# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM 10/A

GENERAL FORM FOR REGISTRATION OF SECURITIES PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934

MACROPORE, INC. (Exact name of registrant as specified in its charter.)

Delaware

330-827-593

(State or other jurisdiction of incorporation or organization)

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

6740 Top Gun Street San Diego, California

92121

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

858-458-0900

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

NONE

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

COMMON STOCK, par value \$0.001

#### TABLE OF CONTENTS

			PAGE
Item	1.	BUSINESS	1
Item	2.	FINANCIAL INFORMATION	.10
Item	3.	PROPERTIES	.19
Item	4.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	.19
Item	5.	DIRECTORS, EXECUTIVE OFFICERS AND FOUNDERS	.21
Item	6.	EXECUTIVE COMPENSATION	.23
Item	7.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	.28
Item	8.	LEGAL PROCEEDINGS	.28
Item	9.	MARKET PRICE AND DIVIDENDS	.29
Item	10.	RECENT SALES OF UNREGISTERED SECURITIES	.31
Item	11.	DESCRIPTION OF CAPITAL STOCK	.32
Item	12.	INDEMNIFICATION OF DIRECTORS AND OFFICERS	.33
Item	13.	FINANCIAL STATEMENTS	.35
Item	14.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	.62
Item	15.	FINANCIAL STATEMENTS AND EXHIBITS	62

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This registration statement contains forward-looking statements that involve risks and uncertainties. These forward-looking statements are often accompanied by words such as "believes," "anticipates," "estimates," "intends," "plans," "expects" and similar expressions. These statements include, without limitation, statements about market opportunity, MacroPore, Inc.'s growth strategy and its expectations, plans and objectives. Actual results will likely differ, perhaps materially, from those anticipated in these forward-looking statements as a result of various factors, including changes in MacroPore, Inc.'s ability to obtain necessary state, federal and foreign approval or clearance for use of its products, acceptance of its products in the medical community or ability to attract and retain key management and research personnel. Because of these uncertainties, you should not place undue reliance on these forward-looking statements. Except to the extent required by applicable laws or rules, MacroPore, Inc. does not intend to update any of the forward-looking statements contained herein, whether as a result of new information, future events or otherwise.

#### GENERAL

MacroPore, Inc. (the "Company") was initially formed as a California general partnership on July 1, 1996. On May 16, 1997, the Company was incorporated in the State of Delaware.

The Company develops, commercializes and manufactures biodegradable surgical implants to aid in the reconstruction, repair and regeneration of bone. The Company's resorbable 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. The lactic acid copolymer used by the Company, while maintaining its strength during the bone healing process, is slowly broken down in the body through hydrolysis into lactic acid molecules and ultimately metabolized into carbon dioxide and water, which are then released from the body through the lungs and the kidneys. The Company believes that its products are easier to use and more cost-effective than products made from alternative materials, such as titanium, by eliminating the need for a second, later surgery to remove the implant. The Company has received regulatory clearance or approval to market and sell some of its products in the United States and Europe, and has entered into an exclusive worldwide marketing and distribution agreement with Medtronic, Inc. ("Medtronic") for the global marketing and distribution of some of its products for use in the craniofacial skeleton.

The Company is also developing additional products for use in spinal fusion procedures, neurosurgery plating, long-bone repair, healing of non-union fractures and cyst or tumor site removal 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

The Company currently manufactures its products solely in the United States at its San Diego facility. The Company markets three product lines in the United States and in Europe for use in the craniofacial skeleton and for certain applications in the entire skeleton. Some of the Company's products are being marketed in Europe for use in spinal applications.

The Company's MacroPore FX system is comprised of more than 120 lactic acid copolymer components, including plates, screws, tacks and mesh which can be used to fixate a bone in place to facilitate healing. This system is currently approved or cleared for use in the craniofacial skeleton in the United States. The Company believes its MacroPore FX products are well-suited for use in other non-load or low-load bearing sites, particularly in orthopedic fracture repair in the hands and feet. MacroPore FX products have been cleared in Europe for use throughout the body in no-load and low-load bearing sites.

The Company also currently manufactures and markets MacroPore PS and MacroPore OS which are malleable, continuous macroporous sheets used to protect bone defects from surrounding soft tissues, such as muscle tissue, which encroach on the site of the bone defect and interfere with the natural healing process by irritating the bone defect site and causing pain. The MacroPore PS and MacroPore OS systems consist of various shapes and sizes of the macroporous sheets and resorbable screws and tacks which are used to fix the macroporous sheets to the skeleton. MacroPore PS is currently approved or cleared for use in the craniofacial skeleton in the United States and in Europe. MacroPore OS is designed for use in bone healing applications in the skeleton other than the craniofacial skeleton. The Company has received regulatory approval to market MacroPore OS in the Unites States for use, other than in spinal applications, in non-load bearing situations and for use in load bearing situations when used in conjunction with traditional rigid fixation. MacroPore OS is currently authorized for marketing in Europe, including for

use in spinal applications. MacroPore OS has been cleared for use in the United States as a containment system for bone grafts or bone graft substitutes to maintain the bone graft or bone graft substitute in place while allowing access to the site for blood vessels and bone-forming cells necessary for healing.

The Company provides a range of support services to its customers, including product demonstrations and training at the Company's San Diego headquarters for surgeons interested in using the Company's products. The Company also provides regional and on-site training seminars and symposia and provides support personnel to advise surgeons during surgery on the use of the Company's products.

To date, revenue realized from the sale of cranofacial products has accounted for more than 87.0% of the Company's revenue.

## PLAN OF OPERATION

During 2001, the Company intends to focus on:

- o continuing to grow its craniofacial and neurosurgical markets by introducing new products into these markets
- o expanding its overseas markets
- o developing new uses for its existing products
- o developing new products for use in new applications

In order to accomplish its goals, the Company intends to support the sales and marketing efforts of its distributors, develop products for orthopedic-spinal and craniomaxillofacial-neurologic applications, and continue its research and development of new products. The Company provides marketing support by attending trade shows and providing product promotional materials, through training of the sales force and medical community and by facilitating communications between the Company and its customers.

## RESEARCH AND DEVELOPMENT

The Company is continuing its research efforts to develop new applications for its resorbable products and to develop new resorbable products. The Company is currently developing multiple new products which target craniofacial and neurosurgery, spinal and orthopedic indications, and expects to continue to develop new technologically advanced products.

In 1998, the Company continued research and development of its resorbable protective sheets, plates and screws and began development of its resorbable tacks for use in craniofacial indications. Research and development expense for the year ended December 31, 1998 was \$1,175,000.

In 1999, the Company's research and development efforts focused on developing its resorbable sheets, plates, screws and tacks for use in other indications, including neurosurgical indications. Research and development expense for the year ended December 31, 1999 was \$1,172,000.

In 2000, the Company's research and development efforts focused on developing its MacroPore DX system and on developing uses of its resorbable sheets, plates, screws and tacks in other indications. Research and development expense for the year ended December 31, 2000 was \$2,584,000.

Medtronic is the primary distributor for the Company's products and is the Company's principal customer, directly accounting for approximately 97.0% of the Company's revenues for the year ended December 31, 2000 and approximately 98.5% of the Company's revenues for the three months ended March 31, 2001.

The Company entered into a distribution agreement with Medtronic in January 2000. The distribution agreement provides Medtronic with exclusive rights in the United States and with exclusive worldwide rights except for rights granted under the Company's existing distribution agreements with other distributors, to market, distribute and sell MacroPore FX and MacroPore PS products solely for use in the reconstruction or fixation of the cranial or facial skeleton. The agreement requires the Company to use its reasonable best efforts to terminate its other existing distribution agreements, or to convert the existing distributors into sub-distributors of Medtronic. The agreement also provides Medtronic with a right of first refusal with respect to any proposed grant to a third party of the distribution or sales representation rights for any of the Company's other products. Under the terms of the agreement, Medtronic paid an up-front payment to the Company and must pay the Company agreed prices for product that Medtronic orders. In addition, Medtronic must submit a minimum amount of purchase orders during the first 12 months of the agreement, or must pay the Company the difference between the amount of purchase orders it actually submits and the stated minimum amount, if any. The Company has agreed to extend by 3 months the period of time in which Medtronic must submit its minimum purchase order amount to allow Medtronic additional time for start up and to train its sales representatives.

