

MACROPORE INC

FORM 10-K (Annual Report)

Filed 3/25/2002 For Period Ending 12/31/2001

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Fiscal Year	12/31

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on January 28, 2002 was \$41,015,068, based on the average of the reported high and low sales price of the registrant's common stock on January 28, 2002 as reported on the Neuer Markt of the Frankfurt Stock Exchange, of 3.90 Euros, or \$3.3525 per share, based on the exchange rate in effect as of such date.

As of January 28, 2002, there were 15,106,623 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2002 Annual Meeting of Stockholders, to be held on May 28, 2002, which will be filed with the Securities and Exchange Commission within 120 days after the end of the year ended December 30, 2001, are incorporated by reference in Part III, Items 10, 11, 12 and 13 of this Form 10-K.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed ‘forward-looking statements’ within the meaning of Section 21E of the Securities Exchange Act of 1934. 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 economic, competitive, governmental and technological factors affecting our operations, markets, products and prices. Such forward-looking statements are not guarantees of future performance and actual results, will likely differ, perhaps materially, from those envisaged by such forward-looking statements.

PART I

Item 1. Business

General

We were initially formed as a California general partnership in July 1996, and incorporated in the State of Delaware in May 1997. We develop, manufacture and market bioresorbable surgical implants to aid in the reconstruction, repair and regeneration of bone and the healing of soft tissues throughout the body, as well as related instruments and accessories used in connection with our implants. Our bioresorbable implants are used in craniomaxillofacial, neurological, orthopedic, spinal and reconstructive surgery. We have also developed a bioresorbable surgical film that we intend to begin marketing later in 2002 for use in a wide variety of surgical applications. Since all of our current products and those in development target the biosurgery market, we began doing business under the name MacroPore Biosurgery in December 2001, to better reflect our company's technology and business as a whole. We will ask our stockholders to approve the change of our name at our annual meeting in May 2002.

Our bioresorbable products are made from a copolymer composed of a lactic acid similar to that which occurs naturally in the human body. The lactic acid copolymer maintains its strength during the healing process, while slowly breaking down in the body through hydrolysis into lactic acid molecules and ultimately metabolizing into carbon dioxide and water, which are then released from the body through the lungs and the kidneys. We believe that our products are easier to use and more cost-effective than products made from alternative materials, such as titanium or other metals. We believe the benefits of using a bioresorbable material in bone healing and regenerating applications include:

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

In addition, because of their thermoplastic properties, our bioresorbable products are easy to shape, size and apply to varying anatomical structures, which we believe allows for a better anatomical fit and saves valuable minutes in the operating room.

We have received regulatory clearance or approval to market and sell some of our products in the United States, Europe and other countries. We entered into an exclusive worldwide agreement with Medtronic, Inc. in January 2000, for the global marketing and distribution of some of our products for use in the craniofacial skeleton. We also entered into an exclusive agreement with Medtronic to co-develop and supply them with bioresorbable implants for spinal fixation, stabilization and fusion.

During 2001, we received regulatory clearance for:

- the use of our MacroPore OS Spine bone graft containment system in spinal fusion procedures
- the use of our MacroPore ENT Reconstruction Film film in ear, nose and throat applications for the prevention of postsurgical adhesions, guided tissue regeneration, splinting and tympanic membrane repair
- the use of our MacroPore TS Surgi-Wrap™ film for wound support and soft tissue reinforcement throughout the entire human body
- the use of our MacroPore LP system in reconstructive surgery to correct pediatric skeletal birth defects and in cranial reconstruction
- the use of our MacroPore IB system as a cement restrictor in specified orthopedic applications
- the expanded use of some of our product lines, including MacroPore FX, MacroPore PS and MacroPore NS, in specified craniomaxillofacial procedures

We continue to seek patents on our technology and recently received a U.S. patent for the design of our high torque, resorbable StarBurst Screws which is used in many of our products.

We are also developing additional products for use in spinal fusion procedures, neurosurgery plating, long-bone repair, healing of non-union fractures and cyst or tumor removal site repair, among other things. These future products may require further development and regulatory clearance or approval, potentially including clinical trials, prior to marketing and commercial use.

Products and Services

We manufacture our products solely in the United States at our San Diego facility. We currently market nine product lines in the United States and Europe for use in the craniofacial skeleton, spine and for certain applications in the entire skeleton, and we intend to release and begin marketing two additional products, MacroPore Surgi-Wrap™ and MacroPore ENT Reconstruction Film, later in 2002. Our current product lines are:

Product Lines	Product Components	Use
MacroPore FX	over 120 bioresorbable components, including specially designed plates, screws, tacks and mesh, as well as instruments and accessories	for use in adult and pediatric patients in trauma, reconstructive procedures, and other surgeries for craniomaxillofacial and neurosurgical applications
MacroPore PS	bioresorbable macroporous sheets of various shapes and sizes, as well as instruments and accessories	for use in adult and pediatric patients to facilitate healing and bone regeneration in the skeletal system by, among other things, maintaining the position of bony fragments in trauma and bone graft procedures, and maintaining space beneath soft tissues and allowing bone growth to occur in a protected environment
MacroPore OS	bioresorbable macroporous sheets of various shapes and sizes, together with instruments, accessories and bioresorbable screws and tacks	for the containment of bone grafts other than in the spine, and for reconstruction of the iliac crest, or hip, bone graft donor site
MacroPore OS Spine	bioresorbable macroporous sheets of various shapes and sizes, together with instruments, accessories and bioresorbable screws and tacks	for the containment of bone grafts or bone graft substitutes in spinal fusion procedures
MacroPore NS	specially designed bioresorbable plates	in cranial reconstruction or cranial closure following neurosurgical applications
MacroPore LP	specially designed bioresorbable macroporous sheets of various shapes and sizes, with related instruments, accessories and low profile bioresorbable screws and tacks	in pediatric and adult patients in plastic, reconstructive, and neurosurgical procedures, as well as other specialized surgical applications
MacroPore MX	specially designed bioresorbable plates and screws with templates and various specialized instrumentation	mandibular fracture fixation
MacroPore DX	fully and partially bioresorbable craniofacial distraction device, together with specialty instruments and accessories	to gradually lengthen the midface cranial skeleton to correct cranial skeleton growth disorders
MacroPore IB	bioresorbable surgical plug	cement restrictor in the femur, tibia and humerus
MacroPore TS Surgi-Wrap™	bioresorbable surgical reconstruction film	soft tissue reinforcement and temporary wound support throughout the body
MacroPore ENT Reconstruction Film	bioresorbable surgical reconstruction film	prevention of adhesions, guided tissue regeneration and surgical repair in specified ear, nose and throat applications

For the year ended December 31, 2001, revenue realized from the sale of our craniofacial products accounted for more than 67.0% of our revenue. Since all of our products are developed and sold for use in the medical device industry and have similar purposes, production processes, markets and regulatory requirements, we report them as a single industry segment.

We provide a range of support services to our customers and to surgeons interested in using our products, including:

- producing promotional, educational and instructional materials and literature
- producing scientific publications
- demonstrating our products
- training at our San Diego headquarters
- teaching regional and on-site training seminars and symposia
- providing support personnel to advise surgeons during surgery on the use of our products

Plan of Operation

During 2002, we intend to focus our efforts on:

- enhancing production planning systems and manufacturing processes to reduce costs and increase capacity of our high volume spinal products
- developing product training materials and publishing pre-clinical research reports to support 2002 Medtronic launches of MacroPore products
- establishing a world-wide distribution network for sales of our bioresorbable surgical film products
- obtaining further clearances and approvals for the use of our bioresorbable surgical film products for the prevention of post-operative adhesion and scarring
- expanding the distribution of our craniomaxillofacial and spinal products in overseas markets
- continuing our development and testing of spinal implants with Medtronic
- continuing our development of new bioresorbable polymers with differing resorbion profiles and handling characteristics for our use in future product development
- continuing our development of the second generation of some of our existing products
- developing new uses for our existing products and continuing our research and development of new products, including additional products for orthopedic, spinal, craniomaxillofacial and neurologic applications
- continuing our development of implant systems and instrumentation to deliver biologics such as adult stem cells, and biological molecules such as bone morphogenetic proteins that may improve healing time and the quality of tissue regeneration
- continuing our collaboration with StemSource to determine optimal applications and techniques for the implantation of adult stem cells

- continuing to provide marketing support to Medtronic by attending trade shows and providing product promotional materials, through training of Medtronic's sales force and the medical community and by facilitating communications with our customers

Research and Development

We are continuing our research efforts to develop new applications for our bioresorbable products and to develop new bioresorbable products. We are currently developing new bioresorbable products and materials for use in cardiovascular surgery, tendon and nerve repair, plastic surgery, ear, nose and throat applications, obstetrics and gynecological applications, abdominal and general surgery, craniomaxillofacial and neurosurgery applications, spinal and orthopedic indications. We expect to continue to develop new, technologically advanced products.

In 2001, our research and development efforts focused on continued development with Medtronic of our spinal products, developing bioresorbable surgical film, our MacroPore LP system, our MacroPore MX system, our MacroPore NS system and our MacroPore DX system, and developing uses for our bioresorbable sheets, plates, screws and tacks in other indications. Research and development expenses were \$5,487,000 for the year ended December 31, 2001, \$2,584,000 for the year ended December 31, 2000 and \$1,172,000 for the year ended December 31, 1999.

Customers

Medtronic is our primary distributor and our principal customer, directly accounting for \$5,547,000, or 98.2%, of our revenues for the year ended December 31, 2001, and \$6,092,000, or 97.5%, of our revenues for the year ended December 31, 2000. Medtronic did not act as our distributor and we did not receive any revenues from Medtronic in the year ended December 31, 1999.

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

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

We are currently considering entering into distribution agreements with other distributors in the United States, Europe, Asia and the Pacific Region, primarily to market our products for use in applications other than craniofacial, or spinal fixation, spinal stabilization or spinal fusion applications.

Market and Competition

We compete with many other companies in developing and marketing our technology and products. In the craniofacial fixation market, we compete primarily with titanium products, although we believe that an increasing number of other companies are developing, or are offering, bioresorbable bone fixation systems.

We believe our Surgi-Wrap™ film can be used to prevent post-operative adhesions and scarring and we intend to obtain the clearances and approvals necessary to market our bioresorbable surgical film for use in cardiothoracic surgery, obstetrics and gynecology, tendon surgery and general surgery applications. We are aware of two other companies that have entered these markets with products designed to prevent post-operative adhesions. We believe that our bioresorbable surgical film is superior to competitive products because it is non-inflammatory, there is no need to secure our film when it is implanted into the patient, it maintains its strength and creates a clear surgical dissection plane, and it is bioresorbable where some of our competitor's products are not.

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

Sales by Geographic Region

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

We recorded our first sales in the year ended December 31, 1999, when we recorded \$1,513,000 in revenues, including \$1,472,000 of product sales in the United States and \$41,000 of product sales outside the United States. For the year end ended December 31, 2000, we recorded \$6,251,000 in revenues, including \$6,200,000 of product sales in the United States and \$51,000 of product sales outside the United States. For the year ending December 31, 2001, we recorded \$5,648,000 in revenues, including \$4,954,000 of product sales in the United States and \$694,000 of product sales outside the United States.

