# MacroPore Biosurgery, Inc.

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# **Annual Report**

For the year ended December 31, 2003

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-K

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

For the fiscal year ended December 31, 2003

OR

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

For the transition period from

to

Commission file number 0-32501

# MACROPORE BIOSURGERY, INC.

(Exact name of Registrant as Specified in Its Charter)

**DELAWARE** 

(State or Other Jurisdiction of Incorporation or Organization)

33-0827593

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

#### 6740 TOP GUN STREET, SAN DIEGO, CALIFORNIA

(Address of principal executive offices)

92121

(Zip Code)

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

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

None

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

Common stock, par value \$0.001

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

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  $\square$  No  $\boxtimes$ 

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

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

#### DOCUMENTS INCORPORATED BY REFERENCE

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

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#### Item 1. Business

#### General

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

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

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

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

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

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

## Bioresorbable Technology

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

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

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

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

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

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

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

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

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

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

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

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

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

#### Regenerative Cell Technology

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

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

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

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

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

#### **Products and Services**

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

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

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

# **Plan of Operation**

During 2004, we intend to focus our efforts on:

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

#### **Research and Development**

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

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

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

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

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

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

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

### **Customers**

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

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

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

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

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

#### Thin Film

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

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

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

# **Market and Competition**

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

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

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

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

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

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

# Sales by Geographic Region

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

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

#### **Working Capital**

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

#### **Raw Materials**

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

#### **Intellectual Property**

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

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

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

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

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

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

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

#### **Government Regulation**

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

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

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

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

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

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

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

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

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

Clearance received for, among other things, the following

	Clearance received for, among other things, the following						
Product Lines	uses:	Clearance received					
MacroPore FX <sup>TM*</sup>	trauma and reconstructive procedures in the midface and craniofacial skeleton	July 1998					
MacroPore PS*	trauma and reconstructive procedures in the midface and craniofacial skeleton	July 1998					
MacroPore PS*	trauma, and reconstructive procedures of the mandible and maxilla when used in conjunction with rigid fixation	March 1999					
MacroPore DX*	for temporary stabilization and gradual lengthening of cranial and midface bones	June 2000					
MacroPore OS <sup>TM*</sup>	bone graft containment in the iliac crest, or hip bone, graft donor sites, tumor resections where bone strength is not compromised and throughout the skeleton, other than in spinal applications, when used in conjunction with traditional rigid fixation devices	July 2000					
MacroPore MX <sup>TM*</sup>	stabilizing fractured bones in the mandible when used in conjunction with maxillomandibular fixation	October 2000					
MacroPore NS <sup>TM</sup> *	fixation of bone flaps after a craniotomy	May 2001					
MacroPore OS Spine™	when used in conjunction with traditional rigid fixation; utilized in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts	July 2001					
MacroPore IB	a cement restrictor in the femur, tibia, and humerus	September 2001					
MacroPore FX <sup>TM*</sup> , PS*, NS <sup>TM*</sup> and LP <sup>TM*</sup>	general and specific pediatric and adult trauma and reconstructive bone fixation and bone graft containment procedures of the midface and craniofacial skeleton	September 2001					
$HYDROSORB^{\scriptscriptstyle TM}CR$	a cement restrictor in the femur, tibia and humerus	September 2001					

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

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

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

Country	Clearance received			
European Community	MacroPore FX <sup>TM</sup> , MacroPore PS, MacroPore NS <sup>TM</sup> , and MacroPore DX products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system.	December 1999		
	MacroPore FX <sup>TM</sup> , MacroPore PS, MacroPore NS <sup>TM</sup> , MacroPore DX, and MacroPore LP <sup>TM</sup> products indicated to fixate non-load bearing fractures in the midface and /or craniofacial skeleton with specific indications for Le Fort procedures along with craniosynostosis, congenital malformation, tumor reconstructions, bone grafting procedures, and midface distraction indications.	March 2002		

MacroPore SurgiWrap<sup>TM</sup> products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system.

March 2002

May 2002

MacroPore SurgiWrapi, TM, CardioWrapi, TM 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:

- 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.)

for temporary wound support, to reinforce soft tissues where weakness exists, for the repair of hernia or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result, including but not limited to vaginal prolapse repair, colon and rectal prolapse repair, and reconstruction of the pelvic floor

MacroPore HYDROSORB<sup>TM</sup> TELAMON® and MacroPore HYDROSORB<sup>TM</sup> 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.

MacroPore OS<sup>TM</sup> is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPore OS Protective sheet is also indicated for cement restriction in total joint arthroplasty procedures. Only when used in conjunction with traditional rigid fixation, the MacroPore OS System is intended to maintain the relative position weak bony tissue in trauma and

- Long bones
- Flat bones
- Short bones
- Irregular bones
- · Appendicular skeleton

reconstructive orthopedic procedures involving:

Thorax

When used alone (without traditional rigid fixation), the MacroPore OS System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving:

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

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

January 2003

July 2003

and bone regeneration in trauma and reconstruction procedures in the skeletal system	December 1999
MacroPore SurgiWrapi <sup>™</sup> , CardioWrapi <sup>™</sup> 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	February 2003
	and bone regeneration in trauma and reconstruction procedures in the skeletal system  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

a) Pericardium, epicardium, and retrosternal

- b) Peritoneum, peritoneal cavity, bowels, cecum, organs
- c) Dura, spinal dura, peridural, epidural

Same as Canada for MacroPore FXTM and PS only

following anatomical regions:

Same as USA for FXTM and PS

d) OB/GYN (e.g. female pelvic, reproductive organs, ovaries, uterus, uterine tubes, etc.)

June 2000

June 2002

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

Wataysia	Same as Canada for Macrof of CTA and TS only	Julic 2000
Singapore	Same as Canada for MacroPore FX <sup>TM</sup> and PS Same as Canada for SurgiWrap <sup>TM</sup> and CardioWrap <sup>TM</sup>	November 2000 December 2003
South Korea	Same as USA for MacroPore FX <sup>TM</sup> and PS	January 2001
	Same as USA for SurgiWrap <sub>i</sub> TM	December 2002
Australia	Same as Canada for MacroPore FX <sup>TM</sup> and PS	March 2001
	Same as Canada for SurgiWrap $_{i}^{TM}$ and CardioWrap $_{i}^{TM}$	November 2002
Thailand	Same as Canada for SurgiWrap $_{i}^{TM}$ and CardioWrap $_{i}^{TM}$	January 2003

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

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

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

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

#### Staff

Malayeia

China

As of December 31, 2003, we had 93 full-time employees, comprised of 39 employees in research and development, 19 employees in manufacturing, 17 employees in management and finance and administration, and 18 employees in sales and

marketing. From time to time, we also employ independent contractors to support our administrative organizations. Our employees are not represented by any collective bargaining unit and we have never experienced a work stoppage.

#### Web Site Access to SEC Filings

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

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

#### Item 2. Properties

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

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

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

## **Item 3. Legal Matters**

None.

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

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

#### PART II

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

#### **Market Prices**

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

	Hig	h Euro	 High US	Low Euro		Low US	
2002	<u> </u>					 	
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	
2003							
Quarter ended March 31, 2003	€	4.63	\$ 4.90	€	2.66	\$ 2.95	
Quarter ended June 30, 2003	€	3.40	\$ 4.00	€	2.56	\$ 3.07	
Quarter ended September 30, 2003	€	3.79	\$ 4.36	€	2.67	\$ 2.96	
Quarter ended December 31, 2003	€	3.74	\$ 4.31	€	2.15	\$ 2.68	

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

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

#### Dividends

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

#### **German Securities Laws**

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

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

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

# **Recent Sales of Unregistered Securities**

Previously reported.

# **Equity Compensation Plan Information**

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

#### Item 6. Selected Consolidated Financial Data

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

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

				Yea	rs E	Ended December	31,				
	_	2003	_	2002	_	2001	_	2000			
			(do	ollars in thousar	ıds,	except shares a	nd p	er share data)			
<b>Statement of Operations Data:</b>											
Revenues:											
Sales to related party	\$	12,893	\$	8,605	\$	5,547	\$	6,092	\$		
Sales to third parties	Ψ	1,195	Ψ	561	Ψ	101	Ψ	159	Ψ	1,513	
sures to time parties	_	14,088	_	9,166	_	5,648	_	6,251	_	1,513	
Cost of revenues:		11,000		<b>7,100</b>		2,010		0,251		1,010	
Cost of revenues		4,244		3,169		2,401		2,394		486	
Inventory provision				1,395		1,750				_	
Gross profit	_	9,844		4,602	_	1,497		3,857		1,027	
1	_	<u> </u>			_	<u> </u>					
Operating expenses:											
Research and development		9,071		5,605		5,487		2,584		1,172	
Sales and marketing		4,417		3,987		4,493		2,629		2,356	
General and administrative		4,581		3,952		3,578		2,555		1,313	
Stock based compensation		985		1,287		1,123		5,698		661	
In-process research and development		_		2,296		_		_		_	
Restructuring charge		451		_,		_		_		_	
Equipment impairment charge		_		370				_		_	
Total operating expenses		19,505	-	17,497	_	14,681		13,466		5,502	
Town operating empended		17,000		27,127		1.,001		10,.00	_	0,002	
Other income (expense):											
Interest income		417		1,037		2,249		1,315		68	
Interest and other expenses, net		(39)		(263)		(168)		(351)		(164)	
Equity loss in investment		_		(882)		(104)		_		_	
Net loss	\$	(9,283)	\$	(13,003)	\$	(11,207)	\$	(8,645)	\$	(4,571)	
Basic and diluted net loss per share	\$	(0.64)	\$	(0.91)	\$	(0.75)	\$	(1.05)	\$	(1.32)	
Shares used in calculating basic and	Ψ_	(6.6.)	Ψ_	(0.51)	4	(0.7.6)	<u>~</u>	(1.00)	Ψ	(1.62)	
diluted net loss per share		14,555,047		14,274,254		14,926,107		8,201,739		3,458,292	
ondico nec 1000 per snare minimum	_	1 1,000,017	_	1 1,27 1,20 1	_	11,520,107		0,201,709	_	2,123,232	
Statement of Cash Flows Data:											
Net cash used in operating activities	\$	(7,245)	\$	(6,886)	\$	(8,322)	\$	(2,982)	\$	(5,107)	
Net cash provided by (used in) investing	Ψ	(7,213)	Ψ	(0,000)	Ψ	(0,322)	Ψ	(2,>02)	Ψ	(3,107)	
activities		5,954		17,265		2,263		(39,450)		(381)	
Net cash (used in) provided by financing		3,731		17,203		2,203		(3), 130)		(301)	
activities		(997)		(7,971)		1,283		47,437		7,924	
Net (decrease) increase in cash	_	(2,288)		2,408	_	(4,776)		5,005	_	2,436	
Cash and cash equivalents at beginning of		(2,200)		2,100		(1,770)		3,003		2,130	
year		5,108		2,700		7,476		2,471		35	
Cash and cash equivalents at end of year	\$	2,820	\$	5,108	\$	2,700	\$	7,476	\$	2,471	
cash and cash equivalents at end of year	Ψ	2,020	Ψ	3,100	Ψ	2,700	Ψ	7,470	Ψ	2,471	
Balance Sheet Data:											
Cash, cash equivalents and short-term											
investments	\$	14,268	\$	24,983	\$	33,951	\$	44,484	\$	2,581	
Working capital	Ψ	12,432	Ψ	25,283	Ψ	35,119	Ψ	46,858	Ψ	3,510	
Total assets		28,089		39,319		43,143		52,269		5,575	
Deferred gain on sale of assets, related		26,069		39,319		43,143		32,209		3,373	
_		7 520		0.622				_		_	
party Long-term obligations, less current		7,539		9,623		_					
		1,157		770		1,791					
portion  Convertible redeemable preferred stock.		1,137		770		1,/91				10,689	
	Ф	14,909	Φ	25,995	\$	38,486	¢	49,335	\$		
Total stockholders' equity (deficit)	\$	14,909	\$	45,993	Φ	30,400	\$	47,333	Φ	(6,147)	

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

#### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

#### Overview

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

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

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

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

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

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

Bioresorbable Technology: Developments

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

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

Regenerative Cell Technology: Developments

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

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

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

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

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

# **Results of Operations**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### Gain on Asset Sale to Medtronic

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

## **Liquidity and Capital Resources**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

	Balance at January 1		(	Additions charges to expenses)		Claims	Balance at December 31		
2003:	¢		•	278,000	Ф	(11,000)	¢	267 000	
Warranty reserve	Ф		Ф	278,000	Φ	(11,000)	Ф	267,000	
Warranty reserve	\$		\$		\$		\$		

#### **Critical Accounting Policies**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

# Net Operating Loss and Tax Credit Carryforwards

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

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

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

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

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

#### **Unearned Compensation**

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

#### **Recent Accounting Pronouncements**

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

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

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

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

#### **Risk Factors**

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

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

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

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

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

#### We have never been profitable

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

# We are adopting a high-risk strategy

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

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

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

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

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

### We rely on Medtronic to distribute our products

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

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

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

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

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

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

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

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

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

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

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

#### We do not have much manufacturing experience

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### We are subject to intensive FDA regulation

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

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

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

Medical devices also are subject to post market reporting requirements for deaths or serious injuries when the device may have caused or contributed to the death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA.

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

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

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

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

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

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

#### We depend on a few key officers

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

officers or key scientific staff or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

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

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

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

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

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

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

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

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

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

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

#### We pay no dividends

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

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

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

## **Interest Rate Exposure**

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

#### Foreign Currency Exchange Rate Exposure

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

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

Foreign currency exchange rates can be obtained from the website at www.oanda.com.

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Independent Auditors' Report

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

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

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

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

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

/s/ KPMG LLP	

San Diego, California February 20, 2004 This is a copy of the audit report previously issued by Arthur Andersen LLP in connection with the filing by MacroPore Biosurgery, Inc. (then known as MacroPore, Inc.) on Form 10-K for the year ended December 31, 2001. This audit report has not been reissued by Arthur Andersen LLP in connection with this filing on Form 10-K. See Exhibit 23.2 for further discussion. The balance sheets as of December 31, 2001 and 2000, and statement of operations and comprehensive income (loss), stockholders' equity and cashflows for the year ended December 31, 2000 referred to in this report have not been included in the accompanying financial statements.

Report of Independent Auditors'

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

We have audited the accompanying balance sheets of MacroPore, Inc. as of December 31, 2001 and 2000 and the related statements of operations and comprehensive income, stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

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

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

### /s/ Arthur Andersen LLP

San Diego, California

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

# MACROPORE BIOSURGERY, INC. CONSOLIDATED BALANCE SHEETS

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

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

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

	For the Years Ended								
	_	2003		2002		2001			
Revenues:									
Sales to related party (note 17)	\$	12,893,000	\$	8,605,000	\$	5,547,000			
	Ф		Φ		φ				
Sales to third parties		1,195,000	_	561,000	_	101,000			
Cost of revenues:		14,088,000		9,166,000		5,648,000			
Cost of revenues (including stock based compensation expense of									
\$12,000, \$14,000, and \$14,000 for the years ended December 31,									
2003, 2002, and 2001, respectively)		4,244,000		3,169,000		2,401,000			
* · · · · · · · · · · · · · · · · · · ·		4,244,000		1,395,000		1,750,000			
Inventory provision			_	1,393,000	_	1,730,000			
Gross profit		9,844,000		4,602,000	-	1,497,000			
Operating expenses:									
Research and development, excluding stock based compensation									
expense of \$78,000, \$211,000 and \$111,000 for the years ended									
December 31, 2003, 2002, and 2001, respectively		9,071,000		5,605,000		5,487,000			
Sales and marketing, excluding stock based compensation expense		2,071,000		3,003,000		3,407,000			
of \$70,000, \$134,000 and \$176,000 for the years ended December									
		4 417 000		2 007 000		4 402 000			
31, 2003, 2002, and 2001, respectively		4,417,000		3,987,000		4,493,000			
General and administrative, excluding stock based compensation									
expense of \$837,000, \$942,000 and \$836,000 for the years ended		. =				• • • • • • • • • • • • • • • • • • • •			
December 31, 2003, 2002, and 2001, respectively		4,581,000		3,952,000		3,578,000			
Stock based compensation (excluding cost of revenues stock based									
compensation)		985,000		1,287,000		1,123,000			
In-process research and development		_		2,296,000		_			
Restructuring charge		451,000		_		_			
Equipment impairment charge				370,000	_				
Total an austing annuage		10 505 000		17 407 000		14 691 000			
Total operating expenses		19,505,000	_	17,497,000	_	14,681,000			
Other income (expense):									
Interest income		417,000		1,037,000		2,249,000			
Interest and other expenses, net		(39,000)		(263,000)		(168,000)			
Equity loss in investment				(882,000)		(104,000)			
Equity 1035 in investment			_	(002,000)	_	(101,000)			
Net loss		(9,283,000)		(13,003,000)		(11,207,000)			
Other comprehensive income (loss) - unrealized holding (loss) gain	_	(133,000)	_	(191,000)	_	170,000			
Comprehensive loss	\$	(9,416,000)	\$	(13,194,000)	\$	(11,037,000)			
Completenessive 1055	Ψ	(2,710,000)	Ψ	(13,177,000)	Ψ	(11,057,000)			
Basic and diluted net loss per share	\$	(0.64)	\$	(0.91)	\$	(0.75)			
Shares used in calculating basic and diluted net loss per share		14,555,047	_	14,274,254	_	14,926,107			

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

## MACROPORE BIOSURGERY, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001

		Common S Shares			Additional Paid-in Capital		Unearned Compensation	A	ccumulated Deficit	Treas Shares	ury	Stock Amount	T	reasury Stock Receivable	(	Accumulated Other Comprehensive Income (Loss)		Total
	Bhares	_	Amount	_	Сарпа	_	ompensation		Denen	Shares		Amount	-	Receivable	_	Income (Loss)	_	Total
Balance at December 31, 2000 Issuance of common stock under	14,814,346	\$	15,000	\$	68,126,000	\$	(3,094,000)	\$	(15,892,000)	_	\$	_	\$	_	\$	180,000	\$	49,335,000
stock option plan Compensatory	292,277		_		128,000													128,000
stock options Purchase of					148,000		989,000											1,137,000
treasury stock Unrealized income on investments										356,120		(1,077,000)						(1,077,000
Net loss for the year ended December																170,000		170,000
31, 2001		_		_		_			(11,207,000)		_		_		_			(11,207,000)
Balance at December 31, 2001 Issuance of common stock under	15,106,623		15,000		68,402,000		(2,105,000)		(27,099,000)	356,120		(1,077,000)		_		350,000		38,486,000
stock option plan Issuance of common stock in	92,286		_		16,000													16,000
acquisition  Compensatory	1,447,755		2,000		5,949,000													5,951,000
stock options Purchase of					253,000		1,048,000											1,301,000
treasury stock Sale of treasury										1,972,863		(7,442,000)						(7,442,000)
stock Unrealized loss on investments					110,000					(210,000)		767,000				(101,000)		877,000
Net loss for the year ended																(191,000)		(191,000)
December 31, 2002		_		_		_		_	(13,003,000)		_		_		_			(13,003,000)
Balance at December 31, 2002 Issuance of common stock under	16,646,664		17,000		74,730,000		(1,057,000)		(40,102,000)	2,118,983		(7,752,000)		_		159,000		25,995,000
stock under stock option plan Compensatory	130,980		_		33,000													33,000
stock options Purchase of					49,000		948,000											997,000
treasury stock Sale of treasury										614,099		(2,266,000)						(2,266,000)
stock Treasury stock receivable					(10,000)					(150,500)		552,000						542,000
Exchange of unlisted common														(976,000)				(976,000)
stock for listed					(104,000)							104,000						_

common stock held in treasury Unrealized loss													
on													
investments													
										(133,00	00)		(133,000)
Net loss for the													
year ended													
December													
31, 2003						(9,283,000)						(	(9,283,000)
			_	,	_				 				
Balance at													
December													
31, 2003	16,777,644	\$ 17,000	\$	74,698,000	\$ (109,000)	\$ (49,385,000)	2,582,582	\$ (9,362,000)	\$ (976,000)	\$ 26,00	00	\$ 1	4,909,000

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

# MACROPORE BIOSURGERY, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,					31,
		2003		2002		2001
Cook flows from an austing activities						
Cash flows from operating activities:  Net loss	\$ (	9,283,000)	2	(13,003,000)	\$	(11,207,000)
Adjustments to reconcile net loss to net cash used in operating activities:	Ф (	9,203,000)	φ	(13,003,000)	Ф	(11,207,000)
Depreciation and amortization		1,657,000		1,471,000		1,184,000
Loss on disposal of assets		14,000		91,000		1,104,000
Equipment impairment charge		14,000		370,000		
Inventory provision				1,395,000		1,750,000
Warranty charge		267,000				
Restructuring charge		153,000				
Amortization of gain on sale of assets, related party	(	2,046,000)		(267,000)		
Stock based compensation	`	997,000		1,301,000		1,137,000
Acquired in-process research and development				2,296,000		
Equity loss in investment		_		882,000		104,000
Increases (decreases) in cash caused by changes in operating assets				002,000		10.,000
and liabilities, excluding effects of acquisition:						
β · · · · · · · · · · · · · · · · · · ·						
Accounts receivable		(53,000)		(775,000)		230,000
Inventories		319,000		(860,000)		(1,157,000)
Other current assets		317,000		284.000		31,000
Other assets		76,000		(304,000)		115,000
Accounts payable and accrued expenses		337,000		458,000		(209,000)
Deferred revenue from license agreement, related party		337,000		(225,000)		(300,000)
Deterred revenue from needse agreement, related party	-		_	(223,000)	_	(300,000)
Net cash used in operating activities	(	7,245,000)		(6,886,000)		(8,322,000)
Cash flows from investing activities:						
Proceeds from the sale and maturity of short-term investments		9,561,000		68,151,000		90,065,000
Purchases of short-term investments	,	1,267,000)		(56,966,000)		(84,138,000)
Purchases of property and equipment	(	1,743,000)		(909,000)		(2,664,000)
Equity investment		_				(1,000,000)
Cost of sale of assets, related party		(38,000)		_		
Acquisition costs, net of cash acquired		(654,000)		(2,896,000)		_
Proceeds from sale of assets, related party, net				9,689,000		
Proceeds from the sale of impaired assets		95,000		196,000		<u> </u>
Net cash provided by investing activities		5,954,000		17,265,000		2,263,000
Cash flows from financing activities:						
Principal payments on capital leases				(256,000)		(114,000)
Principal payments on long-term obligations		(426,000)		(1,166,000)		(87,000)
Proceeds from long-term obligations		1,120,000				2,433,000
Proceeds from the exercise of employee stock options		33,000		16,000		128,000
Purchase of treasury stock	(	2,266,000)		(7,442,000)		(1,077,000)
Proceeds from sale of treasury stock		542,000		877,000		<u> </u>
Net cash (used in) provided by financing activities		(997,000)		(7,971,000)		1,283,000
The east (asea in, provided by intuiting activities infilming	-	(227,000)	_	(1,511,000)	_	1,203,000
Net (decrease) increase in cash	(	2,288,000)		2,408,000		(4,776,000)
Cash and cash equivalents at beginning of year		5,108,000		2,700,000		7,476,000
			Φ.		Φ.	
Cash and cash equivalents at end of year	\$	2,820,000	Э	5,108,000	\$	2,700,000

		For the	Yea	rs Ended Decen	iber 3	31,
		2003		2002		2001
Supplemental disclosure of cash flows information: Cash paid during period for:						
	¢	127,000	¢.	102 000	Φ	92 000
Interest	\$	127,000 12,000	Ф	182,000 800	Þ	82,000 800
Supplemental schedule of investing activities:						
Increase in cost of acquisition (goodwill)	\$	371,000	\$	_		_
Share repurchase payable		976,000		_		_
Tangible assets acquired		_		691,000		_
Goodwill acquired				4,256,000		_
In-process research and development acquired				2,296,000		
Technology acquired				2,695,000		_
Total assets acquired		_		9,938,000		_
Cash acquired				(169,000)		_
Common stock issued				(5,951,000)		_
Accrued costs associated with acquisition				(530,000)		_
Initial investment, net		_		(14,000)		_
Liabilities assumed		_		(378,000)		_
Cash paid, net of cash acquired		_	\$	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, 2003, 2002 AND 2001

