SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

OR

o **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	**33-0827593**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
6740 TOP GUN STREET, SAN DIEGO, CALIFORNIA	**92121**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

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 o No ☒

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2004, the last business day of the registrant's most recently completed second fiscal quarter was $49,126,257 based on the average of the reported high and low sales price of the registrant's common stock on June 30, 2004 as reported on the Frankfurt Stock Exchange, of 3.4 Euros, or $4.17 per share, based on the exchange rate in effect as of such date.

As of January 31, 2005, there were 13,954,684 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2005 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, 2004, are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14 of this Form 10-K.

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PART I.

Item 1. Business

General

MacroPore Biosurgery specializes in the discovery and development of regenerative medicine therapies. We have two principal technology platforms, adipose-derived regenerative cells and bioresorbable implants.

The regenerative cell technology program is developing treatments for cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery using regenerative cells from adipose tissue (fat). This tissue is the richest and most accessible known source for regenerative cells, a population of cells that includes adult stem cells, angiogenic cells (blood vessel forming) and other regeneration-promoting cells. Our lead regenerative cell research program, currently in preclinical testing, targets myocardial infarction (heart attack).

To facilitate the processing and delivery of adipose-derived regenerative cells, we are designing a proprietary point-of-care system, Celution™, to isolate and concentrate a patient's own regenerative cells in real-time. Our goal is to commercialize a system that may be used universally across multiple therapeutic applications. The commercialization model will be based on the sale of a device and related consumables.

Strategically, we are pursuing partnering and licensing agreements with medical device, biotechnology and pharmaceutical companies, as well as universities and private research organizations, to fund the development of applications for adipose-derived regenerative cells outside of cardiovascular disease.

Additionally, we manufacture the HYDROSORB™ family of FDA-cleared bioresorbable spine and orthopedic implants, which are distributed exclusively through Medtronic, Inc ("Medtronic"). As of December 31, 2004, Medtronic owned 7.2% of our outstanding common stock and is considered a related party. Our strategy contemplates that we will use cash flows from HYDROSORB™ revenues, licensing agreements, product line divestitures and milestone payments under development arrangements are used to fund our adipose-derived regenerative cell research and development.

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.

Regenerative Medicine

Regenerative medicine harnesses the body's own healing mechanisms to repair organs and tissues damaged from disease, trauma, congenital abnormalities and the effects of aging. Regenerative therapies, technologies and devices are being developed at corporations, universities, and public and private research organizations around the world to augment the body's own healing mechanisms as an alternative to traditional pharmaceuticals or surgical procedures.

Stem cells are master cells that have the ability to differentiate into multiple cell and tissue types, including bone, muscle (including cardiac muscle), cartilage, fat, and nerve. They reside naturally in several sources, including but not limited to adipose tissue, bone marrow, embryonic and fetal tissue, peripheral and umbilical cord blood. These cells are commonly classified into two types: those which reside in embryonic tissue, known as embryonic stem cells, and all others, known collectively as adult stem cells.

Our investigational therapies use exclusively human adult regenerative cells from adipose tissue.

Regenerative Cell Technology

Regenerative cells from adipose tissue have been shown to differentiate into multiple cell types in vitro, including cells of the heart muscle, bone, fat, cartilage, skeletal muscle, smooth muscle and nerve. The major advantages of adipose tissue as a source of regenerative cells, which separate it from alternative sources, are that:

- Real-time therapy is possible because a therapeutic dose can be isolated in approximately one hour;
- The cells do not need to leave the clinic and are not extensively manipulated since no cell culture is required;
- Patients receive their own cells (autologous-use) so there is no risk of immune rejection and/or disease transmission; and
- Adipose tissue is an easily accessible source of regenerative cells requiring only a minimally invasive procedure.

With our proprietary process and methods, a high yield and high quality of stem and other regenerative cells can be quickly obtained from adipose tissue. Alternative cell sources are difficult to harvest and most do not yield a sufficient number of regenerative-capable cells without extensive cell culture. Cell culture, also known as *ex-vivo* expansion, is a process whereby cells are

grown for a period of at least two days to three weeks in a laboratory to obtain therapeutic quantities. For example, it has been reported that 10,000 stem cells exist within 100 milliliters of bone marrow. In 100 milliliters of adipose tissue, there is an average of 750,000 stem cells in addition to the presence of hundreds of thousands of angiogenic and growth factor producing cells.

Another significant benefit of adipose-derived regenerative cells is that they are well suited to autologous use (using the patient's own cells). This avoids the problems of disease transmission and rejection associated with donor tissue.

Bioresorbable Technology

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. HYDROSORB™ bioresorbable spine and orthopedic surgical implants, which are marketed by Medtronic;

2. Thin Film bioresorbable surgical implants (includes SurgiWrap™ bioresorbable products), which are used for soft tissue indications; and

3. Craniomaxillofacial ("CMF") bioresorbable surgical implants, which consists of bioresorbable bone fixation implants for the face and skull, and associated instruments and accessories.

As discussed below, we have sold most of the assets of the second product line and all of the assets of the third product line.

All three bioresorbable product lines 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.

HYDROSORB™ Bioresorbable Implants

Our HYDROSORB™ bioresorbable family of surgical implant revenues were $3,803,000, $9,882,000 and $5,544,000 for the years ended December 31, 2004, 2003, and 2002, respectively. The HYDROSORB™ product line accounted for 55.8% of our product revenues in 2004. Although our quarterly sales of these implants have been irregular, we currently do not observe seasonal trends for demand of the HYDROSORB™ products from Medtronic.

The HYDROSORB™ BoomerangÒ, HYDROSORB™ Cornerstone™ HSR, HYDROSORB™ Mesh and HYDROSORB™ Telamon® 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 HYDROSORB™ Spine System has received FDA clearance in the United States for use in spinal fusion procedures, in conjunction with traditional rigid fixation, as a means to maintain the relative position of weak bony tissue such as autografts. The HYDROSORB™ Shield has received FDA clearance in the United States for minimizing the attachment of soft tissue, and has received the CE Mark in Europe for the control of post-operative adhesions in spine surgery.

Thin Film Bioresorbable Implants

We sold off a significant portion of the Thin Film product line to MAST Biosurgery AG and its U.S. subsidiary (MAST) in 2004 for $7,000,000 in upfront fees plus $2,000,000 in cash or 19% equity in MAST Biosurgery and other considerations outlined in the Management's Discussion and Analysis of Financial Condition and Results of Operations section. Also, we entered into a distribution and supply agreement with Senko Medical Trading Co. ("Senko")

for the retained rights to market Thin Film products in Japan. The terms of the agreement include a $1,500,000 upfront license fee, which was received in July 2004, a $1,250,000 milestone related to a regulatory submission, which was received in the third quarter of 2004, a $250,000 milestone for a regulatory clearance, plus manufacturing revenues and royalties for a three year-period following initiation of commercialization. We are preparing to sell Thin Film implants to Senko for distribution in Japan following our 2004 submission of a regulatory application for Thin Films to the Japanese Ministry of Health, Labour and Welfare ("MHLW"). We expect regulatory clearance to be received in 2005 or early 2006.

CMF Bioresorbable Implants

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, for what resulted in total consideration of $15,500,000. In accordance with the terms of the Agreement,

we received an initial payment of $13,000,000 from Medtronic and a first milestone payment of $1,000,000 in the fourth quarter of 2002. A final milestone payment of $1,500,000 was received in 2004. The agreement also allowed us to receive up to $5,000,000 if and when we completed successful clinical evaluations for a new faster-resorbing polymer product, as defined in this agreement. In January 2004, we received a $5,000,000 milestone payment from Medtronic and it was recognized as gain on sale of assets, related party, in the accompanying statements of operations. In a separate, but simultaneous transaction, we paid Medtronic $4,000,000 to purchase a waiver of the right of first offer to market our Thin Films in certain fields.

Market and Competition

We compete with many other pharmaceutical, biotechnology and medical device companies as well as universities, government agencies and private organizations that are involved in varying degrees in the discovery, development and commercialization of medical technologies and therapeutic products.

The field of regenerative medicine is rapidly progressing, as many organizations are initiating or expanding their research efforts in this area. Most of these organizations are involved in research using cell sources such as bone marrow, embryonic and fetal tissue, umbilical cord and peripheral blood, muscle (which uses skeletal myoblasts (cells involved in muscle formation)), and regenerative capable cells from adipose tissue, which include adult stem cells. We work exclusively with adult regenerative cells from adipose tissue.

Companies performing regenerative cell research and development include, among others, Aastrom Biosciences, Inc., Baxter International, Inc.,BioHeart, Inc., Cellerix SA, Genzyme, Inc., Geron Corporation, Medtronic, MG Biotherapeutics, a joint venture between Genzyme and Medtronic, Osiris Therapeutics, Inc., Stem Cells, Inc., and ViaCell, Inc. We cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market.

We are aware of two ongoing clinical studies using adipose-derived regenerative cells. One is sponsored by Cellerix, which is performing a 50 patient, Phase IIb clinical trial in Spain where adipose-derived regenerative cells are being used to treat fistulas associated with Crohn's disease. The other is sponsored by the University of Tokyo, where researchers are examining the potential of adipose-derived regenerative cells in breast tissue augmentation. Our researchers are currently acting as consultants to both groups in various capacities.

One of the most studied areas for regenerative cells is cardiovascular disease, due to its growing prevalence worldwide. According to the American Heart Association's "Heart Disease and Stroke Statistics 2005" report, heart failure affects an estimated five million Americans each year. The report added that there have been 13 million cases of coronary heart disease and of those, 865,000 have been new or recurrent cases of myocardial infarction, which is the disease that our most advanced program targets.

Companies with advanced research and development programs for regenerative treatments of cardiovascular disease include Baxter, BioHeart, Genvec, MG Biotherapeutics, Osiris, and ViaCell. A Phase I study has been initiated at St. Elizabeth's Medical center in Boston using stem cells extracted from peripheral blood as an investigational treatment for myocardial ischemia. BioHeart is currently recruiting patients in the United States for a Phase I clinical study on the investigational product MyoHeart™, an autologous, skeletal myoblast cell therapy for heart disorders, which is delivered via a percutaneous catheter system. BioHeart is also conducting a Phase II trial in Europe evaluating MyoHeart™ for congestive heart failure. Using similar technology, Genvec has completed a Phase I trial using skeletal myoblasts, and MG Biotherapeutics is currently recruiting 200 patients in the United States and Europe for a Phase II study with their investigational, autologous skeletal myoblast cell therapy for transplantation into the heart during bypass surgery. Osiris Therapeutics, Inc. is planning to begin Phase I clinical trials in early 2005 for Provacel™, an investigational, allogeneic, adult, mesenchymal (bone-marrow-derived) stem cell therapy for acute myocardial infarction. ViaCell, Inc. is currently in pre clinical development for cardiac disease dealing with congestive heart failure and myocardial infarction.

The only regenerative cell product or service currently marketed by us is our cell banking service, which is being offered on a limited basis, to surgical patients undergoing liposuction procedures. While we are not aware of any other provider of cell banking comparable to our own, there are various companies engaged in umbilical cord blood and bone marrow stem cell preservation.

In regard to our bioresorbable technology, we compete primarily with titanium, allograft tissue (cadaver bone), and polyetheretherketone (PEEK) polymer products. We believe that an increasing number of other companies are developing, or are offering, bioresorbable devices. Stryker, Inc., Interpore Cross (Biomet), and Synthes are three companies that we are aware of who distribute 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 permanent bone fixation implants and allograft tissue.

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 we can, 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, Medtronic may pursue parallel development of other technologies or products, which may result in Medtronic developing additional products that will compete with our bioresorbable spine and orthopedic products. This would in turn induce Medtronic to de-emphasize marketing of our products in favor of more profitable products.

Research and Development

Research and development expenses were $11,007,000, $9,071,000 and $5,605,000 for the years ended December 31, 2004, 2003 and 2002, respectively. For 2004, $7,449,000 was allocated toward our regenerative cell technology and $3,049,000 was allocated toward our bioresorbable technology.

Our regenerative cell technology research and development efforts in 2004 focused on two primary areas:

- Developing the Celution™ System to isolate a patient's own regenerative cells from adipose tissue in real-time; and
- Conducting preclinical research to develop specific therapies from adipose-derived regenerative cells for cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders, and new approaches for aesthetic and reconstructive surgery.

Celution™ System developments in 2004 include the filing and receipt of the first of multiple 510(k) applications that will be required by the U.S. Food and Drug Administration (FDA) in order for us to commercialize a product.

Our preclinical research in 2004 focused predominantly on developing applications for cardiovascular disease, which include myocardial infarction and congestive heart failure. We presented data in conjunction with Cedars-Sinai Medical Center in Los Angeles, from a controlled study on 13 pigs in September 2004, which showed that the animal's own adipose-derived regenerative cells imparted a statistically significant improvement in left ventricular ejection fraction, a measure of the heart's ability to pump oxygenated blood throughout the body. The study also showed that injection of these cells in pigs was safe and well tolerated.

We also have ongoing preclinical collaborations with several other major U.S. and European academic research institutions. Our collaborators include the University of California, Los Angeles, where a team directed by W. Robb MacLellan, M.D., is working with us jointly on a National Institutes of Health Small Business Innovation Research grant worth up to $950,000. We also have research underway both internally and with a collaborator in Europe exploring potential orthopedic applications combining adipose-derived regenerative cells with our bioresorbable technology.

In 2004, our bioresorbable technology research and development efforts resulted in multiple new spine and orthopedic products and product advancements in conjunction with existing products sold to our distributor Medtronic. This included the development and FDA clearance for a radiographically identifiable version of our HYDROSORB™ Spine System, which is the first and only resorbable spinal implant to include a radiopaque marker fabricated from a resorbable material. It will allow physicians to visualize and monitor the position and placement of plates, screws, or other implants over time without obstructing the view of the healing bone.

Additionally, our bioresorbable research and development efforts focused on expanding the applications of our bioresorbable technology geographically; specifically, we have begun efforts to market our Thin Film products in Japan. In September 2004, we submitted an application to the MHLW for approval to market SurgiWrap™ and CardioWrap™. We expect to obtain regulatory clearance from the MHLW in 2005 or early 2006.

Products and Services

We currently manufacture a line of surgical implants derived from our bioresorbable technology. These implants are marketed in the United States, Europe and/or other countries for the repair and regeneration of tissue. We manufacture these products solely in the United States at our San Diego facility.

The HYDROSORB™ line of bioresorbable spine and orthopedic products is manufactured by us and distributed exclusively by Medtronic. HYDROSORB™ is a trademark of Medtronic. In 2004, this product line accounted for 55.8% of our total revenues.

In 2004, the Thin Film product line accounted for 32.8% of our total revenues. In May 2004, we sold most, but not all, of our

intellectual property rights and tangible assets related to our bioresorbable Thin Film product line to MAST and its subsidiaries. As part of the Thin Film disposition agreement, and for a period of up to one year, we must act in the capacity of a back-up supplier to MAST. Under the back-up supply agreement, we have agreed in nearly all cases to supply product ordered by MAST at our manufacturing cost.

In July 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. Specifically, the license covers Thin Film products with the following indications: anti-adhesion, soft tissue support, and minimization of the attachment of soft tissues throughout the body.

Within our regenerative cell technology program, we have not yet developed regenerative cell related therapies or treatments for commercial use. In September of 2004, we received 510(k) clearance for the MacroPore Puricel Lipoplasty System, a point-of-care adipose tissue extraction system, which is designed to extract and collect adipose tissue. This is the first of multiple 510(k) applications that will be required by the FDA in order for us to commercialize a product.

Additionally, we have a California state-licensed tissue bank facility for the preservation of extracted regenerative cells, which is being offered on a limited basis to surgical patients undergoing liposuction procedures. Typically arranged through a patient's physician, cell preservation 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 patient who preserved them. The cells can be preserved indefinitely.

The following table outlines our current line of 510(k)-cleared medical devices and the date they received clearance (excludes divested product lines):

Product Lines	Clearance received for, among other things, the following uses:	Clearance received
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 OS™ Trauma	bone graft containment in the iliac crest, or hip bone, ribs, graft donor sites, tumor resections where bone strength is not compromised and throughout the skeleton, other than in spinal applications, when used in conjunction with traditional rigid fixation devices.	July 2002
HYDROSORB™ Mesh	to maintain the relative position of weak bony tissue in orthopedic procedures when used in conjunction with rigid fixation and for iliac crest / rib reconstruction.	July 2002
CORNERSTONE™ HSR	to maintain the relative position of weak bony tissue in orthopedic procedures when used in conjunction with rigid fixation and for iliac crest / rib reconstruction.	July 2002
HYDROSORB™ TELAMON® BoomerangÒ	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™ Shield	to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists. The resorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.	July 2003
HYDROSORB™ Radiographic Spine System	indicated for use in spinal fusion procedures, in conjunction with traditional rigid fixation, as a means to maintain the relative position of weak bony tissue such as autografts. The radiopaque component of the HYDROSORB™ Spine System contains beads of barium sulfate.	August 2004
MacroPore Puricel Lipoplasty System	The MacroPore Puricel Lipoplasty System is intended for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired: neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, plastic and reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery. The MacroPore Puricel Lipoplasty System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.	September 2004

In addition, we have received marketing authorization for the sale of our products in the following countries:

Country	Authorization received for, among other things, the following uses:	Clearance received
European Community	MacroPore HYDROSORB™ Shield is a temporary physical barrier to: • Separate opposing tissues and prevent the growth of scar tissues and the formation and reformation of adhesions immediately adjacent to the barrier film; • Aid in re-operation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the barrier film; and • Prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane to include the following anatomical regions: dura, spinal dura, peridural, and epidural.	May 2002
	MacroPore HYDROSORB™ TELAMON® and MacroPore HYDROSORB™ Mesh to promote spinal fusion in the lumbar spine by maintaining the relative position of bone graft material and/or growth factors by assisting in maintaining the space between adjacent vertebral bodies in the treatment of spinal disorders such as degenerative disc disease, disc herniation, scoliosis, failed previous surgeries, etc.	January 2003
	MacroPore OS™ is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The MacroPore OS Protective sheet is also indicated for cement restriction in total joint arthroplasty procedures. Only when used in conjunction with traditional rigid fixation, the MacroPore OS System is intended to maintain the relative position weak bony tissue in trauma and reconstructive orthopedic procedures involving: • Long bones • Flat bones • Short bones • Irregular bones • Appendicular skeleton • 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.	July 2003

The MacroPore Resorbable Cervical Interbody Fusion Devices (Cornerstone HSR, Hydrosorb Mesh) are intended to be placed between the cervical vertebral bodies to promote spinal fusion by maintaining the relative position of bone grafting materials (autograft, allograft, xenograft, bone graft substitutes, etc.) and by assisting in maintaining the space between adjacent vertebral bodies when used in conjunction with traditional rigid fixation.

The Macropore Resorbable Cervical Interbody Fusion Devices are indicated to promote segmental arthrodesis in the cervical spinal fusion procedures (trauma, tumor, deformity, pseudoarthrosis, degenerative disease, failed previous fusion, etc.). The device is intended for primary and revision surgeries for the following indications:

- Degenerative disc disease
- Disc herniation
- Spinal stenosis
- Degenerative spondylolisthesis
- Failed previous cervical surgery
- Spondlolysis

CORNERSTONE, HYDROSORB and TELAMON are trademarks of Medtronic, Inc.

Customers

Medtronic is our primary distributor and our principal customer, directly accounting for $4,085,000 or 59.9% of our revenues for the year ended December 31, 2004, $12,893,000 or 91.5%, of our revenues for the year ended December 31, 2003, and $8,605,000, or

93.9% of our revenues for the year ended December 31, 2002.

Under our global co-development and supply agreement with Medtronic, we co-develop bioresorbable implants for spinal or reconstructive fixation, stabilization and fusion. Medtronic has exclusive worldwide rights to market and sell all of the bioresorbable products that we co-develop for this application through 2012. Both companies own an undivided, one-half interest in any inventions we jointly develop. Medtronic continues to retain its right of first offer for distributorship to our bioresorbable plates and mesh for orthopedic applications until January, 2006. Currently our only commercially available product line under this agreement is the HYDROSORB™ family of spine and orthopedic implants.

In May 2004, we sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST. As part of the Thin Film disposition agreement, and for a period of up to one year, we must act in the capacity of a back-up supplier to MAST. Under the back-up supply agreement, we have agreed in nearly all cases to supply product ordered by MAST at our manufacturing cost. Thin Film revenues attributable to sales to MAST were $1,678,000, or 24.6% of our revenues for the year ended December 31, 2004.

In July 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. The Distribution Agreement with Senko commences upon “commercialization.” Following commercialization, the Distribution Agreement has a five-year duration and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees.

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 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, 2004, we recorded $6,818,000 in revenues, including $6,602,000 of sales in the United States and $216,000 of sales outside the United States. For the year ended December 31, 2003, we recorded $14,088,000 in revenues, including $13,727,000 of sales in the United States and $361,000 of sales outside the United States. For the year ended December 31, 2002, we recorded $9,166,000 in revenues, including $8,855,000 of sales in the United States and $311,000 of sales outside the United States.

We hope that our future sales in Japan will increase as a result of our Distribution Agreement with Senko.

Working Capital

We generally build products to order although for selected products we may from time to time maintain an inventory of approximately three to five months of sales. Although capital expenditures may vary significantly depending on a variety of factors, including sales, we presently intend to spend approximately $500,000 on capital equipment purchases in 2005 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 bioresorbable 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, cash flows 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.

With respect to our regenerative cell technology, we are the exclusive, worldwide licensee from the Regents of the University of California to one United States patent (U.S. Patent No. 6,777,231) related to isolated adipose derived stem cells that can differentiate into two or more of a variety of cell types, which was issued in August 2004. In addition, we have been granted certain exclusive and non-exclusive perpetual license rights to five U.S. patent applications and 20 corresponding international patent applications through a license agreement with the Regents of the University of California. We have also filed applications for 19 additional United States patents, as well as 24 corresponding international patent applications, relating to our regenerative cell technology.

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. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested. In addition, further legal risk arises from a lawsuit, filed by the University of Pittsburgh in the fourth quarter of 2004, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. If the University of Pittsburgh wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, and our strategy related to our regenerative cell technology could be materially adversely affected.

We cannot assure 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.