The distribution agreement is terminable if, among other things, either party materially breaches the agreement or becomes insolvent. In addition, the Company may terminate the agreement if Medtronic does not either place a minimum number of purchase orders or pay for the difference between the amount of purchase orders it actually submits and the stated minimum amount. If the agreement is terminated, Medtronic may require the Company to repurchase most of Medtronic's inventory of the Company's products at the Company's invoiced price to Medtronic. If the Company fails to provide Medtronic with an adequate supply of product or fails to supply Medtronic with product that conforms to product specifications, Medtronic may terminate the arrangement to purchase MacroPore FX and MacroPore PS from the Company and Medtronic may itself then manufacture those products and only pay the Company royalties based on sales.

The Company and Medtronic also concurrently entered into a development and supply agreement which provides Medtronic with exclusive worldwide rights to develop, market and sell the Company's products for use in spinal applications. Pursuant to this agreement the Company has the right to use Medtronic's intellectual property in spinal applications in its joint research and development in this area. The development and supply agreement provides that Medtronic shall obtain and maintain regulatory approval for the commercial sale of the products developed pursuant to the agreement. The Company will be responsible for the manufacture of such products. The agreement provides that Medtronic will pay the Company a percentage of Medtronic's net selling price for all of the products sold pursuant to the development and supply agreement.

The development and supply agreement is terminable if, among other things, either party materially breaches the agreement or becomes insolvent. If the Company fails to provide Medtronic with an adequate supply of product or fails to supply Medtronic with product that conforms to product specifications, Medtronic may terminate the arrangement to purchase the products from the Company and Medtronic may itself then manufacture those products and only pay the Company royalties based on sales.

Both of these agreements between the Company and Medtronic have five year terms and automatically renew for successive five year periods, unless either party gives the other party written  $\frac{1}{2}$ 

notice that the agreement will not be renewed at least 180 days prior to the expiration date of that term.

In the event the Company develops new products and Medtronic does not exercise its right of first refusal under its distribution agreement with the Company, the Company may enter into distribution agreements with other distributors for the sale of these new products. The Company is currently considering entering into distribution agreements with other distributors, primarily to market its products for use in applications other than craniomaxillofacial-neuro and spinal, in Europe, Asia and the Pacific Region.

## MARKET AND COMPETITION

The Company competes with many competitors in developing and marketing its technology and products. In the craniofacial fixation market, the Company competes primarily with titanium products, although the Company believes that an increasing number of other companies are developing, or are offering, resorbable bone fixation systems. In particular, Walter Lorenz Surgical, Inc. offers a resorbable fixation system in conjunction with its metallic products, which has primarily been used in pediatric patients, since it loses its strength within eight to twelve weeks and resorbs within one year. Bionx Implants, Inc. also markets a resorbable fixation system for use in the craniofacial skeleton which has some strength advantages over the Company's products and may be preferred to the Company's products for use in the lower jaw. In addition, Synthes Maxillofacial and Stryker Leibinger GmbH & Co. KG, which are primarily metallic fixation companies, market resorbable craniofacial systems. There can be no assurance that the Company's products will be able to compete effectively against such products or against future products that may be developed by these or other competitors.

- elimination of the necessity for additional surgery to remove non-resorbable implants
- o  $\,$  elimination of the risk of migration of plates and screws during the bone healing process
- o lowering the risk of infection
- o elimination of thermal sensitivity from temperature changes
- o elimination of long-term growth restrictions related to the use of metallic plates and screws in pediatric patients
- o no long-term patient palpation
- o do not appear on x-rays
- o will not distort diagnostic and therapeutic imaging modalities and create imaging artifacts which are commonly encountered with metal systems

In addition, because of their thermoplastic properties, the Company's resorbable products are easy to shape, size and apply to varying anatomical structures, which the Company believes allows for a better anatomical fit and saves valuable minutes in the operating room.

Many of the Company's competitors and potential competitors have substantially greater financial,  $% \left( 1\right) =\left( 1\right) \left( 1$ 

technological, research and development, marketing and personnel resources than the Company. These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals, and manufacturing and marketing such products. Certain of these competitors may obtain patent protection, approval or clearance by the FDA or from foreign countries, or may achieve product commercialization earlier than the Company, any of which could materially adversely effect the Company. There can be no assurance that the Company's 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 the Company or that would render the Company's technology and products obsolete and noncompetitive in these fields. Furthermore, under the terms of the Company's 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 the Company's products.

## SALES BY GEOGRAPHIC REGION

The Company sells products in the United States and internationally through a network of independent distributors. International sales may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. The Company's existing distribution agreements provide for payment in U.S. dollars and the Company intends to include similar payment provisions in future distribution agreements. Additionally, fluctuations in currency exchange rates may adversely affect demand for the Company's products by increasing the price of the Company's products in the currency of the countries in which the products are sold.

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 approximately \$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 approximately \$6,200,000 of product in the United States and \$51,000 of product outside the United States. For the three months ended March 31, 2001, the Company recorded \$2,029,000 in sales, all of which was generated from the sale of product in the United States.

#### WORKING CAPITAL

The Company generally maintains an inventory of approximately six to twelve months of products. Although capital expenditures may vary depending on a variety of factors, including sales, the Company presently intends to spend approximately \$3,100,000 on capital equipment purchases in 2001. The Company believes its inventory practices and capital expenditures are consistent with other similar companies at similar levels of development.

# RAW MATERIALS

The Company presently purchases all of its supply of lactic acid copolymer, the primary raw material used in manufacturing the Company's medical devices, from one source. In August 1999, the Company entered into an agreement with B.I. Chemicals, Inc. to provide the Company with its required supply of lactic acid copolymer. The agreement has a three year term and automatically renews for successive one year terms, unless either party gives 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 raw lactic acid copolymer, B.I. Chemicals has agreed to provide the Company with the manufacturing protocol to enable the Company to produce the raw lactic acid copolymer in-house. The lactic acid copolymer is also available from at least one other supplier.

The Company's success depends in large part on its ability to protect its proprietary technology and information, and operate without infringing on the proprietary rights of third parties. The Company relies 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 its proprietary rights. The Company's success also depends on its ability to obtain patents on its technology. The Company has one U.S. patent for the design of its resorbable sheets that was issued in July 1999 and expires in 2016. The Company has filed applications for ten additional U.S. patents, as well as nine corresponding patent applications outside the United States, relating to the Company's technology. There can be no assurance that any of the pending patent applications will be approved, that the Company will develop additional proprietary products that are patentable, that any patents issued to the Company will provide the Company 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 the Company's technology. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of the Company's products or design around the Company's patents.

Litigation, which would result in substantial costs to and diversion of effort by the Company, may also be necessary to enforce any patents issued or licensed to the Company or to determine the scope and validity of third party proprietary rights. If competitors of the Company that claim technology also claimed by the Company prepare and file patent applications in the United States, the Company may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial costs to and diversion of effort by the Company, even if the eventual outcome is favorable to the Company. Any such litigation or interference proceedings, regardless of outcome, could be expensive and time consuming. Litigation could subject the Company to significant liabilities to third parties and require disputed rights to be licensed from third parties or require the Company to cease using certain technology.

The Company currently has five pending patent applications in the European Patent Office, Australia, Japan and Canada and has published four other international patent applications with all countries designated. In addition, the Company has one patent issued in Australia for the design of its resorbable sheets that expires on August 5, 2017, and has four pending patent applications in Australia. 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 the Company's proprietary rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of the Company's patents in foreign countries by way of opposition proceedings. Additionally, if an opposition proceeding is initiated against any of the Company's patent filings in a foreign country, that proceeding could have an adverse effect on the corresponding patents that are issued or pending in the United States. It may be necessary or useful for the Company to participate in proceedings to determine the validity of its, or its company, patents that have been issued in countries other than the United States, which could result in substantial cost, divert the Company's efforts and attention from other aspects of its business, and could have a material adverse effect on the Company's results of operations and financial condition.