Working Capital

We generally maintain an inventory of approximately six to twelve months of products. Although capital expenditures may vary depending on a variety of factors, including sales, we presently intend to spend approximately \$1,300,000 on capital equipment purchases in 2002. We believe our inventory

practices and capital expenditures are consistent with other similar companies at similar levels of development.

Raw Materials

We presently purchase all of our supply of lactic acid copolymer, the primary raw material used in manufacturing our medical devices, from one source. We have entered into an agreement with B.I. Chemicals, Inc. to provide us with our required supply of lactic acid copolymer. This agreement terminates in August 2003, but automatically renews for successive one-year terms unless we give B.I. Chemicals written notice, or B.I. Chemicals gives us written notice, that the agreement will not be renewed six months prior to the end of that term. In the event that B.I. Chemicals is unable to supply the lactic acid copolymer, B.I. Chemicals has agreed to provide us with the manufacturing protocol to enable us to produce the lactic acid copolymer in-house. We believe we would be able to obtain the lactic acid copolymer we use in our products from at least one other supplier if B.I. Chemicals fails to provide us with a sufficient supply.

Intellectual Property

Our success depends in large part on our ability to protect our proprietary technology and information, and operate without infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends on our ability to obtain patents on our technology. We have four U.S. patents for two of our products. Our two U.S. patents for the design of our bioresorbable sheets were issued in July 1999 and August 2001. Our two U.S. patents for the design of our high torque bioresorbable screws were issued in August 2001 and February 2002. Each of our patents will expire 20 years from the date of the patent application.

We have filed applications for sixteen additional U.S. patents, as well as twelve corresponding patent applications outside the United States, relating to our technology. We cannot assure you that any of the pending patent applications will be approved, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, we cannot assure you that others will not independently develop similar products, duplicate any of our products or design around our patents.

Litigation may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention. Any such litigation or interference proceedings, could result in substantial costs to us and divert our management's attention from our business operations, even if the eventual outcome is favorable to us. Litigation could subject us to significant liabilities to third parties and require disputed rights to be licensed from third parties or require us to cease using certain technology.

We currently have pending five patent applications in the European Patent Office, four in Japan and Canada, and three in Australia. We have published five other international patent applications with all countries designated. In addition, we have one patent issued in Australia for the design of our bioresorbable sheets that expires on August 5, 2017. Patent law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries may not protect our proprietary rights to the same extent as United States laws. Third parties may attempt to

oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our, or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

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

Government Regulation

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

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

Before any new medical device may be introduced to the market, the manufacturer generally must obtain either premarket clearance through the 510(k) premarket notification process or premarket approval through the lengthier Premarket Approval Application, or PMA, process. The FDA will grant a 510(k) premarket notification if the submitted data establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device, or to a Class III medical device for which the FDA has not called for PMAs. The FDA may request data, including clinical studies, before it

can make a determination of substantial equivalence. It generally takes from three to 12 months from submission to obtain 510(k) premarket clearance, although it may take longer. There is no assurance that clearance will be granted. We must file a PMA if one of our products is found not to be substantially equivalent to a legally marketed Class I or II device or if it is a Class III device for which the FDA requires PMAs. A PMA must be supported by extensive data to demonstrate the safety and effectiveness of the device, including laboratory, preclinical and clinical trial data, as well as extensive manufacturing information. Before initiating human clinical trials on devices that present a significant risk, we must first obtain an Investigational Device Exemption, or IDE, for the proposed medical device. Toward the end of the PMA review process, the FDA will generally conduct an inspection of our manufacturing facilities to ensure compliance with QSRs. Approval of a PMA could take up to one or more years from the date of submission of the application or petition. The PMA process can be expensive, uncertain and lengthy, and there is no guarantee of ultimate approval.

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

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

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

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

Product Lines	Clearance received for, among other things, the following uses:	Clearance received
MacroPore FX	trauma and reconstructive procedures in the midface and craniofacial skeleton	July 30,1998
MacroPore PS	trauma and reconstructive procedures in the midface and craniofacial skeleton	July 30, 1998
MacroPore PS	trauma, reconstructive and bone augmentation procedures of the mandible	March 19, 1999
MacroPore MX	stabilizing fractured bones in the mandible	October 19, 2000
MacroPore DX	treatment of cranial or midface conditions in reconstructive osteotomy and segment advancement	June 26, 2000
MacroPore OS	protecting iliac crest, or hip bone, graft donor sites, tumor resections where bone strength is not compromised and throughout the skeleton, other than in spinal applications, when used in conjunction with traditional rigid fixation devices	July 24, 2000
MacroPore NS	fixation of bone flaps after a craniotomy	May 2, 2001
MacroPore OS Spine	with traditional rigid fixation in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts, autografts or bone graft substitutes cleared for spinal use	July 20, 2001
MacroPore IB	a cement restrictor in the femur, tibia, and humerus	September 4, 2001
MacroPore FX, PS, NS and LP	specific pediatric and adult plastic, reconstructive and neurosurgical applications in the craniofacial skeleton	September 18, 2001
MacroPore ENT Reconstruction Film	adhesion prevention between the septum and the nasal cavity; tympanic membrane repair; tympanoplasty in the middle ear; nasal splinting and surgical repair of nasal septum; guided tissue regeneration of the external ear	October 25, 2001
MacroPore TS Surgi-Wrap™	for temporary wound support, to reinforce soft tissues where weakness exists, for the repair of hernia or other defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result	December 3, 2001

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

Country	Indications received for, among other things, the following uses:	Received Clearance
European Community	MacroPore FX, MacroPore PS, MacroPore NS, MacroPore DX, MacroPore OS and MacroPore OS Spine products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system, MacroPore TS Surgi-Wrap™ products indicated for use in the craniofacial skeleton, and at some thicknesses, for use throughout the entire skeleton	December 1999
Canada	MacroPore FX and MacroPore PS products indicated to facilitate healing and bone regeneration in trauma and reconstruction procedures in the skeletal system	December 1999
Malaysia	Same as Canada	June 2000
Singapore	Same as Canada	November 2000
South Korea	Same as Canada	January 2001
Australia	Same as Canada	March 2001

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

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

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

Environmental Regulation

Companies in the United States are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and chemicals and certain wastes. We do not currently use any significant amounts of hazardous materials or chemicals in our manufacturing processes.

Staff

As of December 31, 2001, we had 72 full-time employees, comprised of 31 employees in research and development, 17 employees in manufacturing, 16 employees in management and finance and administration, and 8 employees in marketing. As of December 31, 2000, we had 58 full-time employees, comprised of 15 employees in research and development, 20 employees in manufacturing, 13 employees in management and finance and administration and 10 employees in 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. We believe our relations with our employees are good.

Item 2. Properties

Our main facility which we use for our corporate headquarters and for manufacturing is located at 6740 Top Gun Street, San Diego, California. We currently lease approximately 27,000 square feet of space at this location of which approximately 13,000 square feet is laboratory space, 6,000 square feet is office space and 8,000 square feet is manufacturing space. Our lease has a five-year term, expiring in 2003.

We also lease:

- a 14,000 square foot research and development facility located at 6749 Top Gun Street, San Diego, California for a five-year term, expiring in 2006
- 5,800 square feet of office space in Frankfurt, Germany for use in marketing and administration for a five-year term, expiring in 2006
- approximately 400 total square feet of office space in Malvern, Pennsylvania and Atlanta, Georgia for six month terms that renew automatically, unless terminated

We pay an aggregate of approximately \$47,000 in rent per month for our properties located in the United States and approximately €10,000 for our property in Germany.

Item 3. Legal Matters

None.

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

None.

PART II

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

Market Prices

Our common stock has been quoted on the *Neuer Markt* of the Frankfurt Stock Exchange under the symbol "XMP" since our initial public offering on August 8, 2000. Prior to this time, there was no public market for our stock. Our common stock is not currently traded on any United States exchange. The following table shows the high and low sales prices for our common stock for the periods indicated, as reported on Xetra, the Frankfurt Stock Exchange's Exchange Electronic Trading System. These prices do not include retail markups, markdowns or commissions.

	<u>High</u>	<u>Low</u>
2000		
Quarter ended September 30, 2000	€ 27.30	€ 17.65
Quarter ended December 31, 2000	€ 20.00	€ 6.51
2001		
Quarter ended March 31, 2001	€ 14.04	€ 6.00
Quarter ended June 30, 2001	€ 12.08	€ 4.20
Quarter ended September 30, 2001	€ 8.45	€ 2.60
Quarter ended December 31, 2001	€ 5.54	€ 3.50

All of our shares are represented by global stock certificates issued in the name of Concord Effekten AG and deposited with Clearstream Banking AG, Frankfurt, Germany, the German securities depository. As of January 28, 2002, 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 14,000.

Dividends

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

German Securities Laws

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

At present, Germany does not restrict the export or import of capital, except for investments in Iraq and Libya in accordance with applicable resolutions adopted by the United Nations and the European Union. However, for statistical purposes only, every individual or corporation residing in Germany must report to the German Central Bank, subject only to immaterial exceptions, any payment received from or made to an individual or a corporation not a resident of Germany if such payment exceeds Euro 2,550 or the equivalent in a foreign currency. In addition, residents of Germany must report any claims against or

any liabilities payable to non-residents if such claims or liabilities, in the aggregate, exceed Euro 1.53 million or the equivalent in a foreign currency, during any one month. Residents must also report any direct investment outside Germany if such investment exceeds Euro 51,000 or the equivalent in a foreign currency.

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

Recent Sales of Unregistered Securities

During the year ended December 31, 2001, we sold unregistered securities pursuant to our 1997 Amended and Restated Stock Option Plan and an exemption from the registration requirements under the Securities Act provided by Rule 701. During the period from January 1, 2001 through December 31, 2001, we granted options to some of our employees, directors, officers and advisors to purchase a total of 1,578,500 shares of our common stock, at a weighted average exercise price of \$6.18.