With respect to our bioresorbable implant products and technology, we have obtained 13 U.S. patents, three of which were sold in product line dispositions. Our three U.S. patents related to the design of our macro-porous bioresorbable sheets for skeletal repair and regeneration were issued in July 1999, August 2001 and March 2004. 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 in May 2002. Our two U.S. patents related to our bioresorbable barrier film for the control of postsurgical adhesions were issued in March 2003 and January 2004 and assigned to MAST as part of the Thin Film product line sale agreement. Our U.S. patent related to stereotaxic detachable needle extensions was issued in June 2003. Our U.S. patent related to non-scatterable radio-opaque material for imaging applications was issued in October 2003. Our U.S. patent related to a resorbable posterior spinal fusion system was issued in April 2004. Our U.S. patent for a cranial flap fixation device was issued in June 2004 and assigned to Medtronic pursuant to the September 2002 CMF product line sale agreement. We also have two Australian patents related 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 four Australian patents were 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. In addition, we have filed applications for 14 additional U.S. patents as well as 33 corresponding international patents relating to our bioresorbable 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. We currently have pending patent applications in Europe, Australia, Japan, Canada, China, Korea, and Singapore, among others.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce or confirm the ownership of 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 or a foreign patent 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. We may incur

substantial legal costs as a result of the University of Pittsburgh lawsuit, and our president, Marc Hedrick, M.D., is a named individual defendant in that lawsuit because he is one of the inventors identified on the patent. 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.

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. U.S. 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. As noted above regarding the University of Pittsburgh lawsuit, even patents issued to us or our licensors might be judicially determined to belong in full or in part to third parties.

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.

Failure to obtain or maintain patent protection, or protect trade secrets, 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, cash flows and financial condition.

Government Regulation

Most medical devices and treatments for use in humans, including our bioresorbable protective sheets, plates, and screws, 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, biologic license application, new drug application, 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 the 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.

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. Specifically, in regard to our licensing agreement with Senko, marketing authorization from the Japanese Ministry of Health, Labour and Welfare is necessary for commercialization of the Thin Film product line in Japan.

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, cash flows and financial condition.

Staff

As of December 31, 2004, we had 99 full-time employees, comprised of 55 employees in research and development, 16 employees in manufacturing, 21 employees in management and finance and administration and 7 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) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (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 filings for our company and its insiders.

Item 2. Property

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

- 14,000 square feet, of which approximately 4,000 square feet is for research and development and 10,000 square feet is office space, at 6749 Top Gun Street, San Diego, California for a five-year term expiring in 2006. We currently sublease 6,000 square feet of this office and warehouse space at the rate charged per square foot in our current lease agreement. We sublease approximate 5,000 square feet to MAST and the remainder to another unrelated party.
- 16,000 additional square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five-year term expiring 2008.

We pay an aggregate of approximately $60,000 in rent per month for our properties. The aggregate sublease amount is $6,000 per month.

Item 3. Legal Matters

None

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

None

PART II

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

Market Prices

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

	High Euro	High U.S.	Low Euro	Low U.S.
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
2004				
Quarter ended March 31, 2004	€ 3.45	$ 4.30	€ 2.00	$ 2.58
Quarter ended June 30, 2004	€ 3.80	$ 4.61	€ 3.02	$ 3.67
Quarter ended September 30, 2004	€ 3.60	$ 4.40	€ 1.93	$ 2.38
Quarter ended December 31, 2004	€ 2.73	$ 3.37	€ 1.77	$ 2.43

All of our outstanding shares are represented by a global stock certificate issued in the name of Seydler AG Wertpapierhandelsbank and deposited with Clearstream Banking AG, Frankfurt, Germany, the German securities depository. As of January 31, 2005, 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 10,900.

Dividends

We have never declared or paid any dividends and 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.

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

None

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	5,024,000	$ 3.91	466,000
Equity compensation plans not approved by security holders(1)	—	—	3,000,000
Total	5,024,000		3,466,000

(1) The maximum number of Shares shall be cumulatively increased on the first January 1 after the Effective Date and each January 1 thereafter for 9 more years, by a number of Shares equal to the lesser of (a) 2% of the number of Shares issued and outstanding on the immediately preceding December 31, and (b) a number of Shares set by the Board.

On August 24, 2004, the 2004 Equity Incentive Plan of Macropore Biosurgery, Inc. (the "Plan") became effective upon approval by our Board of Directors. The Plan is designed to provide our employees, directors and consultants the opportunity to purchase our common stock through non-qualified stock options, stock appreciation rights, restricted stock units, or restricted stock and cash awards. The Compensation Committee of the Board shall administer the Plan and determine the number of shares underlying each award, the vesting of such shares and other important terms of awards pursuant to the terms of the Plan. Awards may be granted under the Plan over a ten-year period and the Board has initially reserved 3,000,000 shares of common stock for issuance under the Plan. The maximum number of shares reserved for issuance under the Plan may be cumulatively increased (subject to Board discretion) on an annual basis beginning January 1, 2005, as provided in the footnote to the Equity Compensation Plan Information table.

Item 6. Selected Consolidated Financial Data

The selected data presented below under the captions "Statements of Operations Data," "Statements 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, 2004, are derived from the financial statements of MacroPore Biosurgery, Inc. The consolidated balance sheets as of December 31, 2004 and 2003, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, which have been audited by KPMG LLP, an independent registered public accounting firm, and their report thereon, are included elsewhere in this annual report. The consolidated balance sheet as of December 31, 2002, which has been audited by KPMG LLP, and the consolidated financial statements as of December 31, 2001 and 2000 and for each of the years in the two-year period ended December 31, 2001, which have been audited by Arthur Andersen LLP, independent auditors, their reports thereon are included with annual reports previously filed with the Securities and Exchange Commission.

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

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(dollars in thousands except per share data)				
Statements of Operations Data:					
Revenues:					
Sales to related party	$ 4,085	$ 12,893	$ 8,605	$ 5,547	$ 6,092
Sales to third parties	2,247	1,195	561	101	159
Research grant	328	—	—	—	—
Development	158	—	—	—	—
	6,818	14,088	9,166	5,648	6,251
Cost of revenues:					
Cost of revenues	3,142	4,244	3,169	2,401	2,394
Inventory provision	242	—	1,395	1,750	—
Gross profit	3,434	9,844	4,602	1,497	3,857
Operating expenses:					
Research and development	11,007	9,071	5,605	5,487	2,584

Sales and marketing	2,391	4,417	3,987	4,493	2,629
General and administrative	5,825	4,581	3,952	3,578	2,555
Stock based compensation	125	985	1,287	1,123	5,698
In-process research and development	—	—	2,296	—	—
Restructuring charge	107	451	—	—	—
Equipment impairment charge	42	—	370	—	—
Total operating expenses	19,497	19,505	17,497	14,681	13,466
Other income (expense):					
Gain on the sale of assets, related party	13,883	—	—	—	—
Interest income	252	417	1,037	2,249	1,315
Interest expense	(177)	(126)	(241)	(100)	(82)
Other income (expense)	15	87	(22)	(68)	(269)
Equity loss in investment	—	—	(882)	(104)	—
Net loss	$ (2,090)	$ (9,283)	$ (13,003)	$ (11,207)	$ (8,645)
Basic and diluted net loss per share	$ (0.15)	$ (0.64)	$ (0.91)	$ (0.75)	$ (1.05)
Basic and diluted weighted average common shares	13,932,390	14,555,047	14,274,254	14,926,107	8,201,739
Statements of Cash Flows Data:					
Net cash used in operating activities	$ (12,574)	$ (7,245)	$ (6,886)	$ (8,322)	$ (2,982)
Net cash provided by (used in) investing activities	13,425	5,954	17,265	2,263	(39,450)
Net cash (used in) provided by financing activities	(831)	(997)	(7,971)	1,283	47,437
Net increase (decrease) in cash	20	(2,288)	2,408	(4,776)	5,005
Cash and cash equivalents at beginning of year	2,820	5,108	2,700	7,476	2,471
Cash and cash equivalents at end of year	$ 2,840	$ 2,820	$ 5,108	$ 2,700	$ 7,476
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 13,419	$ 14,268	$ 24,983	$ 33,951	$ 44,484
Working capital	12,378	12,432	25,283	35,119	46,858
Total assets	25,470	28,089	39,319	43,143	52,269
Deferred gain on sale of assets, related party	—	7,539	9,623	—	—
Deferred gain on sale of assets	5,650	—	—	—	—
Deferred license fee revenue	1,500	—	—	—	—
Deferred development revenue	1,092	—	—	—	—
Long-term obligations, less current portion	1,128	1,157	770	1,791	—
Total stockholders' equity	$ 12,833	$ 14,909	$ 25,995	$ 38,486	$ 49,335

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 the "Risk Factors" section in this Management's Discussion and Analysis of Financial Conditions and Results of Operations. We encourage you to read those descriptions carefully. We caution you 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 an earlier 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. Finally, we strongly emphasize that our reported net loss of $2,090,000 for the year ended December 31, 2004 should ***not*** *be considered predictive of future results. This is because we recognized $13,883,000 as gain on the sale of assets, related party during the year ended December 31, 2004 that related to our sale of our CMF product line to Medtronic initiated in September 2002.*

Overview

During 2004, we continued to shift our focus toward the discovery and development of therapies for cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery using regenerative cells from adipose tissue. Adipose tissue is the richest and most accessible source for regenerative cells in the human body. This tissue contains adult stem cells, angiogenic cells (blood vessel forming) and other regeneration-promoting cells. Additionally, we continue to develop and manufacture the HYDROSORB™ family of FDA-cleared bioresorbable spine and orthopedic implants, which are distributed exclusively through Medtronic, Inc ("Medtronic"). Medtronic owns approximately 7.2% of our common stock and is a related party.

Our primary regenerative cell research program, currently in preclinical testing, targets cardiovascular disease, including myocardial infarction. Additionally, we have a pipeline of preclinical investigational therapies that target multiple therapeutic areas. To facilitate the processing and delivery of adipose-derived regenerative cells, we are designing a proprietary point-of-care system, Celution™, to isolate and concentrate a patient's own regenerative cells in real-time. Our goal is to commercialize systems that may be used universally across multiple therapeutic applications. The commercialization model will be based on the sale of devices and related consumables.

Developments during 2004 that reflect our transition of focus toward our regenerative cell technology program include:

- The receipt of a 510(k) clearance from the U.S. Food and Drug Administration (FDA) for a point-of-care adipose tissue extraction system;
- The release of positive data from a preclinical study in myocardial infarction;
- An award of up to $950,000 in National Institutes of Health (NIH) Small Business Innovation Research (SBIR) grant funding;
- The issuance of a U.S. patent to the University of California related to adult stem cells isolated from adipose tissue for which we are the exclusive, worldwide licensee; and
- The initiation of multiple preclinical studies with university collaborators to discover treatments for cardiovascular disease, spine and orthopedic conditions, and novel approaches for aesthetic and reconstructive surgery.

Simultaneously, we experienced a reduction in orders from Medtronic for HYDROSORB™ products during the second, third and fourth quarters of 2004 as a result of their inventory stocking patterns, as well as marketing efforts by Medtronic which were significantly less vigorous than we had anticipated and

resulted in slower than anticipated end-use market penetration. During the third and fourth quarters of 2003 and the first quarter of 2004, Medtronic placed initial stocking orders for newly released HYDROSORB™ products, which provided them with sufficient stock for 2004.

For the next several years we will fund the research and development of our regenerative cell technology through:

- Existing cash reserves;
- Profits, if any, from HYDROSORB™ and Thin Film product sales;
- Cash flows related to recent product line divestitures and licensing agreements; and
- Licensing fees and/or equity agreements connected with potential regenerative cell technology partnerships.

During this time, we expect to:

- Complete the engineering and design of our point-of-care regenerative cell technology system and seek relevant regulatory clearances;
- Continue preclinical development of regenerative cell therapies for cardiovascular disease, our primary area of focus, as well as for spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery, among others;
- Expand our intellectual property position related to our regenerative cell program;
- Advance regenerative cell technology programs into clinical development;
- Form at least one key therapeutic development collaboration for therapeutic applications outside the area of cardiovascular disease; and
- Pursue available grant opportunities.

As part of this strategy, in 2004 we sold off a significant portion of our Thin Film product line to MAST Biosurgery AG (MAST) for $7,000,000 in upfront fees plus $2,000,000 in cash or 19% equity in MAST and other considerations outlined below. Also, in the third quarter of 2004 we entered into a distribution agreement with Senko Medical Trading Co. (“Senko”) whereby we granted Senko our retained rights to market Thin Film in Japan. As part of this agreement, we received an upfront license fee of $1,500,000 in July 2004, plus a $1,250,000 milestone for submitting a regulatory application for Thin Film to the Japanese Ministry of Health, Labour and Welfare (“MHLW”), which we received in October 2004. We are also entitled to receive $250,000 following regulatory clearance

from the MHLW plus manufacturing revenues and royalties for a three year-period following initiation of commercialization. However, we acknowledge that the MHLW has not yet issued its final approval and further significant delays are possible. Additionally, we received $6,500,000 in two payments from Medtronic in 2004 related to the sale of our craniomaxillofacial (“CMF”) product line to Medtronic in 2002.

Furthermore, we are closely monitoring the progress of the HYDROSORB™ business and remain cautiously optimistic regarding the eventual success of the product family. This success will depend significantly on the efforts of Medtronic to market the products and obtain additional regulatory clearances and approvals for the product line.

It is possible that we may need to seek capital through additional divestitures or the sale of equity securities, especially if we do not receive sufficient money from therapeutic development collaborations or positive cash flow from HYDROSORB™ and Thin Film revenues.

Total revenues for the year ended December 31, 2004 were $6,818,000 compared to $14,088,000 for 2003, a decrease of 51.6%. Of the total revenue in 2004, $3,803,000 is attributable to sales of HYDROSORB™ products to Medtronic. For a complete breakdown of revenues for the year ended December 31, 2004, see the table located in the results of operations section.

Net loss for the year ended December 31, 2004 was $2,090,000, compared to a net loss of $9,283,000, for 2003. The 2004 loss is not indicative of the loss levels we expect to experience in the future, because it contains the following mitigating components:

- The receipt and recognition of a $1,500,000 payment in the third quarter of 2004 as a result of completing the final milestone related to the September 2002 sale of the CMF product line;
- The recognition of $7,383,000 in the third quarter of 2004 associated with the completion of our obligations related to the September 2002 sale of our CMF product line to Medtronic, which was previously reported as deferred gain on sale of assets, related party on our balance sheet; and
- A one-time $5,000,000 gain in the second quarter of 2004 related to the completion of the clinical research regarding Faster Resorbing Polymers.

Adjusted net loss for the year ended December 31, 2004 is outlined in the table below.

	Year Ended December 31,	
	2004	**2003**
Net loss GAAP	$ (2,090,000)	$ (9,283,000)
Less: Gain on sale of assets, related party	(13,883,000)	—
Adjusted net loss (1)	$ (15,973,000)	$ (9,283,000)

(1) We believe adjusted net loss is a useful measure by which investors can evaluate our operating performance on a comparable basis, unaffected by the large gains we recognized in 2004.

The increase in the adjusted net loss for the year ended December 31, 2004 reflects our decrease in HYDROSORB™ revenues during 2004, with a simultaneous increase in research and development expenses related to our regenerative cell technology program, compared to the same periods in 2003.

2005 Financial Projections

For the next several years, we expect to incur increasing losses as we invest into the research and development of our regenerative cell technology and until the first regenerative cell technology products become commercialized.

In 2005, we expect bioresorbable technology-related revenues to be $6,000,000 to $9,000,000. This is in part due to ongoing market demand for the HYDROSORB™ product family and in part due to anticipated stocking orders for the radiographically identifiable Spine System products, which we received FDA clearance for in August 2004. However it should be noted that on July 19, 2004, we withdrew our 2004 revenue guidance because of our assessment that we were not able to reliably project HYDROSORB™ product revenues. We believe that our visibility challenges have not been fully resolved.

Additionally, we will continue our efforts to prepare for the commercialization of the Thin Film products in Japan, which we anticipate to occur in 2005 or early 2006. Commercialization of the Thin Film product line may result in revenues related to stocking orders and royalty payments from Senko, provided MAST does not exercise its option for Thin Film-related interests and rights in Japan. If MAST does exercise their option, they are required to make a $3,000,000 payment to us and equally share with us their gross profits and royalties from Senko for a three-year period post-commercialization.

Further, we expect our research and development expenses in 2005 to be in the range of $11,000,000 to $13,000,000, as we

continue preclinical studies and prepare to enter clinical studies in 2006 related to our regenerative cell technology program. We expect our domestic and international sales and marketing expenses to decline significantly this year as we will no longer incur expenses related to Thin Film independent sales representatives.

In regard to our cash reserve, we expect to bolster our current position by entering into co-development partnerships related to the regenerative cell technology or seek capital through additional divestitures or the sale of equity securities. At present, we believe we have enough liquid assets to support our operations through at least December 31, 2005.

Disposition of Product Lines

Sale of Craniomaxillofacial Product Line

In September 2002, we entered into an Asset Purchase Agreement (the “Agreement”) to sell assets related to our CMF implant and accessory product line to Medtronic for what resulted in total net consideration of $15,500,000. In accordance with the terms of the Agreement, we received an initial payment of $13,000,000 from Medtronic and a first milestone payment of $1,000,000 in the fourth quarter of 2002. A final milestone payment of $1,500,000 was received in 2004.

The Agreement requires us not to market in the craniomaxillofacial field, for five years, any products that compete with the acquired product line. Additionally, during the technology transfer transition period, we agreed to be a back-up supplier of CMF products to Medtronic at a price equal to our cost of manufacture.

The Agreement also allowed us to receive up to $5,000,000 if and when we completed successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement. In January 2004, we received a $5,000,000 milestone payment from Medtronic and it was recognized as gain on sale of assets, related party, in the accompanying statements of operations.

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

We accounted for the net proceeds of the Agreements as deferred gain on sale of assets, related party. This gain was to be recognized only as certain events occurred. For instance, we recognized 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 correlated to the gross margin normally charged by us on similar products. The remainder of the deferred gain was recognized in the third quarter of 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

During the third quarter of 2004, we completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Accordingly, we recorded $7,383,000 as a component of gain on sale of assets, related party, in the accompanying statements of operations, representing the remaining balance that had theretofore been reported as deferred gain on sale of assets, related party.

Pursuant to the sale of the CMF product line, we were obliged to transfer certain “know-how,” including manufacturing processes, patents, and other intellectual property, to Medtronic. If such know-how was transferred within a certain time frame defined in the Agreement, we would become entitled to a $2,000,000 milestone payment.

In the second quarter of 2004, we provided notice to Medtronic that the requisite know-how associated with the transferred CMF product line had been transferred, pursuant to the terms of, and within the timeframe specified by, the Agreement. Medtronic did not agree that know-how transfer had been completed and asserted that, in any case, the maximum payment due to us was $1,000,000 rather than $2,000,000.

To avoid the risk and expense of arbitration, in the third quarter of 2004 we agreed to accept a negotiated settlement with Medtronic in the amount of $1,500,000 related to the know-how transfer. The $1,500,000 payment has been recognized as gain on sale of assets, related party, in the accompanying statements of operations.

Sale of Thin Film Product Line

In May 2004, we sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST and one of its subsidiaries. We have received $7,000,000 in cash and might receive the following additional contingent

consideration:

- $200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration for a hernia wrap product (thin film combination), and
- $2,000,000 on or before the earlier of (i) May 31, 2005 or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer, provided the Chief Executive Officer has held that position for at least four months and meets other requirements specified in the sale agreement. If MAST had not hired a Chief Executive Officer by January 31, 2005, MAST may, at its sole option, provide us on May 31, 2005 with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 instead of making the $2,000,000 cash payment. We believe that MAST hired a CEO in late 2004 and, thus, became obliged to pay the $2,000,000 obligation in early 2005. However, MAST has objected to our interpretation of the agreement and maintains that the individual hired does not qualify as the CEO under its terms. Regardless, MAST's obligation is due to us no later than May 31, 2005.

As part of the Thin Film disposition agreement, and for a period of up to one year, we must provide training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line, and act in the capacity of a back-up supplier to MAST. Under the back-up supply agreement, we have agreed in nearly all cases to supply product ordered by MAST at our manufacturing cost.

Because of these and other additional performance requirements, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately $6,450,000 as deferred gain on sale in the balance sheet. The amount recorded as deferred gain on sale does not include the potential contingent consideration described above, which will only be added to the deferred gain on sale when the contingencies are resolved.

We do not expect to complete our performance obligations until the second quarter of 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. However, in 2004 we recognized $772,000 of the deferred gain as revenues related to the sale of Thin Film products to MAST under the back-up supply agreement at cost. This was necessary to state revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction.

Even after consummation of the Thin Film asset disposition, we retained all rights to Thin Film business in Japan (subject to a purchase option of MAST, as described below), and we received back a license of all rights to Thin Film technologies in the:

- Spinal field, exclusive at least until 2012, and
- Field of regenerative medicine, non-exclusive on a perpetual basis

The sale agreement grants MAST a "Purchase Right" to acquire our Thin Film-related interests and rights for Japan at the following terms:

- If MAST exercises its option on or before May 31, 2005, the purchase price will be $3,000,000.
- After May 31, 2005 but before May 31, 2007, the exercise price of the Purchase Right will be equal to the fair market value of the Japanese business, but in no event will be less than $3,000,000. Moreover, between June 1, 2005 and May 31, 2007 MAST will have a right of first refusal to match the terms of any outside offer to buy our Japanese Thin Film business.

If MAST exercises the Purchase Right, MAST will become obligated to reimburse us for certain costs we have incurred or will incur related to product development and protection of intellectual property rights in the country of Japan. Moreover, under certain circumstances MAST must share certain milestone payments and gross profits with us, if MAST exercises the Purchase Right and begins marketing Thin Film products in Japan.

Thin Film Distribution Agreement

In the third quarter of 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. Specifically, the license covers Thin Film products with the following indications:

- Anti-adhesion,
- Soft tissue support, and
- Minimization of the attachment of soft tissues throughout the body.

The Distribution Agreement with Senko commences upon "commercialization." In simplest terms, commercialization occurs when one or more Thin Film product registrations are completed with the MHLW.

Following commercialization, the Distribution Agreement has a duration of five years and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees.

We received a $1,500,000 upfront license fee from Senko. We have recorded the $1,500,000 received as deferred license fee revenue in the accompanying balance sheet. Half of the license fee is refundable if the parties agree commercialization is not achievable and a proportional amount is refundable if we terminate the arrangement, other than for material breach by Senko, before three years post-commercialization.

Accordingly, we will begin to recognize this $1,500,000 license fee as revenues only after commercialization has been achieved. Moreover, we will not recognize all of the revenues at one time – instead, we will reflect the fee in revenues on a systematic basis over the expected period of time we anticipate that Senko will benefit from the arrangement. However, we will not recognize deferred license fee revenue in the statements of operations if this would cause the remaining deferred license fee revenue balance to fall below the amount that we potentially would have to refund to Senko.