## 1. Organization and Operations

#### The Company

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

## **Principles of Consolidation**

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

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

#### **Certain Risks and Uncertainties**

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

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

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

#### **Capital Availability**

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

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

## 2. Summary of Significant Accounting Policies

#### **Use of Estimates**

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

#### **Concentration of Credit Risk**

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

#### **Cash and Cash Equivalents**

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

## **Short-term Investments**

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

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

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

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

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

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

#### **Inventories**

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

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

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

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

#### **Long-Lived Assets**

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

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

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

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

Office and computer equipment	\$ 119,000
Manufacturing and development equipment	 93,000
Total	\$ 212,000

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

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

## **Property and Equipment**

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

#### **Goodwill and Intangibles**

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

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

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

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

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

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

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

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

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

	December 31,								
		2003		2002					
Goodwill, net:									
Beginning balance	\$	4,256,000	\$	_					
Acquisition		371,000		4,256,000					
Ending balance		4,627,0000		4,256,000					
Other intangibles, net:									
Beginning balance		2,661,000		_					
Acquisition		_		2,695,000					
Amortization		(269,000)		(34,000)					
Ending balance	_	2,392,000	_	2,661,000					
Total goodwill and other intangibles, net	\$	7,019,000	\$	6,917,000					
Aggregate amortization of intangibles expense for the year ended December 31, 2003:	\$	235,000							

Estimated amortization of intangibles for the years ended:

2004	\$ 269,000
2005	269,000
2006	269,000
2007	269,000
2008	269,000
Thereafter	1,047,000
	\$ 2,392,000

#### **Revenue Recognition**

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

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

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

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

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

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

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

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

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

#### Warranty

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

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

	nce at uary 1	(	Additions (charges to expenses)		Claims	Salance at ecember 31
2003:						
Warranty reserve	\$ _	\$	278,000	\$	(11,000)	\$ 267,000
2002:	 					
Warranty reserve	\$ 	\$		\$		\$ 

#### **Research and Development**

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

#### **Income Taxes**

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

#### **Stock Based Compensation**

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

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

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

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

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

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

#### Other Comprehensive Income (Loss)

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

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

#### **Segment Information**

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

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

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

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

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

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

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

#### **Earnings (Loss) Per Share**

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

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

## **Recent Accounting Pronouncements**

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

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

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

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

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

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

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

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

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

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

#### 4. Acquisition

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### 5. Short-term Investments

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

		Dec	ember 31, 2003		
	 Amortized Cost	Gross Unrealized Gains			Estimated Fair Value
Corporate notes and bonds	\$ 1,569,000 9,853,000	\$	\$ 1,000 25,000		1,570,000 9,878,000
	\$ 11,422,000	\$	26,000	\$	11,448,000
		Dec	ember 31, 2002		
	Amortized Cost		Gross Unrealized Gains		Estimated Fair Value
Corporate notes and bonds	\$ 6,503,000 13,213,000	\$	8,000 151,000	\$	6,511,000 13,364,000
	\$ 19,716,000	\$	159,000	\$	19,875,000

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

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

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

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

## **Inventories**

211 ( 011001 10			Decem	hor 3	<b>L</b> 1
		_	2003		2002
	Raw materials	\$	399,000 432,000	\$	602,000 548,000
		\$	831,000	\$	1,150,000
Property a	and Equipment, net				
			Decem	ber 3	
			2003	_	2002
	Office and computer equipment	\$	1,922,000	\$	1,874,000
	Manufacturing and development equipment		3,685,000		2,721,000
	Leasehold improvements		1,905,000		1,551,000
			7,512,000		6,146,000
	Less accumulated depreciation and amortization	_	(3,690,000)		(2,520,000)
		\$	3,822,000	\$	3,626,000
Other Ass	ets				
			Decem	ber 3	31.
			2003	_	2002
	Deposits	\$	120,000	\$	400,000
	Assets held for sale	Ψ	212,000	Ψ	162,000
		\$	332,000	\$	562,000
Goodwill a	and Intangibles, net				
			Doggom	hou î	21
			2003	ber :	2002
	Intangibles	¢	2,695,000	¢	2 605 000
	Less accumulated amortization	\$	(303,000)	\$	2,695,000 (34,000)
		\$	2,392,,000	\$	2,661,000
		1			
Accounts	Payable and Accrued Liabilities				
			Decem	ber 3	
			2003		2002
	Accounts payable	\$	520,000	\$	599,000
	Share repurchase payable (note 18)		976,000		
	Accrued bonus		631,000		397,000
	Accrued vacation		468,000		325,000
	Warranty provision (note 2)		267,000 153,000		_
	Accrued restructuring costs (note 10)		752,000		1,200,000
	•	ø		Φ.	
		\$	3,767,000	\$	2,521,000

#### 7. Commitments

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

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

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

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

## 8. License Agreement

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

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

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

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

#### 9. Loss on Unused Office Space

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

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

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

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

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

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

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

## 10. Restructuring Event

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

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

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

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

	 Opening Balance	 Charged to Expense*	 Costs Paid	A	ljustments to Liability**	 Ending Balance
One-time termination benefits	\$ _	\$ 282,000	\$ (284,000)	\$	2,000	\$ _
Lease termination	 _	169,000	(28,000)		12,000	153,000
	\$ 	\$ 451,000	\$ (312,000)	\$	14,000	\$ 153,000

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

<sup>\*\*</sup> Revaluation of monetary liability denominated in a foreign currency.

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

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

#### 11. Stockholders Rights Plan

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

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

## 12. Long-term Debt

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

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

Principal payments on the five promissory notes are as follows:

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

#### 13. Income Taxes

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

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

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

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

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

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

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

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

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

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

## 14. Employee Benefit Plan

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

## 15. Stockholders' Equity

#### **Preferred Stock**

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

## **Treasury Stock**

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

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

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

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

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

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

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

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

## 16. Stock Based Compensation

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

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

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

				Years ended l	Decei	nber 31,			
	20	03		200	02		2001		
	Weighted Average Exercise Options Price		Averag Exercis		Veighted Average Exercise Price	Options		Veighted Average Exercise Price	
Options outstanding at									
beginning of period	4,263,000	\$	3.85	3,320,000	\$	4.49	2,750,000	\$	3.44
Granted	896,000	\$	4.26	1,470,000	\$	3.52	1,578,000	\$	6.18
Exercised	(131,000)	\$	0.26	(92,000)	\$	0.17	(292,000)	\$	0.44
Forfeited	(227,000)	\$	5.13	(435,000)	\$	8.44	(716,000)	\$	5.82
Options outstanding at end of period	4,801,000	\$	3.96	4,263,000	\$	3.85	3,320,000	\$	4.49
Options vested at end of period	3,130,000	\$	3.78	2,241,000	\$	3.28	1,329,000	\$	2.88

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

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

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

## **Unearned Stock Based Compensation**

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

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

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

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

#### Warrants

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

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

#### 17. Related Party Transactions

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

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

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

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

## 18. Treasury Stock Receivable Contra-Equity Account

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

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

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

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

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

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

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

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

## 20. Quarterly Information (unaudited)

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

	For the three months ended,									
		March 31, 2003	June 30, 2003		September 30, 2003			December 31, 2003		
Revenues	\$	1,929,000	\$	2,903,000	\$	4,495,000	\$	4,761,000		
Gross profit		1,290,000		2,116,000		3,057,000		3,381,000		
Operating expenses, excluding stock based										
compensation		4,494,000		4,062,000		5,491,000		4,473,000		
Stock based compensation		213,000		212,000		447,000		113,000		
Other income (expenses)		137,000		99,000		82,000		60,000		
Net loss		(3,280,000)		(2,059,000)		(2,799,000)		(1,145,000)		
Basic and diluted net loss per share	\$	(0.23)	\$	(0.14)	\$	(0.19)	\$	(0.08)		
				For the three	nor	nths ended,				
	_	March		June	_	September		December		
	_	March 31, 2002			_	,		December 31, 2002		
Revenues	\$		\$	June	_	September	\$			
RevenuesGross profit	\$	31, 2002	\$	June 30, 2002	_	September 30, 2002	\$	31, 2002		
Gross profit	\$	31, 2002 1,110,000 560,000	\$	June 30, 2002 2,707,000 1,726,000	_	3,302,000 956,000	\$	31, 2002 2,047,000 1,360,000		
Gross profit  Operating expenses, excluding stock based compensation	\$	31, 2002 1,110,000 560,000 3,269,000	\$	June 30, 2002 2,707,000 1,726,000 3,269,000	_	September 30, 2002  3,302,000 956,000  3,622,000	\$	31, 2002 2,047,000 1,360,000 6,050,000		
Gross profit	\$	31, 2002 1,110,000 560,000 3,269,000 469,000	\$	June 30, 2002 2,707,000 1,726,000 3,269,000 275,000	_	September 30, 2002  3,302,000 956,000  3,622,000 273,000	\$	31, 2002 2,047,000 1,360,000 6,050,000 270,000		
Gross profit	\$	31, 2002 1,110,000 560,000 3,269,000 469,000 244,000	\$	June 30, 2002 2,707,000 1,726,000 3,269,000 275,000 215,000	_	September 30, 2002  3,302,000 956,000  3,622,000 273,000 (27,000)	\$	31,2002 2,047,000 1,360,000 6,050,000 270,000 (540,000)		
Gross profit	\$	31, 2002 1,110,000 560,000 3,269,000 469,000		June 30, 2002 2,707,000 1,726,000 3,269,000 275,000	\$	September 30, 2002  3,302,000 956,000  3,622,000 273,000		31, 2002 2,047,000 1,360,000 6,050,000 270,000		

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

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

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

Not applicable.

#### Item 9a. Controls and Procedures

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

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

#### **PART III**

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

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

## **Item 11. Executive Compensation**

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

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

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

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

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

## Item 14. Principal Accountant Fees and Services

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

#### **PART IV**

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

## (a) (1) Financial Statements

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## (a) (2) Financial Statement Schedules

## SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

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

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

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

## (a)(3) Exhibits

Exhibit
Number

2.1 Description

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

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

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

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

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

<sup>+</sup> 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

Christopher J. Calhoun

Chief Executive Officer, and President

March 30, 2004

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

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

#### ASSET PURCHASE AGREEMENT\*\*\*

THIS ASSET PURCHASE AGREEMENT (the "Agreement") is made and entered into as of December 13, 2003, by and among **Medicis Ventures Management GmbH** (as defined herein, "Medicis"), a German corporation, and **MacroPore Biosurgery, Inc.** (as defined herein, "MacroPore"), a Delaware corporation.

#### WITNESSETH:

WHEREAS, MacroPore has developed, manufactures and sells Bioabsorbable Film Implants; and

WHEREAS, the parties hereto desire that MacroPore sell, transfer and assign to Medicis, and Medicis purchase from MacroPore, the Specified Assets relating to the Field of Use Business (as such terms are defined herein) on the terms and for the consideration hereinafter provided; and

WHEREAS, as a condition to MacroPore's sale of the Specified Assets, Medicis will grant MacroPore a perpetual (subject to the conditions of the License Agreement), worldwide exclusive royalty-free sub-licensable license to certain intangible assets relating to the SurgiWrap Business for the Spinal Field, and a perpetual worldwide non-exclusive royalty-free sub-licensable license to certain intangible assets relating to the SurgiWrap Business for the Field of Regenerative Medicine both licenses pursuant to a License Agreement in the form attached hereto as **Exhibit A** (the "License Agreement"); and

NOW, THEREFORE, in consideration of the respective representations, warranties, covenants and agreements contained herein, and subject to the terms and conditions set forth herein, the parties hereto agree as follows:

## ARTICLE 1 DEFINITIONS

- 1.1) <u>Specific Definitions</u>. As used in this Agreement, the following terms shall have the meanings set forth or referenced below:
- "Affiliate" of a specified person (natural or juridical) means a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. "Control" shall mean ownership of more than 50% of the shares of stock entitled to vote for the election of directors in the case of a corporation, and more than 50% of the voting or policy making power or of the equity in the case of a business entity other than a corporation.
- "Assignment and Assumption Agreement" means the agreement in the form attached hereto as **Exhibit D** between MacroPore and Medicis under which MacroPore shall assign to Medicis, and Medicis shall assume from MacroPore, all of MacroPore's rights and obligations, to the extent such rights and obligations arise following the Closing, under the Contracts.
- "Associate Investors" means the named investors as specified on Exhibit C
- "Assumed Liabilities" means the liabilities described in Section 2.6.
- <u>"Bill of Sale"</u> means the document delivered by MacroPore to Medicis under which MacroPore shall convey to Medicis unencumbered title to the Specified Assets, in the form attached hereto as **Exhibit E** (Bill of Sale).

<sup>\*\*\*</sup> Certain confidential portions of this Exhibit were omitted by means of blackout of the text (the "Mark"). This Exhibit has been filed separately with the Secretary of the Commission without the Mark pursuant to the Company's Application Requesting Confidential Treatment under Rule 24b-2 under the 1934 Act.

"<u>Bioabsorbable Film Implants</u>" means bioabsorbable and/or bioresorbable Thin Polymeric Films and similar products, including current Thin Polymeric Films in development, for use as surgical implants in the following medical applications: soft tissue support, anti-scarring, anti-adhesion, minimizing the attachment of soft tissues, and hernia repair.

"Business" means any and all of MacroPore's business activities related to the Bioabsorbable Film Implants, as conducted to the date of Closing.

"Business Development Agreement" means the agreement attached hereto as Exhibit G.

"Closing" and "Closing Date" have the meanings set forth in Section 8.1.

"Code" means the Internal Revenue Code of 1986, as amended.

"Confidential Information" means information disclosed by or on behalf of one of the parties (the "disclosing party") to the other party (the "receiving party"), generated under this Agreement, or otherwise learned by the receiving party from the disclosing party, excluding information which:

- (a) was already in the possession of the receiving party before its original receipt from the disclosing party (provided that the receiving party is able to provide the disclosing party with written proof thereof and, if received from a third party, that such information was acquired without any party's breach of a confidentiality or non-disclosure obligation to the disclosing party related to such information);
  - (b) is or becomes part of the public domain by reason of acts not attributable to the receiving party;
- (c) is or becomes available to the receiving party from a source other than the disclosing party which source has rightfully obtained such information and has no direct or indirect obligation of non-disclosure or confidentiality to the disclosing party with respect thereto; or
- (d) has been independently developed by or for the receiving party without breach of this Agreement or use of any Confidential Information of the other party (provided that the receiving party is able to provide the disclosing party with written proof thereof).

Notwithstanding the forgoing exceptions, all information learned by Medicis personnel during the time they were MacroPore personnel shall be Confidential Information and shall continue to be governed by their agreements with MacroPore.

"Contract(s)" means those contracts, purchase or sale orders, leases, licenses, commitments and other agreements listed on the Letter of Assets attached hereto as **Exhibit F**.

"Disclosure Letter" means the disclosure letter dated December 13, 2003 delivered by MacroPore to Medicis before the execution of this Agreement.

"Environmental Laws" means and includes any one or more of the following: (a) the Comprehensive Environmental Response Compensation and Liability Act ("CERCLA"), as amended by the Superfund Amendments and Reauthorization Act of 1986 ("SARA"), 42 U.S.C. § 9601 et seq.; the Federal Resource Conservation and Recovery Act of 1976 ("RCRA"), 42 U.S.C. § 6921 et seq.; the Clean Water Act, 33 U.S.C. § 1321 et seq.; the Clean Air Act, 42 U.S.C. § 7401 et seq.; the Safe Drinking Water Act, 42 U.S.C. § 300f et seq.; the Occupational Safety and Health Act of 1976, 29 U.S.C. § 651, all as they may be amended from time to time; any other federal, state, county, municipal, local or other statute, law, ordinance or regulation that relates to or deals with Hazardous Substances, human health or the environment, all as they may be amended from time to time; and all regulations promulgated by a regulatory body pursuant to any of the foregoing statutes, laws, regulations, or ordinances; and (b) to the extent that they apply specifically to MacroPore, judgments, orders, decrees, injunctions, permits, concessions, grants, franchises, licenses or agreements, to the extent that either (a) or (b) relate to safety, human health, the environment or emissions, discharges, or releases of Hazardous Substances into the environment including ambient air, surface water, ground water, facilities, structures, or

land, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport, or handling of pollutants, contaminants, Hazardous Substances, or wastes or the investigation, clean-up, or other remediation thereof.

"Facilities" means specialized clean rooms, storage, and/or packaging facilities which specifically are not being provided to Medicis herein.

"FDA" means the United States Food and Drug Administration.

<u>"Field of Regenerative Medicine"</u> means application or delivery of drugs, growth factors, cells or genes to repair or regenerate the human body. Nevertheless, the Field of Regenerative Medicine shall not include any of the above for the sole purpose of, or intended use in soft tissue support, anti-adhesion, anti-scarring or minimization of the attachment of soft tissues or hernia repair.

"Field of Use" means any applications of Bioabsorbable Film Implants throughout the human body for one or more of the following: soft tissue support, anti-adhesion, anti-scarring, minimizing the attachment of (soft) tissues, or hernia repair. The Field of Use specifically does not include any applications in the Spinal Field (as defined herein) or the Field of Regenerative Medicine.

"Field of Use Bioabsorbable Implants" means Bioabsorbable Film Implants that are designed, developed, manufactured, marketed or sold for use in the Field of Use by MacroPore as of the Closing Date.

<u>"Field of Use Business"</u> means MacroPore's activities in connection with the development, manufacturing, marketing and sale of Field of Use Bioabsorbable Implants, as conducted by MacroPore to the date of Closing.

<u>"Financial Statements"</u> means the balance sheet, statement of operations, and statement of cash flow of Medicis prepared under U.S. generally accepted accounting principals.

<u>"Hazardous Substance"</u> means asbestos, urea formaldehyde, polychlorinated biphenyls, nuclear fuel or materials, chemical waste, radioactive materials, explosives, known carcinogens, petroleum products, pesticides, fertilizers, or any other substance that is dangerous, toxic, or hazardous, or that is a pollutant, contaminant, chemical, material or substance defined as hazardous or as a pollutant or contaminant in, or the use, transportation, storage, release or disposal of which is regulated by, any Environmental Laws.

"Intellectual Property" means (a) patents and all divisions, continuations, continuations-in-part, revisions, reissues and reexaminations relative thereto; (b) copyrights and all works of authorship including all translations, adaptations, combinations,
compilations and derivations of each of the foregoing; (c) trademarks, trade names, brand names, service marks, service
names, trade dress, logos and corporate names including all translations, adaptations, combinations and derivations thereof,
together with all common law rights and all goodwill associated with each of the foregoing; (d) technology, know-how,
methods, processes, systems, trade secrets, inventions (whether or not patentable, copyrightable or susceptible to any other
form of legal protection and whether or not reduced to practice), proprietary data, formulae, research and development data,
and confidential information (including conceptions, ideas, innovations, manufacturing, development and production
techniques, drawings, specifications, designs, proposals, financial and accounting data, business and marketing plans,
customer and supplier lists and related information and documentation), in each case irrespective of whether in human or
machine readable form; (e) computer software and all related program listings and data, systems, user and other
documentation; (f) mask works; (g) all other forms of right by which one may effectively exclude another from using or
otherwise enjoying any and each of the foregoing; and (h) all applications for any and each of the foregoing including
applications for patent or registration, together with all registrations, renewals and extensions for any and each of the
foregoing.

"Inventory" or "Inventories" means finished goods, raw materials and ingredients, work-in-process, consignment goods, wares and merchandise. The list of inventory items is attached hereto as **Exhibit I**.

"International Distributorship Agreement(s)" means the distribution agreements related to each of the international distributors identified in Schedule 5.13.

<u>"Knowledge"</u> of a party means actual knowledge of the party's officers, directors, or management or the knowledge that any of such persons would reasonably be expected to have assuming reasonable inquiry of any facts or circumstances actually known to and recognized by such person to create significant doubt concerning the accuracy of any representation, warranty, or statement without regard to such "knowledge" qualifier.

"Letter of Assets" means the listing of assets attached hereto as Exhibit F.

"Letter of Intent" means that specific document signed dated August 27, 2003 and attached hereto as Exhibit B.

"Liens" means liens, mortgages, charges, security interests, pledges, encumbrances, assessments, restrictions or other third-party claims of any nature.

"License Agreement" has the meaning set forth in the recitals.

"MacroPore" means MacroPore Biosurgery, Inc. and its Affiliates.

"MacroPore Intellectual Property" means all right, title and interest in and to all Intellectual Property owned by MacroPore that is necessary to the conduct of the Field of Use Business.

"MacroPore Product Information" means all records, reports (internal and external), submissions (internal and external), data, files, marketing materials, specifications, manufacturing documentation and quality assurance information associated with any products or concepts, or development or manufacturing thereof, that have been created, initiated and/or conducted by MacroPore relating primarily to the Specified Assets and/or the Field of Use Bioabsorbable Implants, including but not limited to all of MacroPore's currently embodied (in written, electronic or magnetical form) information and trade secrets, research materials, inventions, test data, product efficacy, safety data as well as so currently embodied technical information (including application technical information) relating primarily to or necessary for use with the respective Field of Use Bioabsorbable Implants in the Field of Use Business, it being specified that the know-how shall include all documentation on research and development but shall not include whole or part of any information, trade secrets, data etc. owned or controlled by MacroPore which are related exclusively to the Spinal Field and the Field of Regenerative Medicine or information otherwise primarily for use outside the Field of Use Business.

"MacroPore Regulatory Information" means all authorizations, permits, licenses, records, reports (internal and external), submissions (internal and external), data and files associated with regulatory requirements and communications between MacroPore and outside regulatory bodies worldwide, including without limitation the FDA, notified bodies, and other governmental agencies, relating to the Specified Assets and/or the Field of Use Bioabsorbable Implants.

"Manufacturing Cost" of MacroPore with respect to a product means MacroPore's per unit average material, labor and manufacturing overhead costs for such product as specified on **Schedule 5.6** ("Cost Statements").

"Material Adverse Effect" means an effect (other than an effect caused by changes to the economy in general) that, individually or in the aggregate with other related effects, is or could reasonably be expected to be materially adverse to the business, prospects, results of operation or condition (financial or otherwise) of the Specified Assets or the Field of Use Business, considered as a whole, or is or could reasonably be expected to be materially adverse to the ability of Medicis to conduct following the Closing the manufacture and/or sale of Field of Use Bioabsorbable Implants as presently conducted or contemplated to be conducted by MacroPore; provided, however, that any of the following, individually or in the aggregate, shall not constitute a "Material Adverse Effect" on or with respect to MacroPore: (a) any changes, events or effects including without limitation, any acts of terrorism, affecting the United States economy or world economy as a whole or affecting generally the industry in which MacroPore operates (and not specially affecting MacroPore); (b) any adverse changes, events or effects that are demonstrated to be caused by the announcement or pendency of the transactions contemplated in this Agreement; (c) the lack of success of MacroPore in retaining existing employees or of Medicis in hiring MacroPore employees or other employees who are material to Medicis's ability to operate the Field of Use Business or MacroPore's ability to fulfill its obligations under this Agreement; or (d) any changes resulting from compliance by MacroPore with the terms of, or the taking of any action expressly contemplated, permitted or required by, this Agreement.

"Medicis" means Medicis Ventures Management GmbH and its Associate Investors and its and their Affiliates.

<u>"Product Liability"</u> means any liability, claim or expense related to the Field of Use Business, including but not limited to reasonable attorneys' fees and medical expenses, arising in whole or in part out of a breach of any express or implied product warranty, strict liability in tort, negligent manufacture of product, negligent provision of services, product recall, or any other allegation of liability arising from the design, testing, manufacture, packaging, labeling (including instructions for use), marketing, distribution or sale of products (whether for clinical trial purposes, commercial use or otherwise).