Item 6. Selected Financial Data

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

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

Years Ended December 31,

	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>	<u>1997</u>
	(dollars in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Sales to related party	\$ 5,547	\$ 6,092	\$ —	\$ —	\$ —
Sales to distributors and end-users	101	159	1,513	—	—
	<u>5,648</u>	<u>6,251</u>	<u>1,513</u>	<u>—</u>	<u>—</u>
Cost of revenues	2,401	2,394	486	—	—
Inventory provision	1,750	—	—	—	—
Gross profit	<u>1,497</u>	<u>3,857</u>	<u>1,027</u>	<u>—</u>	<u>—</u>
Operating expenses:					
Research and development	5,487	2,584	1,172	1,175	299
Sales and marketing	4,493	2,629	2,356	202	104
General and administrative	3,578	2,555	1,313	604	197
Stock based compensation	1,123	5,698	661	76	9
Total operating expenses	<u>14,681</u>	<u>13,466</u>	<u>5,502</u>	<u>2,057</u>	<u>609</u>
Other income and (expenses):					
Interest income	2,249	1,315	68	10	9
Interest and other expenses	(168)	(351)	(164)	(43)	—
Equity loss in investment	(104)	—	—	—	—
Net loss	<u>\$ (11,207)</u>	<u>\$ (8,645)</u>	<u>\$ (4,571)</u>	<u>\$ (2,090)</u>	<u>\$ (600)</u>
Basic and diluted net loss per share	<u>\$ (.75)</u>	<u>\$ (1.05)</u>	<u>\$ (1.32)</u>	<u>\$ (0.64)</u>	<u>\$ (0.18)</u>
Shares used in calculating basic and diluted net loss per share	<u>14,926,107</u>	<u>8,201,739</u>	<u>3,458,292</u>	<u>3,250,000</u>	<u>3,250,000</u>
Statement of Cash Flows Data:					
Net cash used in operating activities	\$ (8,322)	\$ (2,982)	\$ (5,107)	\$ (1,523)	\$ (545)
Net cash provided by (used in) investing activities	2,263	(39,450)	(381)	(598)	(205)
Net cash provided by financing activities	1,283	47,437	7,924	1,837	1,065
Net (decrease) increase in cash	<u>(4,776)</u>	<u>5,005</u>	<u>2,436</u>	<u>(284)</u>	<u>315</u>
Cash and cash equivalents at beginning of period	7,476	2,471	35	319	4
Cash and cash equivalents at end of period	<u>\$ 2,700</u>	<u>\$ 7,476</u>	<u>\$ 2,471</u>	<u>\$ 35</u>	<u>\$ 319</u>
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 33,951	\$ 44,484	\$ 2,581	\$ 140	\$ 419
Working capital	35,119	46,858	3,510	(493)	387
Total assets	43,143	52,269	5,575	1,020	515
Capital lease obligations, less current portion	135	255	304	209	—
Long-term obligation, less current portion	1,791	—	—	—	—
Convertible redeemable preferred stock, net of offering costs of \$197,000	—	—	10,689	2,696	1,055
Total stockholders' equity (deficit)	<u>\$ 38,486</u>	<u>\$ 49,335</u>	<u>\$ (6,147)</u>	<u>\$ 108</u>	<u>\$ 481</u>

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

Overview

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

We incurred net losses of \$11,207,000 for the year ended December 31, 2001, \$8,645,000 for the year ended December 31, 2000 and \$4,571,000 for the year ended December 31, 1999. As of December 31, 2001, we had an accumulated deficit of \$27,099,000. These net losses resulted to a large extent from expenses associated with developing bioresorbable implant designs, performing preclinical studies, preparing submissions to the FDA and foreign regulatory agencies, expanding marketing and distribution channels, further developing our manufacturing capabilities, securing intellectual property rights and trademarks and supporting our status as a public company traded on the *Neuer Markt*. We expect to expend substantial financial resources to expand marketing, training and customer support needed to generate and support higher sales, expand our manufacturing capabilities, obtain additional regulatory clearances and to develop new products. This investment is likely to result in lower income from operations until operational efficiencies are reached.

In January 1999, we recognized revenue for the first time from the sale of our products. For the years ended December 31, 2001, 2000 and 1999, the majority of our revenues came from sales of our craniomaxillofacial bioresorbable implant products, including our MacroPore FX and MacroPore PS systems. A smaller percentage of our revenues for the years ended December 31, 2001 and 2000 came from sales of instruments and accessories used by surgeons to form, mold and manipulate our bioresorbable products during surgical procedures. We expect to realize the majority of our revenues in 2002 from the sale of our bioresorbable implant products for use in orthopedic, spinal and craniomaxillofacial applications.

Results of Operations

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

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

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

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

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

Research and development expenses. For the year ended December 31, 2001, research and development expenses excluding related stock based compensation expenses were \$5,487,000, compared to \$2,584,000 for the year ended December 31, 2000. Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and clinical trials. The increase in research and development expenses in the year ended December 31, 2001 was primarily attributable to a \$1,465,000 increase in additional personnel costs related to the hiring of employees, and other costs of \$1,438,000 associated with the research into the development of new product lines. In addition, stock based compensation related to research and development was \$111,000 for the year ended December 31, 2001 and \$2,239,000 for the year ended December 31, 2000. For further information regarding fluctuations in research and development inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect research and development spending to continue to increase for the next twelve months as we continue to expand our product development efforts and seek further regulatory approvals.

Sales and marketing expenses. For the year ended December 31, 2001, sales and marketing expenses excluding related stock based compensation expenses were \$4,493,000, compared to \$2,629,000 for the year ended December 31, 2000. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. The increase in sales and marketing expenses in the year ended December 31, 2001 was primarily attributable to a \$1,507,000 increase in additional personnel costs related to the hiring of employees, and other costs of \$357,000 for tradeshow expenses, promotional activities and materials expenses related to the promotion of product lines. In addition, stock based compensation related to sales and marketing was \$176,000 for the year ended December 31, 2001 and \$1,852,000 for the year ended December 31, 2000. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect sales and marketing expenses to remain at current levels for the next twelve months.

General and administrative expenses. For the year ended December 31, 2001, general and administrative expenses excluding related stock based compensation expenses were \$3,578,000, compared to \$2,555,000 for the year ended December 31, 2000. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The increase in general and administrative expenses in the year ended December 31, 2001 was primarily attributable to increased personnel costs of \$554,000, increased administrative costs of \$469,000 for professional services, increased other general corporate expenditures related to all areas of our operations and costs to support our status as a public company traded on the *Neuer Markt*. In addition, stock based compensation related to general and administrative expenses was \$836,000 for the year ended December 31, 2001, compared to \$1,607,000 for the year ended December 31, 2000. For further information regarding fluctuations in general and administrative expenses inclusive of stock based

compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect general and administrative expenses to remain at current levels for the next twelve months.

Stock based compensation expenses . For the year ended December 31, 2001, total non-cash stock based compensation expenses were \$1,123,000, compared to \$5,698,000 for the year ended December 31, 2000. Stock based compensation results from options issued to employees and non-employees. Stock based compensation expenses are amortized over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. The overall decrease in stock based compensation was related to the acceleration of vesting and other modifications to compensatory stock options granted to employees and consultants in the year ended December 31, 2000. The decrease of \$2,128,000 in research and development stock based compensation was primarily due to our decision on August 9, 2000 to accelerate options granted to doctors who performed consulting services, as the services for which these options were granted were deemed complete, and the recognition of the compensation expense related to all of the accelerated options. The decrease of \$1,676,000 in sales and marketing stock based compensation was due primarily to \$1,775,000 in additional expense recorded in the three months ended March 31, 2000 as a result of the extension of the expiration date of some stock options granted to members of our sales force upon the termination of their employment. The decrease of \$771,000 in general and administrative stock based compensation was primarily due to \$636,000 in additional expense recorded in the year ended December 31, 2000 as a result of significant options granted to senior management with immediate vesting and at exercise prices below fair market value.

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

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

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

Year ended December 31, 2000 compared to year ended December 31, 1999

Revenues . For the year ended December 31, 2000, revenues were \$6,251,000 compared to \$1,513,000 for the year ended December 31, 1999, an increase of \$4,738,000. The increase in revenues was primarily the result of sales to Medtronic, our principal distributor, which totaled \$6,092,000, including an initial inventory purchase of \$1,162,000 that occurred in the three months ended June 30, 2000. Revenues attributable to Medtronic, which owned approximately 6.7% of our outstanding common stock on December 31, 2000, represented 97.5% of our revenues for the year ended December 31, 2000.

Cost of revenues . For the year ended December 31, 2000, cost of revenues was \$2,394,000, or 38.3% of revenues, compared to \$486,000, or 32.1% of revenues for the year ended December 31, 1999. Cost of revenues includes material, manufacturing labor and overhead costs. The increase in cost directly related to revenue for the year ended December 31, 2000 was primarily attributable to increased costs to support the increased revenue base. The percentage of revenues increase of 6.2% was due to a decrease in

revenues per unit resulting from our use of third party distributors rather than an internal sales force. Our savings related to the use of third party distributors are reflected below the gross profit line in sales and marketing expenses for the commissions and other selling expenses that were outsourced.

Gross profit . For the year ended December 31, 2000, gross profit was \$3,857,000 or 61.7% of revenues, compared to \$1,027,000 or 67.9% of revenues for the year ended December 31, 1999. The decrease in gross profit as a percentage of revenues was primarily attributable to a decrease in revenues per unit resulting from our use of third party distributors rather than an internal sales force.

Research and development expenses . For the year ended December 31, 2000, research and development expenses excluding related stock based compensation expenses were \$2,584,000, compared to \$1,172,000 for the year ended December 31, 1999. Research and development expenses include costs associated with the design, development, testing, enhancement of our products, regulatory fees, the purchases of laboratory supplies and clinical trials. The increase in research and development expenses in the year ended December 31, 2000 was primarily attributable to research into the development of new product lines. In addition, stock based compensation related to research and development was \$2,239,000 for the year ended December 31, 2000 and \$70,000 for the year ended December 31, 1999. For further information regarding fluctuations in research and development inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

Sales and marketing expenses . For the year ended December 31, 2000, sales and marketing expenses excluding related stock based compensation were \$2,629,000, compared to \$2,356,000 of expenses for the year ended December 31, 1999. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. Despite the elimination of our internal sales force in January 2000, we re-deployed sales costs to marketing personnel and other internal marketing expenses related to the promotion of our product lines. After our initial public offering in August 2000, we allocated some of our available funds to marketing activities. Accordingly, the increase in sales and marketing expenses in the year ended December 31, 2000 was primarily attributable to our increased efforts to provide regional and on-site seminars and symposia and to provide support personnel to demonstrate the use of our new products to surgeons. In addition, stock based compensation related to sales and marketing was \$1,852,000 for the year ended December 31, 2000, compared to \$231,000 for the year ended December 31, 1999. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

General and administrative expenses . For the year ended December 31, 2000, general and administrative expenses excluding related stock based compensation expenses were \$2,555,000, compared to \$1,313,000 for the year ended December 31, 1999. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The increase in general and administrative expenses in the year ended December 31, 2000 was primarily attributable to increased personnel costs of \$605,000 due to the addition of eight full-time employees, increased administrative costs for professional services and insurance, increased other general corporate expenses related to the expansion of all areas of our operations and costs to support our status as a public company traded on the *Neuer Markt* . In addition, stock based compensation related to general and administrative expense was \$1,607,000 for the year ended December 31, 2000, compared to \$360,000 for the year ended December 31, 1999. For further information regarding fluctuations in general and administrative expense inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

Stock based compensation expenses . For the year ended December 31, 2000, total non-cash stock based compensation expenses were \$5,698,000, compared to \$661,000 for the year ended December 31,

1999. Stock based compensation results from options issued to employees and non-employees. Stock based compensation expenses are amortized over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. The overall increase in stock based compensation was related to compensatory stock options granted to employees and consultants, and an increase in the fair market value of our common stock. The increase of \$2,169,000 in research and development stock based compensation was primarily due to a large grant of options to doctors and other professionals who performed consulting services related to our development and start-up activities through August 8, 2000. Approximately \$1,257,000 of this increase was due to our decision to accelerate those options on August 9, 2000, as the services for which those options were granted were deemed complete, and the recognition of the compensation expense related to all of the accelerated options. The increase of \$1,621,000 in sales and marketing stock based compensation was due primarily to \$1,775,000 in additional expense recorded in the three months ended March 31, 2000 as a result of the extension of the expiration date of some stock options granted to former members of our sales force upon the termination of their employment. The increase of \$1,247,000 in general and administrative stock based compensation was primarily due to the grant of significant options to senior management and other employees at exercise prices below fair market value.