We will also be entitled to earn additional payments from Senko based on achieving defined milestones. We will recognize such payments as revenues when the performance criteria for a milestone have been met, presuming that achievement of the milestone involves substantive effort and the fees received

are commensurate with the level of effort expended. On September 28, 2004, we notified Senko of completion of the initial regulatory application to the MHLW for the Thin Film product. As a result, we became entitled to a nonrefundable payment of $1,250,000, which we received in October 2004 and recorded as deferred development revenue. Of the amount deferred, we recognized $158,000 as development revenues in the year ended December 31, 2004. The amount recognized as development revenues represents the relative fair value of the completed milestone as compared with the fair value of all milestones expected to be necessary to achieve regulatory approval by the MHLW.

Results of Operations

Years ended December 31, 2004 and 2003 compared to years ended December 31, 2003 and 2002, respectively.

Revenues

The following table summarizes the components of our revenues for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Spine and orthopedics products	$ 3,803,000	$ 9,882,000	$ 5,544,000	$ (6,079,000)	$ 4,338,000	(61.5)%	78.2%
Thin film products:							
Product sales (non-MAST related)	559,000	1,186,000	561,000	(627,000)	625,000	(52.9)%	111.4%
Product sales to MAST	906,000	—	—	906,000	—	—	—
Amortization of gain on sale (MAST)	772,000	—	—	772,000	—	—	—
Total thin film	2,237,000	1,186,000	561,000	1,051,000	625,000	88.6%	111.4%
Craniomaxillofacial (CMF) products:							
Product sales	126,000	964,000	2,569,000	(838,000)	(1,605,000)	(86.9)%	(62.5)%
Distributor license fees	—	—	225,000	—	(225,000)	—	—
Amortization of gain on sale	156,000	2,047,000	267,000	(1,891,000)	1,780,000	(92.4)%	666.7%
Total craniomaxillofacial	282,000	3,011,000	3,061,000	(2,729,000)	(50,000)	(90.6)%	(1.6)%
Research grant (NIH)	328,000	—	—	328,000	—	—	—
Development (Senko)	158,000	—	—	158,000	—	—	—
Regenerative cell storage services	10,000	9,000	—	1,000	9,000	11.1%	—
Total	$ 6,818,000	$ 14,088,000	$ 9,166,000	$ (7,270,000)	$ 4,922,000	(51.6)%	53.7%
% attributable to Medtronic	59.9%	91.5%	93.9%				

Note: Certain prior period amounts have been reclassified to conform to current period presentation.

- Spine and orthopedic revenues represent sales of bioresorbable implants used in spine and orthopedic surgical procedures. In the second half of 2003 and first quarter of 2004, Medtronic (our sole distributor of spine and orthopedic products) placed initial stocking orders for our newly developed HYDROSORB™ products. We had anticipated that demand for these products from Medtronic's customers would draw down these inventories sufficiently to require Medtronic to buy substantial additional amounts this year. However, sales to Medtronic through, and especially in, the second half of 2004 were well below our expectations. End-user demand has not increased as we thought it would, primarily because of inadequate marketing efforts by Medtronic. Medtronic also markets competing products, some of which generate a higher profit margin for Medtronic. The increase in spine and orthopedics revenue in 2003 as compared to 2002 resulted primarily from filling orders of HYDROSORB™ products. Refer to "The future" discussion below for our expectations regarding the outlook for future spine and orthopedic revenues. Note that Medtronic owns

approximately 7.2% of our outstanding common stock.

- Thin Film product revenues represent sales of SurgiWrap™ bioresorbable Thin Film used 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). The revenue increase in 2004 primarily relates to initial stocking orders placed by MAST following the acquisition of Thin Film product rights from us in the second quarter of 2004. We are obliged by contract to sell these products to MAST at our manufacturing cost. Of the revenues reported during 2004, $772,000 relates to the recognition of a portion of the deferred gain related to sale of Thin Film assets to MAST. This recognition policy is necessary to state our revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction. The increase in Thin Film revenue in 2003 as compared to 2002 was attributable to a full year of sales of this product line in 2003 versus sales in only the second half of 2002. Refer to "The future" discussion below for expected trends regarding future Thin Film revenues.

- The CMF product revenues represent sales of the CMF line of products used for trauma and reconstructive procedures in the midface and craniofacial skeleton (the head and skull). We sold this product line to Medtronic in 2002. As with the Thin Film products, we sold CMF products at cost in 2002, 2003 and 2004 under a contractual back-up supply agreement and we recognized a portion of the deferred gain related to sale of assets in order to reflect the gross margin which would otherwise have been associated with such sales. The decrease in CMF product revenue in 2003 and 2004 reflects Medtronic transitioning the manufacturing of CMF products to its own facilities. During the third quarter of 2004, we completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Therefore, we do not expect to earn any CMF product revenue in the future.

- The research grant revenue relates to our agreement with the National Institutes of Health ("NIH"). Under this arrangement, the NIH reimburses us for "qualifying expenditures" relating to research on Adipose-Derived Cell Therapy for Myocardial Infarction. To receive funds under the grant arrangement, we are required to (i) demonstrate that we incurred "qualifying expenses," as defined in the grant agreement between the NIH and us, (ii) maintain a system of controls, whereby we can accurately track and report all expenditures related solely to research on Adipose-Derived Cell Therapy for Myocardial Infarction, and (iii) file appropriate forms and follow appropriate protocols established by the NIH. As of June 30, 2004, we had completed Phase I of the research grant and incurred the full amount of qualifying expense for reimbursement of $100,000. In the third quarter of 2004, the NIH authorized us to begin Phase II of the research grant which entitled us to receive up to $850,000 (subject to availability of funds and satisfactory progress towards meeting the goals and objectives of our grant application). Our policy is to recognize revenues under the NIH grant arrangement as the lesser of (i) qualifying costs incurred (and not previously recognized) for which we are entitled to funding or (ii) the amount determined by comparing the outputs generated to date versus the total outputs expected to be achieved under the research arrangement. During the second half of 2004, we incurred $222,000 in qualifying

expenditures plus $6,000 in allowable grant fees, for a total of $228,000 in reimbursements related to Phase II of the research grant. We have recorded revenues for the same amount.

- Under a Distribution Agreement with Senko we are entitled to earn payments based on achieving the following defined milestones:

  - Upon notifying Senko of completion of the initial regulatory application to the MHLW for the Thin Film product, we were entitled to a nonrefundable payment of $1,250,000. We so notified Senko on September 28, 2004, received payment in October of 2004, and recorded deferred development revenue. Of the amount deferred, we have recognized development revenues of $158,000, representing the relative fair value of the completed milestone as compared with the fair value of all milestones expected to be necessary to achieve regulatory approval by the MHLW;

  - Upon the achievement of commercialization of the thin film product line in Japan, we are entitled to a nonrefundable payment of $250,000. As of December 31, 2004, commercialization had not occurred; however, commercialization is expected in 2005 or early 2006.

The future: We sell our spine and orthopedic products exclusively to Medtronic at fixed selling prices that are subject to adjustment biannually (based on Medtronic's selling prices to its customers). Our revenue from this product line is dependent upon the market's adoption of our technology, which is largely dependent upon Medtronic's marketing efforts and pricing strategies. To increase our revenues from spine and orthopedic products, we depend largely on Medtronic's ability and commitment to build and expand HYDROSORB™ market share. Additionally, because our HYDROSORB™ products are relatively new to the market, and because our internal estimates of second quarter 2004 HYDROSORB™ sales were proven inaccurate, we concluded that we were unable to accurately forecast Medtronic's, and Medtronic's customers' demand. Therefore, in July 2004, we retracted our previously stated revenue guidance for 2004. Our sales remained weak in the third and fourth quarters of 2004. We continue to believe in the medical value of this product line, but there are significant uncertainties regarding the vigor of Medtronic's marketing efforts and the

rate of adoption by physicians. In August of 2004, we received FDA clearance for our radiographically identifiable Spine System products. We currently expect market demand, and therefore revenues, for these and our other HYDROSORB™ products to increase in 2005 from 2004 levels, particularly as Medtronic and its customers seek to employ our radiographically identifiable Spine System products.

We became entitled to receive up to $850,000 in additional grants related to Adipose-Derived Cell Therapy for Myocardial Infarction as defined by the NIH grant agreement for Phase II research for which we have or expect to incur "qualifying expenses" in 2004 and 2005 subject to availability of NIH funds and satisfactory progress toward meeting the goals and objectives of our grant application. We expect to recognize the remaining grant of approximately $600,000 in revenues during 2005 and 2006.

We will continue to recognize revenue from the milestone payment from Senko, based on the fair value of the milestones completed relative to the total efforts expected to be necessary to obtain regulatory clearance with the MHLW. Obtaining regulatory clearance with the MHLW is expected in 2005 or early 2006, but could potentially continue through 2007 as we perform additional clinical study(s), revise documentation, and negotiate reimbursement points with the MHLW.

To the extent that sales of our spine and orthopedic products to Medtronic (and to Medtronic's customers) recover to any significant degree, we expect the percentage of revenues attributable to Medtronic to increase as sales of Thin Film become a lower percentage of our overall sales revenue, although this may change when commercialization of the Thin Film products in Japan occurs and we begin Thin Film shipments to Senko.

As MAST begins to assume the manufacturing process, we expect domestic revenue from Thin Film products to decline and end in 2005.

Cost of revenues

Cost of revenues includes material, manufacturing labor, overhead costs and an inventory provision. The following table summarizes the components of our cost of revenues for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ and % Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Cost of revenues:							
Cost of revenues	$ 3,142,000	$ 4,244,000	$ 3,169,000	$ (1,102,000)	$ 1,075,000	(26.0)%	33.9%
% of revenue	46.1%	30.1%	34.6%	16.0%	(4.5)%	53.2	(13.0)
Inventory provision	242,000	—	1,395,000	242,000	(1,395,000)	—	—
% of revenue	3.5%	—	15.2%	3.5%	(15.2)%	—	—
Total	$ 3,384,000	$ 4,244,000	$ 4,564,000	$ (860,000)	$ (320,000)	(20.3)%	(7.0)%
% of revenues	49.6%	30.1%	49.8%				

- The cost of revenues, as a percent of revenues (excluding inventory provision amounts), increased 53.2% in the year ended December 31, 2004 as compared to 2003, and decreased 13.0% in 2003 as compared to 2002. The increase in 2004 from 2003 was due to higher cost of revenues associated with the Thin Film products than other product lines (product mix) as well as a lack of inventory production (generated by declining sales demand) to absorb fixed manufacturing and labor expense. The decrease in 2003 from 2002 was primarily attributable to increased sales revenue that allowed us to absorb more of our manufacturing labor and overhead costs. Excess manufacturing capacity expensed in 2004 was $1,119,000 as compared to $423,000 in 2003 and $1,145,000 in 2002.

- The $242,000 inventory provision during the year ended 2004 with no comparable charges in 2003 related to excess inventory. Such inventory was produced in consideration of our responsibility to be a back-up supplier for the CMF product line. We sold the assets related to this product line to a subsidiary of Medtronic in September 2002. In April of 2004, Medtronic indicated that it would no longer purchase CMF inventory from us under the back-up supply arrangement, leading to our determination that the remaining CMF inventory on hand would not be recoverable. The $1,395,000 inventory provision recorded in 2002 was directly related to the CMF asset sale, as the remaining unsold inventory in our CMF bone fixation implants and accessories product line inventory would no longer be recoverable.

The future: Ceasing to manufacture the CMF product line and the May 2004 sale of our non-Japan bioresorbable Thin Film product line will deprive us of economies of scale and will negatively impact our margins unless other sources of revenue grow large enough to compensate for the lost revenue.

Research and development expenses

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 pre clinical studies. It excludes related stock based compensation

expenses. The following table summarizes the components of our research and development expenses for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Regenerative cell technology	$ 7,449,000	$ 4,419,000	$ 359,000	$ 3,030,000	$ 4,060,000	68.6%	1130.9%
Bioresorbable polymer implants	3,049,000	4,652,000	5,246,000	(1,603,000)	(594,000)	(34.5)	(11.3)
Research grants (NIH)	339,000	—	—	339,000	—	—	—
Development milestone-Senko	170,000	—	—	170,000	—	—	—
Total	$ 11,007,000	$ 9,071,000	$ 5,605,000	$ 1,936,000	$ 3,466,000	21.3%	61.8%

- Regenerative cell technology expenses relate to the development of a technology platform that involves using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications. The increases in regenerative cell technology expenses as compared with 2003 and 2002 result primarily from the hiring of additional researchers, engineers and support staff. We incurred an additional $1,370,000 in labor-related expenses in the year ended December 31, 2004, as compared with 2003. We incurred an additional $1,612,000 in labor-related expenses in the year ended December 31, 2003, as compared with 2002. The remainder of the increases related to increases in legal, research supplies, consulting fees and facility expenses of $1,660,000, and $2,448,000, in the years ended December 31, 2004 and 2003 as compared with 2003 and 2002, respectively.

- Bioresorbable polymer surgical implants platform technology is used for development of spine and orthopedic products. The decrease in research and development costs associated with bioresorbable polymer implants in 2004 as compared with 2003 was a result of the successful completion of development of our bioresorbable Thin Film product line in late 2003, as well as a strategic decision to strongly focus our research and development efforts on our regenerative cell technology. The decrease in 2003 costs as compared to 2002 related primarily to the discontinuance of development of the CMF product line that was sold to Medtronic in 2002.

- In 2004, we entered into an agreement with the NIH to reimburse us for up to $950,000 (Phase I $100,000 and Phase II $850,000) in “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. In 2004, we incurred a total of $117,000 of direct qualifying expenses relating to Phase I and $222,000 of direct qualifying expenses related to Phase II, for a total cost relating to NIH grants of $339,000.

- Under a Distribution Agreement with Senko we are responsible for the completion of the initial regulatory application to the MHLW and commercialization of the Thin Film product line in Japan. Commercialization occurs when one or more Thin Film product registrations are completed with the MHLW. In 2004, we have incurred $170,000 of expenses related to this regulatory and registration process.

The future: We are developing a system to isolate autologous, homologous-use, regenerative cells. Simultaneously, we are generating scientific knowledge through internal research to support the clinical use of these cells and have made significant progress in understanding the potential clinical applications. Our most advanced research and development program is in the repair of cardiovascular muscle tissue that is damaged after a heart attack. Our strategy is to continue to increase our research and development efforts in this field and we anticipate expenditures in this area of research to be approximately $8,000,000 to $10,000,000 in 2005. We are also researching therapies for spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery. The expenditures will primarily relate to developing therapeutic applications and the conducting pre clinical studies on harvesting therapeutically useful quantities of regenerative cells for cardiac tissue repair, bone regeneration, cosmetic and reconstructive surgery.

We expect that our current research and development expenditures in the bioresorbable platform technology will decrease as compared with past levels because of the sale of our CMF and Thin Film (non-Japan territory) product lines. However, we will continue to invest in product development for biomaterial/polymer products to develop our pipeline of new and next generation spine and orthopedic products.

We were successful with Phase I of the NIH research on Adipose-Derived Cell Therapy for Myocardial Infarction. Therefore, we were awarded Phase II of the NIH research grant. We expect additional research expenses to be incurred related to Phase II of this project in 2005 and 2006.

Sales and marketing expenses

Sales and marketing expenses include costs of marketing personnel, tradeshows, and promotional activities and materials. It excludes related stock based compensation expenses. Medtronic is responsible for the distribution, marketing and sales support of our

spine and orthopedic devices. Our bioresorbable Thin Film product line (before the sale of the non-Japan Thin Film business to MAST in May 2004) was distributed domestically through a dedicated sales force, independent sales representatives and internationally through independent distributors. As of May 13, 2004, all Thin Film products (except for the Japan territory) are sold exclusively to MAST under a back-up supply agreement. The following table summarizes the components of our sales and marketing expenses for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
General corporate marketing	$ 769,000	$ 313,000	$ 1,892,000	$ 456,000	$ (1,579,000)	145.7%	(83.5)%

Domestic sales and marketing	846,000	3,145,000	1,483,000	(2,299,000)	1,662,000	(73.1)	112.1
International sales and marketing	776,000	959,000	612,000	(183,000)	347,000	(19.1)	56.7
Total	$ 2,391,000	$ 4,417,000	$ 3,987,000	$ (2,026,000)	$ 430,000	(45.9)%	10.8%

- General corporate marketing expenditures relate to expenditures for maintaining our corporate image and reputation within the research and surgical communities. The increase in 2004 as compared to 2003 was due to an educational program which we voluntarily (and not as a result of any commitment to Medtronic) created in 2004 to inform end-users and Medtronic's sale teams of the benefits and surgical applications for our biomaterials products. The decrease in 2003 expenses as compared with 2002 related to our decision to discontinue supplementing Medtronic's marketing of spine and orthopedics and CMF product lines.

- Domestic sales and marketing related to expenses associated with managing our domestic bioresorbable Thin Film product distribution, which included independent sales representatives and our domestic Thin Film sales consultants and marketing staff. The sharp decrease in 2004 as compared to 2003 was due to the transfer of our sales force and marketing staff to MAST upon the sale of the Thin Film product line to MAST in May 2004. The increase in 2003 as compared with 2002 related to the increased salary cost of our Thin Film sales force and marketing team, who were employed for the full year in 2003 versus only the second half of 2002.

- International marketing currently relates to costs associated with developing international bioresorbable Thin Film distributors and supporting a bioresorbable Thin Film sales office in Japan. The decreased spending in 2004 as compared to 2003 related to the closure of our United Kingdom sales office. The increase in 2003 as compared with 2002 related to salary and travel expenses associated with the development of international distributors and the support of a sales office in Japan.

The future: In 2005, we project that corporate marketing as well as our international sales and marketing expenditures will remain at comparable levels to 2004 results, and that domestic sales and marketing expenses will be minimal.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. It excludes related stock based compensation expenses. The following table summarizes the general and administrative expenses for the years ended December 31, 2004, 2003 and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
General and administrative expenses	$ 5,825,000	$ 4,581,000	$ 3,952,000	$ 1,244,000	$ 629,000	27.2%	15.9%

- The primary reason for the increase in 2004 as compared to 2003 was the result of salary, administrative and professional services expenses rising due to the hiring and retaining of a qualified management team to implement and manage our strategic plan. In particular, the increase in 2004 as compared to 2003 resulted from salary and bonus increases of $878,000 and professional services and other general overall corporate expenditure increases of $366,000. The increase in 2003 as compared with 2002 related primarily to the amortization of intangible assets and increases in consulting and professional services.

The future: We expect general and administrative expenses to increase as we incur a full year of salary costs for our new Chief Financial Officer and other professional services related to Sarbanes-Oxley compliance. In addition, we expect to incur legal expenses in connection with the University of Pittsburgh's recently filed lawsuit challenging inventorship of our licensor's U.S. patent relating to adult stem cells isolated from adipose tissue.

Stock based compensation expenses

Stock based compensation expenses include charges related to options issued to employees, directors and non-employees. The stock based compensation expenditures connected to options granted to employees and directors is 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 expenditures connected to options granted to non-employees is the fair value of the underlying common stock on the initial date of grant, as updated 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 following table summarizes the components of our stock based compensation expenses for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Research and development related	$ 32,000	$ 78,000	$ 211,000	$ (46,000)	$ (133,000)	(59.0)%	(63.0)%
Sales and marketing related	22,000	70,000	134,000	(48,000)	(64,000)	(68.6)	(47.8)
General and administrative related	71,000	837,000	942,000	(766,000)	(105,000)	(91.5)	(11.1)
Total	$ 125,000	$ 985,000	$ 1,287,000	$ (860,000)	$ (302,000)	(87.3)%	(23.5)%

- The decreases in stock based compensation expenses for all periods presented were primarily a result of the normal amortization of the stock based compensation expenses over the remaining vesting period, except for stock based compensation relating to research and development. In the second quarter of 2004, we charged $32,000 to research and development for options granted to a consultant. We determined the value of these options using the Black-Scholes option pricing model. There was no comparable charge in the same periods in 2003 or 2002. The options to the consultant were 100% vested and related to services fully rendered. The stock based compensation expense was fully recognized during the second quarter of 2004. In the third quarter of 2003, in addition to the normal amortization of stock based compensation, we also incurred $234,000 of general and administrative stock based compensation due to the modification of certain options granted to the former Chief Financial Officer in his September 2003 separation agreement.

The future: We have expensed all unearned stock based compensation. However, we may from time to time award stock based compensation to consultants, in lieu of, or in addition to, cash compensation. In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("FAS 123R"). This statement is effective for interim or annual periods beginning after June 15, 2005 and will have a material effect on our results of

operations. Upon adoption, FAS 123R will require companies to measure all share-based payment transactions, including those with employees, at fair value. Moreover, the fair value of share-based payment awards will be recognized as expense in the statements of operations over the requisite service period of each award. For example, employee stock options will, to the extent they vest after June 30, 2005, result in stock-based compensation expense charges. FAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications. Even with our adoption of FAS 123R we will continue to grant options (which now will result in an expense).

In-process research and development

The following table summarizes the components of in-process research and development expenses for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
In-process research and development	$ —	$ —	$ 2,296,000	$ —	$ (2,296,000)	—	—

- 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 charges

The following table summarizes the restructuring charges for the years ended December 31, 2004, 2003 and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Restructuring charge	$ 107,000	$ 451,000	$ —	$ (344,000)	$ 451,000	(76.3)%	—

- 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 in 2003, we incurred restructuring charges of $282,000 relating to the involuntary termination of three employees, including our previous Chief Financial Officer and $169,000 relating to a lease termination for a total expense of $451,000. During the third quarter of 2004, we negotiated a settlement of the remaining lease payment with the lessor of the Königstein, Germany office. As a result of the settlement, we recorded an additional expense of $107,000 in 2004.

The future. We do not expect to incur any additional restructuring expenses related to the closure of the Königstein, Germany office.

Equipment impairment charges

The following table summarizes the components of equipment impairment charges for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Equipment impairment charge	$ 42,000	$ —	$ 370,000	$ 42,000	$ (370,000)	—	—

- During the fourth quarter of 2004, as a result of our normal periodic fixed asset review, we determined that certain production assets were impaired. We recorded an impairment charge that represented the excess of the net book value over the estimated fair value of the assets; as the production assets are held for sale, fair value was based on the estimated net proceeds we expect to receive upon sale of these assets, net of selling costs. In 2002, the impairment charge represented the excess of the net book value over the estimated net proceeds 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 of the CMF product line.