"Purchase Price" has the meaning set forth in Section 2.4.

"Retained Liabilities" has the meaning set forth in Section 2.8.

<u>"Specified Assets"</u> means all of the assets set forth on the Letter of Assets, together with all MacroPore Product Information and MacroPore Regulatory Information; provided, however, that copies of certain MacroPore Product Information and MacroPore Regulatory Information necessary for the continuing operation of MacroPore's remaining business, as reasonably agreed to by the parties, may be retained by MacroPore. Expressly excluded from the Specified Assets is any and all Inventory of MacroPore to the extent needed to cover open orders as of the Closing Date.

"Spinal Field" means all applications (including but not limited to: anti-adhesion, anti-scarring, minimizing the attachment of soft tissues, or soft tissue support) related to the anatomy of the spine including, but not limited to, applications in the following: spinal fixation, stabilization and/or fusion, spinal cord coverings, exiting nerve root coverings, cauda equina coverings, lamina coverings and vertebral column-cervical, thoracic, lumbar and sacral. The spinal field does not include distal peripheral nerve and other structures extrinsic and distal to the spine.

<u>"Transfer, Sales and Value Added (VAT) Taxes"</u> means all sales tax, use taxes, stamp taxes, conveyance taxes, transfer taxes, filing fees, recording fees, prepayment fees or penalties, reporting fees and other similar duties, taxes and fees, if any, imposed upon, or resulting from, the transfer of the Specified Assets or the Assumed Liabilities hereunder and the filing of any instruments relating to such transfer.

1.2) Other Terms. Other terms may be defined elsewhere in the text of this Agreement and shall have the meaning indicated throughout this Agreement.

# ARTICLE 2 PURCHASE, SALE AND TRANSFER OF SPECIFIED ASSETS

- 2.1) <u>Purchased Assets</u>. Upon the terms and subject to the conditions set forth in this Agreement, effective as of the Closing, MacroPore agrees to sell, transfer, assign and convey to Medicis, and Medicis agrees to purchase, the Specified Assets, which assets MacroPore represents and warrants includes all assets, contracts and rights necessary to the conduct of the Field of Use Business, other than the Excluded Assets specified in Exhibit H. .
- 2.2) <u>Excluded Assets.</u> MacroPore shall retain all of its respective right, title and interest in and to all open orders as attached in **Schedule 2.2** ("Open Orders") and as subsequently received through the Closing Date, and including any Inventory necessary to meet such Open Orders, and any receivables or other payments accruing prior to the Closing Date, Facilities, and all other assets specified on **Exhibit H** (the "Excluded Assets").
- 2.3) Contracts and International Distributorship Agreements. A sale of contract(s) is subject to the consent of the respective third-party to the assignment of the contract(s) to Medicis. MacroPore shall use its reasonable efforts to obtain the respective third-party's consents and Medicis shall cooperate respectively. If and to the extent the consent of the relevant third parties to the assignment of the Contracts/International Distributorship Agreements has not been obtained until Closing, such Contracts/International Distributorship Agreements by MacroPore and the following shall apply with respect to the individual Contracts/International Distributorship Agreements for which such consent has not been obtained:

If with respect to any of the Contracts/International Distributorship Agreements the contracting party does not consent (where such consent is necessary) to an assignment to Medicis, MacroPore performs such Contracts/Distributorship Agreements on account and on behalf of Medicis and in accordance with the instruction of Medicis, provided, however, that (i) Medicis shall provide all support reasonably to be expected to perform such Contracts/International Distributorship Agreements, and (ii) Medicis shall indemnify and hold harmless MacroPore from any liability resulting out of or in connection with such Contracts/International Distributorship Agreements and the performance therefore after the Closing Date unless MacroPore negligently or willfully breached its duties, and, further provided, that MacroPore shall not be obliged to incur any out-of-pocket expenses or to otherwise accept any contractual liability in order to perform such Contracts/International Distributorship Agreements unless (i) such out-of-pocket expenses are fully paid by Medicis, or (ii) such contractual liabilities are fully performed by Medicis. Within the first [12] months after the Closing MacroPore shall not exercise any termination rights under such Contracts/International Distributorship Agreements and shall not reject any extension of such Contracts/International Distributorship Agreements of Medicis. Thereafter, MacroPore may exercise ordinary termination rights in respect of such Contracts/International Distributorship Agreements at its sole discretion.

If the consent of the relevant third parties as in the first sentence of this subparagraph 2.3 is refused or otherwise not obtained on existing terms to Medicis within 120 days of the Closing Date, Medicis shall be entitled at its sole discretion to require MacroPore to serve proper notice to terminate the Contract/International Distributorship Agreements in accordance with the terms and conditions of that Contract/International Distributorship Agreements.

- 2.4) <u>Purchase Price</u>. The total cash consideration from Medicis for the Specified Assets (the "Purchase Price") shall be Twelve Million Dollars (\$12,000,000).
  - 2.5) Payment of Purchase Price. The Purchase Price shall be paid as follows:
    - (a) on the Closing Date, Medicis shall wire transfer to a bank account designated in writing by MacroPore the sum of Seven Million Dollars (\$7,000,000).
    - (b) on the day after MacroPore notifies Medicis of MacroPore's receipt of any 510K clearance from the U.S. FDA for the hernia wrap product, Medicis shall wire transfer MacroPore the sum of Two Hundred Thousand Dollars (\$200,000).
    - (c) on or before December 1, 2004, Medicis shall wire transfer to a bank account designated by MacroPore the sum of Five Million Dollars (\$5,000,000).
- 2.6. <u>Assumed Liabilities</u>. Subject to Section 2.8, at the Closing, Medicis shall assume and agree to pay, perform and discharge in due course only those liabilities and obligations (the "Assumed Liabilities") that accrue for periods subsequent to the Closing and which (i) are listed in Exhibit J ("Express Liabilities"); (ii) result from those contracts listed on the Letter of Assets (**Exhibit F**); (iii) are international distributor agreements for distributors identified on the International Distributor List (Schedule 5.13), and (iv) any other contracts that Medicis may, upon agreement with MacroPore, elect in writing at or following the Closing to assume (it being understood that Medicis shall not assume any liabilities or obligations, or portions thereof, with respect to such contracts under (i), (ii) or (iii), including any breaches, defaults or other events or actions thereunder, that arise or are accrued or that should have been accrued as of or for periods prior to the Closing). Liabilities arising from Medicis' operation of the Field of Use Business (or disposition of assets acquired hereunder) after the Closing are to be borne by Medicis

If a claim by a third party is made against MacroPore with regard to any of the Assumed Liabilities, Medicis shall indemnify and hold harmless MacroPore from any obligation or liability qualified as Assumed Liabilities in this Section 2.6.

### 2.7) <u>Business Development Agreement.</u>

Prior to closing the parties Shall execute the Business Development Agreement attached hereto as **Exhibit G** with respect to any partnership, distribution or licensing agreement for the Territory of Japan.

- 2.8) Retained Liabilities. The parties agree that Medicis is not, nor shall be considered, the successor to MacroPore, and that Medicis does not hereby agree to assume or become liable to pay, perform or discharge any obligation or liability whatsoever of MacroPore or relating to the Specified Assets prior to the Closing Date or any former or present employees of MacroPore, including those that may be hired by Medicis, except as expressly provided for in Section 2.6). Section 2.6 and the Letter of Assets notwithstanding, and without limitation of the foregoing provisions of this Section 2.8, it is expressly agreed and understood that Medicis shall not assume any of the following obligations or liabilities of MacroPore:
  - (a) any obligation, commitment or liability of or claim against MacroPore that relates to or arises from events occurring before Closing resulting in any lawsuit, action or proceeding against MacroPore, including any obligation or liability of MacroPore under any Environmental Laws or Regulations.
  - (b) any Product Liability claim relating to (i) any product sold, or service performed, by MacroPore accruing before the Closing Date, or (ii) any finished goods manufactured before the Closing Date so long as such products are not repackaged, resterilized or otherwise physically modified by Medicis; or
  - (c) any other liability, obligation or undertaking of MacroPore accruing prior to the Closing Date of any kind or nature whatsoever, whether known or unknown, fixed or contingent, determined or determinable, due or not yet due, or otherwise, that is not expressly assumed by Medicis under Section 2.6 or disclosed in the Disclosure Letter.

If a claim by a third party is made against Medicis with regard to any of the Retained Liabilities, MacroPore shall indemnify and hold harmless Medicis from any obligation or liability qualified as Retained Liabilities in this section 2.8).

- 2.9) Allocation of Purchase Price. Set forth in a letter to be delivered by Medicis to MacroPore concurrently with the execution and delivery of this Agreement is an allocation of the Purchase Price for tax purposes among the Specified Assets. The allocation has been agreed to by MacroPore and Medicis after arm's-length negotiations and in accordance with Section 1060 of the Code and other applicable laws. MacroPore and Medicis will, to the extent permitted by applicable law, adopt and utilize the amounts allocated to each asset or class of assets, as such allocations may be adjusted pursuant to this Agreement, for purposes of all federal, state, local and other tax returns or reports, in any claim for refund, or otherwise with respect to such tax returns or reports. Each party agrees to timely file an IRS Form 8594 reflecting the allocation of the Purchase Price and the Assumed Liabilities among the Specified Assets for the taxable year that includes the Closing and to timely file any comparable or similar forms required by applicable state, local, and foreign tax laws. In the event of any adjustments to the Purchase Price, the parties shall prepare and timely file a supplemental asset acquisition statement on IRS Form 8594 in accordance with the rules under Section 1060 of the Code and the Treasury regulations issued thereunder and shall prepare and timely file any comparable or similar form required by applicable state, local, and foreign tax laws.
  - 2.10) <u>Transfer and Sales Taxes</u>. Medicis shall promptly pay all Transfer, Sales and VAT Taxes.
- 2.11) <u>Transfer of Specified Assets</u>. MacroPore shall on a date to be mutually agreed to by both parties, deliver the Specified Assets to Medicis, FOB the shipping dock of the MacroPore's San Diego facility.
- 2.12) Security of Payment for Intellectual Property Assets. In order to secure the payment obligations of Medicis in Section 2.5 herein ("Obligations"), Medicis does by this Agreement collaterally assign and grant to MacroPore a lien and security interest in all of Medicis' right, title, and interest in and to the MacroPore Intellectual Property, including all patents, patent applications, trademarks and/or trademark applications set forth on Exhibits A and B to the License Agreement, and any future patents, royalties or other fees paid or payment or payments made or to be made to Medicis in respect thereto (referred to collectively in this Agreement as the "Patent Collateral"). The security interest provisions of this Section 2.12 shall be null and void (without prejudice to any other rights or remedies of MacroPore under this agreement) after Medicis has paid MacroPore the Purchase Price obligations in Section 2.5 (a) for \$7,000,000 and Section 2.5 (c) for \$5,000,000, whether or not any such payment occurs prior to the time specified in this Agreement.

#### Medicis further covenants that:

- (a) until all of the Obligations have been satisfied in full, it will (i) not enter into any agreement, including without limitation, license agreements, which are inconsistent with Medicis's undertakings and covenants under this Agreement or which restrict or impair MacroPore's rights under this Agreement, and (ii) maintain the Patent Collateral in full force and effect.
- (b) so long as this security interest is in effect and so long as Medicis has not received notice from MacroPore that an event of default has occurred under the Agreement with respect to the Obligations, Medicis shall continue to have the exclusive right (subject to the License Agreement) to use the Patent Collateral and grant licenses with respect to them as anticipated in this Agreement.
- (c) Medicis agrees not to sell, assign, or further encumber its rights and interests in the Patent Collateral without prior written consent of MacroPore.
- (d) if Medicis fails to meet it's Obligations at the time specified in this Agreement, MacroPore, as the holder of a security interest under the U.S. Uniform Commercial Code as in effect now or in the future in any applicable U.S. jurisdiction, may take such action as is permitted by law or equity, in its sole discretion, to foreclose upon or otherwise realize upon the Patent Collateral covered by this Agreement. For those purposes, Medicis hereby authorizes and empowers MacroPore to make, constitute, and appoint any officer or agent of MacroPore as MacroPore may select in its sole discretion, as Medicis's true and lawful attorney-in-fact with the power to endorse Medicis's name on, and/or file of record, all assignments, applications, documents, papers, and instruments, whether signed by Medicis or by MacroPore on Medicis' behalf, necessary for MacroPore or its transferee, successors, or assigns, to obtain title to and the right to use the Patent Collateral or to grant or issue any exclusive or nonexclusive license under the Patent Collateral to any other person, or to assign, pledge, convey, or otherwise transfer title in or dispose of all or any part of the Patent Collateral to any other person. Medicis here ratifies all that that attorney shall lawfully do or cause to be done by virtue of this Agreement. This power of attorney shall be irrevocable for the life of this Agreement or until all Obligations under this Agreement are satisfied.
- (e) Medicis shall at its own expense, to the extent Medicis deems it necessary, diligently file and prosecute all patent applications relating to the inventions described and claimed in the Patent Collateral in the United States Patent and Trademark Office, and shall pay or cause to be paid in their customary fashion all connected fees and disbursements, and shall not abandon any such application before the exhaustion of all administrative and judicial remedies or disclaim or dedicate any Patent Collateral without the prior written consent of MacroPore. Medicis shall not abandon any Patent Collateral without the prior written consent of MacroPore, that consent not to be unreasonably withheld. Any and all fees, costs, and expenses, including reasonable attorneys' fees and expenses incurred by MacroPore in connection with the preparation, modification, enforcement, or termination of this lien and security interest, including the filing and recording of any documents in public offices, any taxes, counsel fees, maintenance fees, encumbrances, or costs otherwise incurred in defending or prosecuting any actions or proceedings arising out of or related to the Patent Collateral, shall be paid by Medicis on demand by MacroPore and, until paid, shall be added to the Obligations.
- (f) Medicis shall have the right, with the prior written consent of MacroPore, which consent will not be unreasonably withheld, to bring suit in its own name to enforce the Patent Collateral, in which case MacroPore may, at MacroPore's option, be joined as a nominal party to this suit if MacroPore shall be satisfied that that joinder is necessary and that MacroPore is not incurring any risk of liability by that joinder. Medicis shall promptly, upon demand, reimburse and indemnify, defend, and hold harmless MacroPore for all damages, costs, and expenses, including reasonable attorneys' fees, incurred by MacroPore pursuant to this Section 2.12.
- (g) upon full and unconditional satisfaction of all Medicis' Obligations to MacroPore herein, MacroPore shall execute and deliver to Medicis all documents reasonably necessary to terminate MacroPore's interests in the Patent Collateral.

- (h) Medicis here acknowledges and agrees that this Agreement will be recorded in the United States Patent and Trademark Office, and that the obligations of this Section 2.12 shall be binding upon Medicis, its successors, and assigns, and shall inure to the benefit of MacroPore, its successors, and assigns.
- 2.13) <u>Employees</u>. Any claims of or liabilities to those MacroPore employees which Medicis hires for unused vacations, ratifications, bonus payments and similar arrangements shall be born by MacroPore if and to the extent such claims and liabilities relate to the period prior to the Closing Date even if they do not become due until on or after the Closing Date. MacroPore shall not interfere in any material or significant way with the ability of Medicis to hire or retain the employees identified in Section 3.11 (b) of the Disclosure Letter. For example, MacroPore shall not make any counter offers to such employees, or offer them any raises or bonuses beyond the ordinary course of business.

# ARTICLE 3 REPRESENTATIONS AND WARRANTIES OF MACROPORE

MacroPore represents and warrants by way of an independent guarantee to Medicis except as set forth in the Disclosure Letter that the following statements are true and complete on the date of signing this Agreement and on the Closing Date (except where expressly stated otherwise thereafter):

- 3.1) <u>Organization; Directors and Officers</u>. MacroPore is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. MacroPore has all necessary power and authority to own its properties and assets and conduct the business presently being conducted by it.
- 3.2) Authority. MacroPore has full power and authority to enter into this Agreement and to perform its obligations hereunder. This Agreement has been duly authorized, executed, and delivered by MacroPore, and constitutes a legal, valid and binding agreement of MacroPore, enforceable against it in accordance with its terms, subject to (a) bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles and (b) laws relating to the availability of specific performance, injunctive relief or other equitable remedies. No further proceeding on the part of MacroPore is necessary to authorize this Agreement and the transactions contemplated hereby. Neither the execution and delivery of this Agreement nor compliance by MacroPore with its terms and provisions will violate (i) any provision of the certificate of incorporation, bylaws or other governing instruments of MacroPore, (ii) any contract, permit or license of MacroPore, or (iii) any law, statute, regulation, injunction, order or decree of any government agency or authority or court to which MacroPore or any of the Specified Assets is subject, except for violations which, individually or in the aggregate, would not have a Material Adverse Effect.
- 3.3) <u>Absence of Undisclosed Liabilities</u>. MacroPore has not incurred any undisclosed liabilities, claims against or obligations, and there is no reasonable legal basis therefor, that may adversely affect MacroPore's ability to perform its obligations hereunder or may adversely affect the ownership of the Specified Assets or the use thereof by Medicis in the same manner currently used by MacroPore. Except as provided in this Agreement, MacroPore has no claims or rights with respect to, nor has MacroPore created any Liens on, the Specified Assets.
- 3.4) <u>Absence of Certain Changes and Events</u>. Since January 1, 2003, there has not been any (i) Material Adverse Effect; or (ii) to MacroPore's knowledge, any occurrence or event that could reasonably be expected to have a Material Adverse Effect.
- 3.5) <u>Litigation and Claims</u>. There are no actions, suits, claims, or proceedings pending or, to MacroPore's knowledge, threatened against or by MacroPore relating to the Specified Assets, the Assumed Liabilities or the subject matter of this Agreement, at law, in equity or otherwise, in, before, or by, any court, arbitrator, or governmental agency or authority. There are no unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court or administrative agency or by arbitration) against or affecting MacroPore relating to any of the Specified Assets or Assumed Liabilities. MacroPore has never incurred any uninsured or insured Product Liability, or received a claim based upon alleged Product Liability, and, to MacroPore's knowledge, no basis for any such claim exists. Section 3.5 of the

Disclosure Letter also sets forth a true, correct and complete list of all complaint, warranty claim and defective product claims related to the Field of Use Business in the two (2) years prior to the date hereof.

- Compliance with Law. In conducting the Field of Use Business, MacroPore has not violated and is not in violation of any applicable law, ordinance or regulation of any governmental entity. To MacroPore's knowledge, all governmental approvals, registrations, notifications, permits, licenses and other permissions or authorizations (collectively, "Authorizations") required in connection with the conduct of the Field of Use Business are in full force and effect and are being complied with. MacroPore has not received any written notification of any asserted past or present violation in connection with the conduct of the Field of Use Business of any applicable law, ordinance or regulation, or any written complaint, inquiry or request for information from any governmental entity relating thereto, with the exception of one prewarning letter from FDA alleging off-label promotion that has been addressed and resolved. Neither MacroPore nor the Field of Use Business nor any of the Specified Assets is the subject of any federal, state or local enforcement action or, to the knowledge of MacroPore, other investigation, including but not limited to those relating to Environmental Laws. All documentation, correspondence, reports, data, analysis and certifications relating to or regarding any medical devices of the Field of Use Business, filed or delivered (or, if amended, as of the date for which such amendment speaks) by MacroPore on behalf of the Field of Use Business to any governmental authority, agency or body were true and accurate in all material respects when so filed or delivered and remain true and accurate in all material respects. Any failure or omission with respect to a representation or warranty in this section 3.6 which does not amount (either individually or in the aggregate) to a Material Adverse Effect shall not constitute a violation of this section.
- 3.7) <u>Title to and Condition of Specified Assets</u>. MacroPore has full right, title and interest to the intangible Specified Assets and good and valid title to the tangible Specified Assets, free and clear of all Liens. MacroPore is entitled to fully transfer or dispose of the Specified Assets (other than the Contracts) without requiring the further consent of any third party and without such disposal infringing any rights of a third party. The Specified Assets include all assets, rights, interests, contracts, know how, approvals, permissions and claims necessary for the conduct of the Field of Use Business, other than the Excluded Assets. The Specified Assets identified in Sections 2 ("Manufacturing Fixed Assets") and Section 3 ("General and Administrative Fixed Assets") of Exhibit F are suitable for the uses for which they are presently used by MacroPore, in normal operating condition and free from any significant defects, ordinary wear and tear excepted, and have been properly serviced and maintained by MacroPore. All of the Specified Assets are located at MacroPore's corporate headquarters at 6740 Top Gun Street, San Diego, CA 92121, or 6749 Top Gun Street, San Diego, CA 92121 or 61462 Königstein, Ölmühlweg 33, Germany.
- 3.8) <u>Intellectual Property</u>. All right, title and interest in and to the MacroPore Intellectual Property is owned by MacroPore for use in connection with the Specified Assets and Field of Use Bioabsorbable Implants and, in some instances, also for other uses, without royalties or fees, and free and clear of any Liens. To MacroPore's knowledge, neither the use of the MacroPore Intellectual Property in the Field of Use Business, nor any of the assets included in the Specified Assets, infringe or will infringe, misuse, or misappropriate the rights, including Intellectual Property rights or contract rights, of others in the Field of Use Business. The MacroPore Intellectual Property has not been challenged in any judicial or administrative proceeding. Neither any shareholder nor any employee or consultant of MacroPore (or the employer of any such consultant) has any rights in or to any of the MacroPore Intellectual Property. All patent applications listed in the Specified Assets are still pending in good standing and have not been abandoned, and all fees necessary to maintain such MacroPore Intellectual Property in full force and effect have been and as of the Closing will have been paid. To MacroPore's knowledge, no person nor such person's business nor any of its products has infringed, misused, or misappropriated the MacroPore Intellectual Property or currently is infringing, misusing, misappropriating or conflicting with such rights.

  MacroPore has valid confidentiality, assignment of invention and/or non-competition agreements with each person to whom confidential or trade secret information relating to the Field of Use Business has been disclosed.
- 3.9) <u>Relations with Suppliers</u>. No material supplier of MacroPore has cancelled any contract or order for provision of, and there has been no threat by any such supplier not to provide, raw materials, products, supplies, or services to the Field of Use Business when owned by MacroPore or when owned by Medicis.
- 3.10) <u>Environmental Matters</u>. Except for any violation or non-compliance which, individually or the aggregate, would not have a Material Adverse Effect, (a) MacroPore has obtained, and is in compliance

with, all permits, licenses or other approvals necessary under the Environmental Laws with respect to the Field of Use Business and the Specified Assets, and is in compliance with all Environmental Laws; (b) no capital or other expenditures are necessary so that the Field of Use Business and Specified Assets comply fully with any Environmental Law; (c) neither MacroPore nor the Field of Use Business or Specified Assets have been or are subject to any actual or, to MacroPore's knowledge, threatened investigations, administrative proceedings, litigation, regulatory hearings, or other action threatened, proposed or pending that alleges (i) actual or threatened violation of or noncompliance with any Environmental Law, or (ii) actual or threatened personal injury or property damage or contamination of any kind resulting from a release or threatened release of a Hazardous Substance with respect to the Field of Use Business and Specified Assets; (d) MacroPore has not taken or failed to take any action with respect to the Field of Use Business, the Specified Assets or the real property presently or formerly used in connection therewith that could reasonably be expected to result in (i) actual or threatened violation of or noncompliance with any Environmental Law, or (ii) actual or threatened personal injury or property damage or contamination resulting from a release of a Hazardous Substance that requires remediation or other similar corrective action under any applicable Environmental Laws; and (e) no Hazardous Substances have been used, manufactured, generated, transported, released or disposed of in violation of any Environmental Law by MacroPore. MacroPore has delivered to Medicis true and complete copies of all reports, studies or tests in the possession of or initiated by MacroPore that pertain to Hazardous Substances or other environmental concerns regarding the Field of Use Business, the Specified Assets or any real property used in connection with the Field of Use Business or Specified Assets. With respect to the real property presently or formerly used in connection with MacroPore's business and assets, to MacroPore's knowledge, (i) no above-ground or underground storage tanks for Hazardous Substances are or were present on such real property or any improvements or structures thereon, (ii) such real property is not listed on any published federal, state or local list of hazardous waste sites, (iii) no Lien in favor of any governmental authority in response to a release or threatened release of any Hazardous Substance has been filed or attached to such real property, (iv) no person other than MacroPore has used or is using any portion of such real property for the handling, processing, storage or disposal of Hazardous Substances except in compliance with applicable Environmental Laws, (v) in the course of any activities conducted by MacroPore, no Hazardous Substances have been generated or are being used on such real property except in compliance with applicable Environmental Laws, (vi) neither MacroPore nor any other person has caused or is causing any releases or threatened releases of Hazardous Substances near, on, to, from or under such real property, and (vii) any Hazardous Substances that have been generated by MacroPore on any of such real property have been transported offsite and have been treated or disposed of in compliance with applicable Environmental Laws.