In addition to patent protection, the Company relies on unpatented trade secrets and proprietary technological expertise. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent techniques, or otherwise gain access to the Company's trade secrets and proprietary technological expertise or disclose such trade secrets, or that the Company can ultimately protect its rights to such unpatented trade secrets and proprietary technological expertise. The Company relies, in part, on confidentiality agreements with its marketing partners, employees, advisors,

vendors and consultants to protect its trade secrets and proprietary technological expertise. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach or that the Company's unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors. Failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on the Company's results of operations and financial condition.

#### GOVERNMENT REGULATION

Most medical devices for use in humans, including the Company's resorbable 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 the submission of 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. MacroPore FX, MacroPore PS and MacroPore OS 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. A 510(k) premarket notification will be granted if the submitted data establish 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 a substantial equivalence determination can be made. 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. A PMA must be filed if a product 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, the manufacturer 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 the manufacturer's 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.

Medical device manufacturers are subject to periodic inspections by the FDA to ensure that devices continue to be manufactured in accordance with QSR requirements. Device manufacturers also are subject to postmarket reporting requirements for deaths or serious injuries when the 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.

The Company's current human medical devices are at different stages of FDA review. On July 30, 1998, the Company received 510(k) clearance for the use of MacroPore FX and MacroPore PS in trauma and reconstructive procedures in the midface and craniofacial skeleton. On March 19, 1999, the Company received 510(k) clearance for the use of MacroPore PS in trauma, reconstructive and bone augmentation procedures of the mandible. The Company received 510(k) clearance on October 19, 2000 for the use of MacroPore MX in stabilizing fractured bones in the mandible. The Company also received 510(k) clearance on June 26, 2000 for the use of MacroPore DX, a craniofacial distractor system for the treatment of cranial or midface conditions in reconstructive osteotomy and segment advancement, and on July 24, 2000 for the use of MacroPore OS in 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. On May 2, 2001, the Company received 510(k) clearance for the use of MacroPore NS CraniLoc in the fixation of bone flaps after a craniotomy. The Company has submitted 510(k) notifications in connection with two of its products, including one for use in spinal applications and one for use in pediatric applications. All of the Company's products that have received 510(k) clearance are subject to QSR and other FDA postmarket requirements.

Under the terms of the Company's development and supply agreement with Medtronic, Medtronic will be responsible for preparing and filing applications for, and obtaining regulatory approval of the products developed by the Company pursuant to the terms of that agreement for use in spinal applications. The Company or its marketing partners may not be able to obtain necessary 510(k) clearances or PMA approvals to market the products it is developing in the United States for their intended use on a timely basis, if at all.

In addition, the Company must obtain marketing authorization for its products marketed in Europe, Canada and certain other non-U.S. jurisdictions. The Company received marketing authorization for the sale of its MacroSorb System, including MacroPore FX and PS, in the European Community and in Canada in December 1999, in Malaysia in June 2000, in Singapore in November 2000 and in South Korea in January 2001. The marketing authorizations generally permit the Company to market the MacroSorb System, including MacroPore FX and PS, for use in trauma and reconstructive procedures in the skeletal system to facilitate bone healing and bone regeneration. This includes but is not limited to, maintaining the position of bony fragments, regeneration of bone in defects, maintaining space and allowing bone growth to occur in a protected environment, preventing soft tissue prolapsed into bony defects and aiding in reattachment of soft tissue to its anatomic origin. The Company submitted applications in 1999 for marketing authorization for its MacroSorb System in Indonesia, China, Taiwan and Thailand, and in 2000 in Syria, Egypt, United Arab Emirates, India, Hong Kong, Macau, Saudi Arabia, Philippines and Australia. All of these applications are still pending. The Company 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 the Company's distribution agreements, its distributors are responsible for obtaining such approvals.

The Company may not be able to obtain marketing authorization in all of the countries where it intends to market its products, may incur significant costs in obtaining or maintaining its foreign marketing authorizations, or may not be able to successfully commercialize its current or future products in any foreign markets. Delays in receipt of marketing authorizations for the Company's 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 the Company's 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. The Company does not currently use any hazardous materials or chemicals in its manufacturing processes.

STAFF

As of March 31, 2001, the Company had 71 full-time employees, comprised of 24 employees in research and development, 19 employees in manufacturing, 16 employees in management and finance and administration, and 12 employees in marketing. From time to time, the Company also employs independent contractors to support its administrative organizations. The Company's employees are not represented by any collective bargaining unit, and the Company has never experienced a work stoppage. The Company believes its relations with its employees are good.

## SELECTED HISTORICAL FINANCIAL DATA

The following selected financial data are derived from the Company's audited and unaudited financial statements and the related notes thereto. The Company was 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 the 1997 results. The following data should be read in conjunction with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto.