Other income

The following is a table summarizing the gain on the sale of assets, related party for the years ended December 31, 2004, 2003 and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Gain on the sale of assets, related party	$ 13,883,000	$ —	$ —	$ 13,883,000	$ —	—	—

- This gain includes both the initial 2002 payment and milestone payments from Medtronic related to the disposition of our CMF product line. Specifically, as part of the disposal arrangement, we agreed to complete clinical research regarding Faster Resorbable Polymer. In January, 2004 we received a $5,000,000 payment after fulfilling the research requirements set out in the CMF sale agreement. We also were obliged to transfer certain "know-how", including manufacturing processes, patents, and other intellectual property, to Medtronic. This obligation was fulfilled and in the third quarter of 2004 we received $1,500,000 from Medtronic. We completed the last of all remaining performance obligations related to the 2002 sale of the CMF product line when we met these milestones, and therefore recorded an amount of $7,383,000 as gain on sale of assets, representing the remaining balance that had previously been reported as deferred gain on sale of assets, related party.

The future. We expect to be able to recognize most of the deferred gain on the sale of the Thin Film assets to MAST, which is not a related party of ours, in the second quarter of 2005 at the earliest. This would result in a one-time gain of approximately $5,650,000. There is no more deferred gain from the CMF product line sale.

Financing items

The following table summarizes interest income, interest expense, and other income and expenses for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Interest income	$ 252,000	$ 417,000	$ 1,037,000	$ (165,000)	$ (620,000)	(39.6)%	(59.8)%
Interest expense	(177,000)	(126,000)	(241,000)	(51,000)	115,000	40.5	(47.7)
Other income (expense)	15,000	87,000	(22,000)	(72,000)	109,000	(82.8)	(495.5)
Total	$ 90,000	$ 378,000	$ 774,000	$ (288,000)	$ (396,000)	(76.2)%	(51.2)%

- Interest income decreased in 2004 and 2003 as compared to the same periods in 2003 and 2002, respectively, because of a decrease in funds available for investment as well as lower interest rates.

- Interest expense increased in 2004 as compared to 2003 due to $1,039,000 in additional long-term obligations associated with the acquisition of new equipment in late 2003 and in 2004. The decrease of $115,000 in 2003 as compared to 2002 was due to lower average outstanding loan principal balances in 2003.

- The changes in other income (expense) in 2004, 2003 and 2002 resulted primarily from changes in foreign currency exchange rates. Losses on disposal of equipment of $91,000 in 2002 also contributed to the beneficial change from 2002 to 2003.

Equity loss in investment

The following table summarizes equity loss in investments for the years ended December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Equity loss in investment	$ —	$ —	$ 882,000	$ —	$ (882,000)	—	—

- The loss in 2002 related entirely to our former 13.5% equity interest in StemSource, which we accounted for using the equity method until we acquired it in 2002. Under the equity method of accounting, we recognized a pro rata share of StemSource's operating losses.

Deferred gain on sale of assets, related party

During the third quarter of 2004 we completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Therefore, we recorded $7,383,000 as a component of gain on sale of assets, related party representing the remaining balance that had previously been reported as deferred gain on sale of assets, related party.

Pursuant to the sale of the CMF product line, we were obliged to transfer certain "know-how;" including manufacturing processes, patents, and other intellectual property, to Medtronic. If such know-how was transferred within a certain time frame defined in the CMF Asset Purchase Agreement dated September 30, 2002 (the "APA"), we would become entitled to a $2,000,000 milestone payment.

In the second quarter of 2004, we provided notice to Medtronic that the requisite know-how associated with the transferred CMF Product Line had been transferred, pursuant to the terms of, and within the timeframe specified by, the APA. Medtronic did not agree that know-how transfer had been completed and asserted that, in any case, that the maximum payment due to us was $1,000,000 rather than $2,000,000.

To avoid the risk and expense of arbitration, in the third quarter of 2004 we agreed to accept a negotiated settlement with Medtronic in the amount of $1,500,000 related to the know-how transfer. The $1,500,000 payment has been recognized as gain on sale of assets, related party.

In the first quarter of 2004, we received a $5,000,000 milestone payment from Medtronic relating to the disposition of our CMF product line. As part of the disposition arrangement, we agreed to complete clinical research regarding Faster Resorbable Polymers, an area that directly relates to the CMF product line transferred to Medtronic. We became entitled to the $5,000,000 payment after fulfilling the research requirements set out in the CMF sale agreement. The $5,000,000 payment has been recognized as gain on sale of assets, related party.

Deferred gain on sale of assets

At December 31, 2004, we have reflected $5,650,000 of unamortized deferred gain on sale of assets on our balance sheet. This

deferred gain related to the sale of our Thin Film product line to MAST in May 2004. Because of additional performance requirements required under the disposition arrangement, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately $6,450,000 as deferred gain on sale in the balance sheet. These performance requirements include training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line, transfer of Thin Film tangible assets, rights to intangible assets, and acting in the capacity of a back-up supplier to MAST for a period of one year. Under the back-up supply agreement, we have agreed to supply product ordered by MAST at our manufacturing cost.

We do not expect to complete our performance obligations until, at the earliest, the second quarter of 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. However, we have been recognizing a portion of the deferred gain as revenues as and when we sell products to

MAST under the back-up supply agreement. This is necessary to state revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction. Through December 31, 2004 we have recognized $772,000 in deferred gain as revenues.

Deferred license fee revenue

In the third quarter of 2004, we entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan.

The Distribution Agreement with Senko commences upon "commercialization." In simplest terms, commercialization occurs when one or more Thin Film product registrations are completed with the MHLW.

Following commercialization, the Distribution Agreement has a duration of five years and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees. We received a $1,500,000 upfront license fee from Senko and recorded it as deferred license fee revenue. Half of the license fee is refundable if the parties agree commercialization is not achieved, and a proportional amount is refundable if we terminate the arrangement, other than for material breach by Senko, before three years post-commercialization.

We will begin to recognize this $1,500,000 Deferred license fee as revenues only after commercialization has been achieved. We will recognize the revenues on a systematic basis over the expected period of time we anticipate that Senko will benefit from the arrangement. However, we will not recognize deferred license fee revenue if this would cause the remaining deferred license fee revenue balance to fall below the amount that we potentially would have to refund to Senko.

We do not expect commercialization to be achieved until 2005 or early 2006.

Deferred development revenue

Under the Distribution Agreement with Senko we are entitled to earn additional payments based on achieving the following defined milestones:

- Upon our notification to Senko of completion of the initial regulatory application to the MHLW for the Thin Film product, we were entitled to a nonrefundable payment of $1,250,000.
- Upon the achievement of commercialization, we are entitled to a nonrefundable payment of $250,000.

We notified Senko on September 28, 2004 regarding the completion of the initial regulatory application and recorded deferred development revenue of $1,250,000. Of the amount deferred, we have recognized development revenues of $158,000, representing the fair value of the completed milestone relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the MHLW.

Liquidity and Capital Resources

Cash provided by (used in) operating, investing and financing activities for the years ended December 31, 2004, 2003, and 2002 is summarized as follows:

	Years ended		
	2004	2003	2002
Net cash used in operating activities	$ (12,574,000)	$ (7,245,000)	$ (6,886,000)
Net cash provided by investing activities	13,425,000	5,954,000	17,265,000
Net cash used in financing activities	(831,000)	(997,000)	(7,971,000)

Operating activities

Net cash used in operating activities in the year ended 2004 resulted from our adjusted net loss (as adjusted for the $13,883,000 gain on sale of assets, related party) and changes in working capital due to the timing of product shipments and payment of liabilities. The net cash used in operations was partially offset by the $1,500,000 upfront license fee and $1,250,000 development milestone payment received from Senko in 2004.

Net cash used in operating activities in the years ended 2003 and 2002 primarily resulted from our net loss in each year. Net losses for each period resulted largely 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 CMF assets to Medtronic. The non-cash amortization of gain on the sale of assets to a related party was a result of CMF products purchased by Medtronic under a back-up supplier agreement at discounts and the revenue being recognized at the previously agreed prices with the difference reducing the deferred gain in sale of assets on the balance sheet.

In 2002, net cash used in operating activities primarily related to our net loss of $13,003,000. The cash used in these operating activities was adjusted for a cash charge for an inventory provision related to the sale of the CMF product line of $1,395,000 and acquired in-process research and development of $2,296,000 related to the purchase of StemSource.

Investing activities

Net cash provided by investing activities in the year ended 2004 resulted in part from the receipt of non-recurring payments totaling $6,500,000 for the completion of the CMF Faster Resorbable Polymer clinical research and the transfer of the know-how related to the 2002 sale of the CMF product line to Medtronic. In addition, we received net proceeds of $6,931,000 from the sale of our Thin Film product line (except for the territory of Japan) to MAST.

These receipts, although generating positive cash flows in 2004, are the result of one-time disposals of non-core operations, and therefore cannot be considered indicative of future cash inflows from investing activities.

The net cash provided by investing activities in the year ended 2003 primarily related to 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 operating and financing activities).

The net cash provided by investing activities in the year ended 2002 primarily related to net proceeds from the sale of short-term investments, offset in part by short-term investment purchases. Additionally, we received proceeds from the sale of our CMF product line to Medtronic.

Capital spending is essential to our product innovation initiatives and to maintaining our operational capabilities. Therefore, in the years of 2004, 2003, and 2002, we used cash to purchase $789,000, $1,743,000, and $909,000, respectively, of property and equipment primarily to support bioresorbable polymer implant manufacturing and research and development of the regenerative cell technology platform. In 2004, the decrease in capital spending was caused by a decrease in the need for bioresorbable research and development, effected by lower sales demand.

Financing Activities

The net cash used in financing activities in the year ended December 31, 2004 related to:

- The repurchase of 262,602 shares of our common stock for $976,000 from a former director and officer of StemSource at a price of $3.72 per share,
- The repurchase of 27,650 shares of our common stock for $76,000 on the open market at a price of $2.75 per share, and
- The payment of $847,000 on our long-term obligations.

Net cash used in financing activities was offset in part by proceeds totaling $1,039,000 from loans secured under our Amended Master Security Agreement we entered in September 2003 to provide financing for equipment purchases.

The net cash used in financing activities in the year ended December 31, 2003 related to:

- The repurchase from insiders and others of 614,099 shares of our common stock for $2,266,000 on the open market at an average price of 3.69 per share, and

- The payment of $426,000 on our long-term obligations.

Net cash used in financing activities in 2003 was offset in part by proceeds totaling $1,120,000 from loans secured under our Amended Master Security Agreement we entered in September 2003 to provide financing for equipment purchases along with proceeds of approximately $542,000 from the sale of 150,500 shares of our common stock held in treasury at a price of $3.60 per share.

The net cash used in financing activities in the year ended December 31, 2002 related to:

- The repurchase of 1,972,863 shares of our common stock for $7,442,000 on the open market at an average price of $3.77 per share,
- The payment of $1,166,000 on our long-term obligations, and
- The payment of $256,000 on our capital lease obligations.

Net cash used in financing activities in 2002 was offset in part 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.

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at December 31, 2004, 2003, and 2002:

	Years ended			$ Differences		% Differences	
	2004	2003	2002	2004 to 2003	2003 to 2002	2004 to 2003	2003 to 2002
Cash and cash equivalents	$ 2,840,000	$ 2,820,000	$ 5,108,000	$ 20,000	$ (2,288,000)	0.7%	(44.8)%
Short-term investments, available for sale	10,579,000	11,448,000	19,875,000	(869,000)	(8,427,000)	(7.6)%	(42.4)%
Total cash and cash equivalents and short -term investments, available for sale	$ 13,419,000	$ 14,268,000	$ 24,983,000	$ (849,000)	$ (10,715,000)	(6.0)%	(42.9)%
Current assets	$ 15,645,000	$ 16,916,000	$ 28,214,000	$ (1,271,000)	$ (11,298,000)	(7.5)%	(40.0)%
Current liabilities	3,267,000	4,484,000	2,931,000	(1,217,000)	1,553,000	(27.1)%	53.0%
Working capital	$ 12,378,000	$ 12,432,000	$ 25,283,000	$ (54,000)	$ (12,851,000)	(0.4)%	(50.8)%

We believe that existing funds, cash generated by operations, and existing and accessible sources of financing are adequate to satisfy our working capital, capital expenditures and debt service requirements at least through December 31, 2005. However, in order to provide greater financial flexibility and liquidity, and in view of the substantial cash needs of our regenerative cell business during its development stage, we will need to raise additional capital.

From inception to December 31, 2004, we have financed our operations primarily by:

- Issuing our stock,
- Generating revenues,
- Selling the CMF product line in September 2002,
- Selling the Thin Film product line (except for the territory of Japan), in May 2004,

- Entering into a Distribution Agreement for the distribution rights to Thin Film in Japan, in which we received an upfront license fee in July 2004 and an initial development milestone payment in October 2004; and
- Obtaining a modest amount of capital equipment long-term financing.

As a result of the receipt of $6,500,000 for the completion of CMF clinical research and know-how transfer, long-term financing of $1,039,000, the sale of our non-Japan bioresorbable Thin Film product line for net proceeds of $6,931,000, the upfront license fee for the distribution rights to Thin Film product line of $1,500,000, and initial development milestone of $1,250,000, our liquidity metrics as of December 31, 2004 appear comparable to those as of December 31, 2003. However, the cash benefits obtained through the sale of product lines is fundamentally non-recurring and once sold, they cannot be sold again to cover future operating losses.

We believe that our near-term borrowing requirements and debt repayments will continue to involve a relatively small amount of cash. To fund 2005 expected capital expenditures of $500,000, we intend to use available working capital and if available, borrow under our Amended Master Security Agreement.

Any excess funds will be invested in short-term available-for-sale investments. We believe that it is necessary to maintain a large amount of cash and short-term available-for-sale investments on hand to ensure that we have adequate resources to fund future research and development, and to manage legal risks and challenges to our business model.

Our capital requirements for 2005 and beyond will depend on numerous factors, including the resources we devote to developing and supporting our products, Medtronic's marketing efforts, market acceptance of our developed products, regulatory approvals and other factors. We have positioned ourselves to expand our cash position through actively pursuing co-development and marketing agreements, research grants, and licensing agreements related to our technology platforms. Moreover, 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 in large part on the success of Medtronic's (our sole distributor of spine and orthopedics implants) marketing efforts in the bioresorbable spine and orthopedics arena. In the past, Medtronic's efforts in this area have disappointed us.

We expect to incur research and development expenses, well beyond our current level, in our regenerative cell platform for an extended time. This will occur whether or not our spine and orthopedics biomaterials business returns to profitability. We will need to seek collaborations or additional sources of financing, such as through the sale of equity securities.

The following summarizes our contractual obligations and other commitments at December 31, 2004, and the effect such obligations could have on our liquidity and cash flow in future periods:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 – 3 years**	**3 – 5 years**	**More than 5 years**
Long-term debt obligations	$ 2,066,000	$ 938,000	$ 1,128,000	$ —	$ —
Interest commitment on debt	242,000	140,000	102,000	—	—
Operating lease obligations	2,225,000	737,000	1,488,000	—	—
Research study obligations	286,000	286,000	—	—	—
Total	$ 4,819,000	$ 2,101,000	$ 2,718,000	$ —	$ —

Critical Accounting Policies and Significant Estimates

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 recognition and 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.

We believe it is important for you to understand our most critical accounting policies. These are our policies that require us to make our most significant judgments and, as a result, could have the greatest impact on our future financial results.

Revenue Recognition

We derive our revenue from a number of different sources, including but not limited to:

- Product sales,
- Upfront payments from license or distribution agreements, and
- Fees for achieving certain defined milestones under development or commercialization arrangements.

Many of our revenue generating arrangements are relatively simple in nature, meaning that there is little judgment necessary in regards to the timing of when we recognize revenues or how such revenues are presented in the financial statements.

However, we have also entered into more complex arrangements, including but not limited to our contracts with the NIH and Senko. Moreover, some of our non-recurring transactions, such as our disposition of the majority of our Thin Film business to MAST or our sale of our CMF product line to Medtronic, contain elements that relate to our core revenue producing activities.

As a result, some of our most critical accounting judgments relate to the identification, timing, and presentation of revenue related activities. These critical judgments are discussed further in the paragraphs that follow.

Multiple-elements

Some of our revenue generating arrangements contain a number of distinct revenue streams, known as "elements." For example, our Distribution Agreement with Senko contains direct or indirect future revenue streams related to:

- A distribution license fee (which was paid at the outset of the arrangement),
- Milestone payments for achieving commercialization of the Thin Film product line in Japan,
- Training for representatives of Senko,
- Sales of Thin Film products to Senko, and
- Payments in the nature of royalties on future product sales made by Senko to its end customers.

Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables ("EITF 00-21"), governs whether each of the above elements in the arrangement should be accounted for individually, or whether the entire contract should be treated as a single unit of accounting.

EITF 00-21 indicates that individual elements may be separately accounted for only when:

- The delivered element has stand alone value to the customer,
- There is objective evidence of the fair value of the remaining undelivered elements, and
- If the arrangement contains a general right of return related to any products delivered, delivery of the remaining goods and services is probable and within the complete control of the seller.

In the case of the Senko Distribution Agreement, we determined that (a) the milestones payments for achieving commercialization and (b) the future sale of Thin Film products to Senko were "separable" elements. That is, each of these elements, upon delivery, will have stand alone value to Senko and there will be objective evidence of the fair value of any remaining undelivered elements at that time. The arrangement does not contain any general right of return, and so this point is not relevant to our analysis.

On the other hand, we concluded that (a) the upfront distribution license fee, (b) the revenues from training for representatives of Senko, and (c) the payments in the nature of royalties on future product sales are not separable elements under EITF 00-21.

In arriving at our conclusions, we had to consider whether our customer, Senko, would receive stand alone value from each delivered element. We also, in some cases, had to look to third party evidence to support the fair value of certain undelivered elements – notably, training – since we as a company do not routinely deliver this service on a stand alone basis. Finally, we had to make assumptions about how the non-separable elements of the arrangement are earned, particularly the estimated period over which Senko will benefit from the arrangement (refer to the "Recognition" discussion below for further background).

Our conclusions, in effect, cause us to recognize certain revenues from the Senko Distribution Agreement sooner than if we had alternatively concluded that none of the elements in the arrangement were separable. Notably, we recognized in 2004 $158,000 in development revenues from the Senko Distribution Agreement, mostly related to achieving certain milestones related to the commercialization of Thin Film products in Japan. Had our judgments regarding the separation of elements been different, we likely would have recognized as revenues an amount less than this.

Recognition

Besides determining whether to account separately for components of a multiple-element arrangement, we also use judgment in determining the appropriate accounting period in which to recognize revenues that we believe (a) have been earned and (b) are realizable. The following describes a small sampling of the recognition issues we have considered during the reporting period.

- Upfront License Fees
    - As part of the Senko Distribution Agreement, we received an upfront fee upon execution of the arrangement. We concluded that such fee was not earned at that time and, instead, reported the cash as deferred license fee revenue. We then had to consider over what period the upfront fee should be recognized as revenue, especially considering that the fee was refundable under certain conditions. We ultimately concluded that the fee would be earned – and, thus recognized as revenues – beginning when regulatory approval was received to market Thin Film products in Japan. We further concluded that revenues would be reported on a straight-line basis over a five year period. We selected the straight-line method because we otherwise could not reliably estimate the manner in which Senko would benefit from the terms of the Distribution Agreement. The license fees will be recognized over a five year period as this corresponds to the initial term of the Distribution Agreement. We note that the Distribution Agreement is renewable for an additional five year period upon mutual consent of Senko and MacroPore. However, we believe that it is too soon to judge whether Senko will benefit from the upfront license fee payment for longer than the initial five year term; we will re-examine this assumption each reporting period and make any necessary adjustments on a prospective basis.

- Government Grants
    - We are eligible to receive grants from the NIH related to our research on adipose derived cell therapy to treat myocardial infarctions. There are no specific standards under U.S. GAAP that prescribe the recognition or classification of these grants in the income statement. Absent such guidance, we have established an accounting policy to recognize NIH grant revenues at the lesser of:
        - Qualifying costs incurred (and not previously recognized) for which MacroPore is entitled to grant funding; or,

- The amount determined by comparing the research outputs generated to date versus the total outputs that are expected to be achieved under the entire arrangement.

- Our accounting policy could theoretically defer revenue recognition beyond the period in which we have earned the rights to such fees. However, we selected this accounting policy to counteract the possibility of recognizing revenues from the NIH arrangement too early. For instance, if our policy permitted revenues to be recognized solely as qualifying costs were incurred, we could alter the amount of revenue recognized by incurring more or less cost in a given period, irrespective of whether these costs correlate to the research outputs generated. On the other hand, if revenue recognition were based on output measures alone, it would be possible to recognize revenue in excess of costs actually incurred; this is not appropriate since qualifying costs remain the basis of our funding under the NIH grant. The application of our accounting policy, nonetheless, involves significant judgment, particularly in estimating the percentage of outputs realized to date versus the total outputs expected to be achieved under the grant arrangement.

- Milestones

  - In certain of our non-governmental development arrangements, we receive payments upon the achievement of certain defined milestones. Our accounting policy is to recognize milestone payments as revenues when received if:

    - Substantive effort is required to achieve the milestone,
    - The amount of the milestone payments appear reasonably commensurate with the effort expended, and
    - Collection (or retention) of the payment is reasonably assured.

  - Determining whether each of these criteria has been satisfied requires significant judgment. For example, our Distribution Agreement with Senko calls for payments to us when certain defined milestones are achieved. The first such milestone payment for $1,250,000 became payable to us when we filed a commercialization application with the Japanese regulatory authorities. However, we determined that the payment received was not commensurate with the level of effort expended, particularly compared with other steps we believe are necessary to commercialize the Thin Film product line in Japan. Accordingly, we did not recognize the $1,250,000 received as revenues, but instead recorded all but $158,000 of this amount as deferred development revenue. The $158,000 was recognized as development revenues based on our estimates of the level of effort expended as compared with the total level of effort we expect to incur under the arrangement to successfully achieve regulatory approval of the Thin Film product line in Japan. These estimates were subject to judgment and there may be changes in estimates regarding the total level of effort as we continue to seek regulatory approval. Indeed, there can be no assurance that commercialization in Japan will ever be achieved.

- Back-up Supply Arrangements

  - We agreed to serve as a backup supplier of products in connection with our dispositions of both:

    - The CMF product line to Medtronic; and,
    - Specific Thin Film assets to MAST.

Specifically, we agreed to supply CMF or Thin Film product to Medtronic and MAST, respectively, at our cost for a defined period of time. When we actually delivered products under the backup supply arrangements, however, we recognized revenues in the financial statements at the estimated selling price which we would receive in the marketplace. We used judgment, based on historical data and expectations about future market trends, in determining the estimated market selling price of products subject to the backup supply arrangements. During 2004, we recognized $928,000 as revenues or roughly 13.6% of our total revenues recognized during the reporting period. The revenues recognized correlated to the gross margin normally charged by us for selling the same product in an unencumbered transaction.