### 3.11) Employees.

- (a) No employee of MacroPore providing services for the Field of Use Business is subject to or otherwise restricted by any employment or noncompetition agreement between such employee and a former employer of such employee that would restrict such employee from being employed by, or such employee's employment with, MacroPore or (following the Closing) Medicis in their capacity of providing services for the Field of Use Business.
- (b) Set forth in Section 3.11(b) of the Disclosure Letter is a true and complete list of all current MacroPore employees with duties related primarily to the Field of Use Business and, with respect to each such employee thereon, the title, years of service, position, and salary or wages of such employee. No MacroPore employee listed in Section 3.11(b) is on short-term or long-term disability or other authorized leave of absence as of the date of such Disclosure Letter.
- 3.12) Contracts and International Distributorship Agreements. Each Contract and International Distributorship Agreement is valid and subsisting and is in full force and effect in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles, Schedule 5.13 specifies all international distributors with whom MacroPore has Distributorship agreements in the Field of Use Business and being in full force and effect and there have been no amendments, creditors modifications, or supplements to any such Contracts except as disclosed. Prior to the date of this Agreement, MacroPore has delivered or made available to Medicis true and complete copies of all such Contracts. No written or oral amendments or changes of these Contracts and International Distributorship Agreements exist. There is no material default by MacroPore or claim of material default by MacroPore, or any other party thereto, under any such Contract and International Distributorship Agreement and to MacroPore's knowledge, no event has occurred that, with the

passage of time or the giving of notice or both, could reasonably be expected to constitute a material default by MacroPore or any other party thereto under any such Contract and International Distributorship Agreement, or could reasonably be expected to permit modification, acceleration, or termination of any such Contract and International Distributorship Agreement, or result in the creation of any Lien on any of the Specified Assets. MacroPore has not entered into other agreements or obligations relating to these Contracts and International Distributorship Agreements that would, or is likely to, result in a Material Adverse Change thereto.

#### 3.13) Customer List

The Customer List attached as Schedule 3.13 shows all hospitals to which MacroPore has sold Field of Use Bioabsorbable Implants from January 1, 2003 until October 1, 2003.

#### 3.14) Know-How

- a) All know-how which is part of the Specified Assets is adequately documented and has been kept confidential. There is no agreement or other arrangement under which any third party can require disclosure of any part of it. Where such know-how has been made available to a third party this has been done under a signed confidentiality undertaking. Access to the all such confidentiality undertakings has been made available to Medicis through the Data Room and will be made further available upon request.
- b) None of the know-how which is part of the Specified Assets is information from another person received by MacroPore subject to any obligation of confidence.

### 3.15) <u>Miscellaneous</u>

- a) The MacroPore Product Information and the MacroPore Regulatory Information are true and complete. All facts which known to MacroPore to be relevant for purposes of assessing the Specified Assets have been disclosed by MacroPore to Medicis.
- b) To MacroPore's Knowledge, no representation of warranty by MacroPore in this Agreement contains any untrue statement of a material fact or fails to contain any material fact necessary in order to make the statement therein not misleading.

# ARTICLE 4 REPRESENTATIONS AND WARRANTIES OF MEDICIS

Medicis represents and warrants to MacroPore as follows:

- 4.1) <u>Organization of Medicis</u>. Medicis is a corporation duly organized, validly existing and in good standing under the laws of Germany. Medicis has all necessary power and authority to own its properties and assets and conduct the business presently being conducted by it.
- 4.2) Authority. Medicis has full power and authority to enter into this Agreement and to perform its obligations hereunder. This Agreement has been duly authorized, executed, and delivered by Medicis, and constitutes a legal, valid and binding agreement of Medicis, enforceable against Medicis in accordance with its terms, subject to (a) bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles and (b) laws relating to the availability of specific performance, injunctive relief or other equitable remedies. No further proceeding on the part of Medicis is necessary to authorize this Agreement and the transactions contemplated hereby. Neither the execution and delivery of this Agreement nor compliance by Medicis with its terms and provisions will violate (i) any provision of the articles of incorporation or bylaws of Medicis, (ii) any contract, permit or license of Medicis, or (iii) any law, statute, regulation, injunction, order or decree of any government agency or authority or court to which Medicis or any of Medicis's assets are subject.
- 4.3) <u>No Finders</u>. No act of Medicis has given or will give rise to any claim against any of the parties hereto for a brokerage commission, finder's fee or other like payment in connection with the transactions contemplated by this Agreement

4.4) <u>Litigation and Claims</u> There are no actions, suits, claims, or proceedings pending or, to Medicis's knowledge, threatened against or by Medicis relating to the Specified Assets or the subject matter of this Agreement, at law, in equity or otherwise, in, before, or by, any court, arbitrator, or governmental agency or authority that would prevent Medicis from performing its obligations hereunder. There are no unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court or administrative agency or by arbitration) against or affecting Medicis that would prevent Medicis from performing its obligations hereunder.

# ARTICLE 5 CERTAIN COVENANTS AND AGREEMENTS

- 5.1) <u>Approvals and Consents</u>. MacroPore will obtain, at its cost and expense, all approvals and Consents of all third parties necessary for the sale and transfer of the Specified Assets as contemplated herein.
- 5.2) Preserve Accuracy of Representations and Warranties. MacroPore shall refrain from taking any action or inaction, except with the prior written consent of Medicis, which would render any representation, warranty, covenant, or agreement of MacroPore in this Agreement inaccurate or breached in any material respect as of the Closing. Between the date hereof and the Closing, MacroPore will use all reasonable efforts to continue to operate the Field of Use Business according to its ordinary and usual course of business consistent with past practice.
- 5.3) <u>Pre-Closing Access to Information and Records.</u> Subject to Section 12.13, prior to the Closing, MacroPore shall permit Medicis and such persons as it may designate, at Medicis's expense, to visit and inspect any of the properties of MacroPore relating to the Specified Assets and to examine the MacroPore Product Information and MacroPore Regulatory Information and take copies and extracts there from, all at reasonable times and upon reasonable notice.
- 5.4) <u>Further Assurances</u>. At such times and from time to time on and after the Closing Date, upon reasonable request by Medicis, MacroPore will execute, acknowledge and deliver, or will cause to be done, executed, acknowledged and delivered, all such further acts, deeds, assignments, transfers, conveyances, powers of attorney, and assurances that may reasonably be required for the better conveying, transferring, assigning, delivering and confirming ownership to, or reducing to the possession of, Medicis or its respective successors and assigns all of the Specified Assets and to otherwise carry out the purposes of this Agreement.
- 5.5) Training. MacroPore shall make available to Medicis, at MacroPore's facility and during regular business hours, knowledgeable MacroPore employees for the purpose of training Medicis employees in all aspects of the manufacturing processes of the Field of Use Business. Such training is not to exceed 300 (three hundred) hours in aggregate, or if so shall be billed at an hour rate that is competitive with the then going rate for such services, but in any case, shall not exceed a rate of \$250 per hour, per employee. The training period shall not exceed one year from the date of Closing.
- 5.6) <u>Back-Up Supply</u>. For a period from the closing date up to and including December 1, 2004 MacroPore shall act as a back-up supplier to Medicis supplying its requirements (not otherwise provided for or self-manufactured) for Field of Use Bioabsorbable Implants ("Products") as manufactured by MacroPore in the Field of Use Business as follows:
  - 5.6.1) <u>Purchase Price.</u> The purchase price per unit of Product to Medicis under this Section 5.6 shall be as follows:
    - (a) for duration of the back-up supply period, the transfer price to be paid to MacroPore per unit (except as specified in section (b) below) shall be MacroPore's

Manufacturing Cost as specified for each product on the attached **Schedule 5.6** ("Cost Statements") plus a \*\*\* handling fee; and

- (b) Medicis agrees to purchase from MacroPore the first \*\*\* units of TiMesh / SurgiWrap product ("Combination Product") ordered by or for \*\*\* from Medicis, and MacroPore agrees to sell the same to Medicis at a price of \*\*\* per Unit. This arrangement lasts for a period of twelve months after Closing. After the first \*\*\* units are purchased from MacroPore, any additional Combination Product requirements of Medicis during the initial 12 months shall be supplied to on the terms specified in Section 5.6.1 (a) above.
  - (c) the minimum acceptable order for any specific Product shall be 100 units.
- 5.6.2) <u>Purchase Order Payments.</u> Unless otherwise specified in this agreement, all payments to be made by Medicis pursuant to this Agreement shall be due and payable in full within 30 days after the date of invoice by MacroPore. Any payments due hereunder which are not paid on the date such payments are due shall bear interest at the lesser of one and one-half percent (1-1/2%) per month or the maximum rate permitted by law, calculated on the number of days such payment is delinquent. This Section 5.6 shall in no way limit any other remedies available to MacroPore.
- 5.6.3) Purchase Orders. Medicis shall submit purchase orders for Products to MacroPore in writing, whether by mail, telecopier, or otherwise. Each purchase order shall, at a minimum, set forth the product numbers, quantities, delivery dates, and shipping instructions and shipping addresses for all Products ordered. Each purchase order shall be subject to and governed by the terms of this Agreement. Purchase orders shall be binding upon MacroPore to the extent submitted at least 60 days in advance of the earliest scheduled delivery date for such order. The terms and conditions of this Agreement shall so govern and supersede any additional or contrary terms set forth in Medicis's purchase order or any MacroPore or Medicis acceptance, confirmation, invoice or other document. For certain products it may be necessary to temporarily transfer certain molds or other Specified Assets, including tooling, to MacroPore's facility to complete manufacturing. Medicis agrees to cooperate and bear the entire cost and risk of such transfer if and when such transfers are required, subject to MacroPore's obligation to use reasonable care to protect and maintain such assets.
- 5.6.4) Modification of Orders. Medicis may cancel or reschedule purchase orders for Products only with MacroPore's prior written approval. Notwithstanding the foregoing, any purchase order may be cancelled by Medicis as to any Products that are not delivered within 60 days after the delivery date requested by Medicis pursuant to a purchase order, and any such cancellation shall not limit or affect any contract remedies available to Medicis with respect thereto. Any such cancellation by Medicis must be by written notice to MacroPore given within 10 business days after such 60th day.
- 5.6.5) <u>Delivery Terms.</u> All deliveries of Products shall be F.O.B. MacroPore's facility in California. MacroPore shall have no further responsibility for risk of damage to or loss or delay of Products after their delivery at the aforesaid F.O.B point. All Product deliveries shall be made by a common carrier specified by Medicis or, in the event that no carrier shall have been specified by Medicis on or before the date 15 days before the requested shipment date, a reputable common carrier selected by MacroPore.
- 5.6.6) <u>Product Changes.</u> MacroPore shall not, without Medicis's prior written consent, modify the Specifications for a Product in a manner that materially affects the performance or regulatory approval status of the Product or materially increases Medicis's costs or expenses.
- 5.6.7) Manufacture and Supply of Products. MacroPore shall manufacture Products in accordance with the Field of Use Business and ship such Products to Medicis in the quantities ordered by Medicis as contemplated by this Section 5.6. MacroPore shall be responsible for packaging in accordance with packaging specifications to be mutually agreed upon by Medicis and MacroPore, and

<sup>\*\*\*</sup> Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

for any necessary sterilization of Products purchased under this Agreement in accordance with the conduct of the Field of Use Business.

- 5.6.8) Good Manufacturing Practices/Quality Systems Regulations. MacroPore shall be responsible for compliance with present and future applicable statutes, laws, ordinances and regulations of national, federal, state and local governments now or hereafter in effect relating to the manufacture and/or quality of Products. Without limitation of the foregoing, MacroPore represents and warrants to Medicis that all Products sold and delivered to Medicis under this Section 5.6 will have been manufactured and labeled in accordance with all applicable requirements and fully comply with the contractual requirements and Specifications. MacroPore shall cause Medicis's regulatory personnel to be provided with reasonable access from time to time to the facilities and records of MacroPore for the purpose of confirming MacroPore's compliance with this Section 5.6.8.
- 5.6.9) Inspection of Product. Medicis shall inspect all Products promptly upon receipt thereof, and in the event of any shortage, damage or discrepancy in or to a shipment of Products or in the event any of the Products fail to comply with the then current Specifications for the Products (except for latent defects not readily observable by Medicis), Medicis shall report the same to MacroPore within 15 days after delivery thereof to Medicis and furnish such written evidence or other documentation as MacroPore reasonably may deem appropriate. If the substantiating evidence delivered by Medicis reasonably demonstrates that such shortage, damage or discrepancy or nonconformity with Specifications existed at the time of delivery of the Products, Medicis may return the Products to MacroPore, at MacroPore's expense, and, at Medicis's request, MacroPore shall use all reasonable efforts to deliver promptly replacement Products to Medicis in accordance with the delivery procedures set forth herein.
- 5.6.10) Warranty of Product. MacroPore represents and warrants to Medicis that all Products sold under this Section 5.6 will have been manufactured, labeled, packaged and sold to Medicis in accordance with all applicable laws and regulations, including (as applicable) FDA GMP requirements, European Medical Device Directive requirements and ISO 9001 certification or successor requirements. Upon prior written notice, MacroPore shall cause Medicis's regulatory personnel to be provided with reasonable access from time to time to the facilities and records of MacroPore for the purpose of confirming MacroPore's and the Product's compliance with the applicable laws and regulations. MacroPore warrants to that Products shall, when delivered to Medicis, meet the Specifications and, for a period of one (1) year be free from defects in materials and workmanship. MacroPore will repair or replace any Product that it reasonably determines was defective at the time of shipment to Medicis or that does not conform to the express warranties herein; provided, however, that MacroPore shall have no obligation under this warranty to repair or make replacements necessitated in whole or in part by accidents; failure to maintain in accordance with any transportation, storage, handling, or maintenance, instructions supplied by MacroPore; damage by acts of nature, vandalism, burglary, neglect or misuse; or other fault or negligence of Medicis or (except for any strict liability of MacroPore) the customer or user. Before returning any Product alleged to be defective, Medicis shall notify MacroPore in writing of the claimed defect and shall include the model and lot/serial number of such Product, as well as the number and date of the invoice therefor. No Product shall be returned without first obtaining a returned goods authorization from MacroPore, which authorization shall not be unreasonably withheld.

Limited Warranty for Back-Up Supply Product. THE EXPRESS WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY SPECIFICALLY DISCLAIMED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE. IN NO EVENT SHALL MACROPORE'S LIABILITY FOR PRODUCT WARRANTY INCLUDE ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

5.7) Supply of Raw Materials. Until the earlier of 12 months from the Closing Date; or (ii) the date when a supplier reasonably acceptable to Medicis commences delivery to Medicis of its requirements of such raw material related to the Field of Use Business pursuant to an agreement reasonably acceptable to Medicis, MacroPore shall, or shall cause its suppliers to, provide Medicis with such raw material at MacroPore's cost, including shipping and handling costs actually incurred; provided that Medicis shall provide MacroPore

non-cancelable purchase orders recognizing that lead times may be as much as four months, or, as otherwise required by MacroPore's supplier(s). MacroPore further agrees that it shall use commercially reasonable efforts to keep in effect all supply agreements between MacroPore and its suppliers, both before and during the period in which MacroPore is required to supply Medicis with its raw material requirements hereunder. MacroPore provides no warranty for the raw materials supplied hereunder, except for and only to the extent of that specific warranty, if any, actually provided to MacroPore by MacroPore's supplier. Payment terms shall be those specified in section 5.6.2.

- 5.8) <u>Post-Closing Access to Information and Records</u>. From and after the Closing, Medicis shall permit MacroPore and such persons as it may designate, at MacroPore's expense, access to the MacroPore Product Information and MacroPore Regulatory Information and to take copies and extracts there from, as and to the extent required for MacroPore to fulfill its obligations under Section 5.6 hereof and for any other legitimate purpose, all at reasonable times and upon reasonable notice.
- 5.9) Employee Solicitation / Sales Force Transition. Medicis shall be allowed, but is not obligated, to solicit the Field of Use Business employees as set forth in 3.11 (b) of the Disclosure Letter for a period of 30 days following the Closing. MacroPore and Medicis agree that MacroPore shall continue operate and support the U.S. SurgiWrap sales force for up to a period of 30 days after Closing on behalf of Medicis, and Medicis agrees to pay any and all costs and expenses of MacroPore attributable to such activities during this period, however, only in so far as those costs do not exceed \$100,000 USD. At the conclusion of the 30 day period MacroPore shall pass all operations of the sales force to Medicis and MacroPore is free to transfer or terminate any employee of the sales force that Medicis has been entitled to solicit pursuant to this Agreement. Payment terms shall be those specified in section 5.6.2.
- 5.10) No Solicitation of Other Offers. Prior to the Closing and after signing the Letter of Intent, neither MacroPore nor any of its Affiliates shall directly or indirectly discuss or negotiate with any person (other than Medicis and its agents), encourage the submission of inquiries, proposals or offers from any person (other than Medicis), or otherwise provide information to any other person, with respect to the sale of the Specified Assets or the sale, licensing, distribution or other disposition of any of the Specified Assets.
- 5.11) <u>Maintenance of Specified Assets</u>. Until MacroPore shall have effected the transfer of the Specified Assets, MacroPore shall maintain the condition of the Specified Assets so that such Specified Assets continue to be suitable for the uses for which they are used by MacroPore in the Field of Use Business, and are in normal operating condition and free from any significant defects, ordinary wear and tear excepted, including the usual and customary service and maintenance of such Specified Assets.
- 5.12) Enforcement of Agreement(s). If (i) the employment or engagement of any MacroPore employee or consultant is terminated and, following such termination, MacroPore obtains knowledge that such employee or consultant has used or disclosed the confidential information of MacroPore with respect to the Field of Use Business in violation of the terms of any agreement between such employee or consultant and MacroPore, or (ii) any other individual or entity has used or disclosed the confidential information of MacroPore with respect to the Field of Use Business in violation of the terms of any agreement between such individual or entity and MacroPore, then MacroPore shall immediately notify Medicis in writing of such violation. If Medicis determines in good faith that such violation will result in material harm to Medicis's manufacture and/or sale of Field of Use Bioabsorbable Implants, then MacroPore will at Medicis's expense, to the extent enforceable under California law, use its reasonable efforts to enforce any rights of MacroPore, its successors or assigns available under such agreements to prevent further violation by such party.
- 5.13) <u>International Sales.</u> Medicis agrees to assume all rights and obligations relating to each international distribution agreement identified in **Schedule 5.13** ("International Distributor List"), as well as any distribution agreement for the territory of Japan entered into prior to the Closing with Medicis prior written consent. Medicis also agrees to assume all rights and obligations of the manufacturing and distribution agreement (if any) for Combination Product Field of Use Bioabsorbable Implants with \*\*\* as attached hereto in Schedule 5.13 b (if any). In the event that (after the Section 5.6 backup supply period) Medicis or any successor

<sup>\*\*\*</sup> Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

of Medicis fails to supply the contractual requirements for the Japanese distribution partner (as contemplated by the Business Development Agreement), and fails to cure such deficiency within 60 days after delivery of written notice of such failure from the Japanese distributor or MacroPore, MacroPore shall have the right and be granted a limited exclusive license to manufacture and sell Field of Use Bioabsorbable Implants to the Japanese Distributor in amounts sufficient to meet the distributors requirements for the remainder of the initial Japanese distribution agreement or until Medicis proves to the reasonable satisfaction of the distributor that they are able to supply the product required by the distributor as provided in the distribution agreement. During any such exercise of the limited license Medicis shall be paid a royalty equal to 10% of the gross revenues (after deduction of Manufacturing Costs) from such sales.

## ARTICLE 6 CONDITIONS TO MEDICIS'S OBLIGATIONS

The obligations of Medicis under this Agreement shall, at its option, be subject to the satisfaction, on or prior to the Closing Date, of all of the following conditions:

- 6.1) Representations, Warranties and Covenants. The representations and warranties of MacroPore herein shall be true in all material respects on the Closing Date with the same effect as though made at such time. MacroPore shall in all material respects have performed all of its obligations and complied with all of its covenants herein prior to or as of the Closing Date. MacroPore shall have delivered to Medicis a certificate in form and substance satisfactory to Medicis dated as of the Closing Date and executed by its chief executive officer to all such effects.
- 6.2) <u>Approvals; Consents</u>. All permissions, releases, Consents or approvals, governmental or otherwise, necessary on the part of MacroPore and Medicis to consummate the transactions contemplated hereunder shall have been obtained.
- 6.3) <u>Litigation Affecting Closing.</u> No suit, action or other proceeding shall be pending or, to MacroPore's knowledge, threatened by any third party or by or before any court or governmental agency in which it is sought to restrain or prohibit or to obtain damages or other relief in connection with this Agreement or the consummation of the transactions contemplated by this Agreement, and no governmental investigation that might result in any such suit, action or other proceeding shall be pending or threatened.
- 6.4) <u>Transfer Documents</u>. Medicis shall have received from MacroPore such instruments of transfer, assignment, conveyance and other instruments sufficient to convey, transfer and assign to Medicis all right, title and interest in the Specified Assets, free and clear of all Liens, all in form and substance reasonably satisfactory to Medicis and its counsel, including but not limited to the Assignment and Assumption Agreement and the Bill of Sale.
- 6.5) <u>Transaction Documents</u>. MacroPore shall have executed and delivered the License Agreement, the Bill of Sale, and the Assignment and Assumption Agreement.

## ARTICLE 7 CONDITIONS TO MACROPORE'S OBLIGATIONS

The obligations of MacroPore under this Agreement shall, at its option, be subject to the satisfaction, on or prior to the Closing Date, of all of the following conditions:

- 7.1) Representations, Warranties and Covenants. The representations and warranties of Medicis herein, shall be true in all material respects on the Closing Date with the same effect as though made at such time. Medicis shall in all material respects have performed all of its obligations and complied with all of its covenants herein prior to or as of the Closing Date.
- 7.2) <u>Approvals; Consents</u>. All permissions, releases, Consents or approvals, governmental or otherwise, necessary on the part of MacroPore and Medicis to consummate the transactions contemplated hereunder shall have been obtained.

- 7.3) <u>Litigation Affecting Closing.</u> No suit, action or other proceeding shall be pending or to Medicis knowledge, threatened by any third party or by or before any court or governmental agency in which it is sought to restrain or prohibit or to obtain damages or other relief in connection with this Agreement or the consummation of the transactions contemplated by this Agreement, and no governmental investigation that might result in any such suit, action or other proceeding shall be pending or threatened
- 7.4) <u>Transaction Documents</u>. Medicis shall have executed and delivered the Assignment and Assumption Agreement, the License Agreement, and the letter required by Section 2.9 hereof (allocation of purchase price), and the Business Development Agreement.

# ARTICLE 8 CLOSING

- 8.1) <u>Closing Date</u>. The consummation of the transactions provided for herein (the "Closing") shall take place at 9:00 a.m. (California time) on or before Wednesday, January 21, 2004, (the "Closing Date"). The Closing shall take place at such place or in such other manner (<u>e.g.</u>, by telecopy exchange of signature pages with originals to follow by overnight delivery) as the parties hereto may agree. Each party agrees to use its reasonable best efforts to ensure that all closing conditions to the other party's obligations are satisfied at or prior to the Closing.
- 8.2) <u>Proceedings</u>. All proceedings taken and all documents executed and delivered by the parties hereto at the Closing shall be deemed to have been taken and executed simultaneously and no proceedings shall be deemed taken nor any documents executed or delivered until all have been taken, executed and delivered.