# (DOLLARS IN THOUSANDS, EXCEPT PER SHARE DATA)

			YEAR ENDED	DECEMBER 31,	
2001	2000	2000	1999	1998	1997
(UNAUDITED)	(UNAUDITED)				
36	379	\$ 6,092 159	\$ - 1,513	\$ -	\$ -
2,029	1,259	6,251	1,513	-	-
		2,376	481	-	-
1,364	664	3,875	1,032	-	-
1,012 927 143	390 599 3 2,428	2,584 2,629 2,555 5,716	1,172 2,356 1,313 666 5,507	1,175 202 604 76 2,057	299 104 197 9 
12	. (28		68 (164)	10 (43)	9 -
			(4,571)	(2,090)	(600)
\$ (0.08	3) \$ (0.82	) \$ (1.05)	\$ (1.32)	\$ (0.64)	\$ (0.18)
14,917,376	3,704,270	8,201,739	3,458,292	3,250,000	3,250,000
\$ (1,904	9) \$ 688	\$ (2,982)	\$ (5,107)	\$ (1,523)	\$ (545)
1,731	. (312	(39,450)	(381)	(598)	(205)
(7	4,080	47,437	7,924	1,837	1,065
(186	4,456	5,005	2,436	(284)	315
7,476	2,471	2,471	35	319	4
		\$ 7,476 =======	\$ 2,471 =======	\$ 35	\$ 319 =======
41,534 44,992 51,359 1 227	7,039 8,105 10,633 342 14,674	\$ 44,484 46,858 52,269 255	\$ 2,581 3,510 5,575 304 10,689,000 \$ (6,147)	\$ 140 (493) 1,020 209 2,696,000 \$ 108	\$ 419 387 515 - 1,055,000 \$ 481
	\$ 1,999	(UNAUDITED) (UNAUDITED)  \$ 1,999 \$ 880 30 379 2,029 1,259 665 595 1,364 664  1,184 350 1,012 390 927 599 143 2,428 3,266 3,767  676 90 12 (28 (1,214) (3,041 \$ (0.08) \$ (0.82  (1,214) (3,041  \$ (0.08) \$ (0.82  14,917,376 3,704,270  \$ (1,904) \$ 688 1,731 (312 (7) 4,080 (180) 4,456 7,476 2,471 \$ 7,296 \$ 6,927 ====================================	MARCH 31, 2001 2000 2000  (UNAUDITED) (UNAUDITED)  \$ 1,999 \$ 880 \$ 6,092 30 379 159  2,029 1,259 6,251 665 595 2,376  1,364 664 3,875  1,184 350 2,584 1,012 390 2,629 927 599 2,555 143 2,428 5,716  3,266 3,767 13,484  676 90 1,315 12 (28) (351)  (1,214) (3,041) (8,645)  \$ (0.08) \$ (0.82) \$ (1.05)  14,917,376 3,704,270 8,201,739  \$ (1,904) \$ 688 \$ (2,982) 1,731 (312) (39,450)  (7) 4,080 47,437  (180) 4,456 5,005  7,476 2,471 2,471  \$ 7,296 \$ 6,927 \$ 7,476  ===================================	MARCH 31, 2001 2000 2000 1999  (UNAUDITED) (UNAUDITED)  \$ 1,999 \$ 880 \$ 6,092 \$ 30 379 159 1,513  2,029 1,259 6,251 1,513  665 595 2,376 481  1,364 664 3,875 1,032  1,184 350 2,584 1,172 1,012 390 2,629 2,356 927 599 2,555 1,313 143 2,428 5,716 666  3,266 3,767 13,484 5,507  676 90 1,315 68 12 (28) (351) (164)  (1,214) (3,041) (8,645) (4,571)  \$ (0.08) \$ (0.82) \$ (1.05) \$ (1.32)  14,917,376 3,704,270 8,201,739 3,458,292  \$ (1,904) \$ 688 \$ (2,982) \$ (5,107)  1,731 (312) (39,450) (381)  (7) 4,080 47,437 7,924  (180) 4,456 5,005 2,436  7,476 2,471 2,471 35  \$ 7,296 \$ 6,927 \$ 7,476 \$ 2,471  \$ 7,039 \$ 44,484 \$ 2,581  \$ 7,296 \$ 6,927 \$ 7,476 \$ 2,471  \$ 7,039 \$ 44,884 \$ 2,581  \$ 7,296 \$ 6,927 \$ 7,476 \$ 2,471  \$ 7,039 \$ 44,884 \$ 2,581  \$ 7,296 \$ 6,927 \$ 7,476 \$ 2,471  \$ 7,039 \$ 44,884 \$ 2,581  \$ 7,296 \$ 6,927 \$ 7,476 \$ 2,471  \$ 7,039 \$ 44,884 \$ 2,581	MARCH 31, 2001 2000 2000 1999 1998  (UNAUDITED) (UNAUDITED)  \$ 1,999 \$ 880 \$ 6,092 \$ - \$ - \$ - 30 379 159 1,513 - 5665 595 2,376 481 - 1 - 1,364 664 3,875 1,032 - 1 - 1,364 664 3,875 1,032 - 1 - 1,364 390 2,629 2,356 202 927 599 2,555 1,313 604 143 2,428 5,716 666 76  3,266 3,767 13,484 5,507 2,067  676 90 1,315 68 10 (164) (43)  (1,214) (3,041) (8,645) (4,571) (2,090)  \$ (0.08) \$ (0.82) \$ (1.05) \$ (1.32) \$ (0.64)  14,917,376 3,704,270 8,201,739 3,458,292 3,250,000  \$ (1,904) \$ 688 \$ (2,982) \$ (5,107) \$ (1,523) 1,731 (312) (39,459) (381) (598)  (7) 4,080 47,437 7,924 1,837  (180) 4,456 5,005 2,436 (284)  7,476 2,471 2,471 35 319  \$ 7,296 \$ 6,927 \$ 7,476 \$ 2,471 \$ 35

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### OVERVIEW

The Company has a limited operating history and its 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 field. On August 8, 2000, the Company completed its initial public offering in Germany and listed its common stock for trading on the NEUER MARKT segment of the Frankfurt Stock Exchange in Frankfurt, Germany.

The Company incurred a net loss of \$1,214,000 for the three months ended March 31, 2001 and net losses for the years ended December 31, 2000, 1999 and 1998 of \$8,645,000, \$4,571,000 and \$2,090,000, respectively. As of March 31, 2001, the Company had an accumulated deficit of \$17,106,000. As of December 31, 2000, the Company had an accumulated deficit of \$15,892,000. Such losses have resulted to a large extent from expenses associated with the development of the resorbable implant designs, preclinical studies, preparation of submissions to the FDA and foreign regulatory agencies, marketing and distribution channels, and the development of the Company's manufacturing capabilities. The Company expects to expend substantial financial resources to expand marketing, training and customer support needed to generate and support higher sales, expand its manufacturing capabilities and to develop new products. This investment is likely to result in lower gross margins until production efficiencies are reached.

In May 1999, the Company recognized revenue for the first time from the sale of its products. For the three months ended March 31, 2001 and 2000 and the years ended December 31, 2000 and 1999, the majority of the Company's revenues came from the sales of its resorbable protective sheets, plates, screws and tacks, which are high revenue dollar and volume items. A smaller percentage of the Company's revenues for the three months ended March 31, 2001 and 2000 and for the years ended December 31, 2000 and 1999 came from accessories used by surgeons to form, mold and manipulate the Company's resorbable products during surgical procedures, which are lower revenue dollar and lower volume items. The Company expects to continue to realize the majority of its revenues from the sale of its resorbable protective sheets, plates, screws and tacks.

## RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2001 COMPARED TO THREE MONTHS ENDED MARCH 31, 2000

REVENUES. For the three months ended March 31, 2001, revenues were \$2,029,000 compared to \$1,259,000 for the three months ended March 31, 2000. The increase in revenues was primarily the result of sales to Medtronic, the Company's principal distributor, which totaled \$1,999,000. Revenues from this distributor, which owns approximately 6.7% of the outstanding common stock in the Company, represented approximately 98.5% of the Company's revenues for the three months ended March 31,2001.

COST DIRECTLY RELATED TO REVENUES. For the three months ended March 31, 2001, cost directly related to revenues was \$665,000 or 32.8% of revenues, compared to \$595,000 or 47.3% of revenues for the three months ended March 31, 2000. Cost directly related to revenues includes material, manufacturing labor and overhead costs. The dollar increase in cost directly related to revenue for the three months ended March 31, 2001 is primarily attributable to increased costs to support the increased revenue base. The decrease in cost as a percentage of revenues was primarily attributable to certain manufacturing overhead costs decreasing in relation to the increase in revenue volume.

GROSS PROFIT. For the three months ended March 31, 2001, gross profit was \$1,364,000 or 67.2% of revenues, compared to \$664,000 or 52.7% of revenues for the three months ended March 31, 2000.

RESEARCH AND DEVELOPMENT EXPENSES. For the three months ended March 31, 2001, research and development expenses excluding related stock based compensation expenses were \$1,184,000 compared to \$350,000 for the three months ended March 31, 2000. Research and development expenses include costs associated with the design, development, testing, enhancement of the Company's products, regulatory fees, the purchase of laboratory supplies and clinical trials. The Company expenses research and development costs as incurred. The increase in research and development expenses in the three months ended March 31, 2001 is primarily attributable to the hiring of 11 additional people causing an increase of approximately \$302,000 and other costs associated with research into the development of new product lines caused an increase of approximately \$532,000. In addition, stock based compensation related to research and development was \$30,000 for the three months ended March 31, 2000 and \$431,000 for the three months ended March 31, 1999. For further information regarding fluctuations in research and development inclusive of stock based compensation, see the section entitled Stock Based Compensation Expenses. The Company expects research and development spending to continue to increase for the year ending December 31, 2001 as the Company expands its product development efforts and seeks further regulatory approvals.

SALES AND MARKETING EXPENSES. For the three months ended March 31, 2001, sales and marketing expenses excluding related stock based compensation expenses were \$1,012,000, compared to \$390,000 for the three months ended March 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 three months ended March 31, 2001 is primarily attributable to the hiring of 8 additional people causing an increase of approximately \$245,000 and other costs associated with marketing expenses related to the promotion of product lines causing an increase of approximately \$377,000. In addition, stock based compensation related to sales and marketing was (\$52,000) for the three months ended March 31, 2000 and \$1,806,000 for the three months ended March 31, 1999. further information regarding fluctuations in sales and marketing inclusive of stock based compensation, see the section entitled Stock Based Compensation Expenses. The Company expects sales and marketing expenses to increase for the year ending December 31, 2001 to support expanding business activities.