Presentation

We have presented amounts earned under our NIH research arrangement as research grant revenue. Simply, we believe that the activities underlying the NIH agreement constitute our ongoing major or central operations. Moreover, the government obtains rights under the arrangement, in the same manner (but perhaps not to the same extent) as a commercial customer that similarly contracts with MacroPore to perform research activities. For instance, the government and any authorized third parties may use our federally funded research and/or inventions without payment of royalties to us. We recognize that others may conclude that the receipt of amounts under the NIH royalty arrangement should be presented as a reduction of any qualifying expenses incurred – that is, reported in the income statement on a net basis.

Warranty Provisions

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 our operating results. 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 prior to the third quarter of 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 (Medtronic). After detecting this matter, we elected to replace all lots of affected 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. There have been no material warranty claims since the third quarter of 2003.

Goodwill Impairment Testing

In late 2002, we purchased StemSource and recognized over $4,600,000 in goodwill associated with the acquisition, of which $4,387,000 remains on our balance sheet today. As required by Statement of Financial Accounting Standard No. 142, Goodwill and Other Intangible Assets ("SFAS 142"), we must test this goodwill at least annually for impairment. Moreover, this testing must be performed at a level of the organization known as the reporting unit. A reporting unit is at least the same level as a company's operating segments, and sometimes even one level lower.

Specifically, the process for testing goodwill for impairment under SFAS 142 involves the following steps:

- Company assets and liabilities, including goodwill, are allocated to each reporting unit for purposes of completing the goodwill impairment test.
- The carrying value of each reporting unit – that is, the sum of all of the net assets allocated to the reporting unit – is then compared to its fair value.
- If the fair value of the reporting unit is lower than its carrying amount, goodwill may be impaired – additional testing is required.

When we completed our goodwill impairment testing in 2004, the fair values of our two reporting units each exceeded their respective carrying values. Accordingly, we determined that none of our reported goodwill is impaired.

The application of the goodwill impairment test involves a substantial amount of judgment. For instance, SFAS 142 requires that assets and liabilities be assigned to a reporting unit if both of the following criteria are met:

- The asset will be employed in or the liability relates to the operations of a reporting unit.
- The asset or liability will be considered in determining the fair value of the reporting unit.

This allocation process involves judgment. We developed mechanisms to assign company-wide assets like shared property and equipment, as well as company-wide obligations such as borrowings under our GE Loan Facility, to our two reporting units. In some cases, certain assets were not allocable to either reporting unit and were left unassigned.

The most complex and challenging asset to assign to each reporting unit was our acquired goodwill. As noted previously, all of our recorded goodwill relates to our acquisition of StemSource in 2002. All of the StemSource assets and liabilities still on hand at our 2004 testing date were allocated to our regenerative cell reporting unit. However, when we first acquired StemSource, we determined that a portion of the goodwill related to the bioresorbable reporting unit. The amount of goodwill allocated represented our best estimate of the synergies (notably future cost savings from shared research and development activities) that the bioresorbable reporting unit would obtain by virtue of the acquisition.

Finally, with the consultation and assistance of a third party, we estimated the fair value of our reporting units by using various estimation techniques. In particular, we estimated the fair value of our bioresorbable reporting unit based on an equal weighting of the market values of comparable enterprises and discounted projections of estimated future cash flows. Clearly, identifying comparable companies and estimating future cash flows as well as appropriate discount rates involves judgment. On the contrary, we estimated the fair value of our regenerative cell reporting unit solely using an income approach, as we believe there are no comparable enterprises on which to base a valuation. The assumptions underlying this valuation method involve a substantial amount of judgment, particularly since our regenerative cell business has yet to generate any revenues and does not have a commercially viable product.

Again, the manner in which we assigned assets, liabilities, and goodwill to our reporting units, as well as how we determined the fair value of such reporting units, involves significant uncertainties and estimates. The judgments employed may have an effect on whether a goodwill impairment loss is recognized. Notably, the carrying value of our regenerative cell reporting unit, including assigned goodwill, totaled $7,100,000 as of the 2004 testing date. Furthermore, we estimated the fair value of this reporting unit to be $12,600,000 as of this date, meaning that a subtle change in how certain assets and liabilities were allocated to our reporting units, or the manner in which we estimated fair value, could have resulted in a different conclusion as to whether some of our goodwill was impaired.

Dispositions

In 2002, we sold our CMF (skull and face) bone fixation implant and accessory product line to Medtronic.

Moreover, in 2004, we sold most of the assets and intellectual property rights in our (non-Japan) Thin Film business to MAST.

As is common in the life sciences industry, the sale agreements contained provisions beyond the simple transfer of net assets to the acquiring enterprises for a fixed price. Specifically, as part of the arrangement, we also agreed to perform the following services:

- Provide training to Medtronic or MAST personnel on production and other aspects of the CMF and Thin Film product lines, respectively.
- Provide a back-up supply of CMF product to Medtronic and Thin Film products to MAST, at cost, for a specified period of time,
- In the case of Medtronic, perform clinical evaluations for a new faster-resorbing polymer product.

Disposing assets and product lines is not one of our core ongoing or central activities. Accordingly, determining the appropriate accounting for these transactions involved some of our most difficult, subjective and complex judgments. In particular, we made assumptions around the appropriate manner and timing in which to recognize the gain on disposal for each transaction in the statement of operations. Moreover, we considered whether the dispositions should be reflected as discontinued operations in accordance with Statement of Financial Accounting Standard No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets."

For instance, upon the closing of the CMF sale agreement on September 30, 2002, we received net cash of $9,000,000, and transferred assets to Medtronic with a net carrying value of $476,000. The net difference of $8,524,000 was recorded as part of a Deferred gain on sale of assets, related party on our balance sheet. We deferred recognition of the majority of this gain until Medtronic accepted the transferred net assets, which was demonstrated only when Medtronic had:

- Stopped relying on us to provide product under the back-up supply agreement,
- Integrated the acquired CMF manufacturing equipment into its operations, and
- Permitted us to deliver training to Medtronic personnel on production and other aspects of the CMF product line.

Until those events occurred, we did not believe that we have transferred all risk and rewards related to the CMF product line to Medtronic and, accordingly, recognition of the deferred gain in earnings would be inappropriate.

The risks and rewards of ownership related to the CMF product line ultimately passed to Medtronic in August 2004. The remainder of the deferred gain was recognized in the third quarter of 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

Conversely, we have yet to recognize the majority of the deferred gain related to our disposition of certain Thin Film assets, which occurred in May 2004. Again, the Asset Purchase Agreement governing the Thin Film sale obligates us to perform certain actions for the benefit of the buyer – MAST – for a defined period of time, such as serving as a back-up supplier. As of December 31, 2004, we still have not performed all of our obligations under the arrangement and, thus, believe that recognition of the majority of the deferred gain is not appropriate at this time. It is anticipated that we will complete all of the remaining obligations under the Thin Film sale agreement in 2005, meaning that the remaining deferred gain of $5,650,000 at December 31, 2004 likely will be recognized as gain in the statement of operations in the following fiscal year.

We have, however, recognized a portion of the deferred gains when we sell product to Medtronic and MAST under the respective back-up supply agreements. Refer to the “Revenue Recognition” section of this Critical Accounting Policies and Significant Estimates discussion for further details.

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 $19,582,000 as of December 31, 2004 to reflect the estimated amount of deferred tax assets that may not be realized. We increased our valuation allowance by approximately $848,000 during the year ended December 31, 2004. The valuation allowance includes approximately $550,000 related to stock option deductions, the benefit of which will eventually be credited to equity and not to income.

At December 31, 2004, we had federal and state tax loss carryforwards of approximately $32,879,000 and $22,585,000 respectively. The federal and state net operating loss carryfowards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2004, we had federal and state tax credit carryforwards of approximately $768,500 and $824,000 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, we had a foreign tax loss carryforward of $613,000 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 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, 2004, the remaining pre-change federal net operating loss carryforward of $1,546,000 is subject to an annual limitation of approximately $573,000. It is estimated that these pre-change net operating losses and credits will be fully available by 2008.

Additionally, in 2002 when we purchased StemSource, 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, 2004, the remaining pre-change federal and state net operating loss carryforward of $1,420,000 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.

For the 2004 year, we determined that we have not experienced an ownership change through November 1, 2004. We do not expect that an ownership change for purposes of IRC Section 382 occurred during November or December 2004. However, if we did experience an ownership change during this period, 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 2004 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 reflected as such in the Statements of Operations and Comprehensive Income (Loss). As of December 31, 2004 there was no outstanding amount related to unearned compensation.

Under FAS 123R, accounting for stock options grants will change for us and most other companies. We chose not to early-adopt this new standard.

Recent Accounting Pronouncements

In December 2003, the FASB published a revision to Interpretation No. 46, “Consolidation of Variable Interest Entities” (“FIN

46R"), to clarify some of the provisions of the original interpretation, and to exempt certain entities from its requirements. The rules became effective in financial statements for periods ending after March 15, 2004. FIN 46R did not impact our operating results or financial position because we do not have any interests in variable interest entities.

In November 2004, the FASB's Emerging Issues Task Force reached a consensus on Issue No. 03-13, "Applying the Conditions in Paragraph 42 of FASB Statement No. 144 in Determining Whether to Report Discontinued Operations" ("EITF 03-13"). The guidance should be applied to a component of an enterprise that is either disposed of or classified as held for sale in fiscal periods beginning after December 15, 2004. We do not believe that the adoption of EITF 03-13 will have a significant effect on our financial statements.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — An Amendment of ARB No. 43, Chapter 4" ("FAS 151"). FAS 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. Further, FAS 151 requires that allocation of fixed and production facilities overhead to conversion costs should be based on normal capacity of the production facilities. The provisions in FAS 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe that the adoption of FAS 151 will have a significant effect on our financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets — An Amendment of APB Opinion No. 29" ("FAS 153"). The provisions of this statement are effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. This statement eliminates the exception in previous generally accepted accounting principles that precluded the recognition of exchanges of similar productive assets at fair value. Instead, FAS 153 provides for a general exception to the fair value principle for exchange transactions that do not have commercial substance — that is, transactions that are not expected to result in significant changes in the cash flows of the reporting entity. We do not believe that the adoption of FAS 153 will have a significant effect on our financial statements.

In December 2004, the FASB issued Staff Position No. FAS 109-1, "Application of FASB Statement No. 109, "Accounting for Income Taxes," to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004" ("FSP FAS 109-1"). On October 22, 2004, the U.S. President signed into law the American Jobs Creation Act of 2004. This law includes a so-called "production deduction", which allows for manufacturers to receive a deduction each year for maintaining manufacturing operations in the U.S. Under FSP FAS 109-1, entities must account for this provision as a "special deduction" and not as a change in effective tax rate. This means that the tax benefit of the production deduction should be recognized no earlier than the year in which those special deductions are deductible on the tax return. FSP FAS 109-1 became effective upon issuance in December 2004. We do not believe that the adoption of FSP FAS 109-1 will have a significant effect on our financial statements.

In December 2004, the FASB issued Staff Position No. 109-2, "Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004" ("FSP FAS 109-2"). This FSP provides enterprises more time (beyond the financial reporting period during which the Act took effect) to evaluate the Act's impact on the enterprise's plan for reinvestment or repatriation of certain foreign earnings for purposes of applying SFAS No. 109, "Accounting for Income Taxes." FSP FAS 109-2 became effective upon issuance in December 2004. We do not believe that the adoption of FSP FAS 109-2 will have a significant effect on our financial statements.

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In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("FAS 123R"). This statement is effective for interim or annual periods beginning after June 15, 2005 and will have a material effect on our results of operations. Upon adoption, FAS 123R will require companies to measure all share-based payment transactions, including those with employees, at fair value (most notably, this includes employee stock option grants, even where the exercise price is equal to the grant date fair market value). Moreover, the fair value of share-based payment awards will be recognized as expense in the statements of operations over the requisite service period of each award. FAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications.

Based on pro forma amounts for historical periods presented in note 2 of our consolidated financial statements, our net loss will increase (or our net income will be reduced) each annual period as a result of adopting FAS 123R.

To implement the provisions of FAS 123R, we are considering the following actions, but have not as yet made any final decisions:

- Adopting a binomial model to value share-based payment awards. For purposes of pro forma disclosure, we have applied a Black-Scholes valuation model to estimate the fair value of share-based payment awards granted to employees. We are in the process of assessing whether a binomial model may provide a better estimate as to the fair value of the our employee share-based payment awards.

- Adopting the standard on a modified retrospective basis effective January 1, 2005. We are obliged to adopt FAS 123R

in the fiscal third quarter of 2005. As permitted by FAS 123R, we may elect at that time to transition to the standard using a modified retrospective basis – that is, presuming that we adopt the provisions of the standard by January 1, 2005. Adopting this transition approach would allow us to present comparable annualized results in future reporting periods. If we adopt the modified retrospective transition approach, it will not restate our first and second quarter results, as filed on Forms 10-Q, for the periods ended March 31, 2005 and June 30, 2005, respectively. However, in our third quarter Form 10-Q, the year-to-date operating results will reflect nine months of share-based payment expense as though the we had adopted FAS 123R effective January 1, 2005.

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 subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this annual report on Form 10-K. 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:

<u>We have a limited operating history; our operating results can be volatile</u>

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 and biotechnology 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 necessarily 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 results should not be taken as an indication of any future growth or of a sustainable level of revenue. This was demonstrated by our revenue decline in the second, third, and fourth quarters of 2004.

Moreover, our operating results can vary substantially from our previously published financial guidance (such as occurred in the second quarter of 2004), from analyst expectations and from previous periodic results for many reasons, including the timing of product introductions and distributor purchase orders. Also, the 2002 sale of our CMF bone fixation implant and accessory product line, which had represented a large portion of our revenues, plus the 2004 sale of our (non-Japan) Thin Film surgical implants for separation of soft tissues, will distort quarterly and annual earning comparisons through 2004 and 2005. 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 and biotechnology industries.

We had tried to influence our investors' expectations as to our 2004 operating results by periodically announcing financial guidance. However, due to our disappointing revenues in the second quarter of 2004 and our conclusion that we did not have sufficient visibility on the timing and size of end customer demand for the HYDROSORB™ bioresorbable implants which we distribute through Medtronic, we withdrew our previously issued guidance on July 19, 2004.

We have never been profitable on an operational basis

We have incurred net losses in each year since we started doing business. 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, due to the continued need to develop and market new products and fund additional pre clinical research and possibly clinical trials. We expect to continue to incur operational losses in our spine and orthopedics business at least through the end of 2005, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Development-stage losses related to our development of regenerative cell technology are expected to keep us in a loss position on a consolidated basis for several years.

We are adopting a high-risk strategy

We intend to use cash from the profits of the HYDROSORB™ products and the Japan Thin Film products, and the proceeds of the sale of the (non-Japan) Thin Film product line, 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 to preclude other companies from depriving us of market share and profit margins by selling products based on our inventions (legal risk), that we will be able to successfully manage a company in a different business than we have operated in the past (operational risk), that we will be able to successfully deliver regenerative cells where needed in the body (scientific 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 biomaterials medical device product lines (financial risk). Instead of using the cash to reinvest in our biomaterials business, we are using it in one of the riskiest industries in the economy (strategic risk). This fundamentally changes our risk/reward profile and may make our stock an unsuitable investment for some investors.

The financial risk in this strategy is significant, particularly if our bioresorbable products are not independently cash-flow-positive. Although we eliminated the negative cash flow of the early commercialization stage of the (non-Japan) Thin Film business by selling that business to MAST in May 2004, even our core spine and orthopedics implants business fell back into a negative cash flow position in the second quarter of 2004 due to the sharp reduction in orders from and sales to Medtronic. This was followed by an even sharper reduction in third and fourth quarter 2004 spine and orthopedics implant product orders from our sales to Medtronic. With the CMF and (non-Japan) Thin Film product lines sold and the Japanese Thin Film products not yet approved for commercialization, our only remaining bioresorbable implants business from which to derive product revenues in the short term is our spine and orthopedic implants product line.

Further legal risk arises from a lawsuit, filed by the University of Pittsburgh in the fourth quarter of 2004, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. We are the exclusive, worldwide licensee from the University of California under this patent, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. If the University of Pittsburgh wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, and our regenerative cell strategy could be materially adversely affected.

We rely on Medtronic to distribute a majority of 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 revenues from the sale of hard-tissue-fixation bioresorbable implant products to our distribution partner, Medtronic.

We remain significantly dependent on Medtronic to generate sales revenues for all of our spine and orthopedics bioresorbable 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 or pay us any additional option or license fees. There is also no guarantee that it will market any new products under the distribution agreements or that we will derive any significant revenue from such arrangements. Medtronic's sale of our products to end customers in 2004, and its rate of product orders placed with us in the same period, disappointed our expectations. 2004 results were exceptionally weak, and we are significantly disappointed with the marketing efforts of Medtronic for our products at this time.

Our dependence upon Medtronic to market and sell our bioresorbable products places us in a position where we cannot accurately predict the extent to which our products will be actively and effectively marketed, depriving us of some of the reliable data we need to make optimal operational and strategic

decisions. The consequent lack of visibility resulted in our second quarter 2004 falling short of our own and the market's expectations and compelled us to, on July 19, 2004, withdraw our previously announced financial guidance for the remainder of 2004. Our third and fourth quarter 2004 sales were worse than expected as well, further demonstrating the lack of control and visibility.

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

Medtronic owns 7.2% 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, it also distributes other products that are competitive to ours. Medtronic might choose to develop and distribute existing or alternative technologies in preference to our technology in the spine or preferentially market competitive products that can achieve higher profit margins.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that disagreement over rights or technology or other proprietary interests will not occur. 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 we do. 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 bioresorbable 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. It is possible that 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 we, any of which could have a substantial negative effect on our business. Finally, 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. Such inertia may be one reason why demand for the HYDROSORB™ implants we sell through Medtronic was lower in 2004 than we had expected.

We expect physicians' inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future regenerative cell products. We may need to finance lengthy time-consuming clinical studies (so as to provide convincing evidence of the medical benefit) in order to overcome this inertia and skepticism.

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

We are in a relatively early stage of commercialization with many of our products although we have derived revenue from sales of certain products to our distributors, particularly Medtronic. 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 implants and other new products that may result from our research and development activities. We are presently pursuing bioresorbable implant opportunities in spine and orthopedics and other tissue repair and regeneration throughout the body that may 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. The path to commercial profit from our regenerative cell technology is unclear even if we demonstrate the medical benefit of our regenerative cell technology in various applications. There is no proven path for commercializing the technology in a way to earn a durable profit commensurate with the medical benefit. Most of our cell-related products and/or services are at least three to five 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 will need to raise more cash in the future

As of December 31, 2004, we had $13,419,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. Our regenerative cell business will continue to result in a substantial requirement for research and development expenses for several years, during which it could bring in no significant revenues. 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 as well as our ability to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, thus having a substantial negative effect on the results of our operations and financial condition.

We have limited manufacturing experience

We have a limited manufacturing history and limited experience in manufacturing some of our products. In part, our future

success is significantly dependent 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 and our 2004 sale of the (non-Japan) Thin Film product line deprived us of some economies of scale in manufacturing. Current demand for spine and orthopedics products from Medtronic is so low that economies of scale are in some instances lacking in regard to that product line as well.

If we are unable to sufficiently meet Medtronic's requirements for certain products as set forth under its agreement, Medtronic itself may 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 bioresorbable products is subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of those used 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 a potential 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 for our bioresorbable products

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our bioresorbable products, from a single qualified source. Although we have a contract with B.I. Chemicals, Inc., which guarantees continuation of supply through August 15, 2006, 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 the 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 various U.S. patents for the design of our bioresorbable plates and high torque screws and devices and we have filed applications for numerous 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 many of 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. There is also no assurance that any patents issued to us will provide us with competitive advantages, 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 commercialize related products. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested. In addition, further legal risk arises from a lawsuit, recently filed by the University of Pittsburgh, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. We are the exclusive, worldwide licensee from the University of California under this patent, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. If the University of Pittsburgh wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, and our regenerative cell strategy could be materially adversely affected.

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. U.S. 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. As noted above as to the University of Pittsburgh lawsuit, even patents issued to us or our licensors might be judicially determined to belong in full or in part to third parties.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce or confirm the ownership of 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 or a foreign patent 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. We may incur substantial legal costs as a result of the University of Pittsburgh lawsuit, and our president Marc Hedrick is a named individual defendant in that lawsuit because he is one of the inventors identified on the patent. 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 bioresorbable technology and our bioresorbable 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 protection, or protect trade secrets, 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 Europe, Australia, Japan, Canada, China, Korea, and Singapore among others.

We are subject to intensive FDA regulation

As newly developed medical devices, our bioresorbable surgical implants and our regenerative cell harvesting, isolation and delivery devices 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 and our regenerative cell harvesting, isolation and delivery devices 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 United States 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 are also subject to post market reporting requirements for deaths or serious injuries when the device may have caused or contributed to the death or serious injury, and for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or 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 bioresorbable surgical implant 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 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 and Senko, 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, Japan 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 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 Chief Executive Officer, Marc Hedrick, MD, our President and John Fraser, PhD, our Vice President of Research and Technology. We rely upon them for strategic business decisions and guidance. 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 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. It 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 might not avail United States investors

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 March 2003. 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, particularly for United States investors. We cannot assure you that we will achieve our goal to list our common stock on Nasdaq or a major United States stock exchange.

We pay no dividends

We currently do not intend 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 $10,579,000 as of December 31, 2004, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to market 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, 2004, for example, and assuming average investment duration of seven 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 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 transacted business in various foreign countries before the May 2004 sale of our non-Japan Thin Film business to MAST, settlements were 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, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the year ended December 31, 2004, a hypothetical 10% adverse change in the Euro or Yen 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.

Under our Japanese Thin Film agreement with Senko, we would receive payments in the nature of royalties based on Senko's net sales, which would be Yen denominated. We expect such sales or royalties to begin in 2005 or early 2006.

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

Item 8. Consolidated Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of MacroPore Biosurgery, Inc. and subsidiaries (the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004. In connection with our audits of the consolidated financial statements, we have also audited the financial statement schedule for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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.