Interest income . For the year ended December 31, 2000, interest income was \$1,315,000, compared to \$68,000 for the year ended December 31, 1999, an increase of \$1,247,000. The increase in interest income resulted from an increase in cash, cash equivalents and short-term investments upon the completion of our initial public offering in August 2000.

Interest and other expenses . For the year ended December 31, 2000, interest and other expenses was \$351,000, compared to \$164,000 for the year ended December 31, 1999. The increase in interest and other expenses was primarily related to a loss on the conversion of the Euro to the U.S. dollar in connection with the net proceeds we realized from the sale of equity in our initial public offering in August 2000.

Unearned Compensation

We record unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair market value of our common stock on the date of grant. Unearned compensation is amortized to stock based compensation expense and reflected as such in the Statement of Operations and Comprehensive Income. Unearned compensation recorded through December 31, 2001 was \$6,669,000 with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of \$4,564,000. The remaining \$2,105,000 as of December 31, 2001 will be amortized using the straight-line method over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. We expect to record amortization expense for unearned compensation of \$1,040,000 in 2002, \$851,000 in 2003 and \$214,000 in 2004. The amount of unearned compensation expense recorded in future periods may decrease if unvested options for which unearned compensation has been recorded are subsequently forfeited.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2001, we had federal net operating loss carryforwards of \$17,916,000 and state net operating loss carryforwards of \$3,011,000, which may be available to offset future taxable income for tax purposes. The federal net operating loss carryforwards will begin to expire in 2012, if unused. The state net operating loss carryforwards will begin to expire in 2005, if unused. A portion of the net operating losses are limited in their annual utilization. As of December 31, 2001, we also had research tax credit carryforwards of \$345,000 for federal tax purposes and \$339,000 for state tax purposes. The federal and state research tax credit carryforwards will begin to expire in 2012, if unused. In addition, as

of December 31 2001, we had state manufacturer's credit carryforwards of \$252,000, which will begin to expire in 2007, if unused. For financial reporting purposes, we have provided a valuation against our deferred tax assets due to uncertainties regarding their realization.

Liquidity and Capital Resources

As of December 31, 2001, we had cash and cash equivalents, and short-term investments, available-for-sale, of \$33,951,000 and working capital of \$35,119,000. Since inception, we have financed our operations primarily through sales of stock. Our sales of preferred stock in 1997, 1998 and 1999 yielded net proceeds of \$14,679,000. On August 8, 2000, we completed our public offering in Germany and listed our common stock for trading on the *Neuer Markt* segment of the Frankfurt Stock Exchange in Frankfurt, Germany, at which time the outstanding shares of our preferred stock was converted into 6,831,398 shares of common stock. We received net proceeds of \$43,244,000 from the sale of 3,500,000 shares of our common stock in our initial public offering. A portion of those net proceeds have been used for research and development, to expand our manufacturing operations, to promote our brand and to pursue regulatory approvals for our products. In addition, some of the proceeds have been used for working capital and general corporate purposes. We have invested some of the proceeds from the offering in short-term investments, pending other uses of the proceeds in our business.

Net cash used in operating activities was \$8,322,000 for the year ended December 31, 2001, \$2,982,000 for the year ended December 31, 2000 and \$5,107,000 for the year ended December 31, 1999. For each period, net cash used in operating activities resulted primarily from net losses and working capital requirements. Net losses for each period resulted to a large extent from expenses associated with the development of our bioresorbable designs, preclinical studies, preparation of submissions to the FDA and foreign regulatory agencies, the establishment of marketing and distribution channels, and the improvement of our manufacturing capabilities. In the year ended December 31, 2001, net cash used in operating activities primarily related to our net loss of \$11,207,000 and an increase in inventory of \$1,157,000, offset by non-cash charges for inventory provision, stock based compensation, and depreciation and amortization. In the year ended December 31, 2000, net cash used in operating activities resulted primarily from our net loss of \$8,645,000 and an increase in inventory of \$1,143,000, offset by stock based compensation of \$5,716,000 and deferred revenue related to an up-front license fee of \$1,200,000 paid to us by Medtronic. In the year ended December 31, 1999, net cash used in operating activities primarily related to our net loss of \$4,571,000 and an increase in inventory of \$1,097,000 in anticipation of increased sales in the three months ended March 31, 2000, offset by non-cash charges for stock based compensation, and depreciation and amortization. Our working capital requirements fluctuate with changes in our operating activities that include such items as sales and manufacturing costs, which affect the levels of accounts receivable, inventories and current liabilities.

Net cash provided by investing activities was \$2,263,000 for the year ended December 31, 2001. Net cash used in investing activities was \$39,450,000 for the year ended December 31, 2000 and \$381,000 for the year ended December 31, 1999. Net cash provided by investing activities for the year ended December 31, 2001 consisted of net proceeds from the purchase and sale of short-term investments, capital expenditures and our investment in StemSource, Inc. Net cash used in investing activities for the year ended December 31, 2000 included net purchases of short-term investments related to the use of proceeds from our initial public offering in August 2000, as well as capital expenditures. Net cash used in investing activities for the year ended December 31, 1999 was primarily related to the purchase of property and equipment.

Net cash provided by financing activities was \$1,283,000 for the year ended December 31, 2001, \$47,437,000 for the year ended December 31, 2000 and \$7,924,000 for the year ended December 31, 1999. Net cash provided by financing activities for the year ended December 31, 2001 was primarily

related to proceeds from long-term debt financing, partially offset by our repurchase of shares of our common stock. Net cash provided by financing activities for the year ended December 31, 2000 was primarily attributable to our sale of shares of Series D preferred stock and our sale of common stock in our initial public offering. Net cash provided by financing activities for the year ended December 31, 1999 was primarily related to our sale of shares of Series C and Series D preferred stock.

Our revenues, operating results and cash flow are affected by product pricing, fixed costs of sales and fluctuations in variable cost of sales and sales volumes. In January 2000, we entered into an exclusive distribution agreement with Medtronic for the marketing, distribution and sale of our bioresorbable products for use in the craniofacial skeleton. Under the terms of the distribution agreement, we sell our products to Medtronic at fixed prices that are subject to adjustment upon biannual reviews. Although the distribution agreement provides that direct selling costs are borne by the distributor, our cash flow may be adversely affected if our fixed costs increase and we are unable to negotiate an increase in product pricing with Medtronic.

We have equipment lease obligations that mature at various dates through 2004 with interest rates ranging from 12.4% to 23.7%. The total monthly payments under our equipment lease obligations are \$13,000. In October 2001, we obtained \$2,433,000 of equipment financing that matures in October 2005 at an interest rate of 9.3%. Our total monthly payments under the equipment financing arrangement are \$62,000. We have an additional \$1,400,000 of credit, at an interest rate of 9.3%, available to us through September 2002 under an equipment financing master security agreement.

As of December 31, 2001, we had property and equipment of \$7,108,000, less accumulated depreciation of \$1,937,000 to support our clinical, research, development, manufacturing and administrative activities. Our capital expenditures were \$2,664,000 for the year ended December 31, 2001, \$2,732,000 for the year ended December 31, 2000 and \$376,000 for the year ended December 31, 1999. We expect capital expenditures for the next twelve months to be approximately \$1,300,000 as we acquire additional equipment and expand our facilities. We intend to pay for future capital expenditures with available working capital and by using credit available under our equipment financing master security agreement.

In May 2001, we invested \$1,000,000 in cash in exchange for shares of Series A preferred stock of StemSource, representing a 13.4% ownership interest. StemSource was formed in January 2001 to engage in biomedical research. Under our investor rights agreement with StemSource, we have the right to appoint a representative as a member of StemSource's board of directors. We are not obligated to provide StemSource with any additional funding. From time to time, we may enter into collaborative arrangements with, and acquire ownership interest in, other companies for the purpose of engaging in joint research and development activities.

Our capital requirements depend on numerous factors, including market acceptance of our products and regulatory approvals, the resources we devote to developing and supporting our products and other factors. We expect to devote substantial capital resources to continue our research and development efforts, to expand our support and product development activities and for other general corporate activities. We believe that our current cash and investment balances and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through December 31, 2002. However, unless we begin to generate sufficient revenues from our operations to cover our operating costs, we may need to seek additional sources of financing in the future. We cannot assure you that we will generate sufficient revenues to cover our operating costs or that we will be able to obtain additional financing on terms satisfactory to us, if at all.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and no longer permits the use of the pooling-of-interests method. SFAS No. 142 requires that amortization of goodwill cease and the carrying value of goodwill be evaluated for impairment at least annually using a fair value test. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed at least annually for impairment using a method appropriate to the nature of the intangible asset. We adopted SFAS No. 141 on July 1, 2001 and SFAS No. 142 on January 1, 2002. We do not expect our adoption of SFAS No. 141 or SFAS No. 142 to have a material impact on our financial position or results of operations.

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

Also in August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The provisions of SFAS No. 144 are effective for financial statements issued for fiscal years beginning after December 15, 2001. We do not expect our adoption of SFAS No. 144 to have a material impact on our financial position or results of operations.

Critical Accounting Policies

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

Allowance for doubtful accounts. We provide a reserve against our receivables for estimated losses that may result from our customers' inability to pay. These reserves are based on known uncollectible accounts, aged receivables, historical losses and our estimate of our customers' credit-worthiness. Should a customer's account become past due, we generally place a hold on the account and discontinue further shipments to that customer, minimizing further risk of loss. The likelihood of our recognition of a material loss on an uncollectible account mainly depends on a deterioration in the economic financial strength of the customer and the general business environment. Medtronic is our single largest customer, directly accounting for 98.2% of our revenues in the year ended December 31, 2001. We believe that the allowance for doubtful accounts as of December 31, 2001 with respect to Medtronic's account is sufficient, given Medtronic's financial strength.

Inventory adjustments. We state inventories at the lower of average cost, determined on the first-in first-out method, or fair market value. We review the components of our inventory on a regular basis for

potential excess, obsolete and impaired inventory, based on estimated future usage. The likelihood of any material adjustment of our stated inventory depends on significant changes in the competitive conditions in which we operate, new product introductions by us or our competitors, or fluctuations in customer demand.

Litigation reserves. We record as liabilities on our balance sheets estimated amounts for claims that we consider probable and that can be reasonably estimated. The likelihood of a material change in our estimated reserves depends on new claims that arise and our estimations of the favorable or unfavorable outcome of the particular litigation. We adjust our litigation reserves as new facts relevant to the claim or litigation become known.

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

Valuation of deferred income taxes. We establish valuation allowances, when necessary, to reduce deferred tax assets to the amount we expect to realize. The likelihood of a material change in our expected realization of these assets depends on our generation of future taxable income, our ability to deduct tax loss carryforwards against future taxable income, and the effectiveness of our tax planning strategies in the various tax jurisdictions that we operate in.

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

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 \$31,251,000 as of December 31, 2001, consist primarily of investments in debt instruments of financial institutions, corporations with strong credit ratings and United States government obligations. These securities are subject to interest rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at December 31, 2001, for example, and assuming an average investment duration of ten months, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. We believe that we currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows.