GENERAL AND ADMINISTRATIVE EXPENSES. For the three months ended March 31, 2001, general and administrative expenses excluding related stock based compensation expenses were \$927,000, compared to \$599,000 for the three months ended March 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 three months ended March 31, 2001 is primarily attributable to increased personnel costs of approximately \$196,000, as well as increased administrative costs of approximately \$132,000 such as professional services and other general corporate expenditures related to all areas of the Company's operations, as well as costs to support the Company's status as traded on the NEUER MARKT. In addition, stock based compensation related to general and administrative expenses was \$160,000 for the three months ended March 31, 2000 and \$189,000 for the three months ended March 31, 1999. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, see the section entitled Stock Based Compensation Expenses. The Company expects general and administrative expenses to increase for the year ending December 31, 2001 to support expanding business activities.

STOCK BASED COMPENSATION EXPENSES. For the three months ended March 31, 2001, non-cash stock based compensation expenses were \$143,000, compared to \$2,428,000 for the three months ended March 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, generally four years from the date of grant. The overall decrease in stock based compensation was due to approximately \$1,775,000 in additional expense relating to sales and marketing stock based compensation in the three months ended March 31, 2000, which was a result of a modification to extend the expiration date of certain stock options granted to members of the sales force upon their termination.

INTEREST INCOME. For the three months ended March 31, 2001, interest income was \$676,000, compared to \$90,000 for the three months ended March 31, 2000. The increase in interest income resulted from an increase in cash, cash equivalents and short-term investments to approximately \$41,534,000 as of March 31, 2001 from approximately \$7,039,000 as of March 31, 2000.

INTEREST EXPENSE AND OTHER. For the three months ended March 31, 2001, interest expense and other expenses were \$12,000 in income, compared to \$28,000 in expenses for the three months ended March 31, 2000. The income in interest expense and other for the three months ended March 31, 2001 was the result of realized gains on available for sale investments sold during the period.

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. The increase in revenues was primarily the result of sales to Medtronic, the Company's principal distributor, which totaled \$6,092,000 and included an initial inventory purchase of \$1,162,000 which occurred in the three months ended June 30, 2000. Revenues from this distributor, which is a major stockholder in the Company, represented approximately 97.0% of the Company's revenues for the year ended December 31, 2000.

COST DIRECTLY RELATED TO REVENUES. For the year ended December 31, 2000, cost directly related to revenues was \$2,376,000 or 38.0% of revenues, compared to \$481,000 or 31.8% of revenues for the year ended December 31, 1999. Cost directly related to revenues includes material, manufacturing labor and overhead costs. The increase in cost directly related to revenue for the year ended December 31, 2000 is 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 the Company's use of third party distributors rather than an internal sales force. The Company's savings relating 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. The Company sells its products to its principal distributor for fixed prices pursuant to the distribution agreement. Product pricing is subject to biannual reviews with the distributor. 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. Although direct selling costs are borne by the distributor, the percentage of revenues may continue to be adversely affected.

GROSS PROFIT. For the year ended December 31, 2000, gross profit was \$3,875,000 or 62.0% of revenues, compared to \$1,032,000 or 68.2% of revenues for the year ended December 31, 1999.

RESEARCH AND DEVELOPMENT EXPENSES. For the year ended December 31, 2000, research and development expenses were \$2,584,000, compared to \$1,172,000 excluding related stock based compensation expenses for the year ended December 31, 1999. Research and development expenses include costs associated with the design, development, testing, enhancement of the Company's products, regulatory fees, the purchases of laboratory supplies and clinical trials. The Company expenses research and development costs as incurred. The increase in research and development expenses in the year ended December 31, 2000 is 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, see the section entitled Stock Based Compensation Expenses. The Company expects research and development spending to continue to increase in the future as the Company expands its product development efforts and seeks further regulatory approvals.

SALES AND MARKETING EXPENSES. For the year ended December 31, 2000, sales and marketing expenses were \$2,629,000, compared to \$2,356,000 excluding related stock based compensation 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 the Company's internal sales force in January 2000, the Company re-deployed sales costs to marketing personnel and other internal marketing expenses related to the promotion of its product lines. After the initial public offering, the Company allocated some of its available funds to marketing activities. Accordingly, the increase in sales and marketing expenses in the year ended December 31, 2000 is primarily attributable to the Company's increased efforts to provide regional and on-site seminars and symposia and in providing support personnel to give demonstrations on the use of the Company's 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 and \$231,000 for the year ended December 31, 1999. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, see the section entitled Stock Based Compensation Expenses. The Company expects sales and marketing expenses to increase in the future to support expanding business activities.

GENERAL AND ADMINISTRATIVE EXPENSES. For the year ended December 31, 2000, general and administrative expenses were \$2,555,000, compared to \$1,313,000 excluding related stock based compensation expenses 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 is primarily attributable to increased personnel costs of approximately \$605,000 due to the addition of eight full-time employees. In addition, growth of administrative costs such as professional services and insurance by approximately \$366,000 and other general corporate expenses related to the expansion of all areas of the Company's operations, as well as costs to support the Company's listing and trading on the NEUER MARKT caused an increase of approximately \$271,000. In addition, stock based compensation related to general and administrative expense was \$1,607,000 for the year ended December 31, 2000 and \$360,000 for the year ended December 31, 1999. For further information regarding fluctuations in general and administrative expense inclusive of stock based compensation, see the section entitled Stock Based Compensation Expenses. The Company expects general and administrative expenses to increase in the future to support expanding business activities.

STOCK BASED COMPENSATION EXPENSES. For the year ended December 31, 2000, non-cash stock based compensation expenses were \$5,716,000, compared to \$666,000 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, generally four years from the date of grant. The overall increase in stock based compensation is related to compensatory stock options granted to employees and consultants, and the increase in fair market value of the common stock. The \$2,169,000 increase in research and development stock based compensation was due to a large grant of options to doctors and other professionals who performed consulting services related to the Company's development and start-up activities through August 8, 2000. Approximately \$1,257,000 of this increase was due to management's decision to accelerate those options on August 9, 2000, as the services for which they were granted were deemed complete and the compensation expense related to all the accelerated options was recognized. The increase in sales and marketing stock based compensation was due to approximately \$1,775,000 in additional expense recorded in the three months ended March 31, 2000 as a result of a modification to extend the expiration date of some stock options granted to former members of the Company's sales force upon their termination. General and administrative stock based compensation increased by \$1,247,000 as a result of significant option grants to senior management and other employees at 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. The increase in interest income resulted from an increase in cash, cash equivalents

and short-term investments to approximately \$44,500,000 as of December 31, 2000 from approximately \$2,600,000 as of December 31, 1999.

INTEREST EXPENSE AND OTHER EXPENSES. For the year ended December 31, 2000, interest expense and other expenses were \$351,000, compared to \$164,000 for the year ended December 31, 1999. The increase in interest expense and other expenses is primarily related to a loss on the conversion of Euros to

U.S. dollars in connection with the net proceeds realized by the Company from the sale of its common stock in August 2000.

YEAR ENDED DECEMBER 31, 1999 COMPARED TO YEAR ENDED DECEMBER 31, 1998

REVENUES. For the year ended December 31, 1999, the Company recorded \$1,513,000 in revenues of its resorbable implants and related accessory products. The Company did not report any revenues for the year ended December 31, 1998.

COST DIRECTLY RELATED TO REVENUES. For the year ended December 31, 1999, the Company reported cost directly related to revenues of \$481,000 or 31.8% of revenues. Since the Company had no revenues in 1998, the Company did not incur any cost directly related to revenues for the year ended December 31, 1998.

GROSS PROFIT. For the year ended December 31, 1999, gross profit was \$1,032,000 or 68.2% of revenues. The Company did not record gross profit for the year ended December 31, 1998.

RESEARCH AND DEVELOPMENT EXPENSES. For the year ended December 31, 1999, research and development expenses were \$1,172,000, compared to \$1,175,000 for the year ended December 31, 1998. The relatively flat level of expense in research and development expenses in 1999 as compared to 1998 is primarily attributable to a shift from development of the product line to manufacturing of products for sale.