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 financial position of MacroPore Biosurgery, Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule for each of the years in the three-year period ended December 31, 2004, when considered in relation to the basic consolidated financial statements as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

San Diego, California
March 11, 2005

MACROPORE BIOSURGERY, INC.
CONSOLIDATED BALANCE SHEETS

	As of December 31, 2004	As of December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 2,840,000	$ 2,820,000
Short-term investments, available-for-sale	10,579,000	11,448,000
Accounts receivable, net of allowance for doubtful accounts of $8,000 and $62,000 in 2004 and 2003, respectively	863,000	1,291,000
Inventories	379,000	831,000
Other current assets	984,000	526,000
Total current assets	15,645,000	16,916,000
Property and equipment, net	3,080,000	3,822,000
Other assets	236,000	332,000
Intangibles, net	2,122,000	2,392,000
Goodwill	4,387,000	4,627,000
Total assets	$ 25,470,000	$ 28,089,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,329,000	$ 3,767,000
Current portion of long-term obligations	938,000	717,000
Total current liabilities	3,267,000	4,484,000
Deferred gain on sale of assets, related party	—	7,539,000
Deferred gain on sale of assets	5,650,000	—
Deferred license fee revenue	1,500,000	—
Deferred development revenue	1,092,000	—
Long-term obligations, less current portion	1,128,000	1,157,000
Total liabilities	12,637,000	13,180,000
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2004 and 2003	—	—
Common stock, $0.001 par value; 95,000,000 shares authorized; 16,820,018 and 16,777,644 shares issued and 13,947,184 and 14,195,062 shares outstanding in 2004 and 2003, respectively	17,000	17,000
Additional paid-in capital	74,737,000	74,698,000
Unearned compensation	—	(109,000)
Accumulated deficit	(51,475,000)	(49,385,000)
Treasury stock, at cost	(10,414,000)	(9,362,000)
Treasury stock receivable	—	(976,000)
Accumulated other comprehensive (loss) income	(32,000)	26,000
Total stockholders' equity	12,833,000	14,909,000
Total liabilities and stockholders' equity	$ 25,470,000	$ 28,089,000

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

MACROPORE BIOSURGERY, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended December 31, 2004	2003	2002
Revenues:			
Sales to related party	$ 4,085,000	$ 12,893,000	$ 8,605,000
Sales to third parties	2,247,000	1,195,000	561,000
Research grants	328,000	—	—
Development	158,000	—	—
	6,818,000	14,088,000	9,166,000
Cost of revenues:			
Cost of revenues (including stock based compensation expense of $3,000, $12,000, and $14,000 for the years ended December 31, 2004, 2003, and 2002, respectively)	3,142,000	4,244,000	3,169,000
Inventory provision	242,000	—	1,395,000
Gross profit	3,434,000	9,844,000	4,602,000
Operating expenses:			
Research and development, excluding stock based compensation expense of $32,000, $78,000, and $211,000 for the years ended December 31, 2004, 2003, and 2002, respectively	11,007,000	9,071,000	5,605,000
Sales and marketing, excluding stock based compensation expense of $22,000, $70,000, and $134,000 for the years ended December 31, 2004, 2003, and 2002, respectively	2,391,000	4,417,000	3,987,000
General and administrative, excluding stock based compensation expense of $71,000, $837,000, and $942,000 for the years ended December 31, 2004, 2003, and 2002, respectively	5,825,000	4,581,000	3,952,000
Stock based compensation (excluding cost of revenues stock based compensation)	125,000	985,000	1,287,000

In-process research and development	—	—	2,296,000
Restructuring charge	107,000	451,000	—
Equipment impairment charge	42,000	—	370,000
Total operating expenses	19,497,000	19,505,000	17,497,000
Total operating loss	(16,063,000)	(9,661,000)	(12,895,000)
Other income (expense):			
Gain on sale of assets, related party	13,883,000	—	—
Interest income	252,000	417,000	1,037,000
Interest expense	(177,000)	(126,000)	(241,000)
Other income (expense), net	15,000	87,000	(22,000)
Equity loss in investment	—	—	(882,000)
Total other income (expense)	13,973,000	378,000	(108,000)
Net loss	(2,090,000)	(9,283,000)	(13,003,000)
Other comprehensive income (loss): unrealized holding (loss)	(58,000)	(133,000)	(191,000)
Comprehensive loss	$ (2,148,000)	$ (9,416,000)	$ (13,194,000)
Basic and diluted net loss per common share	$ (0.15)	$ (0.64)	$ (0.91)
Basic and diluted weighted average common shares	13,932,390	14,555,047	14,274,254

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, 2004, 2003 AND 2002

	Common Stock		Additional Paid-in	Unearned	Accumulated	Treasury Stock		Treasury Stock	Accumulated Other Comprehensive	
	Shares	Amount	Capital	Compensation	Deficit	Shares	Amount	Receivable	Income (Loss)	Total
Balance at December 31, 2001	15,106,623	$ 15,000	$ 68,402,000	$ (2,105,000)	$ (27,099,000)	356,120	$ (1,077,000)	$ —	$ 350,000	$ 38,486,000
Issuance of common stock under stock option plan	92,286	—	16,000	—	—	—	—	—	—	16,000
Issuance of common stock in acquisition	1,447,755	2,000	5,949,000	—	—	—	—	—	—	5,951,000
Compensatory stock options	—	—	253,000	1,048,000	—	—	—	—	—	1,301,000
Purchase of treasury stock	—	—	—	—	—	1,972,863	(7,442,000)	—	—	(7,442,000)
Sale of treasury stock	—	—	110,000	—	—	(210,000)	767,000	—	—	877,000
Unrealized loss on investments	—	—	—	—	—	—	—	—	(191,000)	(191,000)
Net loss for the year ended December 31, 2002	—	—	—	—	(13,003,000)	—	—	—	—	(13,003,000)
Balance at December 31, 2002	16,646,664	17,000	74,730,000	(1,057,000)	(40,102,000)	2,118,983	(7,752,000)	—	159,000	25,995,000
Issuance of common stock under stock option plan	130,980	—	33,000	—	—	—	—	—	—	33,000
Compensatory stock options	—	—	49,000	948,000	—	—	—	—	—	997,000
Purchase of treasury stock	—	—	—	—	—	614,099	(2,266,000)	—	—	(2,266,000)
Sale of treasury stock	—	—	(10,000)	—	—	(150,500)	552,000	—	—	542,000
Treasury stock receivable	—	—	—	—	—	—	—	(976,000)	—	(976,000)
Exchange of unlisted common stock for listed common stock held in treasury	—	—	(104,000)	—	—	—	104,000	—	—	—
Unrealized loss on investments	—	—	—	—	—	—	—	—	(133,000)	(133,000)
Net loss for the year ended December 31, 2003	—	—	—	—	(9,283,000)	—	—	—	—	(9,283,000)
Balance at December 31, 2003	16,777,644	17,000	74,698,000	(109,000)	(49,385,000)	2,582,582	(9,362,000)	(976,000)	26,000	14,909,000
Issuance of common stock under stock option plan	42,374	—	29,000	—	—	—	—	—	—	29,000
Compensatory stock options	—	—	10,000	109,000	—	—	—	—	—	119,000
Purchase of treasury stock	—	—	—	—	—	27,650	(76,000)	—	—	(76,000)
Treasury stock receivable	—	—	—	—	—	262,602	(976,000)	976,000	—	—
Unrealized loss on investments	—	—	—	—	—	—	—	—	(58,000)	(58,000)
Net loss for the year ended December 31, 2004	—	—	—	—	(2,090,000)	—	—	—	—	(2,090,000)
Balance at December 31, 2004	16,820,018	$ 17,000	$ 74,737,000	$ —	$ (51,475,000)	2,872,834	$ (10,414,000)	$ —	$ (32,000)	$ 12,833,000

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,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	$ (2,090,000)	$ (9,283,000)	$ (13,003,000)
Adjustments to reconcile net loss to net cash used in operating activities:			

Depreciation and amortization	1,752,000	1,657,000	1,471,000
Inventory provision	242,000	—	1,395,000
Reduction in allowance for doubtful accounts	(44,000)	—	—
Loss on disposal of assets	3,000	14,000	91,000
Equipment impairment charge	42,000	—	370,000
Warranty provision	—	267,000	—
Restructuring charge	—	153,000	—
Amortization of gain on sale of assets, related party	(156,000)	(2,046,000)	(267,000)
Amortization of gain on sale of assets	(772,000)	—	—
Gain on sale of assets, related party	(13,883,000)	—	—
Stock based compensation	119,000	997,000	1,301,000
Acquired in-process research and development	—	—	2,296,000
Equity loss in investment	—	—	882,000
Increases (decreases) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisition:			
Accounts receivable	472,000	(53,000)	(775,000)
Inventories	33,000	319,000	(860,000)
Other current assets	(458,000)	317,000	284,000
Other assets	8,000	76,000	(304,000)
Accounts payable and accrued expenses	(434,000)	337,000	458,000
Deferred license fee revenue	1,500,000	—	(225,000)
Deferred development revenue	1,092,000	—	—
Net cash used in operating activities	(12,574,000)	(7,245,000)	(6,886,000)
Cash flows from investing activities:			
Proceeds from the sale and maturity of short-term investments	51,132,000	49,561,000	68,151,000
Purchases of short-term investments	(50,321,000)	(41,267,000)	(56,966,000)
Proceeds from sale of assets, related party	6,500,000	—	9,689,000
Cost of sale of assets, related party	—	(38,000)	—
Proceeds from the sale of assets, net	6,931,000	—	—
Purchases of property and equipment	(789,000)	(1,743,000)	(909,000)
Acquisition costs, net of cash acquired	(28,000)	(654,000)	(2,896,000)
Proceeds from the sale of impaired assets	—	95,000	196,000
Net cash provided by investing activities	13,425,000	5,954,000	17,265,000
Cash flows from financing activities:			
Principal payments on capital leases	—	—	(256,000)
Principal payments on long-term obligations	(847,000)	(426,000)	(1,166,000)
Proceeds from long-term obligations	1,039,000	1,120,000	—
Proceeds from the exercise of employee stock options	29,000	33,000	16,000
Purchase of treasury stock	(1,052,000)	(2,266,000)	(7,442,000)
Proceeds from sale of treasury stock	—	542,000	877,000
Net cash used in financing activities	(831,000)	(997,000)	(7,971,000)
Net increase (decrease) in cash	20,000	(2,288,000)	2,408,000
Cash and cash equivalents at beginning of year	2,820,000	5,108,000	2,700,000
Cash and cash equivalents at end of year	$ 2,840,000	$ 2,820,000	$ 5,108,000

Supplemental disclosure of cash flows information:			
Cash paid during period for:			
Interest	$ 176,000	$ 127,000	$ 182,000
Taxes	7,000	12,000	800
Supplemental schedule of investing and financing activities:			
Increase in cost of acquisition (goodwill) (note 6)	$ —	$ 371,000	$ —
Share repurchase payable	—	976,000	—
Acquisition costs			
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, 2004, 2003 AND 2002

1. Organization and Operations

The Company

MacroPore Biosurgery, Inc. (the “Company”), specializes in the discovery and development of regenerative medicine therapies. The Company has two principal technology platforms, adipose-derived regenerative cells and bioresorbable implants. The regenerative cell technology program is developing treatments for cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery using regenerative cells from adipose tissue. The Company’s lead regenerative cell research program, currently in preclinical testing, targets myocardial infarction (heart attack). To facilitate the processing and delivery of adipose-derived regenerative cells, the Company is designing a

proprietary point-of-care system, Celution™, to isolate and concentrate a patient's own regenerative cells in real-time. The Company's goal is to commercialize a system that may be used universally across multiple therapeutic applications. Additionally, the Company manufactures the HYDROSORB™ family of FDA-cleared bioresorbable spine and orthopedic implants, which are distributed exclusively through Medtronic, Inc. ("Medtronic"). As of December 31, 2004, Medtronic owned 7.2% of the Company's outstanding common stock.

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 acquired StemSource, Inc. ("StemSource") for a combination of cash and stock (note 6). The acquired assets and liabilities of StemSource were recorded based on their estimated fair values at the date of acquisition and the results of operations have been included in the financial statements for the periods subsequent to the acquisition date. The Company's investment in StemSource, prior to acquisition, 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 biotech medical device field. The future viability of the Company largely depends on the ability to complete development of new products and receive 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 research, regulatory and marketing risks. There can be no assurance that 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 that guarantees continuation of supply through August 15, 2006, the Company cannot provide any assurances 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 quantities, at the necessary high quality, within a reasonable period of time or at commercially reasonable rates.

For the years ended December 31, 2004, 2003 and 2002, the Company recorded bioresorbable product revenue from Medtronic, a related party, of $4,085,000, $12,893,000, and $8,605,000, respectively, which represented 59.9%, 91.5%, and 93.9% of total revenues, respectively. The Company's future revenue generated from its bioresorbable products will continue to depend largely on Medtronic's (the Company's 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 $2,090,000, $9,283,000, and $13,003,000 for the years ended December 31, 2004, 2003 and 2002, respectively, and has an accumulated deficit of $51,475,000 as of December 31, 2004. Additionally, the Company has used net cash of $12,574,000, $7,245,000, and $6,886,000 to fund its operating activities for the years ended December 31, 2004, 2003 and 2002, 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, cash equivalent and investment balances to fund operations at least through December 31, 2005. 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 financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. Estimates and assumptions are reviewed periodically, and the effects of revisions are reflected in the consolidated financial statements in the periods they are determined to be necessary.

The Company's most significant estimates and critical accounting policies involve revenue recognition, as well as determining the warranty provision, goodwill impairment evaluation, and the accounting for product line dispositions.

Presentation

Certain prior period amounts have been reclassified to conform to current period presentation.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, short-term investments available-for-sale and accounts receivable, which is substantially due from 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 included with and classified as cash and cash equivalents totaled $2,010,000 and $1,433,000 as of December 31, 2004 and 2003, respectively.

Short-term Investments

The Company invests excess cash in highly liquid 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.

The Company has evaluated its investments in accordance with the provisions of Statement of Financial Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Based on such evaluation, the Company's management has determined that all of its investment securities are properly classified as available-for-sale. Based on the Company's intent, its investment policies and its ability to liquidate debt securities, the Company classifies such short-term investment securities within current assets. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a separate component of Stockholders' Equity as accumulated other comprehensive income (loss). The amortized cost basis of debt securities is periodically adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included as a component of interest income or interest expense. The amortized cost basis of securities sold is based on the specific identification method and all such realized gains and losses are recorded as a component within other income (expense).

The Company reviews the carrying values of its investments and writes down such investments to estimated fair value by a charge to the statements of operations when the severity and duration of a decline in the value of an investment is considered to be other than temporary. The cost of securities sold or purchased is recorded on the settlement date.

At December 31, 2004, the excess of carrying cost over the fair value of the Company's short-term investments is immaterial.

Fair Value of Financial Instruments

The carrying amounts of the Company's cash and cash equivalents, accounts receivable, 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 terms and rates of interest for these instruments approximate terms and market rates of interest currently available to the Company for similar instruments. The Company's short-term investments are already reported at fair value in the financial statements.

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 provisions for any stock deemed excess or obsolete.

During the first quarter of 2004, the Company recorded a provision of approximately $242,000 for excess inventory. Such inventory was produced in consideration of the Company's responsibility to be a back-up supplier for the craniomaxillofacial ("CMF") product line. The Company sold the assets related to this product line to an affiliate of Medtronic on September 30, 2002. In April of 2004, Medtronic indicated that it would no longer purchase CMF inventory from the Company under the back-up supply arrangement, leading to the determination that the remaining CMF inventory on hand would not be recoverable.

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 CMF product line to an affiliate of Medtronic.

Long-Lived Assets

In accordance with SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets," 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 recoverable. Such long-lived assets are deemed to be impaired when the discounted cash flows expected to be generated by the asset (or asset group) are less than the asset's 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.

Impairment

During the year ended December 31, 2004, as a result of its normal periodic fixed asset review, the Company recorded an equipment impairment charge of $42,000 related to production assets which were used in multiple product lines. The impairment charge represented the excess of the net book value

over the estimated net proceeds the Company expected it would receive upon sale of the assets. The remaining carrying amount of the assets totaling $6,000 was reclassified as held for sale and included within other assets in the accompanying balance sheet as of December 31, 2004.

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 product line that 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. These assets were disposed of during 2003.

Other assets held for sale

At December 31, 2003, the Company had certain other assets held for sale which were included within other assets in the accompanying balance sheet as of December 31, 2003. These assets included certain tangible assets related to the Company's Thin Film product line (note 4), as well as certain tangible assets associated with a foreign facility whose lease was terminated in

September 2003 (note 12).

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

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

These assets were disposed of during 2004 at an amount net of estimated selling cost, which exceeded the respective carrying values.

Property and Equipment

Property and equipment is stated at cost, net of accumulated depreciation. Depreciation expense, which includes the amortization of assets recorded under capital leases, is provided for on a straight-line basis over the estimated useful lives of the assets, or the life of the lease, whichever is shorter, 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 on at least an annual basis. The Company last completed this testing on November 30, 2004.

Specifically, 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 (note that the Company only operates as one segment – see "Segment Information" section of this Summary of Significant Accounting Policies note below),
- Meets the accounting definition of a business, and
- Possesses different economic characteristics than other components within the Company.

Based on these criteria, the Company determined that it has two 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.

In 2002, all of the Company's goodwill was assigned to each of the Company's then existing reporting units. The Company has not acquired any additional goodwill since that time. Moreover, all of the goodwill allocated to one of the Company's former reporting units was a component of the gain the Company recognized on disposal of the reporting unit in 2004. See note 4 for further details.

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, 2004 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 as follows:

- Regenerative cell technology- Income approach (weighted 100%, as this reporting unit has no historic or near term future revenues to allow comparison)
- Bioresorbable technology- Income approach (weighted 50%) and Market approach (weighted 50%)

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 as of the testing date.

Intangibles, consisting of core technology and existing technology purchased in the StemSource acquisition (note 6), 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, 2004 and 2003 are as follows:

	December 31, 2004	December 31, 2003
Goodwill, net:		
Beginning balance	$ 4,627,000	$ 4,256,000
Acquisition	—	371,000
Disposal of assets (note 4)	(240,000)	—
Ending balance	4,387,000	4,627,0000
Other intangibles, net:		
Beginning balance	2,392,000	2,661,000
Amortization	(270,000)	(269,000)
Ending balance	2,122,000	2,392,000
Total goodwill and other intangibles, net	$ 6,509,000	$ 7,019,000
Cumulative amount of amortization charged against intangible assets as of December 31, 2004 and 2003	$ 573,000	$ 303,000

Estimated amortization of other intangibles, net, for the years ended:

2005	$ 270,000
2006	270,000
2007	270,000
2008	270,000
2009	270,000
Thereafter	772,000
	$ 2,122,000

Revenue Recognition

Product Sales

The Company sells its products to distributors and, prior to the sale of its Thin Film product line in May 2004, also sold products directly to hospitals. The Company has agreements with its distributors wherein 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. Before the sale of the Thin Film product line in May 2004, revenue from sales to hospitals was recognized upon delivery of the product.

On occasion, the Company offers extended payment terms to customers. The Company does not recognize revenues under these arrangements until the payment becomes due or, if earlier, is received. Moreover, 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.

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 sales to related party in the statements of operations.

Any upfront payments received from license/distribution agreements are recognized as revenues ratably over the term of the agreement, provided no significant obligations or deliverables remain. Any recognized amounts are reported as sales to related party or sales to third parties depending upon the counterparty to the transaction. Refer to note 5 below for the Company's specific policies related to the upfront fees recognized associated with the Senko Medical Trading Co. ("Senko") distribution agreement.

In September 2002, the Company entered into various agreements with Medtronic and a subsidiary of Medtronic for the sale of the Company's CMF product line. The net proceeds received were recorded as deferred gain on sale of assets, related party. The

Company recognized as revenue in 2002 and 2003, and during 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 provided for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized (totaling $156,000, $2,046,000 and $267,000 for the years ended December 31, 2004, 2003, and 2002, respectively) correlates to the gross margin normally realized by the Company on the sale of similar products. The remainder of the deferred gain of $7,383,000 was recognized as gain on sale of assets, related party in the third quarter of 2004 when Medtronic acknowledged that the technology and know-how transfer had been completed pursuant to the CMF product line sale contract terms.

In May 2004, the Company sold most, but not all, of its Thin Film product line. Refer to note 4 below for the Company's specific policies related to the recognition of revenues and gain on sale of assets associated with this transaction.

Research

The Company earns revenue for performing tasks under research agreements with both commercial enterprises and governmental agencies like the National Institutes of Health ("NIH"). 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 following performance criteria for that milestone have been met:

- Substantive effort was required to achieve the milestone,
- The amount of the milestone payments appears reasonably commensurate with the effort expended, and
- Collection (or retention) of the payment is reasonably assured.

When the Company is reimbursed for costs incurred under grant arrangements with the NIH, the Company recognizes revenues for the lesser of:

- Qualifying costs incurred (and not previously recognized) for which the Company is entitled to funding from the NIH; or,
- The amount determined by comparing the outputs generated to date versus the total outputs expected to be achieved under the research arrangement.

Revenue earned under development agreements is classified as research grant or development revenues in the Company's statements of operations, depending on the nature of the arrangement. The costs associated with development agreements are recorded as research and development expense.

In 2004, the Company recognized NIH grant revenue of $328,000 and incurred qualifying costs of $339,000. There were no comparable revenues or costs in 2003 and 2002 for NIH grants. In 2004, the Company recognized development revenue of $158,000 and incurred costs of $170,000 (refer to note 5 below). There were no comparable development revenues or costs in 2003 and 2002.

In the past, the Company earned revenue from contracted development arrangements. These arrangements were generally time and material arrangements and accordingly any revenue was recognized as services were 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 were recognized as cost of revenue as these costs were incurred. There were no revenues of this type during any periods presented in the accompanying statements of operations.

Other revenues

The Company recognizes revenue from the collection and storage of regenerative cell-rich adipose tissue. In its cell banking service, the Company recognizes revenue for collection services 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. In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Elements," 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 remaining undelivered elements exists. If evidence of the fair value of the undelivered elements does not exist, revenue is deferred on all elements and recognized ratably over the period the customer is expected to benefit from the arrangement.

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

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 program.

The following summarizes the Company's warranty reserve at December 31, 2004 and 2003:

	As of January 1,	Additions (charges to expenses)	Claims	As of December 31,
2004:				
Warranty reserve	$ 267,000	$ 86,000	$ (251,000)	$ 102,000
2003:				
Warranty reserve	$ —	$ 278,000	$ (11,000)	$ 267,000

In August 2003, as part of its ongoing product monitoring process, the Company determined that some of the products sold to Medtronic did not meet certain expectations, based on criteria previously communicated by the Company to Medtronic. The Company agreed to a "no charge" replacement of the affected inventory in the possession of Medtronic. In the first half of 2004, the Company incurred claims of $251,000 related to the replacement of this product.