## ARTICLE 9 INDEMNIFICATION

- 9.1) <u>Indemnification of Medicis</u>. MacroPore shall indemnify, defend and hold harmless Medicis and each of its subsidiaries, divisions, officers, directors, employees, and shareholders from and against and in respect of any and all demands, claims, actions or causes of action, assessments, losses, damages, liabilities, interest and penalties, costs and expenses (including, without limitation, reasonable legal fees and disbursements incurred in connection therewith and in seeking indemnification therefore, and any amounts or expenses required to be paid or incurred in connection with any action, suit, proceeding, claim, appeal, demand, assessment or judgment) whether or not involving a third-party claim (collectively "Indemnifiable Losses"), directly or indirectly resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of any one or more of the following:
  - (a) Any breach of any representation, warranty, covenant, obligation or agreement of MacroPore contained in this Agreement or any agreement, certificate or document executed and delivered by MacroPore pursuant hereto or in connection with any of the transactions contemplated by this Agreement; or
  - (b) Any liability or claimed liability of MacroPore not expressly assumed by Medicis pursuant to this Agreement or any other agreement.
- 9.2) <u>Indemnification of MacroPore</u>. Medicis shall indemnify, defend and hold harmless MacroPore and each of its subsidiaries, divisions, officers, directors, employees and shareholders from and against and in respect of any and all Indemnifiable Losses resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of the following:
  - (a) Any breach of any representation, warranty, covenant, obligation or agreement of Medicis contained in this Agreement or any agreement, certificate or document executed and delivered by Medicis pursuant hereto or in connection with the transactions contemplated by this Agreement; or
  - (b) Any liability of MacroPore expressly assumed by or required to be borne by Medicis pursuant to this Agreement or any other agreement; or

- (c) Any liability of MacroPore for personal injury to Medicis employees while receiving training at MacroPore's facility pursuant to the terms of this Agreement, unless due to the gross negligence or willful misconduct of MacroPore or its employees concerned.
- (d) Any liability arising from the operation of the Business or use of the Specified Assets, accruing after the Closing.

#### 9.3) Third-Party Claims and Other Claims.

- If a claim by a third party is made against any indemnified party, and if the indemnified party (a) intends to seek indemnity with respect thereto under this Article 9, such indemnified party shall promptly notify the indemnifying party of such claim; provided, however, that failure to give timely notice shall not affect the rights of the indemnified party so long as the failure to give timely notice does not adversely affect the indemnifying party's ability to defend such claim against a third party. If the indemnifying party acknowledges that the indemnified party is entitled to indemnification hereunder for such claim, the indemnifying party shall be entitled to settle or assume the defense of such claim, including the employment of counsel reasonably satisfactory to the indemnified party. If the indemnifying party elects to settle or defend such claim, the indemnifying party shall notify the indemnified party within thirty (30) days (but in no event less than twenty (20) days before any pleading, filing or response on behalf of the indemnified party is due) of the indemnifying party's intent to do so. If the indemnifying party elects not to settle or defend such claim or fails to notify the indemnified party of the election within thirty (30) days (or such shorter period provided above) after receipt of the indemnified party's notice of a claim of indemnity hereunder, the indemnified party shall have the right to contest, settle or compromise the claim without prejudice to any rights to indemnification hereunder. Regardless of which party is controlling the settlement or defense of any claim, (i) both the indemnified party and indemnifying party shall act in good faith, (ii) the indemnifying party shall not thereby permit to exist any lien, encumbrance or other adverse charge upon any asset of any indemnified party or of its subsidiaries, (iii) the indemnifying party shall permit the indemnified party to participate in such settlement or defense through counsel chosen by the indemnified party, with all fees, costs and expenses of such counsel borne by the indemnified party, unless the indemnifying party and indemnified party have available inconsistent defenses to such third-party claim, in which case such fees, costs and expenses shall be borne by the indemnifying party, (iv) no entry of judgment or settlement of a claim may be agreed to without the written consent of the indemnified party, which consent shall not be unreasonably withheld, and (v) the indemnifying party shall promptly reimburse the indemnified party for the Indemnified Amount as incurred by the indemnified party pursuant to this Article 9. So long as the indemnifying party is reasonably contesting any such third party claim in good faith as permitted herein, the indemnified party shall not pay or settle any such claim (or, if it does, it shall not be indemnified for such settlement amount). The controlling party shall upon request deliver, or cause to be delivered, to the other party copies of all correspondence, pleadings, motions, briefs, appeals or other written statements relating to or submitted in connection with the settlement or defense of any such claim, and timely notices of any hearing or other court proceeding relating to such claim.
- (b) A claim for indemnification for any matter not involving a third-party claim may be asserted by notice to the party from whom indemnification is sought. Such notice shall state the amount of Indemnifiable Losses, if known, the method of computation thereof, and contain a reference to the provisions of the Agreement in respect to which such right of indemnification is claimed or arises. If the party from whom indemnification is sought disputes such claim, then the parties shall then follow the dispute resolution mechanism set forth in Section 12.7.
- 9.4) <u>Indemnification Limitations</u>. MacroPore shall have no liability (for indemnification or otherwise) with respect to claims under Section 9.1 until the total of all Indemnifiable Losses with respect to such matters, when added to the amount of all claims of Medicis to indemnification under this Agreement and the License Agreement exceeds Four Hundred Thousand Dollars (\$400,000) (the "Threshold Amount") and then only for the amount by which such Indemnifiable Losses exceed the Threshold Amount. Notwithstanding anything to the contrary in the Agreement, the total amount of Indemnifiable Losses that MacroPore shall be obligated to pay to Medicis in the aggregate shall not exceed 50 % of the total Purchase Price actually paid. The total amount of Indemnifiable Losses that Medicis shall be obligated to pay to MacroPore in the aggregate shall not exceed 50% of the Purchase Price. The Threshhold Amount under this section 9.4, does also apply for any liability of Medicis. For purposes of these Section 9.4 limitations, contractual obligations of Medicis to pay

specific or calculable amounts of money to MacroPore shall not be so limited to enable Medicis to avoid any purchase payment or product payment obligations to MacroPore.

- 9.5) <u>Cooperation as to Indemnified Liability</u>. Each party hereto shall cooperate fully with the other parties with respect to access to books, records, or other documentation within such party's control, if deemed reasonably necessary or appropriate by any party in the defense of any claim that may give rise to indemnification hereunder.
- 9.6) <u>Tax Treatment</u>. The parties shall report any indemnification payment made pursuant to this Article 9 as a purchase price adjustment unless otherwise required by law.

### ARTICLE 10 TERMINATION

- 10.1) <u>Termination Prior to Closing</u>. Notwithstanding any contrary provisions of this Agreement, the respective obligations of the parties hereto to consummate the Closing may be terminated and abandoned at any time at or before the Closing only as follows:
  - (a) By and at the option of Medicis if the Closing shall not have occurred by January 21, 2004; provided that Medicis shall not have breached in any material respect its obligations under this Agreement in any manner that shall have been the proximate cause of, or resulted in, the failure to consummate the Closing.
  - (b) By and at the option of MacroPore if the Closing shall not have occurred by January 21, 2004; provided that MacroPore shall not have breached in any material respect its obligations under this Agreement in any manner that shall have been the proximate cause of, or resulted in, the failure to consummate the Closing.
  - (c) At any time, without liability of any party to the others, upon the mutual written consent of MacroPore and Medicis.
  - 10.2) <u>Medicis Termination</u>. If at any time at or before the Closing Date:
  - (a) MacroPore fails to comply with all or any of its obligations contained in this Agreement whether to be performed on or before the Closing Date; or
  - (b) Medicis becomes aware of any fact or event (not being effect or event provided for by the Agreement) which in its reasonable opinion:
    - (i) is a material breach of or in any way materially inconsistent with any of the representations or warranties contained in Section 3 or would be a material breach of or in any way materially inconsistent with any of the representations or warranties contained in Section 3 when repeated at the Closing Date; or
    - (ii) is evidence that any of the representations or warranties is misleading in any respect material to Medicis or that any obligation of MacroPore has not been or will not be complied with within the period required by this Agreement; or
    - (iii) would affect the willingness of a prudent purchaser for value of the Field of Use Business to complete its purchase or the price which such purchaser would be prepared to pay for the Field of Use Business or the terms of such purchase; or
    - (iv) would be likely to prevent or hinder Medicis from having effective use and possession of or from disposing of any of the Specified Assets or from carrying on the Field of Use Business following the Closing Date in substantially the same manner as it is now carried on; or

- (c) any of the Specified Assets are effected by loss or damage on account of fire, flat, explosion, death, strike or any other course (whether similar or not) which in the reasonable opinion of Medicis materially and adversely affects the value of the Specified Assets or the Field of Use Business or the manner in which it can continue to be carried on; or
- (d) circumstances occur with respect to the Field of Use Business which would have a material adverse effect on the Field of Use Business and/or if, between the date of signing this Agreement and the Closing Date, there is any material adverse change, either individually or in the aggregate, in the assets, financial situation or operational results of the Field of Use Business.

then Medicis may elect to withdraw from this Agreement without prejudice to its remedies against MacroPore.

10.3) No Waiver. Nothing contained in this Article 10 shall be construed as a release or waiver by any party hereto of any of its rights against any other party arising out of any breach of this Agreement by the other party.

#### ARTICLE 11 COMPETITION RESTRAINT

- 11.1) For a period of [2] years after the Closing Date MacroPore shall not (except in connection with its Development and Supply arrangements with Medtronic for the Spinal Field, and products of MacroPore for use in the Field of Regenerative Medicine):
  - (a) develop, manufacture or distribute Bioabsorbable Film Implants (hereinafter referred to as "Competitive Products") except as provided for in this Agreement;
  - (b) establish an enterprise which develops, manufactures or distributes Competitive Products, acquire such enterprise, participate in any manner whatsoever in such enterprise and support such enterprise in any other manner;
  - (c) compete directly or indirectly in any other manner in the business of developing, manufacturing or distributing Competitive Products or support such competition by third parties, e.g. by contacting customers of the Field of Use Business.
- 11.2 This competition restraint shall not apply to the acquisition of shares, which are quoted on the stock exchange in competitive companies, for the purpose of a mere capital investment with a maximum participation of 10 %.
- 11.3 The competition restrained pursuant to section 11.1 shall apply to all countries in which MacroPore presently conducts and solicits all or part of its Field of Use Business or has conducted or solicited any Field of Use Business during the last five years prior to the Closing Date, including, but not limited to the countries which are listed in Schedule 5.13.

### ARTICLE 12 MISCELLANEOUS

- 12.1) <u>Cooperation</u>. The Parties shall, also after the Closing Date, execute such documents and do such other things and acts as may still be necessary or desirable to perform and fully carry out the terms and purposes of this Agreement.
- 12.2 <u>Complete Agreement</u>. The Schedules and Exhibits to this Agreement shall be construed as an integral part of this Agreement to the same extent as if they had been set forth verbatim herein. This Agreement and the Schedules and Exhibits hereto constitute the entire agreement between the parties hereto with respect to the subject matter hereof and supersede all prior agreements whether written or oral relating hereto.
- 12.3) <u>Survival of Representations and Warranties</u>. The representations and warranties contained in this Agreement shall survive and remain in full force and effect for one year after the Closing Date.

- 12.4) <u>Waiver, Discharge, Amendment, Etc.</u> The failure of any party hereto to enforce at any time any of the provisions of this Agreement, shall in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of the party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. Any amendment to this Agreement shall be in writing and signed by the parties hereto.
- 12.5) <u>Notices</u>. All notices hereunder shall be deemed given if in writing and delivered personally or sent by telecopy (with confirmation of transmission) or certified mail (return receipt requested) or reputable courier service to the parties at the following addresses (or at such other addresses as shall be specified by like notice):

if to Medicis, to:

Managing Director Medicis Ventures Management GmbH Poschingerstr. 9 D-81679 München, Germany Fax

and if to MacroPore, to:

MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121 Attention: Christopher J. Calhoun FAX (858) 458-0995

with separate copies thereof addressed to:

MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121 Attention: In-House Counsel FAX (858) 458-0994

Any party may change the above specified recipient and/or mailing address by notice to all other parties given in the manner herein prescribed. All notices shall be deemed given on the day when actually delivered as provided above (if delivered personally, by telecopy or by reputable courier service) or on the date that is three days after the date shown on the return receipt (if delivered by mail).

- 12.6) <u>Expenses</u>. Except as otherwise expressly provided herein, Medicis and MacroPore shall each pay their own expenses (including, but not limited to, all compensation and expenses of counsel, financial advisors, consultants, actuaries and independent accountants) incident to this Agreement and the preparation for, and consummation of, the transactions provided for herein.
- 12.7) Governing Law and Arbitration. This Agreement shall be governed by and interpreted in accordance with the laws of the State of California, including all matters of construction, validity, performance and enforcement, without giving effect to principles of conflict of laws and without application of the United Nations Convention for the International Sale of Goods. Any dispute arising out of or relating to this Agreement (including the formation, interpretation or alleged breach thereof) shall be settled by final and binding alternative dispute resolution conducted under the auspices of, and in accordance with, the Commercial Arbitration Rules of the American Arbitration Association, in San Francisco, California. The results of such arbitration proceedings shall be binding upon the parties hereto, and judgment may be entered upon the arbitration award in any court having jurisdiction thereof. Notwithstanding the foregoing, either party may seek interim injunctive relief from any court of competent jurisdiction. Any legal actions or proceedings relating to the Agreement or the enforcement of any provision of the Agreement shall be brought or otherwise commenced

in California (and if in court, in any state or federal court located in the California). Each of the parties hereto expressly and irrevocably consents and submits to the jurisdiction of each state and federal court located in California in connection with any such legal proceedings.

- 12.8) Public Announcement. In the event any party proposes to issue any press release or public announcement concerning any provisions of this Agreement or the transactions contemplated hereby, such party shall so advise the other parties hereto, and the parties shall thereafter use their best efforts to cause a mutually agreeable release or announcement to be issued. Neither party will publicly disclose or divulge any provisions of this Agreement or the transactions contemplated hereby without the other party's written consent, except as may be required by applicable law or stock exchange regulation, and except for communications to such party's employees or customers or investors or prospective investors (subject to appropriate confidentiality obligations); provided that, prior to disclosure of any provision of this Agreement that either party considers particularly sensitive or confidential to any governmental agency or stock exchange, the parties shall cooperate to seek confidential treatment or other applicable limitations on the public availability of such information.
- 12.9) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and the successors or assigns of the parties hereto; provided that the rights and obligations of MacroPore herein may not be assigned except that all such rights and obligations of MacroPore may be assigned to an entity that will succeed to substantially all of the polylactic-acid-related business of MacroPore, and the rights of Medicis may be assigned only to an Affiliate of Medicis or to such business organization that shall succeed to substantially all of the Field of Use Business of Medicis or of such subsidiary to which this Agreement relates.
- 12.10) <u>Titles and Headings; Construction</u>. The titles and headings to Sections herein and Exhibits and Schedules hereto are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties hereto or their respective permitted successors or assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.
- 12.11) Severability. If any provision of this Agreement is held invalid, unenforceable or void by a court of competent jurisdiction, the remaining provisions shall nonetheless be enforceable according to their terms. In such case, the parties agree to negotiate in good faith to create an enforceable contractual provision to achieve the purpose of the invalid provision. Further, if any provision is held to be overbroad as written, such provision shall be deemed amended to narrow its application to the extent necessary to make the provision enforceable according to applicable law and shall be enforced as amended.
- 12.12) <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed as original and all of which together shall constitute one instrument.
- 12.13) Confidentiality. Each party will (i) keep confidential, and not disclose to others, all Confidential Information of the other party, and (ii) not use any of the other party's Confidential Information for its own direct or indirect benefit, or the direct or indirect benefit of any third party, except that a party may use the other party's Confidential Information to the extent necessary to perform its duties and obligations, or to enforce such party's rights, under this Agreement, or to exercise such party's rights under the License Agreement. The foregoing shall not prohibit disclosures: (x) made to the receiving party's sub-distributors, employees or agents who have a "need to know" the other party's Confidential Information to the extent such disclosure is necessary to perform such party's duties and obligations, or to enforce such party's rights, under this Agreement or the License Agreement, provided that such sub-distributors, employees or agents agree in writing or are otherwise actually compelled to comply with the obligations of this Section 12.13, and the receiving party remains directly responsible to the disclosing party for their compliance; or (y) compelled to be made by any requirement of law or pursuant to any legal, regulatory or investigative proceeding before any court, or governmental or regulatory authority, agency or commission so long as the party so compelled to make disclosure of Confidential Information of the other party provides prior written notice to such other party so that the other party may seek a protective order or other remedy to protect the confidentiality of the Confidential Information and/or waive the compelled party's compliance with this Section 12.13, provided that all such information so disclosed (other than in a way which makes it generally available to the public) shall remain Confidential Information for all

other purposes. If such protective order, other remedy or waiver is not obtained by the time the compelled party is required to comply, the compelled party may furnish only that portion of the Confidential Information of the other party that it is legally compelled, in the opinion of counsel, to disclose and shall request, at the other party's expense, that such Confidential Information be accorded confidential treatment (if such procedure is available), including redaction of any payment terms specified herein. Each party further agrees to take appropriate measures to prevent any such prohibited disclosure of Confidential Information by its present and future employees, officers, agents, subsidiaries, or consultants. This Section shall survive indefinitely with respect to manufacturing information and, with respect to all other Confidential Information, for a period of three years from and after the Closing or any termination of this Agreement.

(Remainder of page intentionally blank; signatures follow on next page)

IN WITNESS WHEREOF, each of the parties has caused this Asset Purchase Agreement to be executed in the manner appropriate for each, as of the date first above written.

MEDICIS Ventures Management GmbH

By /s/ Kai Deusch.

Its Managing Director.

MACROPORE BIOSURGERY, INC.

By /s/ Christopher J. Calhoun

Its Chief Executive Officer

### SCHEDULES:

2.2 – Open Orders

3.13 – Customer List

5.6 – Cost Statements

5.13 – International Distributor List

#### **EXHIBITS:**

A – License Agreement

B – Letter of Intent

C – Associate Investors List

D – Assignment and Assumption Agreement

E – Bill of Sale F – Letter of Assets

G – Business Development Agreement

H – Excluded Assets

I – Inventory

J – Express Liabilities

pdf

### EXHIBIT A LICENSE AGREEMENT

#### LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is made and entered into as of December 13, 2003, (the "Effective Date") between **Medicis Ventures Management GmbH**, ("Medicis"), a German corporation, and **MacroPore Biosurgery, Inc.**, a Delaware corporation ("MacroPore").

#### WITNESSETH:

WHEREAS, MacroPore and Medicis have entered into an Asset Purchase Agreement dated December 13, 2003 pursuant to which MacroPore is selling Medicis certain assets (the "Purchase Agreement"); and

WHEREAS, as part of the transaction between the parties relating to the Purchase Agreement, Medicis will license to MacroPore certain rights to intellectual property in accordance with the terms of the Agreement and the Purchase Agreement; and

WHEREAS, the execution and delivery of this Agreement is a condition precedent to the consummation of the Purchase Agreement.

#### **AGREEMENTS:**

NOW THEREFORE, in consideration of the representations, warranties, covenants and agreements contained herein, and in the Purchase Agreement and for other valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties mutually agree as follows:

# ARTICLE 1 DEFINITIONS

- 1.1 <u>Specific Definitions</u>. As used in this Agreement, the following definitions and terms shall have the designated meanings:
- "Affiliate" has the meaning set forth in the Purchase Agreement.
- "Agreement" means this Agreement and all Exhibits hereto.
- "Bioabsorbable Film Implants" has the meaning set forth in the Purchase Agreement..
- "Confidential Information" means Intellectual Property (as defined below) disclosed (whether before or during the term of this Agreement) by or on behalf of one of the parties (the "disclosing party") to the other party (the "receiving party"), generated under this Agreement, or otherwise learned by the receiving party from the disclosing party, excluding information which:
- (a) was already in the possession of the receiving party before its original receipt from the disclosing party (provided that the receiving party is able to provide the disclosing party with written proof thereof and, if received from a third party, that such information was acquired without any party's breach of a confidentiality or non-disclosure obligation to the disclosing party related to such information);
  - (b) is or becomes part of the public domain by reason of acts not attributable to the receiving party;
- (c) shall have been disclosed to the receiving party from a source other than the disclosing party which source has rightfully obtained such information and has no direct or indirect obligation of non-disclosure or confidentiality to the disclosing party with respect thereto; or

(d) has been independently developed by or for the receiving party without breach of this Agreement or use of any Confidential Information of the other party (provided that the receiving party is able to provide the disclosing party with written proof thereof).

Notwithstanding the foregoing exceptions, all information learned by Medicis personnel during the time they were MacroPore personnel shall be Confidential Information of MacroPore and shall continue to be governed by their agreements with MacroPore.

"Expiration" or "Expired" means, with respect to a particular patent, the patent's expiration, abandonment, cancellation, disclaimer, award to another party other than Medicis or MacroPore in an interference proceeding, or declaration of invalidity or unenforceability by a court or other authority of competent jurisdiction (including final rejection in a re-examination or reissue proceeding).

"Field of Regenerative Medicine" has the meaning set forth in the Purchase Agreement.

"Intellectual Property" means U.S. and foreign patents and patent applications, trademarks, service marks and registrations thereof and applications therefor, copyrights and copyright registrations and applications, mask works and registrations thereof, know-how, trade secrets, inventions, discoveries, works of authorship, ideas, technology, data, information, methods, processes, drawings, designs, licenses, computer programs and software, and technical information including but not limited to information embodied in material specifications, processing instructions, equipment specifications, product specifications, confidential data, electronic files, research notebooks, invention disclosures, research and development reports and the like related thereto, and all amendments, modifications, and improvements to any of the foregoing.

"Invention" means any invention, discovery, works of authorship, know-how, trade secret, data, information, technology, process or concept, whether or not patented or patentable, and whether or not memorialized in writing.

"Knowledge" shall have the meaning set forth in the Purchase Agreement.

"<u>Licensed Product(s)</u>" means Bioabsorbable Film Implants covered by MacroPore Intellectual Property (as sold to Medicis pursuant the Purchase Agreement) and any related products.

"MacroPore Intellectual Property" means all Intellectual Property sold to Medicis pursuant to the Purchase Agreement, including, without limitation, the Patents and the Trademarks.

"Medicis" means Medicis Ventures Management GmbH and its Associate Investors and its and their Affiliates and successors.

"Patents" means: (a) the patents and patent applications, together with any patents that may issue based thereon, set forth on **Exhibit A**; (b) all continuation, divisional, re-issue, re-examination and substitution applications that may be filed by or for the benefit of Medicis based on the foregoing referenced patents or patent application, together with any patents that may issue based thereon; and (c) all foreign applications that may be filed by or for the benefit of Medicis based on the foregoing referenced patents and patent applications, together with all patents which may issue based thereon.

"Specified Assets" has the meaning set forth in the Purchase Agreement.

"Spinal Field" means all applications (including but not limited to: anti-adhesion, anti-scarring, minimizing the attachment of soft tissues, or soft or hard tissue support) related to the anatomy of the spine including, but not limited to, applications in the following: spinal fixation, stabilization and/or fusion, spinal cord coverings, exiting nerve root coverings, cauda equina coverings, lamina coverings and vertebral column-cervical, thoracic, lumbar and sacral.

"<u>Trademarks</u>" means any trademark and trademark applications, together with any registrations that may issue based thereon, set forth on **Exhibit B**.

1.2 <u>Other Terms</u>. Other terms may be defined elsewhere in the text of this Agreement and shall have the meaning indicated throughout this Agreement.