SALES AND MARKETING EXPENSES. For the year ended December 31, 1999, sales and marketing expenses were \$2,356,000, compared to \$202,000 for the year ended December 31, 1998. The increase is primarily attributable to an increase in personnel costs related to hiring a sales force of thirteen people and the associated sales and marketing expenses such as travel, trade shows and product promotion materials. The sales force was subsequently terminated in 2000 after the Company entered into its distribution agreement with Medtronic.

GENERAL AND ADMINISTRATIVE EXPENSES. For the year ended December 31, 1999, general and administrative expenses were \$1,313,000, compared to \$604,000 for the year ended December 31, 1998. The increase is primarily attributable to increased personnel costs and growth of administrative costs such as professional services, insurance and other general corporate expenses related to the expansion of all areas of the Company's operations.

STOCK BASED COMPENSATION EXPENSES. For the year ended December 31, 1999, non-cash stock based compensation expenses were \$666,000, compared to \$76,000 for the year ended December 31, 1998. The increase was primarily due to the grants of additional options to new and existing employees and consultants as well as an increase in the fair market value of the common stock.

INTEREST INCOME. For the year ended December 31, 1999, interest income was \$68,000, compared to \$10,000 for the year ended December 31, 1998. The increase in interest income resulted from an increase in the average cash balances.

INTEREST EXPENSE AND OTHER EXPENSES. For the year ended December 31, 1999, interest expense and other expenses were \$164,000, compared to \$43,000 for the year ended December 31, 1998. The increase in interest expense and other expenses related to increased interest expense on capital lease financing and the use of short-term financing until the debt was converted to preferred stock in September 1999.

#### UNEARNED COMPENSATION

The Company records unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair value of its common stock at the time 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 March 31, 2001 was \$6,562,000 with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of \$3,679,000. The remaining \$2,883,000 as of March 31, 2001 will be amortized using the straight-line method over the remaining vesting periods of the options, generally four years from the date of grant. The Company expects to record amortization expense for unearned compensation of \$789,000 for the period April 1, 2001 to December 31, 2001, \$1,022,000 in 2002, \$856,000 in 2003 and \$216,000 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 CARRY FORWARDS

As of December 31, 2000, the Company had federal net operating loss carryforwards of approximately \$7,789,000 and state net operating loss carryforwards of approximately \$6,710,000, which may be available to offset future taxable income for tax purposes. The federal net operating loss carryforwards begin to expire in 2012. The state net operating loss carryforwards begin to expire in 2005. A portion of the net operating losses are limited in their annual utilization. As of December 31, 2000, the Company also had research tax credit carryforwards of approximately \$170,000 and \$141,000 for federal and state tax purposes, respectively. The federal carryforward will begin to expire in 2012, if unused. As of December 31, 2000, the Company also had California manufacturer's credit carryforwards of approximately \$160,000, which begin to expire in 2007, if unused.

## RECENT ACCOUNTING PRONOUNCEMENTS

The Company has adopted Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). SFAS 133, which is effective for fiscal years beginning after June 15, 2000, requires that all derivative instruments be recorded on the balance sheet at their fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, unless specific hedge accounting criteria are met. The Company does not expect that the adoption of SFAS 133 will have a material impact on its financial statements

because it does not currently hold any derivative instruments and does not engage in any hedging activities.

In December 1999, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 summarizes the SEC's views regarding the application of generally accepted accounting principles to revenue recognition in financial statements. The Company believes that its current revenue recognition principles comply with SAB 101.

In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation" ("FIN 44"). This interpretation clarifies the application of APB Opinion No. 25 for certain issues related to stock based compensation, including the definition of employee for the purposes of applying APB 25, the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequences of modifications to the terms of a previously fixed stock option award, and the accounting for an exchange of stock compensation awards in a business combination. FIN 44 was effective July 1, 2000, but covers certain events that occur either after December 15, 1998 or January 12, 2000. The Company has applied the interpretations set forth in FIN 44 for the recognition of certain stock based compensation during the year ended December 31, 2000.

#### LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2001, the Company had cash, cash equivalents and short-term investments of \$41,534,000 and working capital of \$44,992,000. Since inception, the Company has financed its operations primarily through sales of stock. The sale of preferred stock in 1997, 1998 and 1999 yielded net proceeds of approximately \$14,679,000. On August 8, 2000, the Company completed its initial public offering in Germany and listed its common stock for trading on the NEUER MARKT segment of the Frankfurt Stock Exchange in Frankfurt, Germany. The net proceeds to the Company from the sale of 3,500,000 shares of common stock in the offering were approximately \$43,244,000. A portion of those net proceeds have been used for research and development, to expand the Company's manufacturing operations, to promote the Company's brand and to pursue regulatory approvals for the Company's products. In addition, some of the proceeds have been used for working capital and general corporate purposes. The Company has invested some of the proceeds from the offering in short-term investments, pending other uses of the proceeds in its business.

Net cash used in operating activities was approximately \$1,904,000 for the three months ended March 31, 2001. Net cash used primarily relates to net loss and the use of working capital to build up inventory of approximately \$534,000 in anticipation of sales in 2001 and the increase in accounts receivable of \$503,000. Net cash provided by operating activities was \$688,000 for the three months ended March 31, 2000. The net cash provided by operating activities resulted primarily from a net loss that was offset by an up-front license fee of \$1,425,000 paid to the Company by a distributor for exclusive worldwide distribution rights on all of the Company's products for use in the craniofacial areas and from stock based compensation expenses of \$2,428,000.

Net cash used in operating activities was approximately \$2,982,000 for the year ended December 31, 2000, \$5,107,000 for the year ended December 31, 1999 and \$1,523,000 for the year ended December 31, 1998. For each such period, net cash used in operating activities resulted primarily from net losses and working capital requirements. Net losses resulted to a large extent from expenses associated with the development of MacroPore's resorbable designs, preclinical studies, preparation of submissions to the FDA and foreign regulatory agencies, marketing and distribution channels, and the improvement of MacroPore's manufacturing capabilities. The \$2,125,000 decrease in cash used in operating activities from December 31, 2000 to 1999 primarily related to MacroPore's net loss of \$8,645,000 for the year ended . December 31, 2000 which was offset by stock based compensation of \$5,716,000 and deferred revenue related to the license fee and other activities of \$1,090,000. In addition, inventories increased by \$1,143,000 in 2000 in anticipation of increased sales of continued and new products in early 2001. The \$3,584,000 increase in cash used in operating activities from December 31, 1999 to 1998 primarily related to MacroPore's net loss of \$4,571,000 for the year ended December 31, 1999. In addition, inventories increased by \$1,097,000 in 1999 in anticipation of increased sales in the three months ended March 31, 2000. These increases in cash used for operating activities were partially offset by stock based compensation and other activities of approximately \$561,000. MacroPore's working capital requirements fluctuate with changes in its 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 approximately \$1,731,000 for the three months ended March 31, 2001. The net cash investing activities primarily consisted of the purchase and sale of short-term investments and capital expenditures. Net cash used in investing activities was \$312,000 for the three months ended March 31, 2000 and primarily related to the purchase of fixed assets to be used in the manufacturing process.

Net cash used in investing activities was approximately \$39,450,000 for the year ended December 31, 2000, \$381,000 for the year ended December 31, 1999 and \$598,000 for the year ended December 31, 1998. The Company's investing activities primarily consist of the purchase of short-term investments and capital expenditures. The Company's investing activities in the year ended December 31, 2000 included increased short-term investments related to the short-term investment of the proceeds of the Company's initial public offering in August 2000.

Net cash used in financing activities was approximately \$7,000 for the three months ended March 31, 2001 and resulted primarily from principal payments on the Company's capital leases. Net cash provided by financing activities was approximately \$4,080,000 for the three months ended March 31, 2000 and related to the sale of Series D preferred stock.