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 employee stock option plans. Under the intrinsic value method, compensation expense is recognized only if the current market price of the underlying stock exceeds the

exercise price as of the measurement date (typically the date of grant). Any resulting expense 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 permitted 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."

The pro forma effects of stock-based compensation on net loss and net loss per common share have been estimated using a grant date fair value model (Black-Scholes option-pricing model).

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no restrictions and are fully transferable and negotiable in a free trading market. Black-Scholes does not consider the employment, transfer or vesting restrictions that are inherent in the Company's employee options. Use of an option valuation model, as required by SFAS No. 123, includes highly subjective assumptions based on long-term predictions, including the expected stock price volatility and average life of each option grant. Because the Company's employee stock options have characteristics significantly different from those of freely traded options, and because the assumptions underlying the Black-Scholes model involve substantial judgment, the Company's estimate of the fair value of its awarded stock options may differ from the ultimate value realized by the recipient employee.

The Company estimated the weighted average estimated fair values of stock options granted during 2004, 2003, and 2002 at $3.26, $3.54, and $2.48 per share, respectively, on the date of grant. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	Years ended December 31,		
	2004	2003	2002
Expected term	6 Years	7 years	7 years
Interest rate	3.31-4.35%	2.8 - 3.96%	3.5 -5.1%
Volatility	85%	91%	100%
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 loss and net loss per share amounts:

	Years ended December 31,		
	2004	2003	2002
Net loss:			
As reported	$ (2,090,000)	$ (9,283,000)	$ (13,003,000)
Add: Stock based employee compensation expense included in reported net loss, net of related tax effects	96,000	997,000	1,147,000
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(2,586,000)	(4,367,000)	(4,378,000)
Pro forma	$ (4,580,000)	$ (12,653,000)	$ (16,234,000)
Basic and diluted loss per common share:			
As reported	$ (0.15)	$ (0.64)	$ (0.91)
Pro forma	$ (0.33)	$ (0.87)	$ (1.14)

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

Other Comprehensive Income (Loss)

Comprehensive income is the total of net income and all other non-owner changes in equity. Other comprehensive income refers to these revenues, expenses, gains, and losses that, under generally accepted accounting principles, are included in comprehensive income but excluded from net income.

During the years ended December 31, 2004, 2003 and 2002 the Company's only element of other comprehensive income (loss) resulted from unrealized gains (losses) on available-for-sale investments, which are reflected in the statements of changes in stockholders' equity as accumulated other comprehensive income (loss).

Segment Information

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

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

For the Years Ended:	U.S. Revenues	Non-U.S. Revenues	Total Revenues
December 31, 2004	$ 6,602,000	$ 216,000	$ 6,818,000
December 31, 2003	$ 13,727,000	$ 361,000	$ 14,088,000
December 31, 2002	$ 8,855,000	$ 311,000	$ 9,166,000

The Company derives its revenues from the following products, research grants, development and service activities:

	Years ended December 31,		
	2004	2003	2002
Spine & Orthopedic implants	$ 3,803,000	$ 9,882,000	$ 5,544,000
Bioresorbable Thin Film	2,237,000	1,186,000	561,000
Craniomaxillofacial implants	282,000	3,011,000	3,061,000
Research grants	328,000	—	—
Development activities	158,000	—	—
Regenerative cell storage services	10,000	9,000	—

Totals	$ 6,818,000	$ 14,088,000	$ 9,166,000

At December 31, 2004 and 2003, the Company's long-lived assets, excluding goodwill and intangibles, are located in the following jurisdictions:

For the Years Ended:	U.S. Domiciled	Non-U.S. Domiciled	Total
December 31, 2004	$ 3,311,000	$ 5,000	$ 3,316,000
December 31, 2003	$ 4,060,000	$ 94,000	$ 4,154,000

Earnings (Loss) Per Share

The Company computes income (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, 2004, 2003, and 2002 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, 2004, 2003, and 2002 was 5,024,000, 4,848,000, and 4,311,000, respectively. These potential common shares were related entirely to outstanding but unexercised option awards and warrants (note 18).

Recent Accounting Pronouncements

In December 2003, the FASB published a revision to Interpretation No. 46, "Consolidation of Variable Interest Entities" ("FIN 46R"), to clarify some of the provisions of the original interpretation, and to exempt certain entities from its requirements. The rules became effective in financial statements for periods ending after March 15, 2004. FIN 46R did not impact the Company's operating results or financial position because the Company does not have any interests in variable interest entities.

In November 2004, the FASB's Emerging Issues Task Force reached a consensus on Issue No. 03-13, "Applying the Conditions in Paragraph 42 of FASB Statement No. 144 in Determining Whether to Report Discontinued Operations" ("EITF 03-13"). The guidance should be applied to a component of an enterprise that is either disposed of or classified as held for sale in fiscal periods beginning after December 15, 2004. The Company does not believe that the adoption of EITF 03-13 will have a significant effect on its financial statements.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — An Amendment of ARB No. 43, Chapter 4" ("FAS 151"). FAS 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. Further, FAS 151 requires that allocation of fixed and production facilities overhead to conversion costs should be based on normal capacity of the production facilities. The provisions in FAS 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe that the adoption of FAS 151 will have a significant effect on its financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets — An Amendment of APB Opinion No. 29" ("FAS 153"). The provisions of this statement are effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. This statement eliminates the exception in previous generally accepted accounting principles that precluded the recognition of exchanges of similar productive assets at fair value. Instead, FAS 153 provides for a general exception to the fair value principle for exchange transactions that do not have commercial substance — that is, transactions that are not expected to result in significant changes in the cash flows of the reporting entity. The Company does not believe that the adoption of FAS 153 will have a significant effect on its financial statements.

In December 2004, the FASB issued Staff Position No. FAS 109-1, "Application of FASB Statement No. 109, "Accounting for Income Taxes," to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004" ("FSP FAS 109-1"). On October 22, 2004, the U.S. President signed into law the American Jobs Creation Act of 2004. This law includes a so-called "production deduction", which allows for manufacturers to receive a deduction each year for maintaining manufacturing operations in the U.S. Under FSP FAS 109-1, entities must account for this provision as a "special deduction" and not as a change in effective tax rate. This means that the tax benefit of the production deduction should be recognized no earlier than the year in which those special deductions are deductible on the tax return. FSP FAS 109-1 became effective upon issuance in December 2004. The Company does not believe that the adoption of FSP FAS 109-1 will have a significant effect on its financial statements.

In December 2004, the FASB issued Staff Position No. 109-2, "Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004" ("FSP FAS 109-2"). This FSP provides enterprises more time (beyond the financial reporting period during which the Act took effect) to evaluate the Act's impact on the enterprise's plan for reinvestment or repatriation of certain foreign earnings for purposes of applying SFAS No. 109, "Accounting for Income Taxes." FSP FAS 109-2 became effective upon issuance in December 2004. The Company does not believe that the adoption of FSP FAS 109-2 will have a significant effect on its financial statements.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("FAS 123R"). This statement is effective for interim or annual periods beginning after June 15, 2005 and will have a material effect on the Company's results of operations. Upon adoption, FAS 123R will require companies to measure all share-based payment transactions, including those with employees, at fair value. Moreover, the fair value of share-based payment awards (as a notable example: employee stock option grants) will be recognized as expense in the statements of operations over the requisite service period of each award. FAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications.

Based on pro forma amounts for historical periods presented earlier in this note, the Company's net loss will likely increase (or its net income reduced) each annual period as a result of adopting FAS 123R.

To implement the provisions of FAS 123R, the Company is considering the following actions, but has not as yet made any final decisions:

- Adopting a binomial model to value share-based payment awards. For purposes of pro forma disclosure, the Company has applied a Black-Scholes valuation model to estimate the fair value of share-based payment awards granted to employees. The Company is in the process of assessing whether a binomial model may provide a better estimate as to the fair value of the Company's employee share-based payment awards.

- Adopting the standard on a retrospective basis effective January 1, 2005. The Company is obliged to adopt FAS 123R in its fiscal third quarter of 2005. As permitted by FAS 123R, the Company may elect at that time to transition to the standard using a modified retrospective basis – that is, presuming that the provisions of the standard were adopted by the Company as of January 1, 2005. Adopting this transition approach would allow the Company to present comparable annualized results in future reporting periods. If the Company adopts the modified retrospective transition approach, it will not restate its first and second quarter results, as filed on Forms 10-Q, for the periods ended March 31, 2005 and June 30, 2005, respectively. However, in the Company's third quarter Form 10-Q, the year-to-date operating results would reflect nine months of share-based payment expense as though the Company had adopted FAS 123R effective January 1, 2005.

3. Sale of Craniomaxillofacial ("CMF") 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 total net consideration of $15,500,000. In accordance with the terms of the Agreement, the Company received an initial payment of $13,000,000 from Medtronic and a first milestone payment of $1,000,000 in the fourth quarter of 2002. A final milestone payment of $1,500,000 was received in 2004.

The Agreement 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, during the technology transfer transition period, agreed to be a back-up supplier of CMF products to Medtronic at a price equal to the Company's cost of manufacture (refer to the "Revenue Recognition" section of note 2 above).

The Agreement also allowed the Company to receive up to $5,000,000 if and when the Company completed successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement. In January 2004, the Company received the $5,000,000 milestone payment from Medtronic and it was recognized as gain on sale of assets, related party, in the accompanying statements of operations.

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 bioresorbable 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 accounted for the net proceeds of the Agreements as deferred gain on sale of assets, related party. This gain was to be recognized only as certain events occurred. For instance, the Company recognized a portion of the deferred gain upon the sale of the CMF products to Medtronic under the Company's back-up supply arrangement, which provided for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized correlated to the gross margin normally charged by

the Company on similar products. The remainder of the deferred gain was recognized in the third quarter of 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

During the third quarter of 2004, the Company completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Accordingly, the Company recorded $7,383,000 as a component of gain on sale of assets, related party, in the accompanying statements of operations, representing the remaining balance that had theretofore been reported as deferred gain on sale of assets, related party.

Pursuant to the sale of the CMF product line, the Company was obliged to transfer certain "know-how," including manufacturing processes, patents, and other intellectual property, to Medtronic. If such know-how was transferred within a certain time frame defined in the Agreement the Company would become entitled to a $2,000,000 milestone payment.

In the second quarter of 2004, the Company provided notice to Medtronic that the requisite know-how associated with the transferred CMF product line had been transferred, pursuant to the terms of, and within the timeframe specified by, the Agreement. Medtronic did not agree that know-how transfer had been completed and asserted that, in any case, the maximum payment due to the Company was $1,000,000 rather than $2,000,000.

To avoid the risk and expense of arbitration, in the third quarter of 2004 the Company agreed to accept a negotiated settlement with Medtronic in the amount of $1,500,000 related to the know-how transfer. The $1,500,000 payment has been recognized as gain on sale of assets, related party, in the accompanying statements of operations.

4. Sale of Thin Film Product Line

In May 2004, the Company sold most, but not all, of its intellectual property rights and tangible assets related to its Thin Film product line to MAST Biosurgery AG, a Swiss corporation ("MAST") and a subsidiary of MAST, neither of which were related parties of the Company.

To date, the Company has received $7,000,000 in cash related to the disposition. The Company is also entitled to the following additional contingent consideration:

- $200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for a hernia wrap product (thin film combined product), and

- $2,000,000 on or before the earlier of (i) May 31, 2005, known as the "Settlement Date," or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer ("CEO"), provided the CEO has held that position for at least four months and meets other requirements specified in the sale agreement. Note that clause (ii) effectively means that the Company will not receive payment of $2,000,000 before May 31, 2005 unless MAST has hired a CEO on or before January 31, 2005 (four months prior to the Settlement Date). Moreover, in the event that MAST does not hire a CEO on or before January 31, 2005, MAST may (at its sole option and subject to the requirements of the sale agreement) alternatively provide the Company with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 in lieu of making the $2,000,000 payment. The Company currently believes that MAST has hired a CEO in late 2004 and thus will be obligated to pay the $2,000,000 obligation in 2005. However, MAST has objected to the Company's interpretation of the agreement and maintains that the individual hired does not qualify as the CEO under its terms.

The assets comprising the Thin Film product line transferred to MAST were as follows:

	Carrying Value Prior to Disposition
Inventory (finished goods)	$ 177,000
Manufacturing and development equipment	217,000
Goodwill	240,000
	$ 634,000

In addition to transferring certain assets to MAST, the Company agreed to perform the following under the sale agreement:

- For a period of up to one year after the closing date, provide up to 300 hours of training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line,
- For a period of up to one year after the closing date, act as a back-up supplier to MAST, and provide, in almost all cases, ordered product at the Company's manufacturing cost, and
- For a period of up to one year after the closing date, supply or cause its suppliers to provide MAST with specified raw

material at the Company's cost.

Because of these additional performance requirements, the Company did not initially recognize any gain on sale of the Thin Film assets in the accompanying statement of operations. Instead, at the time of the sale, the Company initially recorded approximately $6,450,000 as deferred gain on sale of assets in the accompanying balance sheet. The amount recorded as deferred gain on sale of assets does not include the two potential elements of contingent consideration described above, (i.e., the $200,000 payment due upon 510(k) clearance and the $2,000,000 payment due May 31, 2005, which may be potentially settled in equity of the MAST business managing the Thin Film assets), which will only be recognized when the contingencies are resolved.

The majority of the deferred gain on sale of assets will be recognized as gain on sale of assets in the statements of operations when the Company provides all remaining performance under the Thin Film sale agreement. Specifically, the Company will continue to defer recognition of the majority of this gain until the following has been demonstrated:

- MAST has stopped relying on the Company to provide product under the back-up supply agreement,
- The Thin Film tangible assets and rights to intangible assets have been transferred and accepted by MAST, and
- The Company has delivered all requisite training.

In addition, the Company has been recognizing (and will continue to recognize) a portion of the deferred gain on sale of assets as revenues as and when the Company sells products to MAST under the back-up supply agreement. This is necessary to record revenues (and gross margin) at the amount the Company would normally charge for selling the same product in an unencumbered transaction. In 2004, the Company recognized $772,000 of the deferred gain as revenues.

As part of the disposition, the Company has recorded an asset of $124,000 entitled retained interest in transferred assets, which is recorded as a component of other assets on the accompanying balance sheet. This asset represents the potential 19% equity interest in the MAST business that is managing the Thin Film assets that the Company might receive back in the event that MAST does not hire a CEO on or before January 31, 2005. The Company has no ability to control whether, in such event, it will receive a $2,000,000 cash payment or a 19% interest in the business entity. Accordingly, at the date of closing, the Company has not transferred all of the risks and rewards associated with 19% of the assets sold to MAST, and has established an asset reflecting its residual interest in the transferred assets. This asset will be reviewed for impairment, as necessary, in accordance with the Company's accounting policies.

Even after consummation of the Thin Film asset disposition, the Company has retained all rights to Thin Film business in Japan (subject to a purchase right option of MAST), and the Company has received back a license from MAST of all rights to Thin Film technologies in the:

- Spinal field, exclusive at least until 2012, and
- Field of regenerative medicine, non-exclusive on a perpetual basis

The sale agreement grants MAST a right (the "Purchase Right") to acquire the Company's Thin Film-related interests and rights for Japan:

- If MAST exercises its option on or before May 31, 2005, the purchase price will be $3,000,000, although such amount could have been reduced if MAST exercised its option within forty-five days of the Company entering into a business arrangement in Japan that involves the Company receiving an upfront, non-refundable license fee. On July 16, 2004, the Company did enter into a business arrangement in Japan with Senko, and received an upfront license fee of $1,500,000 (see note 5 below). However, the forty-five day time period in which MAST could have obtained a reduced exercise price has now expired.
- After May 31, 2005 and until May 31, 2007, the exercise price of the Purchase Right will be equal to the fair market value of the Japanese business, but in no event will be less than $3,000,000. Moreover, if the Company receives an outside offer for the Japanese business after

May 31, 2005 but prior to May 13, 2007, MAST will have a right of first refusal to match the terms of the outside offer.

The Purchase Right is a written option, which must be recognized as a liability, at fair value, in the accompanying financial statements. As of December 31, 2004, the value of this Purchase Right is de minimis based on a fair value analysis performed by a third party.

If MAST exercises the Purchase Right, MAST becomes obligated to reimburse the Company for certain costs incurred by the Company related to product development and intellectual property prosecution in Japan. Moreover, as part of a Business Development Agreement ("BDA") entered into contemporaneously with the Thin Film disposition, MAST has agreed that if (i) MAST exercises the Purchase Right and (ii) the Company or MAST enters into a Japanese distribution agreement before

February 13, 2005 then MAST must share certain upfront payment and milestone payments with the Company and the Company would be entitled to a 50% share in MAST's gross profits and royalties for three years once MAST begins marketing Thin Film products in Japan. Since the Company has entered into the Distribution Agreement with Senko (note 5) prior to the deadline, and has already received the upfront license fee, MAST would be required to share any subsequent milestone payments and 50% of gross profits for three years post-commercialization. The Company has not recognized any amounts related to these potential cash inflows and will not do so until the contingent arrangement ("Purchase Right") is resolved and the Company has completed the earnings process.

5. Distribution Agreement

In the third quarter of 2004, the Company entered into a Distribution Agreement with Senko.

Under this agreement, the Company granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan. Specifically, the license covers Thin Film products with the following indications:

- Anti-adhesion,
- Soft tissue support, and
- Minimization of the attachment of soft tissues throughout the body.

The Distribution Agreement with Senko commences upon "commercialization". In simplest terms, commercialization occurs when one or more Thin Film product registrations are completed with the Japanese Ministry of Health, Labour and Welfare ("MHLW").

Following commercialization, the Distribution Agreement has a duration of five years and is renewable for an additional five years after reaching mutually agreed minimum purchase guarantees.

At the inception of this arrangement, the Company received a $1,500,000 license fee which was recorded as deferred license fee revenue in the accompanying balance sheet. The Company will recognize the deferred license fee as revenue systematically over the term of the Distribution Agreement once commercialization has been achieved. The Distribution Agreement contains certain provisions that could require the Company to return a portion of the upfront license fee. For instance, if it is determined in good faith by the Company and Senko that commercialization of the Thin Film product is unobtainable, then 50% of the $1,500,000 license fee will be returned to Senko. Also, if the Company terminates the Distribution Agreement at any time within the initial three years post-commercialization, for any reason except for material breach by Senko, then a pro-rata share of the license fee will be returned to Senko.

In no event will the Company recognize deferred license fee revenue in the statements of operations if this would cause the remaining deferred income balance to fall below the amount that the Company potentially would have to refund to Senko.

The Company has earned or will be entitled to earn additional payments under the Distribution Agreement based on achieving the following defined milestones:

- Upon the Company notifying Senko of completion of the initial regulatory application to the MHLW for the Thin Film product, the Company is entitled to a nonrefundable payment of $1,250,000. The Company notified Senko of the completion of the regulatory application in September 2004, received payment in October 2004, and recorded deferred development revenue of $1,250,000. Of the amount deferred, the Company has recognized development revenues of $158,000, representing the fair value of the completed milestones relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the MHLW.
- Upon the achievement of commercialization, the Company is entitled to a nonrefundable payment of $250,000.

The Distribution Agreement also provides for the Company to supply certain products to Senko at fixed prices over the life of the agreement once the Company has received approval to market these products in Japan. In addition to the product price, Senko will also be obligated to pay the Company payments in the nature of a royalty of 5% of the sales value of any products Senko sells to its customers during the first three years post-commercialization.

As discussed in note 4 above, the Company has granted MAST a Purchase Right to acquire the Company's Thin Film-related interests and rights for Japan for $3,000,000 or, in some circumstances, a higher amount.

The Company has agreed to provide back-up supply of products to Senko subject to the terms of the Distribution Agreement in the event that (a) MAST exercises its Purchase Right and (b) MAST materially fails to deliver product to Senko. In this circumstance, Senko will pay any amounts due for purchases of product, as well as payments in the nature of royalties, directly to

MacroPore. MacroPore will be obliged to remit 5% of the gross margin to MAST on any products sold to Senko. The Company believes that it is unlikely in practice that this contingency will materialize. Accordingly, the Company estimates the fair value of this guarantee to be de minimis as of the end of the current reporting period.

6. 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 adipose-derived 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). This was in exchange for 759,341 shares of StemSource series A preferred stock, 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 year ended December 31, 2002 the Company recognized an equity loss in investment of $882,000. 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

Approximately $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 an 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 are 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, 2002. 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 below include a write-off of $2,296,000 relating to the in-process research and development acquired in the StemSource acquisition.

		For the Year ended December 31, 2002 (Unaudited proforma)
Net revenues	$	9,180,000
Net loss	$	(14,507,000)
Basic and diluted loss per share	$	(0.91)

In the 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, for a total of $371,000.

7. Short-term Investments

As of December 31, 2004 and 2003, all short-term investments were classified as available-for-sale, which consisted of the following:

	December 31, 2004		
	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 1,633,000	$ (5,000)	$ 1,628,000
Agency securities	8,978,000	(27,000)	8,951,000
	$ 10,611,000	$ (32,000)	$ 10,579,000

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

As of December 31, 2004 and 2003, investments available-for-sale had the following maturities:

	December 31, 2004		December 31, 2003	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Corporate notes and bonds:				
with maturity of less than 1 year	$ 1,529,000	$ 1,524,000	$ 1,365,000	$ 1,365,000
with maturity of 1 to 2 years	104,000	104,000	204,000	205,000
Agency securities:				
with maturity of less than 1 year	7,898,000	7,877,000	6,503,000	6,519,000
with maturity of 1 to 2 years	1,080,000	1,074,000	3,350,000	3,359,000
	$ 10,611,000	$ 10,579,000	$ 11,422,000	$ 11,448,000

Proceeds from sales and maturity of short term investments for the year ended December 31, 2004, 2003 and 2002 were $51,132,000, $49,561,000, and $68,151,000, respectively. Gross realized gains on such sales for the years ended December 31, 2004, 2003 and 2002 were approximately $4,000, $38,000, and $166,000, respectively.

Based on the Company's ability and intent to hold the investments for a reasonable period of time sufficient for a forecasted recovery of fair value and the low severity of impairment, the Company does not consider these investments to be other-than-temporarily impaired as of December 31, 2004.