Foreign Currency Exchange Rate Exposure

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to sales of our products in Europe and other foreign markets. Although we transact business in various foreign countries, settlement amounts are usually based on the U.S. dollar or the Euro. Transaction gains or losses resulting from sales revenues have not been significant in the past and we are not engaged in any hedging activity on the Euro or other currencies. Based on our revenues derived from markets other than the United States for the year ended December 31, 2001, a hypothetical 10% adverse change in the Euro against the U.S. dollar would not result in a material foreign 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 in 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.

Item 8. Financial Statements and Supplementary Data

[Report of Arthur Andersen LLP, Independent Public Accountants](#)

[Report of Pricewaterhouse Coopers LLP, Independent Accountants](#)

[Balance Sheets as of December 31, 2001 and 2000](#)

[Statements of Operations and Comprehensive Income for the years ended December 31, 2001, 2000 and 1999](#)

[Statements of Stockholders' Equity for the years ended December 31, 2001, 2000 and 1999](#)

[Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999](#)

[Notes to Financial Statements](#)

Report of Independent Public Accountants

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

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

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

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

Our audits were made for the purpose of forming an opinion of the basic financial statements taken as a whole. The schedule presented in Item 14(a)(2) of the Company's Report on Form 10-K for the period ended December 31, 2001 is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This schedule, for the years ended December 31, 2001 and 2002, has been subjected to the auditing procedures applied in our audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

/s/ Arthur Andersen LLP

San Diego, California

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

Report of Independent Accountants

To the Board of Directors of
MacroPore, Inc.

In our opinion, the statements of operations and comprehensive income, of stockholders' equity and of cash flows listed in the index appearing under Item 14(a)(1) on page 46 present fairly, in all material respects, the results of operations and cash flows of MacroPore, Inc. for the year ended December 31, 1999, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 14(a)(2) on page 47 presents fairly, in all material respects, the information set forth therein for the year ended December 31, 1999 when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Diego, California
June 30, 2000

MACROPORE, INC.
BALANCE SHEETS

	As of December 31,	
	2001	2000
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,700,000	\$ 7,476,000
Short-term investments, available-for-sale	31,251,000	37,008,000
Accounts receivable, related party, net of allowance for bad debts of \$35,000 and \$75,000 in 2001 and 2000, respectively	463,000	693,000
Inventories	1,685,000	2,278,000
Other current assets	851,000	882,000
Total current assets	36,950,000	48,337,000
Property and equipment, net	5,171,000	3,691,000
Other assets	1,022,000	241,000
Total assets	\$ 43,143,000	\$ 52,269,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,155,000	\$ 1,364,000
Current portion of capital lease obligations	121,000	115,000
Current portion of long-term obligations	555,000	—
Total current liabilities	1,831,000	1,479,000
Deferred revenue, related party	900,000	1,200,000
Capital lease obligations, less current portion	135,000	255,000
Long-term obligations, less current portion	1,791,000	—
Total liabilities	4,657,000	2,934,000
Commitments (Note 6)		
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 authorized; -0- shares issued and outstanding in 2001 and 2000	—	—
Common stock; \$0.001 par value; 95,000,000 shares authorized; 15,106,623 and 14,814,346 issued and outstanding in 2001 and 2000, respectively	15,000	15,000
Additional paid-in capital	68,402,000	68,126,000
Unearned compensation	(2,105,000)	(3,094,000)
Accumulated deficit	(27,099,000)	(15,892,000)
Treasury stock, at cost; 356,120 and -0- shares in 2001 and 2000, respectively	(1,077,000)	—
Other accumulated comprehensive income	350,000	180,000
Total stockholders' equity	38,486,000	49,335,000
Total liabilities and stockholders' equity	\$ 43,143,000	\$ 52,269,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS

MACROPORE, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

	For the Years Ended December 31,		
	2001	2000	1999
Revenues:			
Sales to related party (Note 12)	\$ 5,547,000	\$ 6,092,000	\$ —
Sales to distributors and end-users	101,000	159,000	1,513,000
	5,648,000	6,251,000	1,513,000
Cost of revenues:			
Cost of revenues including stock based compensation expense of \$14,000, \$18,000, and \$5,000 for the years ended December 31, 2001, 2000, and 1999, respectively	2,401,000	2,394,000	486,000
Inventory provision	1,750,000	—	—
	1,497,000	3,857,000	1,027,000
Operating expenses:			
Research and development, net of stock based compensation expense of \$111,000, \$2,239,000 and \$70,000 for the years ended December 31, 2001, 2000, and 1999, respectively	5,487,000	2,584,000	1,172,000
Sales and marketing, net of stock based compensation expense of \$176,000, \$1,852,000 and \$231,000 for the years ended December 31, 2001, 2000, and 1999, respectively	4,493,000	2,629,000	2,356,000
General and administrative, net of stock based compensation expense of \$836,000, \$1,607,000 and \$360,000 for the years ended December 31, 2001, 2000, and 1999, respectively	3,578,000	2,555,000	1,313,000
Stock based compensation (excluding cost of revenues stock based compensation)	1,123,000	5,698,000	661,000
	14,681,000	13,466,000	5,502,000
Other income (expense):			
Interest income	2,249,000	1,315,000	68,000
Interest and other expense	(168,000)	(351,000)	(164,000)
Equity loss in investment	(104,000)	—	—
	(11,207,000)	(8,645,000)	(4,571,000)
Other comprehensive income:			
Unrealized holding gains arising during period	350,000	180,000	—
	\$ (10,857,000)	\$ (8,465,000)	\$ (4,571,000)
Basic and diluted net loss per share	\$ (0.75)	\$ (1.05)	\$ (1.32)
Shares used in calculating basic and diluted net loss per share	14,926,107	8,201,739	3,458,292

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS

MACROPORE, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999

	Preferred Stock	Preferred A		Preferred B		Preferred C		Preferred D		Common Stock	
	Subscribed	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance at December 31, 1998	\$ 519,000	1,267,000	\$ 630,000	1,032,583	\$ 1,547,000	—	\$ —	—	\$ —	3,250,000	\$ 3,000
Issuance of common stock for services rendered										66,339	
Issuance of common stock under stock option plan										190,500	
Issuance of common stock for cash	(172,000)									132,666	1,000
Compensatory stock options											
Issuance of Series C Preferred shares for cash, at \$2.25 per share, net of issuance costs of \$137,000	(347,000)			—		2,574,989	5,657,000				
Issuance of Series D Preferred shares for cash, at \$3.50 per share, net of issuance costs of \$58,000				—				832,226	2,855,000		
Net loss for the year ended December 31, 1999										—	—
Balance at December 31, 1999	—	1,267,000	630,000	1,032,583	1,547,000	2,574,989	5,657,000	832,226	2,855,000	3,639,505	4,000
Issuance of common stock under stock option plan										784,124	—
Conversion of Series C Preferred shares to common stock						(45,951)	(103,000)			45,951	—
Issuance of Series C Preferred shares for cash, at \$2.25 per share						2,777	6,000				
Issuance of Series D Preferred shares for cash, at \$3.50 per share								1,167,774	4,087,000		
Issuance of common stock for services rendered										13,368	—
Issuance of common stock in initial public offering, net of issuance costs of \$3,957,000										3,500,000	4,000
Conversion of preferred stock in connection with initial public offering		(1,267,000)	(630,000)	(1,032,583)	(1,547,000)	(2,531,815)	(5,560,000)	(2,000,000)	(6,942,000)	6,831,398	7,000
Compensatory stock options											
Unrealized income on investments											
Net loss for the year ended December 31, 2000											
Balance at December 31, 2000	—	—	—	—	—	—	—	—	—	14,814,346	15,000
Issuance of common stock under stock option plan										292,277	
Compensatory stock options											
Unrealized income on investments											
Purchase of treasury stock											
Net loss for the year ended December 31, 2001											
Balance at December 31, 2001	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	15,106,623	\$ 15,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS

	Additional Paid-In Capital	Unearned Compensation	Accumulated Deficit	Treasury Stock	Other Accumulated Comprehensive Income	Total
Balance at December 31, 1998	\$ 301,000	\$ (216,000)	\$ (2,676,000)	\$ —	\$ —	\$ 108,000
Issuance of common stock for services rendered	13,000					13,000
Issuance of common stock under stock option plan	14,000					14,000
Issuance of common stock for cash	303,000					132,000
Compensatory stock options	1,750,000	(1,069,000)				681,000
Issuance of Series C Preferred shares for cash, at \$2.25 per share, net of issuance costs of \$137,000	—					5,310,000
Issuance of Series D Preferred shares for cash, at \$3.50 per share, net of issuance costs of \$58,000	—					2,855,000
Net loss for the year ended December 31, 1999	—		(4,571,000)			(4,571,000)
Balance at December 31, 1999	2,381,000	(1,285,000)	(7,247,000)	—	—	4,542,000
Issuance of common stock under stock option plan	156,000					156,000
Conversion of Series C Preferred shares to common stock	103,000					—
Issuance of Series C Preferred shares for cash, at \$2.25 per share	—					6,000
Issuance of Series D Preferred shares for cash, at \$3.50 per share	—					4,087,000
Issuance of common stock for services rendered	161,000					161,000
Issuance of common stock in initial public offering, net of issuance costs of \$3,957,000	43,240,000					43,244,000
Conversion of preferred stock in connection with initial public offering	14,672,000					—
Compensatory stock options	7,413,000	(1,809,000)				5,604,000
Unrealized income on investments					180,000	180,000

Net loss for the year ended December 31, 2000			(8,645,000)		(8,645,000)
Balance at December 31, 2000	68,126,000	(3,094,000)	(15,892,000)	180,000	49,335,000
Issuance of common stock under stock option plan	128,000				128,000
Compensatory stock options	148,000	989,000			1,137,000
Unrealized income on investments				170,000	170,000
Purchase of treasury stock			(1,077,000)		(1,077,000)
Net loss for the year ended December 31, 2001			(11,207,000)		(11,207,000)
Balance at December 31, 2001	<u>\$ 68,402,000</u>	<u>\$ (2,105,000)</u>	<u>\$ (27,099,000)</u>	<u>\$ (1,077,000)</u>	<u>\$ 38,486,000</u>