#### 1.3 Definitional Provisions.

The words "hereof," "herein," and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provisions of this Agreement.

The terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa.

References to an "Exhibit" are, unless otherwise specified, to one of the Exhibits attached to or referenced in this Agreement, and references to an "Article" or a "Section" are, unless otherwise specified, to one of the Articles or Sections of this Agreement.

The term "person" includes any individual, partnership, joint venture, corporation, limited liability company, trust, unincorporated organization or government or any department or agency thereof.

### ARTICLE 2 LICENSE TO MACROPORE

- 2.1 <u>Grant of License for the Spinal Field.</u> Subject to the terms and conditions of this Agreement, Medicis hereby grants to MacroPore and its Affiliates a worldwide, sublicensable (subject to the limitations set forth in Section 2.3 and 2.4 below), exclusive, royalty-free license to the MacroPore Intellectual Property to make, have made, use, import, offer to sell, sell and distribute Licensed Products in the Spinal Field and otherwise to commercialize and exploit the MacroPore Intellectual Property in the Spinal Field for a term equal to and determined by the length of the Spinal Development and Supply Agreement (including any extensions thereof) between MacroPore (including any of its affiliates, subsidiaries and assigns) and Medtronic, Inc. (including any of its affiliates, subsidiaries and assigns).
- 2.2 <u>Grant of License for the Field of Regenerative Medicine.</u> Subject to the terms and conditions of this Agreement, Medicis hereby grants to MacroPore and its Affiliates a perpetual, worldwide, sublicensable (subject to the limitations set forth in Section 2.3 below), non-exclusive, royalty-free license to the MacroPore Intellectual Property to make, have made, use, import, offer to sell, sell and distribute Licensed Products in the Field of Regenerative Medicine and otherwise to commercialize and exploit the MacroPore Intellectual Property in the Field of Regenerative Medicine and to perform MacroPore's back-up supply obligations as specified in the Purchase Agreement.
- 2.3 Restriction on Sublicense. MacroPore's right to sublicense its rights hereunder shall be limited as follows: (a) MacroPore shall be responsible for and indemnify Medicis for actions or omissions of sublicensees and any breach by the sublicensee (whether by action, omission or otherwise) shall be deemed a breach by MacroPore; (b) all sublicense agreements shall contain terms at least as protective of the MacroPore Intellectual Property as the terms in this Agreement; and (c) all sublicense agreements shall expressly state that Medicis retains all right, title, and interest in and to all MacroPore Intellectual Property, other than those rights herein licensed to MacroPore and its Affiliates, and there shall be no license or rights granted by implication.
- 2.4 <u>Efforts to Terminate License for the Spinal Field.</u> No more than one year prior and no less than six months prior to the termination of the current term of the MacroPore-Medtronic Development & Supply Agreement (On or about July 7, 2011), MacroPore shall give notice to Medtronic that the rights to the Spinal Field are to be terminated at

the end of the term in the event that Medtronic is not selling the Hydrosorb Bioabsorbable Film Implants for use in the spine.

# ARTICLE 3 ADDITIONAL OBLIGATIONS

3.1 <u>Maintain Intellectual Property in Force.</u> Medicis agrees to maintain in full force and effect (including, without limitation, preventing disclosures which would defeat trade secret status) all MacroPore Intellectual Property covering applications within the Spinal Field and/or the Field of Regenerative Medicine, or if Medicis wishes to abandon any such MacroPore Intellectual Property, it shall notify MacroPore in writing at least ninety days before any abandonment of such MacroPore Intellectual Property and MacroPore shall have the right, but not the obligation, to maintain such MacroPore Intellectual Property in full force and effect at its own expense. In the event that MacroPore elects to assume the prosecution or maintenance of any MacroPore Intellectual Property abandoned by Medicis, Medicis agrees to assign all right, title and interest to the abandoned property to MacroPore. Medicis also agrees that it shall not transfer any of its rights, title or interest in the MacroPore Intellectual Property to any third party without first notifying such third party of MacroPore's rights under this Agreement and obtaining such third party's express agreement to assume Medicis's obligations under this Agreement.

# ARTICLE 4 INTELLECTUAL PROPERTY

- Confidentiality. Each party will, for the term of this Agreement and thereafter, (i) keep confidential and 4.1 not disclose to others, all Confidential Information of the other party, and (ii) not use any of the other party's Confidential Information for its own direct or indirect benefit, or the direct or indirect benefit of any third party, except that a party may use the other party's Confidential Information to the extent necessary to perform its duties and obligations, or to enforce such party's rights, under this Agreement; and if the Confidential Information is part of the MacroPore Intellectual Property, MacroPore and its Affiliates may use it within the scope of the licenses granted in Sections 2.1 and 2.2 herein. The foregoing shall not prohibit disclosures: (x) made to the receiving party's distributors, employees or agents who have a "need to know" the other party's Confidential Information to the extent such disclosure is necessary to perform such party's duties and obligations, or to enforce such party's rights, under this Agreement, provided that such distributors, employees or agents agree in writing or are otherwise actually compelled to comply with the obligations of this Section 4.1, and the receiving party remains directly responsible to the disclosing party for their compliance; or (y) compelled to be made by any requirement of law or pursuant to any legal, regulatory or investigative proceeding before any court, or governmental or regulatory authority, agency or commission so long as the party so compelled to make disclosure of Confidential Information of the other party provides prior written notice to such other party so that the other party may seek a protective order or other remedy to protect the confidentiality of the Confidential Information and/or waive the compelled party's compliance with this Section 4.1, provided that all such information so disclosed (other than in a way which makes it generally available to the public) shall remain Confidential Information for all other purposes. If such protective order, other remedy or waiver is not obtained by the time the compelled party is required to comply, the compelled party may furnish only that portion of the Confidential Information of the other party that it is legally compelled, in the opinion of counsel, to disclose and shall request, at the other party's expense, that such Confidential Information be accorded confidential treatment (if such procedure is available), including redaction of any payment terms specified. Each party further agrees to take appropriate measures to prevent any such prohibited disclosure of Confidential Information by its present and future employees, officers, agents, subsidiaries, or consultants.
- 4.2 <u>Prosecution of Infringement of MacroPore Intellectual Property.</u> Each of MacroPore and Medicis shall promptly notify the other if it knows or has reason to believe that rights to the MacroPore Intellectual Property in the Spinal Field or Field of Regenerative Medicine are being infringed or misappropriated by a third party or that such infringement or misappropriation is threatened. MacroPore shall have the first right to prosecute such alleged infringement or misappropriation for MacroPore's own account. In the event MacroPore elects to prosecute such alleged infringement or misappropriation for its own account, MacroPore shall be solely responsible for payment of all of its own costs of prosecution and of negotiating settlement, and shall retain all proceeds from such prosecution.

MacroPore's prosecution of such infringement shall be by counsel reasonably acceptable to Medicis. MacroPore shall have the right to join Medicis as a party plaintiff to any such proceeding if MacroPore believes it is necessary to successfully prosecute such infringement or misappropriation. Medicis shall cooperate in connection with the initiation and prosecution by MacroPore of such suit. Notwithstanding the foregoing, Medicis shall have the right to initiate or join in any prosecution concerning the MacroPore Intellectual Property. In the event Medicis initiates or joins as a plaintiff in any such action involving the MacroPore Intellectual Property, MacroPore and Medicis shall attempt to agree on a sharing ratio which shall apply to the expenses of prosecution and to the proceeds of prosecution. If MacroPore and Medicis cannot agree, the ratio shall be that of the gross revenues for each party (for the preceding 12 months) attributable to the use of the MacroPore Intellectual Property to the extent that such gross revenues are consistent with the terms of this Agreement. In any case where MacroPore exercises its first right to prosecute, MacroPore shall control the handling of the case; provided, that if the alleged infringer challenges the validity of a claim of a Patent which has primary applicability outside the Spinal Field or the Field of Regenerative Medicine, Medicis shall control the handling of that portion of the case. If MacroPore elects not to prosecute any infringement involving the MacroPore Intellectual Property, then Medicis shall be entitled to prosecute it without any participation by MacroPore and to keep all proceeds from such prosecution.

# ARTICLE 5 REPRESENTATIONS AND WARRANTIES

- 5.1 <u>Representations of Medicis.</u> Medicis represents, warrants and covenants to MacroPore that:
- (a) Medicis is a corporation duly organized, validly existing, and in good standing under the laws of Germany and has full corporate power to conduct the business in which it is presently engaged and to enter into and perform its obligations under this Agreement.
- (b) Medicis has taken all necessary corporate action under the laws of the place of its incorporation and its governing documents to authorize the execution and consummation of this Agreement and this Agreement constitutes the valid and legally binding agreement of Medicis enforceable against Medicis in accordance with the terms hereof, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles.
- (c) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated herein will violate any provision of the governing documents of Medicis or any law, rule, regulation, writ, judgment, injunction, decree, determination, award or other order of any court or governmental agency or instrumentality, domestic or foreign, or conflict with or result in any breach of any of the terms of or constitute a default under or result in termination of or the creation or imposition of any mortgage, deed of trust, pledge, lien, security interest or other charge or encumbrance of any nature pursuant to the terms of any contract or agreement to which Medicis is a party or by which Medicis or any of its assets is bound.
  - 5.2 <u>Representations of MacroPore</u>. MacroPore represents, warrants and covenants to Medicis that:
- (a) MacroPore is a corporation duly organized, validly existing, and in good standing under the laws of the State of Delaware and has full corporate power to conduct the business in which it is presently engaged and to enter into and perform its obligations under this Agreement.
- (b) MacroPore has taken all necessary corporate action under the laws of the state of its incorporation and its certificate of incorporation and bylaws to authorize the execution and consummation of this Agreement and this Agreement constitutes the valid and legally binding agreement of MacroPore enforceable against MacroPore in accordance with the terms hereof, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles.
- (c) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated herein will violate any provision of the certificate and bylaws of MacroPore or any law, rule, regulation,

writ, judgment, injunction, decree, determination, award or other order of any court or governmental agency or instrumentality, domestic or foreign, or conflict with or result in any breach of any of the terms of or constitute a default under or result in termination of or the creation or imposition of any mortgage, deed of trust, pledge, lien, security interest or other charge or encumbrance of any nature pursuant to the terms of any contract or agreement to which MacroPore is a party or by which MacroPore or any of its assets is bound.

5.3 <u>Warranties.</u> Unless otherwise expressly provided herein, the MacroPore Intellectual Property is provided "as is" without any warranty whatsoever. Medicis disclaims all warranties, conditions, representations, indemnities and guarantees, whether express, implied or statutory, as to any matter whatsoever, including all implied warranties of merchantability, fitness for a particular purpose and non-infringement of third party rights. Especially, this applies to any infringement, alleged or otherwise, of patent, utility model, design, trade mark, copyright or any other Intellectual Property Rights in connection with the MacroPore Intellectual Property. Medicis disclaims any warranty or representation to any person other than MacroPore with respect to the MacroPore Intellectual Property.

# ARTICLE 6 INDEMNIFICATION

- 6.1 <u>Indemnification by Medicis</u>. Medicis shall indemnify, defend and hold harmless MacroPore and each of its subsidiaries, officers, directors, shareholders, employees, agents and affiliates (collectively, all such indemnitees are referred to in this Section as "MacroPore") against and in respect of any and all claims, demands, losses, obligations, liabilities, damages, penalties, deficiencies, actions, settlements, judgments, costs and expenses which MacroPore may incur or suffer or with which it may be faced (including reasonable costs and legal fees incident thereto or in seeking indemnification therefor), (referred to as "Costs") arising out of or based upon the breach by Medicis of any of its representations, warranties, covenants or agreements contained or incorporated in this Agreement or any agreement, certificate or document executed and delivered to MacroPore by Medicis in connection with the transactions hereunder. An amount for which MacroPore is entitled to indemnification pursuant hereto is referred to as an "Indemnified Amount."
- 6.2 <u>Indemnification by MacroPore</u>. MacroPore shall indemnify, defend and hold harmless Medicis and each of its subsidiaries, officers, directors, shareholders, employees, agents and affiliates (collectively, all such indemnitees are referred to in this Section as "Medicis") against and in respect of any and all claims, demands, losses, obligations, liabilities, damages, penalties, deficiencies, actions, settlements, judgments, costs and expenses which Medicis may incur or suffer or with which it may be faced (including reasonable costs and legal fees incident thereto or in seeking indemnification therefor), (referred to as "Costs") arising out of or based upon the breach by MacroPore of any of its representations, warranties, covenants or agreements contained or incorporated in this Agreement. An amount for which Medicis is entitled to indemnification pursuant hereto is referred to as an "Indemnified Amount."
- Third Party Claims. If a claim by a third party is made against any indemnified party, and if the 6.3 indemnified party intends to seek indemnity with respect thereto under this Article 6, such indemnified party shall promptly notify the indemnifying party of such claim; provided, however, that failure to give timely notice shall not affect the rights of the indemnified party so long as the failure to give timely notice does not adversely affect the indemnifying party's ability to defend such claim against a third party. If the indemnifying party acknowledges that the indemnified party is entitled to indemnification hereunder for such claim, the indemnifying party shall be entitled to settle or assume the defense of such claim, including the employment of counsel reasonably satisfactory to the indemnified party. If the indemnifying party elects to settle or defend such claim, the indemnifying party shall notify the indemnified party within thirty (30) days (but in no event less than twenty (20) days before any pleading, filing or response on behalf of the indemnified party is due) of the indemnifying party's intent to do so. If the indemnifying party elects not to settle or defend such claim or fails to notify the indemnified party of the election within thirty (30) days (or such shorter period provided above) after receipt of the indemnified party's notice of a claim of indemnity hereunder, the indemnified party shall have the right to contest, settle or compromise the claim without prejudice to any rights to indemnification hereunder. Regardless of which party is controlling the settlement of defense of any claim, (a) both the indemnified party and indemnifying party shall act in good faith, (b) the indemnifying party shall not thereby permit to exist any lien, encumbrance or other adverse charge upon any asset of any indemnified party or of its subsidiaries, (c) the

indemnifying party shall permit the indemnified party to participate in such settlement or defense through counsel chosen by the indemnified party, with all fees, costs and expenses of such counsel borne by the indemnified party, unless the indemnifying party and indemnified party have available inconsistent defenses to such third-party claim, in which case such fees, costs and expenses shall be borne by the indemnifying party, (d) no entry of judgment or settlement of a claim may be agreed to without the written consent of the indemnified party, which consent shall not be unreasonably withheld, and (e) the indemnifying party shall promptly reimburse the indemnified party for the Indemnified Amount as incurred by the indemnified party pursuant to this Article 6. So long as the indemnifying party is reasonably contesting any such third party claim in good faith and the foregoing clause (b) is being complied with, the indemnified party shall not pay or settle any such claim (or, if it does, it shall not be indemnified for such settlement amount). The controlling party shall upon request deliver, or cause to be delivered, to the other party copies of all correspondence, pleadings, motions, briefs, appeals or other written statements relating to or submitted in connection with the settlement or defense of any such claim, and timely notices of any hearing or other court proceeding relating to such claim.

- 6.4 <u>Non-Third Party Claims.</u> A claim for indemnification for any matter not involving a third-party claim may be asserted by notice to the party from whom indemnification is sought. Such notice shall state the amount of the Indemnified Amount, if known, the method of computation thereof, and contain a reference to the provisions of this Agreement in respect to which such right of indemnification is claimed or arises. If the party from whom indemnification is sought disputes such claim then the parties shall then follow the dispute resolution mechanism set forth in Section 9.15 of this Agreement.
- 6.5) <u>Indemnification Limitations</u>. MacroPore shall have no liability (for indemnification or otherwise) with respect to claims under Article 6 until the total of all Indemnifiable Losses with respect to such matters, when added to the amount of all claims of Medicis to indemnification under the Purchase Agreement exceeds Five Hundred Thousand Dollars (\$500,000) (the "Threshold Amount") and then only for the amount by which such Indemnifiable Losses exceed the Threshold Amount. Notwithstanding anything to the contrary in the Agreement, the total amount of Indemnifiable Losses that MacroPore shall be obligated to pay to Medicis in the aggregate shall not exceed the lesser of fifty percent (50%) of the total Purchase Price (as defined in the Purchase Agreement) or the portion of the Purchase Price actually paid to and received by MacroPore pursuant to the terms of the Purchase Agreement (i.e., if the total amount of Indemnified Amounts exceeds the portion of the Purchase Price actually paid to MacroPore prior to such time but is less than 50% of the total Purchase Price, then Medicis shall only offset such amounts against future installments of the Purchase Price up to the maximum of 50% of the total Purchase Price).
- 6.6) <u>Cooperation as to Indemnified Liability</u>. Each party hereto shall cooperate fully with the other parties with respect to access to books, records, or other documentation within such party's control, if deemed reasonably necessary or appropriate by any party in the defense of any claim that may give rise to indemnification hereunder.

# ARTICLE 7 TERM AND TERMINATION

- 7.1 <u>Term.</u> Unless otherwise terminated under provisions of Section 7.2, this Agreement shall continue as to each respective item of MacroPore Intellectual Property until such item has Expired or is otherwise no longer legally-protectable Intellectual Property. Termination of this Agreement for any reason will not affect Section 4.1 or the license rights granted to MacroPore in Sections 2.1 and 2.2, or either party's pre-termination rights and remedies, which shall survive termination of this Agreement.
- 7.2 <u>Termination</u>. MacroPore may terminate this Agreement, at its option and without prejudice to any of its other legal and equitable rights and remedies, by giving Medicis notice in writing at least thirty (30) days in advance of the effective date of such termination.

# ARTICLE 8 FORCE MAJEURE

- 8.1 <u>Force Majeure</u>. Neither party shall be in default because of any failure to perform such party's obligations under this Agreement to the extent such failure is due to causes beyond the control of such party ("the first party") and without the fault or negligence of such first party, including without limitation, Acts of God or of the public enemy, acts of terrorism, acts of the Government in either its sovereign or contractual capacity, fires, floods, earthquakes, epidemics, quarantine restrictions, strikes, or freight embargoes (each a "Force Majeure Event"). In each instance, the failure to perform must be beyond the reasonable control and without the fault or negligence of the first party. Once performance is again possible, performance must be given.
- 8.2 <u>Notice</u>. If it appears that performance under of obligations may be delayed by a Force Majeure Event, the first party will immediately notify the other party as soon as practicable in writing at the address specified in this Agreement. During the period that the performance by one of the parties of its obligations has been suspended by reason of a Force Majeure Event, the other party may likewise suspend the performance of all or part of its obligations hereunder to the extent that such suspension is commercially reasonable.

# ARTICLE 9 MISCELLANEOUS

- 9.1 <u>Assignment.</u> Neither party shall have the right to assign or otherwise transfer its rights and obligations under this Agreement (whether by merger, share exchange, combination or consolidation of any type, operation of law, purchase or otherwise) except with the prior written consent of the other party, which consent will not be unreasonably withheld, provided that either MacroPore or Medicis may, without a need for consent, assign its respective rights and obligations pursuant to this Agreement to any person who, by merger, share exchange, combination or consolidation of any type, purchase, operation of law, asset purchase or otherwise, acquires substantially all of the business of the assigning party to which this Agreement relates. MacroPore may assign the license for the Spinal Field granted in Section 2.1 to the purchasing party without the need for a consent in the event that MacroPore sells all or substantially all of the assets of its spinal implant business. Any prohibited assignment shall be null and void.
- 9.2 <u>Complete Agreement</u>. This Agreement, the Purchase Agreement and the Exhibits of each constitute the entire agreement between the parties hereto with respect to the subject matter hereof and supersede all prior or contemporaneous agreements whether written or oral relating hereto.
- 9.3 <u>Governing Law.</u> This Agreement shall be governed by and interpreted in accordance with the laws of the State of California, including all matters of construction, validity, performance and enforcement, without giving effect to principles of conflict of laws and without application of the United Nations Convention on Contracts for the International Sale of Goods.
- 9.4 <u>Waiver, Discharge, Amendment, Etc.</u> The failure of any party hereto to enforce at any time any of the provisions of this Agreement shall not, absent an express written waiver signed by the party making such waiver specifying the provision being waived, be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of the party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. Any amendment to this Agreement shall be in writing and signed by the parties hereto or else it shall be of no effect.
- 9.5 <u>Notices</u>. All notices hereunder shall be deemed given if in writing and delivered personally or sent by telecopy (with confirmation of transmission) or certified mail (return receipt requested) or reputable courier service to the parties at the following addresses (or at such other addresses as shall be specified by like notice):

if to MacroPore, to:

MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121 USA

Attention: Christopher J. Calhoun

FAX: (858) 458-0995

with duplicate copy thereof addressed to

MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121 USA

Attention: In-House Counsel FAX: (858) 458-0994

and if to Medicis, to:

Medicis Ventures Management GmbH Poschingerstr. 9 D-81679 München, Germany Attention: Managing Director

FAX:

with duplicate copy thereof addressed to:

Any party may change the above specified recipient and/or mailing address by notice to all other parties given in the manner herein prescribed. All notices shall be deemed given on the day when actually delivered as provided above (if delivered personally, by telecopy or by reputable courier service) or three business days after the date sent (if delivered by mail).

- 9.6 <u>Expenses</u>. Except as expressly provided herein, Medicis and MacroPore shall each pay their own expenses incident to this Agreement and the preparation for, and consummation of, the transactions provided for herein.
- 9.7 <u>Titles and Headings; Construction</u>. The titles and headings to Sections and Articles herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.
- 9.8 <u>Severability</u>. If any provision of this Agreement is held invalid, illegal or unenforceable, such provision shall be deemed replaced with a provision which enables the enforcement, to the maximum extent possible, of the parties' original intent, and the remaining provisions shall nonetheless be enforceable according to their terms.
- 9.9 <u>Relationship</u>. This Agreement does not make either party the employee, partner, agent or legal representative of the other for any purpose whatsoever. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party, and each

party agrees not to purport to do so. In fulfilling its obligations pursuant to this Agreement, each party shall be acting as an independent contractor.

- 9.10 <u>Benefit</u>. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties to this Agreement or their respective successors or permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.
- 9.11 <u>Survival</u>. All of the representations, warranties, and covenants made in this Agreement, and all terms and provisions hereof intended to be observed and performed by the parties after the termination hereof, shall survive such termination and continue thereafter in full force and effect, subject to any applicable statutes of limitations.
- 9.12 <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed as original and all of which together shall constitute one instrument.
- 9.13 <u>Execution of Further Documents</u>. Each party agrees to execute and deliver without further consideration any further applications, licenses, assignments or other documents, and to perform such other lawful acts as the other party may reasonably request to fully secure and/or evidence the rights or interests herein.
- 9.14 <u>Public Announcement</u>. In the event either party proposes to issue any press release or public announcement concerning any provisions of this Agreement or the transactions contemplated hereby, such party shall so advise the other party hereto, and the parties shall thereafter use their best efforts to cause a mutually agreeable release or announcement to be issued. Neither party will publicly disclose or divulge any provisions of this Agreement or the transactions contemplated hereby without the other party's written consent, except as may be required by applicable law or stock exchange regulation, and except for communications to such party's employees or customers or investors or prospective investors (subject to appropriate confidentiality obligations).
- 9.15 <u>Dispute Resolution</u>. Any dispute arising out of or relating to this Agreement (including the formation, interpretation or alleged breach thereof) shall be settled by final and binding arbitration conducted under the auspices of, and in accordance with, the Commercial Arbitration Rules of the American Arbitration Association, in San Francisco, California. The results of such arbitration proceedings shall be binding upon the parties hereto, and judgment may be entered upon the arbitration award in any court having jurisdiction thereof. Notwithstanding the foregoing, a party may seek interim injunctive relief from any court of competent jurisdiction.

(Remainder of page intentionally blank; signatures follow on next page)

IN WITNESS WHEREOF, each of the parties has caused this License Agreement to be executed in the manner appropriate to each, as of the date first written above.