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

Inventories

	As of December 31,	
	2004	2003
Raw materials	$ 189,000	$ 399,000
Finished goods	190,000	432,000
	$ 379,000	$ 831,000

Other Current Assets

	As of December 31,	
	2004	2003
Prepaid expenses	$ 809,000	$ 316,000
Accrued interest receivable	121,000	157,000
Other receivables	54,000	53,000
	$ 984,000	$ 526,000

Property and Equipment, net

	As of December 31,	
	2004	2003
Office and computer equipment	$ 3,928,000	$ 1,922,000
Manufacturing and development equipment	2,186,000	3,685,000
Leasehold improvements	1,963,000	1,905,000
	8,077,000	7,512,000
Less accumulated depreciation and amortization	(4,997,000)	(3,690,000)
	$ 3,080,000	$ 3,822,000

Accounts Payable and Accrued Expenses

	As of December 31,	
	2004	2003
Accounts payable	$ 481,000	$ 520,000
Accrued bonus	472,000	631,000
Accrued vacation	579,000	468,000
Accrued expenses	695,000	752,000
Warranty reserve (note 2)	102,000	267,000
Accrued restructuring expense (note 12)	—	153,000
Share repurchase payable (note 20)	—	976,000
	$ 2,329,000	$ 3,767,000

9. **Commitments**

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

Years Ending December 31,	Operating Leases
2005	$ 737,000
2006	653,000
2007	621,000
2008	214,000
Total	$ 2,225,000

Rent expense for the years ended December 31, 2004, 2003 and 2002 was $801,000, $931,000, and $622,000, 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 281 kilograms of copolymer in 2004.

10. **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 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 following: (a) the filing of an investigational new drug application, (b) applying for marketing approval, or (c) 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 years ending December 31, 2004 and 2003 the Company paid UC $190,000 and $112,000, respectively, under this license agreement. No payments were made in 2002.

11. **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 and thereafter, the accrual for loss on unused office space relating to lease assumed in the StemSource acquisition was zero.

12. **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 United States.

In connection with the facility closure, the Company involuntarily terminated three employees and relocated another employee to the United States. The Company incurred a liability of approximately $282,000 related to severance benefits and paid all the severance benefits prior to December 31, 2003.

The Königstein, Germany office was 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 would have expired in February 2006. The Company sought 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 expected that a sublease of the entire facility (if one was successfully negotiated) would yield only approximately 65% of the Company's monthly rental obligation. Accordingly, the Company recorded a restructuring expense of $169,000 in the year 2003.

During the second quarter of 2004, the Company re-assessed the expected range of probable sublease rates giving consideration to the current market for commercial real estate, the condition of the property, its location, and other relevant factors. It was expected that the Company could potentially sublease the entire facility (if one was successfully negotiated) for only 45% of its current monthly rental obligation. It was also expected to take a minimum of seven months to find such a tenant. As a result of this analysis, the Company recorded an additional provision of $70,000 in the second quarter of 2004. This additional provision was recorded as restructuring expense.

During the third quarter of 2004, the Company negotiated a settlement of the remaining lease payments with the lessor. As a result of the settlement, the Company recorded an additional provision of $37,000 in the third quarter of 2004. This additional provision was recorded as restructuring expense.

The following outlines the restructuring activity recorded to the liability account during the years ended December 31, 2004 and 2003:

	As of January 1,	Charged to Expense*	Costs Paid	Adjustments to Liability**	As of December 31,
2004:					
Lease termination	$ 153,000	$ 107,000	$ (255,000)	$ (5,000)	$ —
2003:					
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

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

** Revaluation of monetary liability denominated in a foreign currency, which was charged to other income (expense) during the period.

13. **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.

14. **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. The first note was secured by equipment with a cost of $227,000. This note was paid in full in November of 2004. The second promissory note is 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 are secured by equipment with a cost of $1,120,000.

In 2004, the Company issued three additional promissory notes to its lender under the Amended Master Security Agreement in an aggregate principal amount of approximately $1,039,000. These notes are secured by equipment with a cost of $1,039,000.

Additional details relating to the above promissory notes are presented in the following table:

Origination Date	Interest Rate	Current Monthly Payment*	Term	Remaining Principal
November 2001	9.3%	$ 7,000	36 Months	$ —
November 2001	8.4%	34,000	35 Months	354,000
October 2003	8.6%	6,000	48 Months	167,000
October 2003	8.6%	8,000	36 Months	170,000
October 2003	8.8%	17,000	48 Months	465,000
March 2004	8.2%	16,000	48 Months	495,000
April 2004	9.0%	3,000	48 Months	111,000
September 2004	9.0%	9,000	48 Months	304,000
				$ 2,066,000

*Includes principal and interest

As of December 31, 2004, the future contractual principal payments on all of the Company's promissory notes are as follows:

Years Ending December 31,	
2005	$ 938,000
2006	613,000
2007	427,000
2008	88,000
Total	$ 2,066,000

The interest expense for the years ended December 31, 2004, 2003, and 2002 was $177,000, $126,000 and $241,000, respectively.

15. Income Taxes

Due to the Company's net loss position for the years ended December 31, 2004, 2003 and 2002, 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, 2004, 2003, and 2002.

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, 2004, 2003 and 2002 is as follows:

	2004	2003	2002
Income tax expense (benefit) at federal statutory rate	(34.00)%	(34.00)%	(34.00)%
Stock based compensation	1.54%	3.38%	2.50%
Credits	(3.58)%	(1.99)%	(0.35)%
Change in federal valuation allowance	31.05%	30.00%	31.50%
Other, net	4.99%	2.61%	0.35%
	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, 2004 and 2003 are as follows:

	2004	2003
Deferred tax assets:		
Allowances and reserves	$ 46,000	$ 139,000
Accrued expenses	251,000	303,000
Deferred revenue and gain on sale of assets	3,833,000	4,025,000
Stock based compensation	1,509,000	1,593,000
Net operating loss carryforwards	13,228,000	11,866,000
Income tax credit carryforwards	1,517,000	1,383,000
Capitalized assets and other	434,000	507,000
	20,818,000	19,816,000
Valuation allowance	(19,582,000)	(18,734,000)
Total deferred tax assets, net of allowance	1,236,000	1,082,000
Deferred tax liabilities:		
Property and equipment, principally due to differences in depreciation	(378,000)	(118,000)
Intangibles	(845,000)	(953,000)
Other	(13,000)	(11,000)
Total deferred tax liability	(1,236,000)	(1,082,000)
Net deferred tax assets (liability)	$ —	$ —

The Company has established a valuation allowance against its net 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 $19,582,000 as of December 31, 2004 to reflect the estimated amount of deferred tax assets that may not be realized. The Company increased its valuation allowance by approximately $848,000 for the year ended December 31, 2004. The valuation allowance includes approximately $550,000 related to stock option deductions, the benefit of which will, if they are ever utilized, be credited to equity.

At December 31, 2004, the Company had federal and state tax loss carryforwards of approximately $32,879,000 and $22,585,000, respectively. The federal and state net operating loss carryfowards begin to expire in 2019 and 2007 respectively, if unused. At December 31, 2004, the Company had federal and state tax credit carryforwards of approximately $768,000 and $824,000, 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 $613,000 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, 2004, the remaining pre-change federal net operating loss carryforward of $1,546,000 is subject to an annual limitation of approximately $573,000. 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, 2004, this remaining pre-change federal and state net operating loss carryforward of $1,420,000 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.

For the 2004 year, the Company has determined that it has not experienced an ownership change under IRC Section 382 through November 1, 2004. The Company does not expect that an ownership change for purposes of IRC Section 382 occurred during November or December 2004. However, if the Company did experience an ownership change during this period, 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 2004 has not been determined at this time.

16. **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 discretionary or matching contributions made by the Company to the Plan in 2004, 2003 and 2002.

17. **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, 2004 and 2003. 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 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 for $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 for $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 1,447,755 shares of common stock (all listed on the Frankfurt Stock Exchange) held in its treasury for 1,447,755 of unlisted outstanding Company common stock issued to former StemSource shareholders. $104,000 was accounted for as a charge against additional paid-in capital relating to the difference between the weighted average purchase price and fair market value of the listed shares held in treasury at the time of the exchange.

In 2004, the Company repurchased 27,650 shares of its common stock for $76,000 on the open market at a price of $2.75 per share. Additionally in 2004, the Company repurchased 262,602 shares of its common stock for $976,000 from a former director and officer of StemSource at a price of $3.72 per share as discussed in note 20.

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 as of December 31, 2004, 2003 and 2002.

See also the description in note 19, Related Party Transactions, regarding the repurchase of 375,000 shares from related parties.

18. **Stock Based Compensation**

During 2004, the Company adopted the 2004 Equity Incentive Plan, which provides the Company's employees, directors and consultants the opportunity to purchase common stock of the Company through non-qualified stock options, stock appreciation rights, restricted stock units, or restricted stock and cash awards. The Plan initially provides for issuance of 3,000,000 shares of common stock of the Company, which number may be cumulatively increased (subject to Board discretion) on an annual basis beginning January 1, 2005, which increase shall not exceed 2% of the then outstanding stock of the Company. No options or shares had been issued under the 2004 Plan as of December 31, 2004.

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

provides for the issuance of up to 7,000,000 shares of the Company's common stock.

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

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

	Years ended December 31,					
	2004		2003		2002	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	4,801,000	$ 3.96	4,263,000	$ 3.85	3,320,000	$ 4.49
Granted	681,000	$ 4.14	896,000	$ 4.26	1,470,000	$ 3.52
Exercised	(42,000)	$ 0.69	(131,000)	$ 0.26	(92,000)	$ 0.17
Forfeited	(439,000)	$ 5.02	(227,000)	$ 5.13	(435,000)	$ 8.44
Options outstanding at end of period	5,001,000	$ 3.92	4,801,000	$ 3.96	4,263,000	$ 3.85
Options vested at end of period	3,609,000	$ 3.87	3,130,000	$ 3.78	2,241,000	$ 3.28

The following table summarizes information about options outstanding under the 1997 Plan as of December 31, 2004:

Range of Exercise Price	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Options Vested	Weighted Average Exercise Price
$ 0.05 – $1.90	588,000	$ 0.25	3.9	588,000	$ 0.25
$ 2.50 – 3.00	1,018,000	$ 2.92	5.3	988,000	$ 2.93
$ 3.09 – 3.88	730,000	$ 3.22	7.2	500,000	$ 3.19
$ 4.00 – 5.00	1,803,000	$ 4.24	8.4	695,000	$ 4.28
$ 5.50 – 7.50	761,000	$ 6.95	5.9	739,000	$ 6.96
$ 8.00 – 17.26	101,000	$ 12.05	5.8	99,000	$ 12.13
$ 0.05 - $17.26	5,001,000	$ 3.92	6.6	3,609,000	$ 3.87

The weighted-average fair value of options granted for the years ended 2004, 2003 and 2002 was $3.26, $3.54, and $2.48, 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 $(13,000), $49,000, and $99,000 during the years ended December 31, 2004, 2003 and 2002, 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 $96,000, $997,000, and $1,147,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

There was no remaining unearned stock based compensation at December 31, 2004.

Non-Employee Stock Based Compensation

The Company issued 10,000 stock options to a non-employee for consulting services for the year ended December 31, 2004. The weighted average fair value per share of stock options issued and re-measured to non-employees for the year ended December 31, 2004 was $3.17. As a result, the Company recorded stock based compensation expense of $32,000 for the year ended December 31, 2004. The fair value of the grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the year ended December 31, 2004: expected dividend yield of 0.0%, risk-free interest rate of 4.3%, expected volatility factor of 87% and life of 7 years.

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 re-measured to non-employees for the year ended December 31, 2002 was $2.19. As a result, the Company recorded stock based compensation expense of $154,000 for the year ended December 31 2002. The fair value of the grants was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the year ended December 31, 2002: 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 life of 4 years.

Warrants

In connection with its convertible bridge loan financing in 1998 and 1999, the Company issued warrants to purchase 25,000

shares of Series C convertible preferred stock with an exercise price of $2.25 per share. All of the warrants are currently exercisable and begin to expire in September 2008. As of December 31, 2004, 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. 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. All of these warrants expired unexercised in July 2004.

19. **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 was initially to 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 provided 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, 2004, 1,000,000 shares of the Company's common stock, which constitutes approximately 7.2% of the Company's outstanding common stock at December 31, 2004. For the years ended December 31, 2004, 2003 and 2002, the Company had sales to Medtronic of $4,085,000, $12,893,000 and $8,605,000, respectively, which represented 59.9%, 91.5%, and 93.9% of total revenues, respectively. At December 31, 2004 and 2003, the Company had amounts due from Medtronic of $767,000 and $1,136,000, respectively. In connection with the sale of the craniomaxillofacial product line to Medtronic, the terms of this agreement have changed substantially. Moreover, any unrecognized amounts related to the upfront license fee received were recorded as part of gain on sale of asset, related party (see note 3).

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 (this repurchase was part of the 614,099 share repurchase discussed in note 17). 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.

20. **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 and were not registered for 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 exchanged 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 respective 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.

As of December 31, 2003, the Company had 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 8). The Company also recorded the shares to be received as "Treasury stock receivable," a contra-equity account in 2003. The repurchase was effected in January 2004.

21. **Risks and Uncertainties**

The Company is the exclusive, worldwide licensee from the University of California under U.S. Patent No. 6,777,231, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. Although the Company's power as licensee to successfully use these rights to exclude competitors from the market is untested, the Company believes that the loss of such rights could significantly impact its development of the regenerative cell technology and/or commercialization of related products.

The University of Pittsburgh filed a lawsuit in the fourth quarter of 2004, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. This lawsuit could subject the Company to significant costs and, if the University of Pittsburgh wins the lawsuit, the Company's license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, Furthermore, the Company might find it necessary or desirable to either obtain licenses from third parties or cease using certain technology. Accordingly, if the University of Pittsburgh wins the lawsuit, the Company's regenerative cell strategy could be materially adversely affected.

The Company is not named as a party to the lawsuit but the Company's president, Marc Hedrick, is a named individual defendant because he is one of the inventors identified on the patent. The Company is providing financial and other assistance to the defense of the lawsuit.

The Company is subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate. Management believes that any liability to the Company that may arise as a result of currently pending legal proceedings will not have a material adverse effect on the financial condition of the Company taken as a whole.

22. **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, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Revenues	$ 2,352,000	$ 1,540,000	$ 1,774,000	$ 1,152,000
Gross profit	1,233,000	1,226,000	590,000	385,000
Operating expenses, excluding stock based compensation	4,691,000	4,967,000	4,952,000	4,762,000
Stock based compensation	46,000	79,000	—	—
Other income	4,994,000	10,000	8,908,000	61,000
Net income (loss)	1,490,000	(3,810,000)	4,546,000	(4,316,000)
Basic net income (loss) per share	$ 0.11	$ (0.27)	$ 0.33	$ (0.31)
Diluted net income (loss) per share	$ 0.10	$ (0.27)	$ 0.31	$ (0.31)

	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	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)

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

Not applicable.

Item 9A. Controls and Procedures

Christopher J. Calhoun, our Chief Executive Officer, and Mark E. Saad, our Chief Financial Officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in Securities Exchange Act Rule 13a-15(e)), have concluded that as of December 31, 2004, our disclosure controls and procedures are effective.

Item 9B. Other Information

None

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 "Directors and Executive Officers of the Registrant" in our proxy statement for our 2005 annual stockholders' meeting, which will be filed with the SEC on or before May 2, 2005.

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 "Executive Compensation" in our proxy statement for our 2005 annual stockholders' meeting, which will be filed with the SEC on or before May 2, 2005.

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 2005 annual stockholders' meeting, which will be filed with the SEC on or before May 2, 2005.

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 2005 annual stockholders' meeting, which will be filed with the SEC on or before May 2, 2005.

Item 14. Principal Accountant Fees and Services

The information called for by Item 14 with respect to principal accountant fees and services is incorporated herein by reference to the material under the caption "Principal Accountant Fees and Services" in our proxy statement for our 2005 annual stockholders meeting, which will be filed with the SEC on or before May 2, 2005.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) Financial Statements

(a) (2) Financial Statement Schedules

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

For the years ended December 31, 2004, 2003 and 2002
(in thousands of dollars)

	Balance at beginning of year	Additions/(Reductions) ((charges)/ credits to expense)	Charged to Other Accounts	Deductions	Balance at end of year
Allowance for doubtful accounts					
Year ended December 31, 2004	$ 62	$ (44)	$	$ 10	$ 8
Year ended December 31, 2003	50	15	—	3	62
Year ended December 31, 2002	$ 35	$ 15	$ —	$ —	$ 50
Purchase accounting reserves					
Year ended December 31, 2004	$ 28	—	—	28	—
Year ended December 31, 2003	$ 515	$ —	$ 371*	$ 858	$ 28
Year ended December 31, 2002	$ —	—	735	220	515

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

(a)(3) Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to our Form 10-Q Quarterly Report as filed on August 13, 2002 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 to our 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+	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)
10.3+	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)
10.4+	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)

10.5+	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)
10.6+	Exclusive License Agreement, effective October 16, 2001, by and between The Regents of the University of California and StemSource, Inc. (the Company was substituted for StemSource in the agreement effective November 8, 2002) (filed as Exhibit 10.10 to our Annual Report on Form 10-K which was filed on March 31, 2003 and incorporated by reference herein)
10.7	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)
10.8	Lease Termination Agreement for the Premises Located at 1125 Business Center Circle, Thousand Oaks, California, July 31, 2003 (filed as Exhibit 10.2 to our Form 10-Q Quarterly Report, as filed on November 12, 2003 and incorporated by reference herein)
10.9+#	Separation Agreement and General Release between the Company and Ari Bizimis, September 30, 2003 (filed as Exhibit 10.3 to our Form 10-Q Quarterly Report, as filed on November 12, 2003 and incorporated by reference herein)
10.10	Asset Purchase Agreement dated May 7, 2004 between MacroPore Biosurgery, Inc. and MAST Biosurgery AG (filed as Exhibit 2.1 to our Form 8-K Current Report, as filed on May 28, 2004 and incorporated by reference herein.)
10.11#	Offer Letter for the Position of Chief Financial Officer dated June 2, 2004 between MacroPore Biosurgery, Inc. and Mark Saad (filed as Exhibit 10.18 to our Form 10-Q Quarterly Report, as filed on August 16, 2004 and incorporated by reference herein)
10.12#	2004 Equity Incentive Plan of MacroPore Biosurgery, Inc. (filed as Exhibit 10.1 to our Form 8-K Current Report, as filed on August 27, 2004 and incorporated by reference herein)
10.13	Exclusive Distribution Agreement, effective July16, 2004 by and between the Company and Senko Medical Trading Co. (filed as Exhibit 10.25 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
10.14#	Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory) (filed as Exhibit 10.19 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
10.15#	Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory) with Cliff (filed as Exhibit 10.20 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
10.16#	Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive) (filed as Exhibit 10.21 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
10.17#	Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive) with Cliff (filed as Exhibit 10.22 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
10.18#	Form of Options Exercise and Stock Purchase Agreement Relating to the 2004 Equity Incentive Plan (filed as Exhibit 10.23 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)
10.19#	Form of Notice of Stock Options Grant Relating to the 2004 Equity Incentive Plan (filed as Exhibit 10.24 to our Form 10-Q Quarterly Report, as filed on November 15, 2004 and incorporated by reference herein)

10.20#	Description of December 8, 2003 stock repurchase transaction with insiders (filed herewith).
14.1	Code of Ethics (filed as Exhibit 14.1 to our Annual Report on Form 10-K which was filed on March 30, 2004 and incorporated by reference herewith)
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm (filed herewith)
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906of the Sarbanes – Oxley Act of 2002 (filed herewith).

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

# Indicates management contract or compensatory plan or arrangement.

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
March 31, 2005

Pursuant to the requirements of the Securities Exchange 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 31, 2005
/s/ Christopher J. Calhoun Christopher J. Calhoun	*Chief Executive Officer, Director (Principal Executive Officer)*	March 31, 2005
/s/ Marc H. Hedrick, MD Marc H. Hedrick, MD	*President, Director*	March 31, 2005
/s/ Mark E. Saad Mark E. Saad	*Chief Financial Officer (Principal Financial Officer)*	March 31, 2005
/s/ Charles E. Galetto Charles E. Galetto	*Senior Vice President of Finance (Principal Accounting Officer)*	March 31, 2005
/s/ David M. Rickey David M. Rickey	*Director*	March 31, 2005
/s/ Ronald D. Henriksen Ronald D. Henriksen	*Director*	March 31, 2005
/s/ Carmack E. Holmes, MD Carmack E. Holmes, MD	*Director*	March 31, 2005
/s/ Paul W. Hawran Paul W. Hawran	*Director*	March 31, 2005

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EXHIBIT INDEX

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31.2 Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).

32.1 Certification Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes — Oxley Act of 2002 (filed herewith)

# Indicates management contract or compensatory plan or arrangement.

EXHIBIT 10.20

Description Of December 8, 2003 Stock Repurchase Transaction With Insiders

On December 8, 2003, we repurchased from Marshall G. Cox, Chairman of the Board of Directors, and Marc H. Hadrick, MD, Chief Scientific Officer and Director, and from a trust for the benefit of the family of Christopher I. Calhoun, Chief Executive 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 our common stock on the Frankfurt Stock Exchange over the 10 trading days before the repurchase. We are holding the 375,000 shares as treasury stock.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

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

We consent to the incorporation by reference in the registration statements, No. 333-82074 and No. 333-122691, on Form S-8 of the Company, of our report dated March 11, 2005, relating to the consolidated balance sheets of MacroPore Biosurgery, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004, and the related financial statement schedule, which report appears in the December 31, 2004 annual report on Form 10-K of MacroPore Biosurgery, Inc. Our report on the consolidated financial statements refers to the Company deriving a substantial portion of its revenues from a related party.

/s/ KPMG LLP

San Diego, California
March 30, 2005

EXHIBIT 31.1

Certification of Chief Executive Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher J. Calhoun, the Chief Executive Officer of MacroPore Biosurgery, Inc., 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 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our 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. The registrant's other certifying officer and I have disclosed, based on our 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 31, 2005

/s/ Christopher J. Calhoun

Christopher J. Calhoun,
Chief Executive Officer

EXHIBIT 31.2

Certification of Chief Financial Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Mark E. Saad, the Chief Financial Officer of MacroPore Biosurgery, Inc., 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 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-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 our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our 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. The registrant's other certifying officer and I have disclosed, based on our 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 31, 2005

/s/ Mark E. Saad
Mark E. Saad,
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350/ SECURITIES EXCHANGE ACT RULE 13a-14(b), AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Macropore Biosurgery, Inc. for the year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof, Christopher J. Calhoun, as Chief Executive Officer of MacroPore Biosurgery, Inc., and Mark E. Saad, as Chief Financial Officer of MacroPore Biosurgery, Inc., each hereby certifies, respectively, that:

1. 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.

2. 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.

By: /s/ Christopher J. Calhoun
Christopher J. Calhoun
Chief Executive Officer

Dated: March 31, 2005

By: /s/ Mark E. Saad
Mark E. Saad
Chief Financial Officer

Dated: March 31, 2005