
| Basic and diluted net loss per<br>share                   | <u>\$ (0.20)</u>            | <u>\$ (0.11)</u> | <u>\$ (0.21)</u>      | <u>\$ (0.37)</u>     |

|   | For the three months ended, |                  |                       |                      |
|---|-----------------------------|------------------|-----------------------|----------------------|
|   | March<br>31, 2001           | June<br>30, 2001 | September<br>30, 2001 | December<br>31, 2001 |
| Revenues  | \$ 2,029,000                | \$ 768,000       | \$ 1,400,000          | \$ 1,451,000         |
| Gross profit  | 1,364,000                   | (715,000)        | 747,000               | 101,000              |
| Operating expenses, excluding<br>stock based compensation | 3,123,000                   | 3,856,000        | 3,615,000             | 2,964,000            |
| Stock based compensation                                  | 143,000                     | 370,000          | 335,000               | 275,000              |
| Other expenses  | 688,000                     | 599,000          | 467,000               | 223,000              |
| Net loss  | (1,214,000)                 | (4,342,000)      | (2,736,000)           | (2,915,000)          |
| Basic and diluted net loss per<br>share                   | <u>\$ (0.08)</u>            | <u>\$ (0.29)</u> | <u>\$ (0.18)</u>      | <u>\$ (0.20)</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 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.

### 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 2003 annual stockholders meeting, which will be filed with the Commission before April 30, 2003.

## 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 2003 annual stockholders meeting, which will be filed with the Commission before April 30, 2003.

## 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 2003 annual stockholders meeting, which will be filed with the Commission before April 30, 2003.

## 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 2003 annual stockholders meeting, which will be filed with the Commission before April 30, 2003.

## Item 14. Controls and Procedures

### (a) Evaluation of Controls and Procedures

Within 90 days before the filing of this report, our Chief Executive Officer, Mr. Calhoun, and Chief Financial Officer, Mr. Bizimis, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, Mr. Calhoun and Mr. Bizimis 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 IV

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

| (a) (1) Financial Statements  | Page |
|---|------|
| <u>Report of KPMG LLP, Independent Public Accountants..</u>   | 45   |
| <u>Report of Arthur Andersen LLP, Independent Public Accountants</u>  | 46   |
| <u>Consolidated Balance Sheets as of December 31, 2002 and 2001</u>   | 47   |
| <u>Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2002, 2001 and 2000</u> | 48   |
| <u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2002, 2001 and 2000</u>                       | 49   |
| <u>Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000</u>                                 | 50   |
| <u>Notes to Consolidated Financial Statements</u>   | 52   |

(a) (2) **Financial Statement Schedules**

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

For the years ended December 31, 2002, 2001 and 2000  
(in thousand of dollars)

|  | <u>Balance at<br/>beginning of<br/>year</u> | <u>Additions<br/>(charges to<br/>expense)</u> | <u>Charged to<br/>Other<br/>Accounts</u> | <u>Deductions</u> | <u>Balance at<br/>end of year</u> |
|--|---|---|--|-------------------|-----------------------------------|
| <u>Allowance for doubtful accounts</u> |   |   |  |                   |                                   |
| Year ended December 31, 2002           | \$ 35                                       | \$ 15   | \$ —                                     | \$ —              | \$ 50                             |
| Year ended December 31, 2001           | 75  | 4   | —  | 44                | 35                                |
| Year ended December 31, 2000           | \$ 53                                       | \$ 82   | \$ —                                     | \$ 60             | \$ 75                             |
| <u>Purchase accounting reserves</u>    |   |   |  |                   |                                   |
| Year ended December 31, 2002           | \$ —  | \$ —  | \$ 734,000                               | \$ 204,000        | \$ 530,000                        |

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

On October 23, 2002, we filed a Current Report on Form 8-K with the SEC to report under Item 2 of that form an event of October 8, 2002: the sale of our craniomaxillofacial bone fixationline of business to a subsidiary of Medtronic, Inc. We also reported, under Item 5 of that form, matters relating to our proposed acquisition of StemSource, Inc.

On November 27, 2002, we filed a Current Report on Form 8-K with the SEC to report under Item 2 of that form an event of November 13, 2002: the acquisition of StemSource, Inc.

(c) **Exhibits**

| <u>Exhibit<br/>Number</u> | <u>Description</u>   |
|---------------------------|--|
| 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                       | Bylaws of MacroPore, Inc. (filed as Exhibit 3.2 to our Form 10 registration statement, as amended, as filed on March 30, 2001 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)
- 10.11 Pledge Agreement, effective February 26, 2002, by and between The Company and Ari Bisimis
- 10.12 Secured Promissory Note, effective February 26, 2002, by and between The Company and Ari Bisimis
- 10.13 Pledge Agreement, effective February 26, 2002, by and between The Company and Christopher J. Calhoun
- 10.14 Secured Promissory Note, effective February 26, 2002, by and between The Company and Christopher J. Calhoun
- 10.15 Retirement Separation Agreement and General Release, effective April 1, 2002, by and between The Company and Michael J. Simpson
- 10.16 Consulting Services Agreement, effective April 1, 2002, by and between The Company and Michael J. Simpson
- 23.1 Consent of KPMG LLP, independent public accountants
- 23.2 Notice regarding consent of Arthur Andersen LLP
- 24.1 Power of Attorney (contained in the signature page).

- 99.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 99.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).

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

## 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  
*Chief Executive Officer, and President*  
 March 28, 2003

Pursuant to the requirements of the Securities Act of 1934, this annual report has been signed by the following persons in the capacities and on the date indicated. Each person whose signature appears below hereby constitutes and appoints Christopher J. Calhoun, his true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this annual report, and to file the same with all the exhibits thereto, and other documents in connection therewith with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform any and all acts and things requisite and necessary to be done, as fully as to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents of said attorney-in-fact, or his substitute, may lawfully do or cause to be done by virtue hereof.

| SIGNATURE                            | TITLE  | DATE           |
|--------------------------------------|--|----------------|
| <u>/s/</u><br>Marshall G. Cox        | <i>Chairman of the Board of Directors</i>                      | March 28, 2003 |
| <u>/s/</u><br>Christopher J. Calhoun | <i>Chief Executive Officer, President, and Director</i>        | March 28, 2003 |
| <u>/s/</u><br>Ari E. Bizimis         | <i>Chief Financial Officer and Director</i>                    | March 28, 2003 |
| <u>/s/</u><br>Marc H. Hedrick, MD    | <i>Chief Scientific Officer, Medical Director and Director</i> | March 28, 2003 |
| <u>/s/</u><br>David Rickey           | <i>Director</i>  | March 28, 2003 |
| <u>/s/</u><br>Ron Henriksen          | <i>Director</i>  | March 28, 2003 |

**Certification of Principal Executive Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Christopher J. Calhoun, certify that:

1. I have reviewed this annual report on Form 10-K of MacroPore Biosurgery, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - (c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ Christopher J. Calhoun

Christopher J. Calhoun,  
Chief Executive Officer

**Certification of Principal Financial Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Ari E. Bizimis, certify that:

1. I have reviewed this annual report on Form 10-K of MacroPore Biosurgery, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - (c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ Ari E. Bizimis

Ari E. Bizimis,  
Chief Financial Officer

*Exhibits to the Annual Report have been omitted from the mailing to our Stockholders and may be obtained by visiting our website at [www.macropore.com](http://www.macropore.com) or by writing or calling us directly at:*

*MacroPore Biosurgery, Inc.  
6740 Top Gun Street  
San Diego, CA 92121  
Phone: +1 (858) 458-0900  
Fax: +1 (858) 458-0994*