By:
Its:
MACROPORE BIOSURGERY, INC.
By:
Its:

MEDICIS VENTURES MANAGEMENT GmbH

# EXHIBIT D ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT is made as of January 21, 2004, by and among Medicis Ventures Management GmbH., a German corporation ("Buyer") and **MacroPore Biosurgery, Inc.**, a Delaware corporation ("Seller").

WHEREAS, Buyer and Seller are parties to that certain Asset Purchase Agreement dated December 13, 2003 (the "Purchase Agreement") pursuant to which Buyer will purchase certain businesses and assets of the Seller effective as of the close of business on the date hereof (the "Effective Date"); and

WHEREAS, as part of the transfer of the businesses and assets of Seller, Seller desires to assign and delegate to Buyer, and Buyer desires to accept an assignment of and assume Seller's obligations pursuant to, the "Assumed Liabilities" (as defined in the Purchase Agreement).

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

- 1. <u>Assignment and Delegation</u>. Seller hereby sells, assigns, delegates, and transfers to Buyer all of Seller's duties and, Agreement obligations under and to the Assumed Liabilities, effective as of the Effective Date.
- 2. <u>Assumption</u>. Buyer hereby assumes and agrees to perform all of the duties and Agreement obligations of Seller under the Assumed Liabilities from and after the Effective Date.
- 3. <u>Binding Upon Assigns</u>. This Assignment and Assumption Agreement shall bind and inure to the benefit of Sellers and Buyer and their respective successors and assigns.
- 4. <u>Miscellaneous</u>. All representations, warranties and covenants of Seller and of Buyer with respect to the Assumed Liabilities contained in the Purchase Agreement, subject to the limitations therein contained, are incorporated herein by reference. This Agreement shall be construed and enforced in accordance with and governed by the laws of California, without regard to principles of conflicts of laws. This Assignment and Assumption may be executed in any number of counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, this Assignment and Assumption Agreement has been duly executed and delivered on behalf of the parties as of the date first above written.

,	
By:	
By:	_
MEDICIS VENTURES MANAGEMENT	GmbH
Ву:	
By: Its:	_

MACROPORE BIOSURGERY, INC.

# EXHIBIT E BILL OF SALE

THIS BILL OF SALE is made, executed and delivered as of January 21, 2004 ("Bill of Sale") by **MacroPore Biosurgery, Inc.**, a Delaware corporation ("Seller") to Medicis Ventures Management GmbH, a German corporation ("Medicis").

#### WITNESSETH:

WHEREAS, Buyer and Seller have entered into an Asset Purchase Agreement, dated as of December 13, 2003 (the "Purchase Agreement"), pursuant to which Seller agreed, among other things, to sell, convey, assign, transfer and deliver to Buyer the Specified Assets (such term and all other capitalized terms used but not defined herein having the same meanings ascribed to such terms in the Purchase Agreement) all as more fully described in the Purchase Agreement, for consideration in the amount and on the terms and conditions provided in the Purchase Agreement; and

WHEREAS, Seller and Buyer now desire to carry out the intent and purpose of the Purchase Agreement by Seller's execution and delivery to Buyer of this instrument evidencing the sale, conveyance, assignment, transfer and delivery to Buyer of the Specified Assets;

NOW, THEREFORE, in consideration of the foregoing premises and for other good and valuable consideration to Seller, the receipt and adequacy of which are hereby acknowledged, Seller, as of the close of business on the date hereof, is selling, conveying, assigning, transferring and delivering, and by this Bill of Sale does, effective as of the close of business on the date hereof, sell, convey, assign, transfer and deliver unto Buyer, its successors and assigns in accordance with the terms and provisions of the Purchase Agreement:

TO HAVE AND TO HOLD all of Seller's right, title and interest in and to the Specified Assets unto Buyer, and Buyer's successors and assigns, all in accordance with the terms of the Purchase Agreement FOREVER.

- 2. Seller further covenants and agrees that the covenants herein contained shall inure to the benefit of the successors and assigns of Buyer.
- 3. All representations, warranties and covenants of the Seller with respect to the Specified Assets contained in the Purchase Agreement, subject to the limitations therein contained, are incorporated hereby by reference.
- 4. This Bill of Sale shall be construed and enforced in accordance with and governed by the laws of the State of California, without giving effect to principles of conflicts of laws.
- 5. Seller shall do such acts and shall execute such further documents, conveyances, deeds, assignments, transfers and the like, and will cause the doing of such acts and will cause the execution of such further documents as are within its power as Buyer may in writing at any time and from time to time reasonably request be done or executed, in order to give full effect to the provisions of this Bill of Sale.

IN WITNESS WHEREOF, this Bill of Sale has been duly executed and delivered on behalf of Seller as of the date first above written.

MACROPORE BIOSURGERY, INC.
By:
Its:

# EXHIBIT G BUSINESS DEVELOPMENT AGREEMENT

### **Business Development Agreement\*\*\***

This Business Development Agreement ("Development Agreement") is made and entered into as of January , 2004, by and among **Medicis Ventures Management GmbH** (as defined herein, "Medicis"), a German corporation, and **MacroPore Biosurgery, Inc.** (as defined herein, "MacroPore"), a Delaware corporation.

#### WITNESSETH:

MacroPore has sold Medicis certain assets pursuant to the Asset Purchase Agreement ("Asset Agreement") and the License Agreement of even date. This Development Agreement is the one contemplated by the Asset Agreement. Capitalized terms not otherwise defined herein shall have the meanings given to them in the Asset Agreement.

WHEREAS, Medicis desires to establish a partnership, distribution or licensing arrangement ("Business Arrangement") between Medicis and a Japanese company ("Partner" the identity of which is not yet determined) for marketing Bioabsorbable Film Implants ("Implants") in and for use in Japan ("Territory"); and

WHEREAS, MacroPore has contacts, relationships and abilities to assist Medicis in establishing a Business Arrangement with a Partner, and relevant regulatory experience related to the marketing of the Implants;

NOW, THEREFORE, in consideration of the agreements contained herein, and subject to the terms and conditions set forth herein, the parties hereto agree as follows:

# ARTICLE 1 DEVELOPMENT ACTIVITES OF MACROPORE

- 1.1) General Development Assistance. MacroPore shall exercise all commercially reasonable efforts until December 1, 2004 to: (i) jointly establish (on behalf of and subject to advice and consent of Medicis), a Business Arrangement with a Partner related to the sale of Implants in the Territory; and, (ii) assist Medicis in obtaining the required regulatory clearances to market the Implants in the Territory.
- 1.2) <u>Regulatory Clearances in Japan.</u> Subject to Section 1.1, MacroPore will provide Medicis and the Partner strategic, documentary and technical support to assist them in obtaining regulatory clearance for the Implants in the Territory.

# ARTICLE 2 DEVELOPMENT ACTIVITES OF MEDICIS

2.1) <u>General Development Assistance</u>. Medicis shall exercise all commercially reasonable efforts and work with MacroPore to: (i) establish a business relationship with a Partner to the sell Implants in the Territory and (ii) cooperate with the Partner in the Territory to obtain the required regulatory clearances to market the Implants in the Territory.

# ARTICLE 3 OBLIGATIONS, COSTS AND EXPENSES

- 3.1) <u>Authority</u>. This Development Agreement does not create any relationship of partnership, agency or joint venture. Neither party has authority for and on behalf of the other. Neither party may incur any debt, obligation, expense, or liability of any kind which is binding against the other without the other's express written approval.
- 3.2) <u>Costs</u>. Except as otherwise provided in this agreement, each party shall be responsible for their own costs and expenses in fulfilling their obligations hereunder.

<sup>\*\*\*</sup> Certain confidential portions of this Exhibit were omitted by means of blackout of the text (the "Mark"). This Exhibit has been filed separately with the Secretary of the Commission without the Mark pursuant to the Company's Application Requesting Confidential Treatment under Rule 24b-2 under the 1934 Act.

3.3) <u>Clinical/Pre-Clinical Trials</u>. In the event that it is necessary to conduct clinical trials to commercially market Implants in the Territory, all costs and expenses related to the clinical trial shall be borne by Medicis. MacroPore shall be immediately reimbursed for any reasonable costs and expenses incurred with Medicis' prior written consent (which consent shall not be unreasonable withheld) in supporting such activities. In the event that any additional pre-clinical work is required to obtain regulatory approval in the Territory, MacroPore and Medicis shall divide these costs as far as incurred with Medicis' prior written consent (which consent shall not be unreasonable withheld) equally between the parties with the costs to MacroPore not to exceed \$50,000. MacroPore shall be immediately reimbursed for any such reasonable costs and expenses that exceed \$50,000 in supporting such pre-clinical activities.

# ARTICLE 4 COMPENSATION

- 4.1) Agreement Fee / Up-Front Payments. Within 10 days of Medicis having received any payment relating to any Business Arrangement with a Partner in the Territory, Medicis shall pay MacroPore \*\*\* of any \*\*\* fee or \*\*\* payable to Medicis by way of such agreement. Medicis agrees not to \*\*\* as are currently contemplated in negotiations with any potential partner, in such a way as to transfer economic value away from the \*\*\* and toward another manner of transferring economic benefit, and effectively to reduce the amount payable to MacroPore. If such \*\*\* fails to provide for \*\*\* to Medicis at the execution of the agreement, then MacroPore shall be entitled to \*\*\* payment of \*\*\* of any deferred payment for a \*\*\* (including any easily-achievable \*\*\* payment, even if not expressly identified as a \*\*\*, etc.). In the event that the \*\*\* contains any type of regulatory milestone payments, \*\*\* of any such payments received by Medicis shall be \*\*\* paid to MacroPore by Medicis (net of any pre-clinical or clinical trial costs referenced in section 3.3). Any other milestone payment that may be agreed upon between the parties shall be shared equally by MacroPore and Medicis.
- 4.2) Regulatory Approval Fee. For a period of \*\*\* years from the first lawful commercial launch of Qualified Implants into the Territory, MacroPore shall receive quarterly payments from Medicis equal to \*\*\* of the excess of (a) the \*\*\* of Medicis from sales (whether or not to Partner) of all Implants in the Territory, over (b) the actual \*\*\* incurred by Medicis (if any) for the goods sold. In no event shall the cost subtracted \*\*\* or specified by MacroPore in the Asset Agreement. This fee is payable whether or not any clinical or pre-clinical trials are required by authorities in the Territory prior to commercial launch. The fee shall be paid for all products sold during such \*\*\* year period even though actual payments for such products are not received by Medicis until a later date. "Qualified Implants" include any Implant with Japanese regulatory approval at least as favorable as the 510 K clearance received by MacroPore on September 22, 2003 for the minimization of attachment of soft tissue ("MAST") in the U.S. In addition, in the event and to the extent that the Business Arrangement is structured in such a way that the Medicis is to receive \*\*\* for products sold in the Territory, then MacroPore shall be entitled to \*\*\* of any such \*\*\* received from the first lawful commercial launch of Qualified Implants into the Territory for a period of \*\*\* years thereafter.
- 4.3) MacroPore Liability Waiver By Medicis / Japanese Partner. Medicis agrees that any definitive written agreements between Medicis and any Partner for distribution or licensing of Implants in the Territory shall include provisions providing a full and complete waiver by both parties of liability of MacroPore in regards to such agreement. MacroPore shall by no means be held liable for any breach of contract or warranty whether express or implied resulting from such agreement except in so far as it shall be established according to U.S. law that MacroPore acted with gross negligence or clear intent to defraud the either party to such contract.

# ARTICLE 5 REPORTS AND RECORDS

- 5.1) Quarterly Revenue Reports. Beginning at the first commercial launch of Qualified Implants into the Territory as provided in Section 4.2 above, Medicis will make quarterly fee reports to MacroPore on or before each January 21 (for the quarter ending December 31), April 21 (for the quarter ending March 31), July 21 (for the quarter ending June 30) and October 21 (for the quarter ending September 30) of each year. Each fee report will cover Medicis's most recently completed calendar quarter and will, at a minimum, show:
  - 5.1.1) the gross invoice prices for all Implants sold in the Territory and actual manufacturing costs (incurred by Medicis) for those goods sold;
  - 5.1.2) the Section 4.2 fees due, in United States dollars, payable to MacroPore for the quarter being reported;

<sup>\*\*\*</sup> Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

- 5.1.3) the amount of the cash and the amount of the cash equivalent of the non-cash consideration including the method used to calculate the non-cash consideration;
- 5.1.4) any other information reasonably necessary to confirm Medicis's calculation of its fee obligations \*\*\* hereunder;
- 5.2) Quarterly Fee Payments. All fees payable to MacroPore as identified in Section 4.2 shall be paid simultaneously with the delivery of the quarterly report with which they correspond. Conversion into US dollars shall be at the mean average daily closing conversion rate over the quarter in question, based on rates as reported in the Wall Street Journal.
- 5.3) <u>Document Retention</u>. Medicis will keep accurate books and records showing all Implants sold in or for the Territory sufficient to verify the quarterly reports required in Section 5.1. Such books and records will be preserved for at least three (3) years after the date of the payment to which they pertain.
- 5.4) <u>Document Inspection</u>. The books and records required to be maintained in Section 5.3 will be open to inspection by experts appointed by MacroPore and bound by their obligation to professional secrecy at reasonable times to determine their accuracy and assess Medicis's compliance with the terms of this Agreement. MacroPore shall bear the fees and expenses of such examination. If, however, an error in fees of more than five percent (5%) of the total fees due for any year is discovered in any examination, then Medicis shall bear the fees and expenses related to such examination.
- 5.5) <u>Provision of Financial Statements</u>. Medicis (or their successor in interest) shall provide MacroPore financial statements for every calendar quarter within 30 calendar days of the quarter most recently ended. The statements must contain the balance sheet, statement of operations, and statement of cash flow of Medicis. The obligation to provide financial statements terminates after the last payment required to be made under this agreement has been paid to MacroPore.

# ARTICLE 6 INDEMNIFICATION

- 6.1) <u>Indemnification by Medicis</u>. Each Party shall indemnify, defend and hold harmless the other and each of its subsidiaries, officers, directors, shareholders, employees, agents and affiliates (collectively, all such indemnitees are referred to in this Section as "Indemnified Party") against and in respect of any and all claims, demands, losses, obligations, liabilities, damages, penalties, deficiencies, actions, settlements, judgments, costs and expenses which Indemnified Party may incur or suffer or with which it may be faced (including reasonable costs and legal fees incident thereto or in seeking indemnification therefor), (referred to as "Costs") arising out of or primarily based upon activities of the other party ("Indemnitor") in performing under the terms of this agreement. An amount for which the Indemnified Party is entitled to indemnification pursuant hereto is referred to as an "Indemnified Amount."
- Third Party Claims. If a claim by a third party is made against any Indemnified Party, and if the Indemnified Party intends to seek indemnity with respect thereto under this Article 6, such Indemnified Party shall promptly notify the Indemnitor of such claim; provided, however, that failure to give timely notice shall not affect the rights of the Indemnified Party so long as the failure to give timely notice does not adversely affect the Indemnitor' ability to defend such claim against a third party. If Indemnitor acknowledges that the Indemnified Party is entitled to indemnification hereunder for such claim, Indemnitor shall be entitled to settle or assume the defense of such claim, including the employment of counsel reasonably satisfactory to the Indemnified Party. If Indemnitor elects to settle or defend such claim, Indemnitor shall notify the Indemnified Party within thirty (30) days (but in no event less than twenty (20) days before any pleading, filing or response on behalf of the Indemnified Party is due) of Indemnitor' intent to do so. If Indemnitor elects not to settle or defend such claim or fails to notify the Indemnified Party of the election within thirty (30) days (or such shorter period provided above) after receipt of the Indemnified Party's notice of a claim of indemnity hereunder, the Indemnified Party shall have the right to contest, settle or compromise the claim without prejudice to any rights to indemnification hereunder. Regardless of which party is controlling the settlement or defense of any claim, (a) both the Indemnified Party and Indemnitor shall act in good faith, (b) Indemnitor shall not thereby permit to exist any lien, encumbrance or other adverse charge upon any asset of any Indemnified Party or of its subsidiaries, (c) Indemnitor shall permit the Indemnified Party to participate in such settlement or defense through counsel chosen by the Indemnified Party, with all fees, costs and expenses of such counsel borne by the Indemnified Party, unless Indemnitor and Indemnified Party have available inconsistent defenses to such thirdparty claim, in which case such fees, costs and expenses shall be borne by Indemnitor, (d) no entry of judgment or settlement of a claim may be agreed to without the written consent of the Indemnified Party, which consent shall not be unreasonably

withheld, and (e) Indemnitor shall promptly reimburse the Indemnified Party for the Indemnified Amount as incurred by the Indemnified Party pursuant to this Article 6. So long as Indemnitor is reasonably contesting any such third party claim in good faith and the foregoing clause (b) is being complied with, the Indemnified Party shall not pay or settle any such claim (or, if it does, it shall not be indemnified for such settlement amount). The controlling party shall upon request deliver, or cause to be delivered, to the other party

<sup>\*\*\*</sup> Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

copies of all correspondence, pleadings, motions, briefs, appeals or other written statements relating to or submitted in connection with the settlement or defense of any such claim, and timely notices of any hearing or other court proceeding relating to such claim.

6.3) Non-Third Party Claims. A claim for indemnification for any matter not involving a third-party claim may be asserted by notice to Indemnitor. Such notice shall state the amount of the Indemnified Amount, if known, the method of computation thereof, and contain a reference to the provisions of this Agreement in respect to which such right of indemnification is claimed or arises. If Indemnitor disputes such claim then the parties shall then follow the dispute resolution mechanism set forth in Section 8.10 of this Development Agreement.

# ARTICLE 7 CONFIDENTIALITY

7.1) Confidential Information. The parties shall keep in confidence and trust all Confidential Information disclosed under this Agreement. The party which receives such Confidential Information from the other is called the "Recipient". Each party agrees not to use or disclose any Confidential Information or anything relating to it without the written consent of the other. As used in this Agreement, Confidential Information means information related to the subject matter of this Agreement provided by MacroPore or Medicis, and designated at time of such disclosure as proprietary or Confidential Information. Any oral or other non-written disclosures of Confidential Information will be reduced to writing within thirty (30) days of disclosure. Notwithstanding the foregoing, the parties shall regard all advice, counsel, information and strategies of MacroPore relating to potential Partners and regulatory strategies provided hereunder as Confidential Information whether or not any specific designation or reduction to writing is provided. Confidential Information does not include information which (1) is now public knowledge or subsequently becomes such through no breach of this Agreement; (2) is rightfully in Recipient's possession prior to the other parties disclosure to Recipient as shown by written records, (3) is rightfully disclosed to Recipient by a third party; (4) is independently developed by or for Recipient without reliance upon confidential information received from the other party. In addition, to the extent Confidential Information is required to be disclosed by law, it may be disclosed as required. This Article 7 shall survive any expiration or termination of this Development Agreement.

# ARTICLE 8 MISCELLANEOUS

- 8.1) <u>Complete Agreement</u>. This Agreement (together with the Asset Agreement and the other agreements contemplated by the Asset Agreement) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior or contemporaneous discussions or agreements whether written or oral relating hereto.
- 8.2) <u>Governing Law</u>. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, including all matters of construction, validity, performance and enforcement, without giving effect to principles of conflict of laws and without application of the United Nations Convention on Contracts for the International Sale of Goods.
- 8.3) Waiver, Discharge, Amendment, Etc. The failure of any party hereto to enforce at any time any of the provisions of this Agreement shall not, absent an express written waiver signed by the party making such waiver specifying the provision being waived, be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of the party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. Any amendment to this Agreement shall be in writing and signed by the parties hereto or else it shall be of no effect.
- 8.4) <u>Notices</u>. All notices hereunder shall be deemed given if in writing and delivered personally or sent by telecopy (with confirmation of transmission) or certified mail (return receipt requested) or reputable courier service to the parties at the following addresses (or at such other addresses as shall be specified by like notice):

if to MacroPore, to:

MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121 USA Attention: Christopher J. Calhoun

FAX: (858) 458-0995

with duplicate copy thereof addressed to

MacroPore Biosurgery, Inc. 6740 Top Gun Street San Diego, CA 92121 USA

Attention: In-House Counsel FAX: (858) 458-0994

and if to Medicis, to:

Medicis Ventures Management GmbH Poschingerstr. 9 D-81679 München, Germany Attention: Managing Director

with duplicate copy thereof addressed to:

Any party may change the above specified recipient and/or mailing address by notice to all other parties given in the manner herein prescribed. All notices shall be deemed given on the day when actually delivered as provided above (if delivered personally, by telecopy or by reputable courier service) or three business days after the date sent (if delivered by mail).

- 8.5) <u>Titles and Headings; Construction</u>. The titles and headings to Sections and Articles herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.
- 8.6) **Severability**. If any provision of this Agreement is held invalid, illegal or unenforceable, such provision shall be deemed replaced with a provision which enables the enforcement, to the maximum extent possible, of the parties' original intent, and the remaining provisions shall nonetheless be enforceable according to their terms.
- 8.7) **Relationship**. This Agreement does not make either party the employee, partner, agent or legal representative of the other for any purpose whatsoever. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party, and each party agrees not to purport to do so. In fulfilling its obligations pursuant to this Agreement, each party shall be acting as an independent contractor.
- 8.8) <u>Counterparts</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed as original and all of which together shall constitute one instrument.
- 8.9) <u>Execution of Further Documents</u>. Each party agrees to execute and deliver without further consideration any further applications, licenses, assignments or other documents, and to perform such other lawful acts as the other party may reasonably request to fully secure and/or evidence the rights or interests herein.
- 8.10) <u>Dispute Resolution</u>. Any dispute arising out of or relating to this Agreement (including the formation, interpretation or alleged breach thereof) shall be settled by final and binding arbitration conducted under the auspices of, and in accordance with, the Commercial Arbitration Rules of the American Arbitration Association, in San Francisco, California. The results of such arbitration proceedings shall be binding upon the parties hereto, and judgment may be entered upon the arbitration award in any court having jurisdiction thereof. Notwithstanding the foregoing, a party may seek interim injunctive relief from any court of competent jurisdiction.

(Remainder of page intentionally blank; signatures follow on next page)

IN WITNESS WHEREOF, each of the parties has caused this Business Development Agreement to be executed in the manner appropriate to each, as of the date first written above.

By:
Its:
MACROPORE BIOSURGERY, INC.
By:
Its:

MEDICIS VENTURES MANAGEMENT GmbH



#### Code of Ethics

### CODE OF BUSINESS CONDUCT AND ETHICS

We are committed to maintaining the highest standards of business conduct and ethics. This Code of Business Conduct and Ethics reflects the business practices and principles of behavior that support this commitment. We expect every employee, officer and director to read and understand this Code and its application to the performance of his or her business responsibilities. References in this Code to employees are intended to cover officers and, as applicable, directors. Nothing in this Code alters the employment at-will policy of MacroPore Biosurgery applicable to all U.S. employees.

Officers, managers and other supervisors are expected to develop in employees a sense of commitment to the spirit, as well as the letter, of this Code. Supervisors are also expected to ensure that all agents and contractors conform to Code standards when working for or on behalf of MacroPore Biosurgery. To facilitate compliance with this Code, we have established the position of Compliance Officer. The Compliance Officer reports on matters covered by this Code to the Chairman of the Governance and Nominating Committee during all times when the Board has such a committee, and at all other times to the Chairman of the Audit Committee ("Board Committee Chairman"). The persons currently occupying these positions are:

Chairman of the Audit Committee of the Board of Ronald D. Henriksen rhenriks@guidant.com

Directors

Compliance Officer Jonathan Soneff jsoneff@macropore.com

This Code cannot possibly describe every practice or principle related to honest and ethical conduct. This Code addresses conduct that is particularly important to proper dealings with the people and entities with whom we interact, but reflects only a part of our commitment. Although the MacroPore Insider Trading Policy and the Employee Handbook are not part of the Code, our employees are notified that adoption of the Code does not supercede those policies, and in fact, they remain in place.

The successful business operation and reputation of MacroPore is built upon the principles of fair dealing and ethical conduct of our employees. Our reputation for integrity and excellence requires careful observance of the spirit and letter of all applicable laws and regulations, as well as a scrupulous regard for the highest standards of conduct and personal integrity.