Net cash provided by financing activities was approximately \$47,437,000 for the year ended December 31, 2000, \$7,924,000 for the year ended December 31, 1999 and \$1,837,000 for the year ended December 31, 1998. The net cash provided by financing activities was primarily attributable to the sale of common stock in the initial public offering and to the sale of preferred stock.

The Company has equipment lease obligations that mature at various dates through 2004 with interest rates ranging from 12.4% to 30.5%. The monthly payments under the equipment lease obligations are \$14,000.

As of March 31, 2001, the Company had capital equipment of \$5,638,000 less accumulated depreciation of \$981,000 to support its clinical, research, development, manufacturing and administrative activities. For the three months ended March 31, 2001, the Company's capital expenditures were \$1,192,000. For the year ended December 31, 2000, the Company's capital expenditures were \$2,732,000. The Company expects capital expenditures for the year ended December 31, 2001 to be approximately \$3,100,000 as the Company acquires additional equipment and expands its facilities. In addition, the Company is negotiating the purchase of its manufacturing facility in San Diego, California at a cost of approximately \$2,750,000. The Company intends to pay for all capital expenditures with available working capital.

In May 2001, the Company acquired an ownership interest in StemSource, Inc. StemSource, which is in its early stages of development, was formed to principally engage in biomedical research. The Company is negotiating the terms of a collaborative agreement with StemSource for the purpose of engaging in joint research and development activities. From time to time, the Company may enter into collaborative arrangements with, and acquire ownership interest in, other companies for the purpose of engaging in joint research and development activities.

The Company's capital requirements depend on numerous factors, including market acceptance of its products, the resources the Company devotes to developing and supporting its products and other factors. The Company expects to devote substantial capital resources to continue its research and development efforts, to expand its support and product development activities and for other general corporate activities. The Company believes that its current cash and investment balances and revenue to be derived from the sale of its products will be sufficient to fund its operations at least through December 31, 2002.

#### QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

The Company is exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

INTEREST RATE EXPOSURE. The Company's exposure to market risk due to fluctuations in interest rates relates primarily to short term investments, which consist primarily of investments in debt instruments of financial institutions, corporations with strong credit ratings and United States government obligations, reported at an aggregate fair market value of \$40,362,000 as of March 31, 2001. 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 March 31, 2001, for example, and assuming an average investment duration of nine months, the fair value of the portfolio would not decline by a material amount. The Company does not use derivative financial instruments to mitigate the risk inherent in these securities. However, the Company does attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying its investments and limiting the amount of credit exposure with any one issuer. The Company believes that it currently has the ability to hold these investments until maturity and, therefore, believes that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect its financial position, results of operations or cash flows.

FOREIGN CURRENCY EXCHANGE RATE EXPOSURE. The Company's exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to sales of the Company's products in Europe and other foreign markets. Although the Company transacts business in various foreign countries, settlement amounts are usually based on U.S. dollars or the Euro. Transaction gains or losses resulting from sales revenues have not been significant in the past and there is no hedging activity on the Euro or other currencies. Based on the Company's revenues derived from markets other than the United States for

the three months ended March 31, 2001, a hypothetical 10% adverse change in Euros against U.S. dollars would not result in a material foreign exchange loss. Consequently, the Company does 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 its 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 the Company's business, financial condition and results of operations. For example, international demand for the Company's products may be affected by foreign currency exchange rates. In addition, interest rate fluctuations may affect the buying patterns of the Company's customers. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on the Company's business, financial condition and results of operations.

#### ITEM 3. PROPERTIES.

The Company's main facility is located at 6740 Top Gun Street, San Diego, California. The Company currently leases approximately 27,000 square feet of space at this location which it uses for its corporate headquarters and for manufacturing. Of the 27,000 square feet, approximately 8,500 square feet is laboratory space, 6,000 square feet is office space and 12,500 square feet is manufacturing space. The Company's lease has a five year term and will expire in 2003. The Company is currently negotiating to purchase this property at an approximate purchase price of \$2,750,000.

The Company also leases a facility located at 6749 Top Gun Street, San Diego, California. The Company expects to use the 14,000 square foot facility primarily for research and development. The lease has a five year term and expires in 2006.

The Company leases approximately 5,800 square feet of office space in Frankfurt, Germany for use in marketing and administration. The lease has a five year term and expires in 2006.

In addition, the Company collectively leases approximately 400 square feet of office space in Malvern, Pennsylvania and Atlanta, Georgia. These offices have been leased for six month terms that renew automatically, unless terminated.

The Company pays an aggregate of approximately \$41,000 in rent per month for its properties located in the United States and approximately DM9,500 for its property in Germany.

ITEM 4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The following table provides certain information regarding beneficial ownership of the Company's common stock as of May 10, 2001 by:

- o each shareholder known by the Company to own beneficially more than 5% of the outstanding shares
- o all directors
- o  $\,$  the Company's Chief Executive Officer and four other executive officers  $\,$
- o all of the Company's directors and executive officers, as a group

The amounts and percentages of common stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or to direct the voting of such security, or "investment power," which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities for which that person has a right to acquire beneficial

ownership within 60 days. Under these rules, more than one person may be deemed a beneficial owner of the same securities and a person may be deemed to be the beneficial owner of securities as to which that person has no economic interest.

All of the individuals listed below who hold stock options granted by the Company prior to January 1, 2001 may exercise stock option grants which have not yet vested. Shares of common stock issued by the Company upon the exercise of unvested options are held in escrow with the Secretary of the Company. None of the option shares are held in escrow at this time. Unless otherwise indicated, the address for each person or entity named below is c/o MacroPore, Inc., 6740 Top Gun Street, San Diego, California 92121.

NAME 	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED	PERCENTAGE OF OUTSTANDING SHARES
Marshall Cox (1) Christopher J. Calhoun (2). Michael Simpson (3) Ari Bisimis (4) Charles E. Galetto (5).	768,980 875,000 268,750 298,368 100,000 100,000	5.1% 5.8 1.8 2.0
Stefan M. Lemperle (7)	766,194 50,000 800,000 1,000,000	5.1 * 5.4 6.7
Edmund Krix (11)	296,386 2,954,989	2.0 18.5

<sup>\*</sup> Less than one percent.

- (1) Includes 115,625 shares issuable upon the exercise of stock options and 22,223 shares issuable upon exercise of warrants. Also includes 48,530 shares held of record by Saratoga Boys Club and 5,334 shares held of record by his spouse. Mr. Cox is the managing director of Saratoga Boys Club and has sole voting and investment power with respect to the shares of the Company's common stock held by Saratoga Boys Club. Mr. Cox disclaims beneficial ownership of shares held by his spouse.
- (2) Includes 218,750 shares issuable upon the exercise of stock options. Also includes a total of 600,000 shares held of record by TTMC Investments, Inc., a total of 37,500 shares held of record by the Calhoun Family Trust and 18,750 shares held of record by Mr. Calhoun and his wife. Mr. Calhoun has sole voting and investment power with respect to the shares of the Company's common stock held by TTMC Investments. Mr. Calhoun and his wife are co-trustees of the Calhoun Family Trust and share voting and investment power with respect to the shares of the Company's common stock held by the Calhoun Family Trust.
- (3) Includes 213,125 shares issuable upon the exercise of stock options.
- (4) Includes 260,000 shares issuable upon the exercise of stock options. Also includes 25,000 shares of the Company's common stock pledged to the Company to secure the repayment of two loans made by the Company to Mr. Bisimis.
- (5) Includes 100,000 shares issuable upon the exercise of stock options.
- (6) Includes 100,000 shares issuable upon the exercise of stock options.

- (7) Includes 600,000 shares held of record by Creative Microspheres, Inc. Dr. Lemperle has sole voting and investment power with respect to the shares of the Company's common stock held by Creative Microspheres. The address for Dr. Lemperle is c/o Artes Medical, 4660 La Jolla Village Drive Suite 825, San Diego, California 92122.
- (8) Includes 50,000 shares issuable upon the exercise of stock options.
- (9) The address for Dr. Holmes is 8010 Frost Street Suite 412, San Diego, California 92123.
- (10) The address for Medtronic Asset Management, Inc. is Medtronic, Inc. Corporate Center, 7000 Central Avenue, N.E., Minneapolis, Minnesota 55432.
- (11) Includes 50,000 shares issuable upon the exercise of stock options.
- (12) Includes all shares and options exercisable within sixty days owned by all directors and executive officers and their spouses.