MACROPORE, INC.
STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2001	2000	1999
Cash flows from operating activities:			
Net loss	\$ (11,207,000)	\$ (8,645,000)	\$ (4,571,000)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,184,000	441,000	235,000
Inventory provision	1,750,000	—	—
Stock based compensation	1,137,000	5,716,000	666,000
Equity loss in investment	104,000	—	—
Increases (decreases) in cash caused by changes in operating assets and liabilities:			
Accounts receivable, related party	230,000	(201,000)	(492,000)
Inventories	(1,157,000)	(1,143,000)	(1,097,000)
Other current assets	31,000	(851,000)	1,000
Other assets	115,000	(223,000)	(6,000)
Accounts payable and accrued expenses	(209,000)	724,000	157,000
Deferred revenue, related party	(300,000)	1,200,000	—
Net cash used in operating activities	(8,322,000)	(2,982,000)	(5,107,000)
Cash flows from investing activities:			
Proceeds from the sale and maturity of short-term investments	90,065,000	85,610,000	—
Purchases of short-term investments	(84,138,000)	(122,328,000)	(5,000)
Purchases of property and equipment	(2,664,000)	(2,732,000)	(376,000)
Equity investment	(1,000,000)	—	—
Net cash provided by (used in) investing activities	2,263,000	(39,450,000)	(381,000)
Cash flows from financing activities:			
Principal payments on capital leases	(114,000)	(105,000)	(73,000)
Principal payments on long-term obligations	(87,000)	—	—
Proceeds from short-term debt	—	—	51,000
Proceeds from long-term debt	2,433,000	—	—
Proceeds from sale of Common Stock	128,000	205,000	146,000
Purchase of treasury stock	(1,077,000)	—	—
Proceeds from sale of Series C and Series D preferred stock, net of issuance costs	—	4,093,000	7,800,000
Proceeds from initial public offering, net of offering costs	—	43,244,000	—
Net cash provided by financing activities	1,283,000	47,437,000	7,924,000
Net (decrease) increase in cash	(4,776,000)	5,005,000	2,436,000
Cash and cash equivalents at beginning of period	7,476,000	2,471,000	35,000
Cash and cash equivalents at end of period	\$ 2,700,000	\$ 7,476,000	\$ 2,471,000
Supplemental disclosure of cash flows information:			
Cash paid during period for:			
Interest	\$ 100,000	\$ 82,000	\$ 111,000
Taxes	800	800	800
Supplemental schedule of noncash operating, investing, and financing activities:			
Unearned stock based compensation	\$ 115,000	\$ 4,980,000	\$ 1,452,000
Equipment acquired under capital leases	—	82,000	211,000
Conversion of bridge loan to Series C preferred stock	—	—	225,000
Issuance of Series C preferred stock for purchase of equipment	—	—	140,000
Issuance of common stock for services rendered	—	112,000	—

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS

MACROPORE, INC.
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2001, 2000, AND 1999

1. Organization and Operations

The Company

MacroPore, Inc. (the "Company") was founded as MacroPore (the "Partnership"), a California general partnership with three equal partners, on July 1, 1996. On May 16, 1997, the Company was incorporated in the State of Delaware. The Company received assets from and liabilities of the Partnership and a cash contribution from a shareholder solely in exchange for common stock on May 20, 1997 (the "Transfer").

The Transfer was undertaken to reconstitute the Company as a corporation for tax purposes, at which time the Company transferred the amount of the Partnership's accumulated deficit to the additional paid-in-capital balance until it was zero, with the remainder transferred to the deficit accumulated during the development stage.

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

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 particularly by such companies in rapidly evolving and technologically advanced fields such as the medical device field. The future viability of the Company largely depends on the Company completing development of new products and receiving regulatory approvals for those products. No assurance can be given that the Company's new products will be successfully developed, regulatory approvals will be granted, or acceptance of these products will be achieved.

Capital Availability

The Company has a limited operating history and recorded the first sale of its products in 1999. The Company incurred losses of \$11,207,000, \$8,645,000 and \$4,571,000 for the years ended December 31, 2001, 2000 and 1999, respectively, and has an accumulated deficit of \$27,099,000 as of December 31, 2001. Additionally, the Company has experienced cash flow losses from operations of \$8,322,000, \$2,982,000 and \$5,107,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

Management recognizes the need to generate positive cash flows in future periods and/or to acquire additional capital from various sources. The Company currently has adequate cash and cash equivalent and investment balances to fund operations at least through December 31, 2002. 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 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Investments with original maturities of three months or less that were classified as cash equivalents totaled \$754,000 and \$4,522,000 as of December 31, 2001 and 2000, respectively, and consisted primarily of cash and highly liquid investments.

Short-Term Investments

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

Investments are accounted for in accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities," which requires that the Company determine the appropriate classification of investments at the time of purchase based on management's intent. Held to maturity investments are recorded at amortized cost as management has the positive intention and ability to hold such investments to maturity. Any premiums or discounts are amortized to income over the term of the investment using a method, which approximates the interest method. Available-for-sale investments are stated at fair value, with net unrealized gains or losses, if any, net of tax, reported as a separate component of stockholders' equity. Realized gains or losses from the sale of investments, interest income and dividends are included in interest income in the accompanying statements of operations and comprehensive income.

Management reviews the carrying values of its investments and writes down such investments to estimated fair value by a charge to operations when such review results in management's determination that an investment's impairment is considered to be other than temporary. The cost of securities sold is based on the specific identification method.

Fair Value of Financial Instruments

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

Inventories

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

During the year ended December 2001, the Company recorded an inventory provision of \$1,750,000 for excess and obsolete inventory related to the Company's craniofacial skeleton implant and instrument products. The provision for potential excess and obsolete inventory was

determined based on an anticipated reduction in expected future revenues of these products. The provision includes inventory held on-hand as of December 31, 2001.

Long-Lived Assets

The Company assesses potential impairments to its long-lived assets when there is a change in circumstances that indicate carrying values of assets may not be recovered. An impairment loss is recognized when the undiscounted cash flows expected to be generated by an asset is less than its carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. The Company has not incurred any such losses.

Property and Equipment

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

Revenue Recognition

The Company generally sells its products to hospitals and distributors. Revenue from sales to hospitals is recognized upon delivery of the product. The Company has agreements with its distributors that title and risk of loss pass to the distributor upon shipment of the products. The Company warrants that its products are free from manufacturing defects at the time of shipment to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order.

Revenue from license agreements is recognized ratably over the term of the agreement, provided no significant obligations remain. For the years ended December 31, 2001 and 2000, the Company recognized \$300,000 in revenue in each period from license agreements. There was no revenue from the license agreements for the year ended December 31, 1999. See note 12.

Research and Development

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

Income Taxes

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

Stock Based Compensation

The Company has adopted the disclosure-only provisions of SFAS No. 123, "Accounting for Stock Based Compensation." Accordingly, the Company accounts for its stock based compensation plan under the provisions of Accounting Principle Board (APB) No. 25, "Accounting for Stock Issued to Employees" under which compensation cost is measured by the

excess, if any, of the fair market value of the Company's common stock at the date of grant over the exercise price of the option. Compensation cost is amortized using the straight-line method over the related vesting periods. Accrued compensation costs for awards that are forfeited are reversed against compensation expense in the period of forfeiture. Stock based awards issued to non-employees are accounted for using a fair value method and are remeasured to estimated fair value at each period end until the earlier of the date that performance by the counterparty is complete or the awards are fully vested.

Other Comprehensive Income (Loss)

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

During the years ended December 31, 2000, 2000 and 1999 the Company's only element of other comprehensive income resulted from unrealized gains on investments, which are reflected in the statements of changes in stockholders' equity as other accumulated comprehensive income.

Segment Information

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

The Company recorded its first sales in 1999. For the year ended December 31, 1999, the Company recorded \$1,513,000 in sales. The Company sold \$1,472,000 of product in the United States and \$41,000 of product outside the United States. For the year ended December 31, 2000, the Company recorded \$6,251,000 in sales. The Company sold \$6,200,000 of product in the United States and \$51,000 of product outside the United States. For the year ending December 31, 2001, the Company recorded \$5,648,000 in sales. The Company sold \$4,954,000 of product in the United States and \$694,000 of product outside the United States.

Earnings (Loss) Per Share

The Company computes earnings (loss) per share based on the provision of SFAS No. 128 "Earnings Per Share." Basic per share data is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Weighted average shares exclude shares of unvested common stock subject to repurchase by the Company. 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. The dilutive effect of outstanding stock options and unvested common stock subject to repurchase is reflected in diluted loss per share by application of the treasury stock method.

The Company has excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the periods ended December 31, 2001, 2000 and 1999 as their inclusion would be antidilutive. The number of potential common shares

excluded from the calculations of diluted loss per share for the years ended December 31, 2001, 2000 and 1999 was 3,367,000, 2,797,000 and 5,907,420, respectively.

Reclassification

Certain amounts reported in the Company's Statements of Operations and Comprehensive Income have been reclassified to conform to the presentation for the current year.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("FASB") issued two new pronouncements: Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and no longer permits the use of the pooling-of-interests method. SFAS No. 142 requires that upon adoption, amortization of goodwill will cease and instead, the carrying value of goodwill will be evaluated for impairment at least annually using a fair value test. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed at least annually for impairment using a method appropriate to the nature of the intangible asset. The Company was required to implement SFAS No. 141 on July 1, 2001 and SFAS No. 142 at the beginning of its next fiscal year, January 1, 2002. The Company has determined that the implementation of these standards will not have a material impact on its financial position or results of operations.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to (a) all entities and (b) legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal operation of long-lived assets, except for certain obligations of lessees. This statement amends SFAS No. 19, "Financial Accounting and Reporting by Oil and Gas Producing Companies," and is effective for financial statements issued for fiscal years beginning after June 15, 2002. Management does not believe that the adoption of this statement will have a material impact on its financial position or results of operations.

Also in August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of a business (as previously defined in that Opinion). The provisions of SFAS No. 144 are effective for financial statements issued for fiscal years beginning after December 15, 2001. The Company does not expect the adoption of SFAS No. 144 to have a material impact on its financial position or results of operations.

3. Short-Term Investments

As of December 31, 2001 and 2000, all investments were classified as available-for-sale, which consisted of the following:

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

	December 31, 2000		
	Amortized Cost	Gross Unrealized Gains	Estimated Fair Value
Corporate notes and bonds	\$ 17,594,000	\$ 45,000	\$ 17,639,000
Agency securities	17,740,000	133,000	17,873,000
Treasury note	1,494,000	2,000	1,496,000
	<u>\$ 36,828,000</u>	<u>\$ 180,000</u>	<u>\$ 37,008,000</u>

As of December 31, 2001 and 2000, investments available for sale have the following maturities:

	December 31, 2001		December 31, 2000	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Corporate notes and bonds:				
with maturity of less than 1 year	\$ 9,000,000	\$ 9,057,000	\$ 17,594,000	\$ 17,639,000
with maturity of 1 to 2 years	718,000	718,000		
Agency securities:				
with maturity of less than 1 year	8,963,000	9,109,000	5,639,000	5,677,000
with maturity of 1 to 2 years	10,079,000	10,225,000	12,101,000	12,196,000
Treasury note:				
with maturity of less than 1 year	2,141,000	2,142,000	1,494,000	1,496,000
	<u>\$ 30,901,000</u>	<u>\$ 31,251,000</u>	<u>\$ 36,828,000</u>	<u>\$ 37,008,000</u>

Proceeds from sales of investments for the year ended December 31, 2001 and 2000 were \$90,065,000 and \$85,610,000, respectively. Gross realized gains on such sales for the years ended December 31, 2001 and 2000 were approximately \$217,000 and \$6,000, respectively. There were no sales of investments for the year ended December 31, 1999.