YOU SHOULD NOT HESITATE TO ASK QUESTIONS ABOUT WHETHER ANY CONDUCT MAY VIOLATE THIS CODE, VOICE CONCERNS OR CLARIFY GRAY AREAS. SECTION 14 DETAILS THE COMPLIANCE RESOURCES AVAILABLE TO YOU. IN ADDITION, YOU SHOULD BE ALERT TO POSSIBLE VIOLATIONS OF THIS CODE BY OTHERS AND REPORT SUSPECTED VIOLATIONS, WITHOUT FEAR OF ANY FORM OF RETALIATION, AS FURTHER DESCRIBED IN SECTION 14. Violations of this Code will not be tolerated. Any employee who violates the standards in this Code will be subject to disciplinary action, up to and including termination of employment and, in appropriate cases, civil legal action or referral for criminal prosecution.

## 1. Legal Compliance

Obeying the law, both in letter and in spirit, is the foundation of this Code. Our success depends upon each employee's operating within legal guidelines and cooperating with local, national and international

authorities. It is therefore essential that you understand the legal and regulatory requirements applicable to your business unit and area of responsibility. We hold periodic training sessions to ensure that all employees comply with the relevant laws, rules and regulations associated with their employment. While we do not expect you to memorize every detail of these laws, rules and regulations, we want you to be able to determine when to seek advice from others. If you do have a question in the area of legal compliance, it is important that you not hesitate to seek answers from your supervisor or the Compliance Officer.

Disregard of the law will not be tolerated. Violation of domestic or foreign laws, rules and regulations may subject an individual, as well as MacroPore Biosurgery, to civil or criminal penalties. You should be aware that conduct and records, including emails, are subject to internal and external audits, and to discovery by third parties in the event of a government investigation or civil litigation. It is in everyone's best interests to know and comply with our legal and ethical obligations.

## Misuse of Company Computer Equipment

Computers, computer files, the e-mail system, and software furnished to employees are MacroPore property intended for business use. Employees should not use a password, access a file, or retrieve any stored communication without authorization. To ensure compliance with this policy, computer and e-mail usage may be monitored. Contents of email may be disclosed within the Company and to third parties without notice or permission from the employee.

All Internet data that is composed, transmitted, or received via our computer communications systems is considered to be part of the official records of MacroPore and, as such, is subject to disclosure to law enforcement or other third parties. Consequently, employees should always ensure that the business information contained in Internet e-mail messages and other transmissions is accurate, appropriate, ethical, and lawful.

You may not, while acting on behalf of MacroPore Biosurgery or while using our computing or communications equipment or facilities, either:

- access the internal computer system (also known as "hacking") or other resource of a third party without express written authorization from the party responsible for operating that resource; or
- commit any unlawful or illegal act, including harassment, libel, fraud, sending of unsolicited bulk email (also known as "spam") in violation of applicable law, trafficking in contraband of any kind, or espionage.

### 2. Insider Trading

Employees who have access to confidential (or "inside") information are not permitted to use or share that information for stock trading purposes or for any other purpose except to conduct our business. All non-public information about MacroPore Biosurgery or about companies with which we do business is considered confidential information. To use material non-public information in connection with buying or selling securities, including "tipping" others who might make an investment decision on the basis of this information, is not only unethical, it is illegal. Employees must exercise the utmost care when handling material inside information. We have a separate Insider Trading Policy to which you are bound as a condition of your employment here. You should consult the Insider Trading Policy for more specific information on the definition of "material inside information" and on buying and selling our securities or securities of companies with which we do business.

#### 3. International Business Laws

Our employees are expected to comply with the applicable laws in all countries to which they travel, in which they operate and where we otherwise do business, including laws prohibiting bribery, corruption or

the conduct of business with specified individuals, companies or countries. The fact that in some countries certain laws are not enforced or that violation of those laws is not subject to public criticism will not be accepted as an excuse for noncompliance. In addition, we expect employees to comply with U.S. laws, rules and regulations governing the conduct of business by its citizens and corporations outside the United States.

These U.S. laws, rules and regulations, which extend to all our activities outside the United States, include:

- The Foreign Corrupt Practices Act, which prohibits directly or indirectly giving anything of value to a government official to obtain or retain business or favorable treatment, and requires the maintenance of accurate books of account, with all company transactions being properly recorded:
- U.S. Embargoes, which restrict or, in some cases, prohibit companies, their subsidiaries and their employees from doing business with certain other countries identified on a list that changes periodically (including, for example, Angola (partial), Burma (partial), Cuba, Iran, Iraq, Libya, North Korea, Sudan and Syria) or specific companies or individuals;
- Export Controls, which restrict travel to designated countries or prohibit or restrict the export of goods, services
  and technology to designated countries, denied persons or denied entities from the United States, or the reexport of U.S.-origin goods from the country of original destination to such designated countries, denied
  companies or denied entities; and
- Antiboycott Compliance, which prohibits U.S. companies from taking any action that has the effect of
  furthering or supporting a restrictive trade practice or boycott that is fostered or imposed by a foreign country
  against a country friendly to the United States or against any U.S. person.

If you have a question as to whether an activity is restricted or prohibited, seek assistance before taking any action, including giving any verbal assurances that might be regulated by international laws.

### 4. Conflicts of Interest

An actual or potential conflict of interest occurs when an employee is in a position to influence a decision that may result in a personal gain for that employee or for a relative as a result of MacroPore's business dealings. For the purposes of this policy, a relative is any person who is related by blood or marriage, or whose relationship with the employee is similar to that of persons who are related by blood or marriage.

No "presumption of guilt" is created by the mere existence of a relationship with outside firms. However, if employees have any influence on transactions involving purchases, contracts, or leases, it is imperative that they disclose to an officer of MacroPore as soon as possible the existence of any actual or potential conflict of interest so that safeguards can be established to protect all parties.

Even the appearance of a conflict of interest where none actually exists can be damaging and should be avoided. If you have any questions about a potential conflict or if you become aware of an actual or potential conflict, and you are not an officer or director of MacroPore Biosurgery, you should discuss the matter with your supervisor or the Compliance Officer. If the supervisor is involved in the potential or actual conflict, you should discuss the matter directly with the Compliance Officer. Officers and directors may seek authorization from the Chairman of the Board Committee with oversight of the Code.

Factors that may be considered in evaluating a potential conflict of interest include:

- whether it may interfere with the employee's job performance, responsibilities or morale;
- whether the employee has access to confidential information;

- whether it may interfere with the job performance, responsibilities or morale of others within the organization;
- any potential adverse or beneficial impact on our business;
- any potential adverse or beneficial impact on our relationships with our customers or suppliers or other service providers;
- whether it would enhance or support a competitor's position;
- the extent to which it would result in financial or other benefit (direct or indirect) to the employee;
- the extent to which it would result in financial or other benefit (direct or indirect) to one of our customers, suppliers or other service providers; and
- the extent to which it would appear improper to an outside observer.

The following are examples of situations that may, depending on the facts and circumstances, involve conflicts of interests:

- Employment by, consulting for or service on the board of a competitor, customer, supplier or service provider. Activity that enhances or supports the position of a competitor to the detriment of MacroPore Biosurgery is prohibited, including employment by or service on the board of a competitor.
- Owning, directly or indirectly, a significant financial interest in any entity that does business, seeks to do business or competes with us.
- Soliciting or accepting gifts, favors, loans or preferential treatment from any person or entity that does business
  or seeks to do business with us. See Section 8 for further discussion of the issues involved in this type of
  conflict.
- Soliciting contributions to any charity or for any political candidate from any person or entity that does business or seeks to do business with us.
- Taking personal advantage of corporate opportunities. See Section 5 for further discussion of the issues involved in this type of conflict.
- Conducting our business transactions with your family member or person who shares your household or a business in which you have a significant financial interest. Material related-party transactions approved by the Audit Committee and involving any executive officer or director will be publicly disclosed as required by applicable laws and regulations.
- Exercising supervisory or other authority on behalf of MacroPore Biosurgery over a co-worker who is also a family member.

Loans to, or guarantees of obligations of, employees or their family members by MacroPore Biosurgery could constitute an improper personal benefit to the recipients of these loans or guarantees, depending on the facts and circumstances. Some loans are expressly prohibited by law and applicable law requires that our Board of Directors approve all loans and guarantees to employees. As a result, all loans and guarantees by MacroPore Biosurgery must be approved in advance by the Governance and Nominating Committee or the Audit Committee (if a Governance and Nominating Committee has not been established).

# 5. Corporate Opportunities

You may not take personal advantage of opportunities that are presented to you or discovered by you as a result of your position with us or through your use of corporate property or information, unless authorized by your supervisor, the Compliance Officer or the Governance and Nominating Committee, as described in Section 4. Even opportunities that are acquired privately by you may be questionable if they are related to our existing or proposed lines of business. Participation in an investment or outside business opportunity that is related to our existing or proposed lines of business must be preapproved. You cannot use your position with us or corporate property or information for improper personal gain, nor can you compete with us in any way.

# 6. Maintenance of Corporate Books, Records, Documents and Accounts; Financial Integrity; Public Reporting

The integrity of our records and public disclosure depends on the validity, accuracy and completeness of the information supporting the entries to our books of account. Therefore, our corporate and business records should be completed accurately and honestly. The making of false or misleading entries, whether they relate to financial results or test results, is strictly prohibited. Our records serve as a basis for managing our business and are important in meeting our obligations to customers, suppliers, creditors, employees and others with whom we do business. As a result, it is important that our books, records and accounts accurately and fairly reflect, in reasonable detail, our assets, liabilities, revenues, costs and expenses, as well as all transactions and changes in assets and liabilities. We require that:

- no entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities, or misclassifies any transactions as to accounts or accounting periods;
- transactions be supported by appropriate documentation;
- the terms of sales and other commercial transactions be reflected accurately in the documentation for those transactions and all such documentation be reflected accurately in our books and records;
- employees comply with our system of internal controls; and
- no cash or other assets be maintained for any purpose in any unrecorded or "off-the-books" fund.

Our accounting records are also relied upon to produce reports for our management, stockholders and creditors, as well as for governmental agencies. In particular, we rely upon our accounting and other business and corporate records in preparing the periodic and current reports that we file with the Securities and Exchange Commission. These reports must provide full, fair, accurate, timely and understandable disclosure and fairly present our financial condition and results of operations. Employees who collect, provide or analyze information for or otherwise contribute in any way in preparing or verifying these reports should strive to ensure that our financial disclosure is accurate and transparent and that our reports contain all of the information about MacroPore Biosurgery that would be important to enable stockholders and potential investors to assess the soundness and risks of our business and finances and the quality and integrity of our accounting and disclosures. In addition:

- no employee may take or authorize any action that would cause our financial records or financial disclosure to fail to comply with generally accepted accounting principles, the rules and regulations of the SEC or other applicable laws, rules and regulations;
- all employees must cooperate fully with our Accounting department, as well as our independent public accountants and counsel, respond to their questions with candor and

provide them with complete and accurate information to help ensure that our books and records, as well as our reports filed with the SEC, are accurate and complete; and

• no employee should knowingly make (or cause or encourage any other person to make) any false or misleading statement in any of our reports filed with the SEC or knowingly omit (or cause or encourage any other person to omit) any information necessary to make the disclosure in any of our reports accurate in all material respects.

Any employee who becomes aware of any departure from these standards has a responsibility to report his or her knowledge promptly to a supervisor, the Compliance Officer or one of the other compliance resources described in Section 14.

### 7. Fair Dealing

We strive to outperform our competition fairly and honestly. Advantages over our competitors are to be obtained through superior performance of our products and services, not through unethical or illegal business practices. Acquiring proprietary information from others through improper means, possessing trade secret information that was improperly obtained, or inducing improper disclosure of confidential information from past or present employees of other companies is prohibited, even if motivated by an intention to advance our interests. If information is obtained by mistake that may constitute a trade secret or other confidential information of another business, or if you have any questions about the legality of proposed information gathering, you must consult your supervisor or the Compliance Officer, as further described in Section 14.

You are expected to deal fairly with our customers, suppliers, employees and anyone else with whom you have contact in the course of performing your job. No employee may take unfair advantage of anyone through misuse of confidential information, misrepresentation of material facts or any other unfair dealing practice.

Employees involved in procurement have a special responsibility to adhere to principles of fair competition in the purchase of products and services by selecting suppliers based exclusively on normal commercial considerations, such as quality, cost, availability, service and reputation, and not on the receipt of special favors.

#### 8. Gifts and Entertainment

Business entertainment and gifts are meant to create goodwill and sound working relationships and not to gain improper advantage with customers or facilitate approvals from government officials. Unless express permission is received from a supervisor, the Compliance Officer or the Board Committee with Oversight of the Code (*identified on the first page of this policy*), entertainment and gifts cannot be offered, provided or accepted by any employee unless consistent with customary business practices and not (a) excessive in value, (b) in cash, (c) susceptible of being construed as a bribe or kickback or (d) in violation of any laws. This principle, which does not prohibit reasonable customer or prospect entertainment, applies to our transactions everywhere in the world, even where the practice is widely considered "a way of doing business." Under some statutes, such as the United States Foreign Corrupt Practices Act (further described in Section 3), giving anything of value to a government official to obtain or retain business or favorable treatment is a criminal act subject to prosecution and conviction. Discuss with your supervisor or the Compliance Officer any proposed entertainment or gifts if you are uncertain about their appropriateness.

### 9. Antitrust

Antitrust laws are designed to protect the competitive process. These laws generally prohibit:

- agreements, formal or informal, with competitors that harm competition or customers, including price fixing and allocations of customers, territories or contracts;
- · agreements, formal or informal, that establish or fix the price at which a customer may resell a product; and
- the acquisition or maintenance of a monopoly or attempted monopoly through anti-competitive conduct.

Certain kinds of information, such as pricing, production and inventory, should not be exchanged with competitors, regardless of how innocent or casual the exchange may be and regardless of the setting, whether business or social.

Understanding the requirements of antitrust and unfair competition laws of the various jurisdictions where we do business can be difficult, and you are urged to seek assistance from your supervisor or the Compliance Officer whenever you have a question relating to these laws.

# 10. Protection and Proper Use of Company Assets

All employees are expected to protect our assets and ensure their efficient use. Theft, carelessness and waste have a direct impact on our profitability. Our property, such as computer equipment, buildings, furniture and furnishings office supplies and products and inventories, are expected to be used only for legitimate business purposes, although incidental personal use may be permitted. Employees should be mindful of the fact that we retain the right to access, review, monitor and disclose any information transmitted, received or stored using our electronic equipment, with or without an employee's or third party's knowledge, consent or approval. Any misuse or suspected misuse of our assets must be immediately reported to your supervisor or the Compliance Officer.

# 11. Confidentiality

One of our most important assets is our confidential information. Employees who have received or have access to confidential information should take care to keep this information confidential. Confidential information may include business, marketing and service plans, financial information, product architecture, source codes, engineering and manufacturing ideas, designs, databases, customer lists, pricing strategies, personnel data, personally identifiable information pertaining to our employees, customers or other individuals (including, for example, names, addresses, telephone numbers and social security numbers), and similar types of information provided to us by our customers, suppliers and partners. This information may be protected by patent, trademark, copyright or trade secret laws.

Except when disclosure is authorized or legally mandated, you must not share our or our suppliers' or customers' confidential information with third parties or others within MacroPore Biosurgery who have no legitimate business purpose for receiving that information. Doing so would constitute a violation of the Employment, Confidentiality and Assignment Agreement that you signed upon joining us. Unauthorized use or distribution of this information could also be illegal and result in civil liability and/or criminal penalties.

You should also take care not to inadvertently disclose confidential information. Materials that contain confidential information, such as memos, notebooks, computer disks and laptop computers should be stored securely. Unauthorized posting or discussion of any information concerning our business, information or prospects on the Internet is prohibited. You may not discuss our business, information or prospects in any "chat room," regardless of whether you use your own name or a pseudonym. Be cautious when discussing sensitive information in public places like elevators, airports, restaurants and "quasi-public" areas within MacroPore Biosurgery, such as cafeterias. All MacroPore Biosurgery emails, voicemails and other communications are presumed confidential

and should not be forwarded or otherwise disseminated outside of MacroPore Biosurgery, except where required for legitimate business purposes.

In addition to the above responsibilities, if you are handling information protected by any privacy policy published by us, then you must handle that information solely in accordance with the applicable policy. The provisions of this Section 11 are in addition to, not in limitation of, your obligations under the proprietary information and inventions agreement or any other confidentiality or nondisclosure agreement that you have entered into with MacroPore Biosurgery.

#### 12. Media/Public Discussions

It is our policy to disclose material information concerning MacroPore Biosurgery to the public only through specific limited channels in accordance with our Disclosure Policy to avoid inappropriate publicity and to ensure that all those with an interest in the company will have equal access to information. All inquiries or calls from the press and financial analysts should be referred to the Chief Financial Officer or the Investor Relations department. We have designated our Chief Executive Officer, Chief Financial Officer and Investor Relations department as our official spokespersons for financial matters. Unless a specific exception has been made by the Chief Executive Officer or Chief Financial Officer, these designees are the only people who may communicate with the press on behalf of MacroPore Biosurgery.

#### 13. Waivers

Any waiver of this Code for executive officers or directors may be authorized only by our Board of Directors or a committee of the Board and will be disclosed to stockholders as required by applicable laws, rules and regulations.

### 14. Compliance Standards and Procedures

### Compliance Resources

To facilitate compliance with this Code, we have implemented a program of Code awareness, training and review. The Compliance Officer will oversee this program. The Compliance Officer is a person to whom you can address any questions or concerns. In addition to fielding questions or concerns with respect to potential violations of this Code, the Compliance Officer is responsible for:

- investigating possible violations of this Code;
- training new employees in Code policies;
- conducting annual training sessions to refresh employees' familiarity with this Code;
- distributing copies of this Code annually to each employee with a reminder that each employee is responsible for reading, understanding and complying with this Code
- updating this Code as needed and alerting employees to any updates, with approval of the appropriate Board Committee, to reflect changes in the law, MacroPore Biosurgery operations and in recognized best practices, and to reflect MacroPore Biosurgery experience; and
- otherwise promoting an atmosphere of responsible and ethical conduct.

Your most immediate resource for any matter related to this Code is your supervisor. He or she may have the information you need, or may be able to refer the question to another appropriate source. There may, however, be times when you prefer not to go to your supervisor. In these instances, you should feel free to discuss your concern with the Compliance Officer. If you are uncomfortable speaking with the Compliance Officer for any reason, you may pose your question anonymously through the Ethicspoint® hotline, an

independent third party we have engaged for this purpose, by telephone at 866-ETHICSP (384-4277) or online at www.ethicspoint.com.

# Clarifying Questions and Concerns; Reporting Possible Violations

If you encounter a situation or are considering a course of action and its appropriateness is unclear, discuss the matter promptly with your supervisor or the Compliance Officer; even the appearance of impropriety can be very damaging and should be avoided.

If you are aware of a suspected or actual violation of Code standards by others, you have a responsibility to report it. You are expected to promptly provide a compliance resource with a specific description of the violation that you believe has occurred, including any information you have about the persons involved and the time of the violation. Whether you choose to speak with your supervisor or the Compliance Officer, or report anonymously through Ethicspoint® (866-ETHICSP or www.ethicspoint.com), you should do so without fear of any form of retaliation. We will take prompt disciplinary action against any employee who retaliates against you, up to and including termination of employment.

Supervisors must promptly report any complaints or observations of Code violations to the Compliance Officer. The Compliance Officer will investigate all reported possible Code violations promptly and with the highest degree of confidentiality that is possible under the specific circumstances. Your cooperation in the investigation will be expected. As needed, the Compliance Officer will consult with the Legal department, the Human Resources department or the Chairman of the Board Committee with Oversight of the Code (*identified on the first page of this policy*).

If the investigation indicates that a violation of this Code has probably occurred, we will take such action as we believe to be appropriate under the circumstances. If we determine that an employee is responsible for a Code violation, he or she will be subject to disciplinary action up to, and including, termination of employment and, in appropriate cases, civil action or referral for criminal prosecution. Appropriate action may also be taken to deter any future Code violations.

# **Independent Auditors' Consent**

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

We consent to the incorporation by reference in the registration statement, No. 333-82074 on Form S-8 of the Company, of our report dated February 20, 2004, relating to the consolidated balance sheets of MacroPore Biosurgery, Inc. as of December 31, 2003 and 2002 and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the years then ended which report appears in the December 31, 2003 annual report on Form 10-K of MacroPore Biosurgery, Inc.

/s/ KPMG LLP

San Diego, California March 29, 2004

### NOTICE REGARDING CONSENT OF ARTHUR ANDERSEN LLP

On May 8, 2002, MacroPore dismissed Arthur Andersen LLP as its independent auditor and appointed KPMG LLP to replace Arthur Andersen. MacroPore's understanding is that the staff of the Securities and Exchange Commission has taken the position that it will not accept consents from Arthur Andersen if the engagement partner and the manager for the MacroPore audit are no longer with Arthur Andersen. Both the engagement partner and the manager for the MacroPore audit are no longer with Arthur Andersen. As a result, MacroPore has been unable to obtain Arthur Andersen's written consent to the incorporation by reference into MacroPore's registration statement on Form S-8, SEC File No. 333-82074 (the "Registration Statement") of its audit report with respect to MacroPore's consolidated financial statements as of December 31, 2001 and 2000 and for the years then ended. (Arthur Andersen had duly consented to the inclusion of this audit report in the Registration Statement as originally filed, and the audit report was duly included.) Under these circumstances, we believe that Rule 437 (a) under the Securities Act permits MacroPore to file this Form 10-K without a written consent from Arthur Andersen.

Section 11(a) of the Securities Act of 1933, as amended (the "Securities Act"), provides that if any part of a registration statement at the time such part becomes effective contains an untrue statement of a material fact or an omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, any person acquiring a security pursuant to such registration statement (unless it is proved that at the time of such acquisition such person knew of such untruth or omission) may sue, among others, every accountant who has consented to be named as having prepared or certified any part of the registration statement, or as having prepared or certified any report or valuation which is used in connection with the registration statement, with respect to the statement in such registration statement, report or valuation which purports to have been prepared or certified by the accountant.

SEC regulations indicate that whenever a new Form 10-K report is incorporated by reference into a previous registration statement on Form S-8, there shall be deemed a new registration statement applicable to the offering thereafter of securities under the registration statement, for purposes of determining liability under the Securities Act.

Accordingly, it would follow that for the offering after today of securities under the Registration Statement, Arthur Andersen will not have any liability under Section 11(a) of the Securities Act for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen or any omissions of a material fact required to be stated therein. Accordingly, you would be unable to assert a claim against Arthur Andersen under Section 11(a) of the Securities Act for any purchases of securities under the Registration Statements made on or after the date of this Form 10-K. To the extent provided in Section 11(b)(3)(C) of the Securities Act, however, other persons who are liable under Section 11(a) of the Securities Act, including the Company's officers and directors, may still rely on Arthur Andersen's original audit reports as being made by an expert for purposes of establishing a due diligence defense under Section 11(b) of the Securities Act.

# Certification of Principal Executive Officer and Principal Financial 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 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 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 report;
- 4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; 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 over financial reporting.

Date: March 30, 2004 /s/ Christopher J. Calhoun

Christopher J. Calhoun,

Chief Executive Officer and Principal Financial Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002

# CHRISTOPHER J. CALHOUN hereby certifies that:

- 1. He is the Chief Executive Officer and Principal Financial Officer of MacroPore Biosurgery, Inc.
- 2. The Form 10-K report of MacroPore Biosurgery, Inc. that this certification accompanies fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934.
- 3. The information contained in the Form 10-K report of MacroPore Biosurgery, Inc. that this certification accompanies fairly presents, in all material respects, the financial condition and results of operations of MacroPore Biosurgery, Inc.

Dated: March 30, 2004

By: /s/ Christopher J. Calhoun

Christopher J. Calhoun

Chief Executive Officer and Principal Financial

Officer