4. Composition of Certain Financial Statement Captions

Inventories

	December 31,	
	2001	2000
Raw materials	\$ 959,000	\$ 706,000
Finished goods	726,000	1,572,000
	<u>\$ 1,685,000</u>	<u>\$ 2,278,000</u>

Property and Equipment, net

	December 31,	
	2001	2000
Office and computer equipment	\$ 1,406,000	\$ 845,000
Manufacturing and development equipment	4,235,000	2,684,000
Leasehold improvements	<u>1,467,000</u>	<u>916,000</u>
	7,108,000	4,445,000
Less accumulated depreciation and amortization	<u>(1,937,000)</u>	<u>(754,000)</u>
	<u>\$ 5,171,000</u>	<u>\$ 3,691,000</u>

Accounts Payable and Accrued Liabilities

	December 31,	
	2001	2000
Accounts payable	\$ 294,000	\$ 784,000
Accrued bonus	398,000	195,000
Accrued vacation	244,000	121,000
Accrued expenses	<u>219,000</u>	<u>264,000</u>
	<u>\$ 1,155,000</u>	<u>\$ 1,364,000</u>

5. Equity Investment in StemSource

In 2001 the Company invested \$1,000,000 in cash in exchange for shares of Series A preferred stock, a 13.4% ownership interest, in StemSource, Inc. ("StemSource"), a development stage company primarily engaged in biomedical research. Under the Investors' Rights Agreement, each StemSource investor shall use their best efforts to maintain a Company representative on the Board of Directors of StemSource so long as the Company continues to hold at least 50% of the investment shares. StemSource has continued to rely on the Company's cash investment for the continuance of its operations. The investment is accounted for under the equity method of accounting as the Company may be able to exercise significant influence over the operations of StemSource because of its board of director representation and its initial cash investment. Realization of this investment depends on the successful development of products and the future operating results of StemSource. For the year ended December 31, 2001, the Company recognized an equity loss in investment of \$104,000.

6. Commitments

The Company leases office space and equipment under noncancelable leases as follows:

Years Ending December 31,	Capital Leases	Operating Leases
2002	\$ 152,000	\$ 486,000
2003	115,000	240,000
2004	29,000	189,000
2005	—	189,000
2006	—	54,000
Thereafter	—	—
Total minimum lease payments	296,000	\$ 1,158,000
Less amounts representing interest	(40,000)	
Present value of minimum capital lease obligations	256,000	
Less current portion	(121,000)	
Long term portion of capital lease obligations	\$ 135,000	

Equipment acquired under capital leases included in property and equipment amount to \$543,000 (\$331,000 net of accumulated depreciation and amortization) as of December 31, 2001. The Company's capital lease obligations mature at various dates through 2004 with interest rates ranging from 12.4% to 23.7%.

Rent expense for the years ended December 31, 2001, 2000 and 1999 was \$579,000, \$369,000 and \$210,000, respectively.

The Company has entered into a long-term supply agreement for copolymer. The Company has agreed to purchase at least 50 kilograms of copolymer per year, at a cost of between \$2,480 and \$2,655 per kilogram, depending on the volume purchased by the Company. If the Company purchases less than 50 kilograms of the product per year, the purchase price the Company pays for the product will be subject to renegotiation.

7. Long-Term Debt

In 2001 the Company entered into a Master Security Agreement to provide financing for equipment purchases. In connection with the agreement, the Company issued two promissory notes to its lender under the agreement for a total of approximately \$2,433,000. These notes bear interest at 9.3% per annum with principal and interest due in monthly payments of approximately \$55,000 and \$7,000, respectively, and mature over 48 and 36 month periods, respectively, and are secured by equipment with a cost of \$2,752,000. The Company has \$1,400,000 of remaining available credit under the Master Security Agreement through September 2002.

8. Income Taxes

Due to the Company's net loss position for the years ended December 31, 2001, 2000 and 1999, 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, 2001, 2000 and 1999.

The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	Years Ended December 31,		
	2001	2000	1999
Tax benefit at statutory rate	-34.00 %	-34.00 %	-34.00 %
State tax, net of federal tax benefit	-3.30 %	-3.00 %	-5.95 %
Stock based compensation	-	-	3.43 %
Research and other credits	-3.14 %	-5.44 %	-0.68 %
Other permanent differences	-6.17 %	0.14 %	0.66 %
Change in valuation allowance	46.61 %	42.30 %	36.54 %
	<u>0.00 %</u>	<u>0.00 %</u>	<u>0.00 %</u>

The components of the deferred tax assets and liabilities are as follows:

	December 31,	
	2001	2000
Deferred Tax Assets		
Accrued expenses	\$ 86,000	\$ 42,000
Accounts receivable/Inventory reserve	762,000	30,000
Deferred expenses	83,000	136,000
Deferred revenue	359,000	480,000
Property and equipment	(232,000)	(173,000)
Stock based compensation	2,819,000	2,376,000
R&D Capitalization — Sec. 59(e)	391,000	—
Net operating loss carryforwards	6,599,000	3,051,000
Research credits	561,000	310,000
California manufacturer's credits	174,000	160,000
	11,602,000	6,412,000
Less valuation allowance	(11,602,000)	(6,412,000)
Net deferred tax assets, net	\$ —	\$ —

The Company has established a valuation allowance against its deferred tax asset due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that deferred tax assets are realizable, the valuation allowance will be reduced.

At December 31, 2001, the Company had federal net operating loss carryforwards of approximately \$17,916,000 and state net operating loss carryforwards of approximately \$3,011,000, which may be available to offset future taxable income for tax purposes. The federal net operating loss carryforwards begin to expire in 2012, if unused. The state net operating loss carryforwards begin to expire in 2005.

At December 31, 2001, the Company had a research tax credit carryforwards of approximately \$345,000 and \$339,000 for federal and state tax purposes, respectively. The federal carryforward will begin to expire in 2012, if unused. At December 31, 2001, the Company also had a

California manufacturer's credit carryforwards of approximately \$252,000, which begin to expire in 2007, if unused.

The Internal Revenue Code limits the future availability of net operating loss and tax credit carryforwards that arose prior to certain cumulative changes in a corporation's ownership resulting in a change of control of the Company. Due to prior ownership changes as defined in IRC Section 382, a portion of the net operating loss and tax credit carryforwards are limited in their annual utilization.

9. 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 contributions made by the Company to the Plan in 2001, 2000 and 1999.

10. Stockholders' Equity

Convertible Preferred Stock

In August 1997, the Company issued 1,267,000 shares of Series A non-cumulative convertible preferred stock ("Series A") at \$0.50 per share. Proceeds, net of issuance costs, were \$630,000. In July 1998, the Company issued 1,032,583 shares of Series B non-cumulative convertible preferred stock ("Series B") at \$1.50 per share. Proceeds, net of issuance costs, were \$1,547,000. In September 1999, the Company issued 2,574,989 shares of Series C non-cumulative convertible preferred stock ("Series C") at \$2.25 per share. Proceeds, net of issuance costs, were \$5,657,000. In December 1999, the Company issued 832,226 shares of Series D non-cumulative convertible preferred stock ("Series D") at \$3.50 per share. Proceeds, net of issuance costs, were \$2,855,000. In May 2000, the Company issued an additional 2,777 shares of Series C at \$2.25 per share for \$6,000 upon the exercise of warrants. In March 2000, the Company issued an additional 1,167,774 shares of Series D at \$3.50 per share for \$4,087,000.

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

Preferred Stock

The Company has authorized 5,000,000 shares of \$.001 par value preferred stock, with no shares outstanding as of December 31, 2001 and 2000. The Board of Directors of the Company is authorized to designate the terms and conditions of any preferred stock issued by the Company without further action by the common stockholders.

Treasury Stock

On April 3, 2001, the Board of Directors authorized the repurchase of up to 1,000,000 shares of the Company's common stock in the open market, from time to time until March 31, 2002, subject to the Company's assessment of market conditions and buying opportunities, and at a purchase price per share not to exceed €7.50, or \$6.77, based on the exchangerate in effect on

that date. During 2001 the Company spent \$1,077,000 to repurchase 356,120 shares of its Common Stock at an average cost of \$3.02 per share.

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

11. Stock Based Compensation

During 1997, the Company adopted the "1997 Stock Option and Stock Purchase Plan" (the "1997 Plan") which provides for the direct award or sale of shares and for the grant of incentive stock options ("ISO") and non-statutory options ("NSO") to employees, directors or consultants. The Plan, as amended, provides for the issuance of up to 5,000,000 shares of the Company's common stock.

Under the provisions of the 1997 Plan, the exercise price of ISOs is not less than the fair market value of the underlying shares on the date of grant. 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,					
	2001		2000		1999	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Options outstanding at beginning of period	2,750,000	\$ 3.44	2,151,000	\$ 0.19	1,035,000	\$ 0.11
Granted	1,578,000	\$ 6.18	1,577,000	\$ 5.92	1,306,000	\$ 0.25
Exercised	(292,000)	\$ 0.44	(784,000)	\$ 0.20	(190,000)	\$ 0.07
Forfeited	(716,000)	\$ 5.82	(194,000)	\$ 0.65	—	—
Options outstanding at end of period	<u>3,320,000</u>	\$ 4.49	<u>2,750,000</u>	\$ 3.44	<u>2,151,000</u>	\$ 0.19
Options vested at end of period	<u>1,329,000</u>	\$ 2.88	<u>840,000</u>	\$ 1.41	<u>499,000</u>	\$ 0.13

The following table summarizes information about options outstanding under the 1997 Plan as of December 31, 2001:

Exercise Prices		Options Outstanding	Weighted Average Remaining Contractual Life (in years)	Options Vested
\$ 0.05	-\$ 0.45	807,000	6.9	574,000
\$ 1.90	-\$ 3.51	1,158,000	8.5	579,000
\$ 3.53	-\$ 7.34	859,000	9.1	—
\$ 7.43	-\$ 10.84	131,000	8.9	32,000
\$ 11.68	-\$ 17.26	365,000	8.6	144,000
		<u>3,320,000</u>		<u>1,329,000</u>

The weighted-average fair value of options granted for the years ended 2001, 2000 and 1999 was \$3.11, \$6.40 and \$1.42, respectively.

As required by SFAS 123, the Company has determined the pro forma information as if the Company had accounted for stock options under the minimum value method of SFAS 123. The following weighted average assumptions were used; risk free interest rates ranging from 3.52% to 6.71%, dividend yield of zero, expected market price volatility factor of 60% and a weighted average expected life of the options of four years. Had compensation cost for stock options granted during the years ended December 31, 2001, 2000 and 1999 been determined consistent with SFAS 123, the Company's net loss and related per share amounts on a pro forma basis would be as follows:

	Years ended December 31,		
	2001	2000	1999
Net loss:			
As reported	\$ (11,207,000)	\$ (8,645,000)	\$ (4,571,000)
Pro forma	(12,427,000)	(9,456,000)	(4,962,000)
Loss per common share:			
As reported	\$ (.75)	\$ (1.05)	\$ (1.32)
Pro forma	(.83)	(1.15)	(1.43)

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

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 \$115,000, \$4,980,000 and \$1,480,000 during the years ended December 31, 2001, 2000 and 1999, respectively. This represents the difference between the exercise price of these stock based awards and the deemed market value of the underlying common stock on the date of grant. Amortization of unearned stock based compensation, net of any charges reversed during the period for the forfeiture of unvested awards, was \$1,104,000, \$3,171,000 and \$411,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

The remaining unearned stock based compensation of \$2,105,000 at December 31, 2001 will be amortized as follows: \$1,040,000 in 2002, \$851,000 in 2003 and \$214,000 in 2004. The amount of stock based compensation expense to be recorded in future periods could decrease if awards are forfeited for which accrued but unamortized compensation expense has been recorded.

Non-Employee Stock Based Compensation

The Company issued 298,000 and 226,000 stock options to non-employees for consulting services for the years ended December 31, 2000 and 1999, respectively. The weighted-average fair value per share of stock options issued and remeasured to non-employees for the years ended December 31, 2001, 2000 and 1999 was \$4.21, \$9.42 and \$1.49, respectively. As a result, the Company recorded stock based compensation expense of \$33,000, \$2,545,000 and \$255,000 for the years ended December 31, 2001, 2000 and 1999, respectively. The fair value of the grants was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions for the years ended December 31, 2001, 2000 and 1999: expected dividend yield of 0.0%, risk-free interest rate ranging from 4.47% to 6.52%, expected volatility ranging from 60% to 100% and expected life of 2 to 4 years.

Warrants

The Company issued warrants to purchase 25,000 shares of Series C convertible preferred stock with an exercise price of \$2.25 per share, in connection with its convertible bridge loan financing in 1998 and 1999. All of the warrants are currently exercisable and begin to expire in September 2008. As of December 31, 2001, 2,777 of these warrants had been exercised. Upon conversion of the Company's outstanding preferred stock into common stock, which occurred in August 2000, the warrants became immediately exercisable into shares of the Company's common stock.

In connection with a termination of a sales distribution agreement in 2000, the Company issued warrants to purchase 25,000 shares of common stock with an exercise price of \$12.00 per share. All the warrants are exercisable and expire in July 2004. As of December 31, 2001, none of these warrants have been exercised.

12. Related Party Transactions

In the years ended December 31, 2000 and 1999, consulting fees, manufacturing and out-of-pocket expenses paid to various stockholders and employees were included in research and development expenses. These expenses amounted to \$19,000 and \$151,000 for the years ended December 31, 2000 and 1999, respectively. There were no similar related party transactions in year ended December 31, 2001.

In January 2000, the Company entered into a five-year distribution agreement with a distributor. Under the terms of the agreement, the Company granted the distributor 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, the distributor paid a \$1,500,000 up-front license fee to the Company, which will be recognized ratably over the same five-year period. Additionally, the distributor is 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 the distributor concurrently entered into a five-year development and supply agreement, which provides the distributor 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, the

distributor purchased 1,000,000 shares Series D convertible preferred stock for \$3,500,000. The terms of the sale of the Series D convertible preferred stock were equivalent to the terms and price paid by unaffiliated third parties who also purchased shares of Series D convertible preferred stock. For the years ended December 31, 2001 and 2000, the Company had sales to the distributor of \$5,547,000 and \$6,092,000, respectively, which represented 98.2% and 97.5% of total revenues, respectively. At December 31, 2001 and 2000, the Company had amounts due from the distributor of \$463,000 and \$693,000, respectively. There were no sales or receivables from the related party distributor in the year ended December 31, 1999.

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

13. Subsequent Event

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

In addition, the Company is authorized to loan the two directors up to an aggregate of an additional \$3,022,000 for the purchase of additional shares of the Company's common stock from another of its stockholders. As authorized, any additional loans the Company makes to the directors will be made on the same terms and conditions as the February 2002 loans, and must be made prior to March 31, 2002, if at all.

MACROPORE, INC.
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2001, 2000, AND 1999

14. 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.

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Year 2001				
Revenues	\$ 2,029,000	\$ 768,000	\$ 1,400,000	\$ 1,451,000
Gross profit	1,364,000	(715,000)	747,000	101,000
Operating expenses, excluding stock based compensation	3,123,000	3,856,000	3,615,000	2,964,000
Stock base compensation	143,000	370,000	335,000	275,000
Other expenses	688,000	599,000	467,000	223,000
Net loss	<u>(1,214,000)</u>	<u>(4,342,000)</u>	<u>(2,736,000)</u>	<u>(2,915,000)</u>
Basic and diluted net loss per share	<u>\$ (0.08)</u>	<u>\$ (0.29)</u>	<u>\$ (0.18)</u>	<u>\$ (0.20)</u>
Year 2000				
Revenues	\$ 1,259,000	\$ 2,206,000	\$ 1,114,000	\$ 1,672,000
Gross profit	662,000	1,668,000	760,000	767,000
Operating expenses, excluding stock based compensation	1,339,000	1,702,000	2,076,000	2,651,000
Stock base compensation	2,426,000	1,426,000	1,739,000	107,000
Other expenses	62,000	84,000	81,000	737,000
Net loss	<u>(3,041,000)</u>	<u>(1,376,000)</u>	<u>(2,974,000)</u>	<u>(1,254,000)</u>
Basic and diluted net loss per share	<u>\$ (0.82)</u>	<u>\$ (0.36)</u>	<u>\$ (0.50)</u>	<u>\$ (0.15)</u>

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

Not applicable.

PART III

Item 10. Directors and Executive Officers of the Registrant

The information called for by Item 10 with respect to identification of our directors and executive officers is incorporated herein by reference to the material under the captions “Election of Directors” and “Compensation and Other Information Concerning Directors and Executive Officers” in our proxy statement for our 2002 annual stockholders meeting, which will be filed with the Commission before April 30, 2002.

Item 11. Executive Compensation

The information called for by Item 11 with respect to executive compensation is incorporated herein by reference to the material under the caption “Compensation and Other Information Concerning Directors and Executive Officers” in our proxy statement for our 2002 annual stockholders meeting, which will be filed with the Commission before April 30, 2002.

Item 12. Security Ownership of Certain Beneficial Owners and Management

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 2002 annual stockholders meeting, which will be filed with the Commission before April 30, 2002.

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 2002 annual stockholders meeting, which will be filed with the Commission before April 30, 2002.

PART IV

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

(a) (1) Financial Statements

[Report of Arthur Andersen LLP, Independent Public Accountants](#)

[Report of PricewaterhouseCoopers LLP, Independent Accountants](#)

[Balance Sheets as of December 31, 2001 and 2000](#)

[Statements of Operations and Comprehensive Income for the years ended December 31, 2001, 2000 and 1999](#)

[Statements of Stockholders' Equity for the years ended December 31, 2001, 2000 and 1999](#)

[Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999](#)

[Notes to Financial Statements](#)

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

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

For the years ended December 31, 2001, 2000 and 1999
(in thousands of dollars)

	Balance at beginning of year	Additions (charges to expense)	Charged to Other Accounts	Deductions	Balance at end of year
Allowance for doubtful accounts — 2001	\$ 75	\$ 4	\$ —	\$ 44	\$ 35
Allowance for doubtful accounts — 2000	53	82	—	60	75
Allowance for doubtful accounts — 1999	—	53	—	—	53

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

On August 13, 2001, we filed a Current Report on Form 8-K with the Commission pursuant to Item 5 of that Form in which we provided information on our results of operations for the six months ended June 30, 2001.

On November 12, 2001, we filed a Current Report on Form 8-K with the Commission pursuant to Item 5 of that Form in which we provided information on our results of operations for the three months and nine months ended September 30, 2001.

(c) **Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of MacroPore, Inc. (filed as Exhibit 3.1 to our Form 10 registration statement, as amended, as filed on March 30, 2001 (file number 000-32501) and incorporated by reference herein)
3.2	Bylaws of MacroPore, Inc. (filed as Exhibit 3.2 to our Form 10 registration statement, as amended, as filed on March 30, 2001 (file number 000-32501) and incorporated by reference herein)
10.1	Amended and Restated Stock Option and Stock Repurchase Plan (filed as Exhibit 10.1 to our Form 10 registration statement, as amended, as filed on March 30, 2001 (file number 000-32501) and incorporated by reference herein)
10.2+	Distribution Agreement, made and entered into as of January 5, 2000, between MacroPore, Inc. and Medtronic, Inc. (filed as Exhibit 10.2 to our Form 10 registration statement, as amended, as filed on June 1, 2001 (file number 000-32501) and incorporated by reference herein)
10.3+	Amendment No. 1 to Distribution Agreement, effective as of December 22, 2000, by and between the Company and Medtronic (filed as Exhibit 10.3 to our Form 10 registration statement, as amended, as filed on June 1, 2001 (file number 000-32501) and incorporated by reference herein)
10.4+	Development and Supply Agreement, made and entered into as of January 5, 2000, by and between the Company and Medtronic (filed as Exhibit 10.4 to our Form 10 registration statement, as amended, as filed on June 1, 2001 (file number 000-32501) and incorporated by reference herein)
10.5+	Amendment No. 1 to Development and Supply Agreement, effective as of December 22, 2000, by and between the Company and Medtronic (filed as Exhibit 10.5 to our Form 10 registration statement, as amended, as filed on June 1, 2001 (file number 000-32501) and incorporated by reference herein)
23.1	Consent of Arthur Andersen LLP, independent public accountants
23.2	Consent of PricewaterhouseCoopers LLP, independent accountants
24.1	Power of Attorney (contained in the signature page).
99.1	Confirmation of Receipt of Assurances from Arthur Andersen LLP

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

SIGNATURES

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

MACROPORE, INC .

By: /s/ Christopher J. Calhoun

Christopher J. Calhoun
Vice-Chairman, Chief Executive Officer and Secretary
March 22, 2002

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

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Marshall G. Cox</u> Marshall G. Cox	<i>Chairman of the Board of Directors</i>	March 21, 2002
<u>/s/ Christopher J. Calhoun</u> Christopher J. Calhoun	<i>Vice-Chairman, Chief Executive Officer, Secretary and Director</i>	March 22, 2002
<u>/s/ Michael Simpson</u> Michael Simpson	<i>President and Director</i>	March 22, 2002
<u>/s/ Ari Bisimis</u> Ari Bisimis	<i>Chief Financial Officer and Director</i>	March 22, 2002
<u>/s/ David Rickey</u> David Rickey	<i>Director</i>	March 21, 2002
<u>/s/ Edmund Krix</u> Edmund Krix	<i>Director</i>	March 21, 2002

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EXHIBIT 23.1

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report included in this Form 10-K, into the Company's previously filed registration statement on Form S-8, File No. 333-82074.

/s/ Arthur Andersen LLP
San Diego, California
March 20, 2002

EXHIBIT 23.2

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-82074) of MacroPore, Inc. of our

report dated June 30, 2000 relating to the financial statements and financial statement schedule, which appears in this Form 10-K. We also hereby consent to the reference to us under the heading "Selected Financial Data" which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Diego, California
March 25, 2002

Exhibit 99.1

*MacroPore, Inc.
6740 Top Gun Street
San Diego, California 92121*

March 22, 2002

Securities and Exchange Commission
450 5th Street, N.W.
Washington, D.C. 20549

Re: Confirmation of Receipt of Assurances from Arthur Andersen LLP

Ladies and Gentlemen:

MacroPore, Inc. ("MacroPore") has received a representation letter from Arthur Andersen LLP ("Andersen"), MacroPore's independent public accountants, in connection with the issuance of Andersen's audit report included in MacroPore's Annual Report on Form 10-K for the fiscal year ended December 31, 2001. In its letter, Andersen represented to MacroPore that Andersen's audit of the balance sheets of MacroPore as of December 31, 2001 and 2000, and the related statements of operations and comprehensive income, stockholder's equity and cash flows for the years then ended, was subject to Andersen's quality control system for the U.S. accounting and auditing practice to provide reasonable assurance that the engagement was conducted in compliance with professional standards, that there was appropriate continuity of Andersen personnel working on the audit, availability of national office consultation and availability of personnel at foreign affiliates of Andersen to conduct the relevant portions of the audit.

Very truly yours,

/s/ Christopher J. Calhoun

Christopher J. Calhoun
Vice-Chairman of the Board,
Chief Executive Officer and Secretary

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