ITEM 5. DIRECTORS, EXECUTIVE OFFICERS AND FOUNDERS.

The following table sets forth certain information regarding the directors and executive officers of the Company as of May 10, 2001.

NAME AGE	POSITION(S)
Marshall G. Cox65	Chairman of the Board and Director
Christopher J. Calhoun35	Chief Executive Officer, Vice-Chairman, Secretary and Director
Michael Simpson55	President and Director
Ari Bisimis32	Chief Financial Officer and Director
Charles Galetto50	Senior Vice President - Finance and Administration, and Treasurer
Gary Sohngen41	Vice President - Research & Development
Sharon Schulzki43	Vice President and General Manager - Spine & Orthopedics
Bruce Reuter52	Vice President - Market Development
R. Mark Lane53	Vice President - U.S. Sales
David Rickey45	Director
Edmund Krix42	Director

MARSHALL G. COX, a current employee of the Company, has served as Chairman of the Board of Directors of the Company since May 1997. He founded Western Micro Technology, Inc. and from 1994 to 1997 served as its chairman and chief executive officer. Mr. Cox retired from Western Micro as Chairman Emeritus in 1997. He is the Managing Director of the Saratoga Boy's Club, formerly a major stockholder in the Company and he serves on the board of directors of Internix, Inc. Mr. Cox holds a B.S. from the University of California, Los Angeles.

CHRISTOPHER J. CALHOUN is a co-founder of the Company and has served as the Company's Vice-Chairman, Chief Executive Officer and Secretary since May 1997. Since 1989, Mr. Calhoun has been involved in research and management for the Plastic Surgery Bone Histology and Histometry Laboratory at the University of California at San Diego. Mr. Calhoun received a B.A. from the University of California at San Diego, and an M.B.A. from the University of Phoenix.

MICHAEL SIMPSON has served as the Company's President since September 1998. From 1986 to 1996,

Mr. Simpson served as President of Synthes (USA) Maxillofacial Division, a medical devices company. From 1997 to 1998, he served as President of the Craniofacial Division at Bionx Implants, Inc. Mr. Simpson holds a B.A. from St. Bonaventure University.

ARI BISIMIS has served as the Company's Chief Financial Officer since April 2000. Mr. Bisimis worked in various investment banking firms before joining the Company. From 1998 to 2000, Mr. Bisimis served as head of Eurobond trading for Dresdner Kleinwort Benson. From 1997 to 1998, he served as Senior Fixed Income Trader for Commerzbank and from 1994 to 1997 as Eurobond trader for JP Morgan. Mr. Bisimis holds a Diplom Kaufmann degree from Johann Wolfgang Goethe University in Frankfurt, Germany.

CHARLES E. GALETTO has served as the Company's Senior Vice President - Finance and Administration and Treasurer since April 2000. From August 1997 to January 2000, Mr. Galetto served in various positions with PMR Corporation, a company specializing in mental health care programs, including service as Senior Vice President-Finance and Treasurer of PMR Corporation. From June 1996 to July 1997, he served as Vice President-Corporate Controller of Medtrans, a medical transportation service, a division of Laidlaw, Inc. and from 1989 to 1996, as Chief Finance Officer, Treasurer and Secretary of Data/Ware Development, Inc. Mr. Galetto is a Certified Public Accountant and holds a B.S. from Wayne State University.

GARY SOHNGEN has served as the Company's Vice President - Research & Development since January 2000. From 1985 to 1999, Mr. Sohngen served as Vice President of Research and Development for DePuy ACE, a Johnson & Johnson company specializing in the manufacture of orthopedic implants. He holds a B.S. from Twickenham Technical College in the United Kingdom and an M.B.A. from the University of Phoenix.

SHARON SCHULZKI has served as the Company's Vice President and General Manager - Spine & Orthopedics business unit since July 2000. Prior to July 2000, her most recent employment was at Howmedica, Inc. Division of Pfizer, a manufacturer of medical devices, where she served in various positions from 1983 to 1998, including Vice President. During that time she also served as Senior Vice President, Worldwide Marketing and Product Development, Howmedica Leibinger, Inc. Ms. Schulzki holds a B.S. from Loyola College, Baltimore, MD.

BRUCE REUTER has served as the Company's Vice President - Market Development since February 2001. From 1990 to 2000, Mr. Reuter served as the Vice President and Managing Director of Mentor International, a multi-national marketer of medical devices. He holds a B.A. from the University of Rhode Island and An M.B.A. from Memphis State University.

R. MARK LANE has served as the Company's Vice President - U.S. Sales since March 2001. From 1998 to 2001, Mr. Lane served as the Executive Vice President of Business Development for dotMD.Inc, a company licensing URL domain names, and President and Chief Operating Officer of MedAscend, Inc., a company providing education and training to physicians worldwide. From 1994 to 1998, he served as Vice President of Marketing Services and Promotions for Genzyme Surgical Products (formerly DSP Worldwide, Inc.). Mr. Lane holds a B.A. from the University of Kentucky.

DAVID RICKEY has served as a director of the Company since November 1999. Since 1996, Mr. Rickey has served as President and Chief Executive Officer of Applied Micro Circuits Corporation, which provides high-performance, high-bandwidth silicon solutions for optical networks. Mr. Rickey also serves as a director of Applied Micro Circuits Corporation and Silicon Wave. He holds a B.S. from Marietta College, a B.S. from Columbia University and an M.S. from Stanford University.

EDMUND KRIX has served as a director of the Company since August 2000. Since 1984, Mr. Krix has served as Chief Executive Officer and Chairman of the Board of Teleplan International N.V., an office products service and maintenance company.

The Board of Directors is responsible for managing the Company in accordance with the provisions of the Company's bylaws (the "Bylaws") and certificate of incorporation (the "Certificate of Incorporation") and applicable law. The number of directors which constitutes the Board of Directors is established by the Board, subject to a minimum of three directors. Currently, all directors hold office for a term ending on the date of the annual meeting following the annual meeting at which such director was elected.

Except as otherwise provided by the Bylaws for filling vacancies on the Company's Board of Directors, the Company's directors are elected at the Company's annual meeting of stockholders and hold office until their respective successors are elected, or until their earlier resignation or removal.

 $\mbox{Mr. Cox, a director of the Company and Chairman of the Board of Directors, is <math display="inline">\mbox{Mr. Calhoun's father-in-law.}$ 

#### BOARD COMMITTEES

The Board of Directors has established a committee (the "Committee") to handle compensation matters and administer the Company's Stock Option and Stock Purchase Plan, as amended (the "Stock Option Plan"). The Committee consists of Mr. Calhoun and Mr. Cox. The Committee determines the compensation received by the Company's directors and executive officers and administers the Company's Stock Option Plan. The committee reviews and approves the compensation and benefits for the Company's executive officers, and makes recommendations to the Board of Directors regarding these matters.

The Board of Directors has also established an Audit Committee consisting of Mr. Rickey and Mr. Krix. Paul Araquistain, an employee and former member of the Board of Directors of the Company also serves on the Audit Committee. The Audit Committee provides recommendations to the Board of Directors regarding the selection of the Company's independent public accountants, reviews the scope of the annual audit of the Company's books and records, approves the audit fees to be paid, and reviews the Company's financial accounting controls with the Company's staff and its independent public accountants.

#### ITEM 6. EXECUTIVE COMPENSATION.

#### DIRECTOR COMPENSATION

Presently, other than expenses in connection with attendance at meetings and other approved expenses, the Company does not compensate any non-employee members of its Board of Directors. Non-employee directors are eligible to receive options under the Company's Stock Option Plan.

# EXECUTIVE COMPENSATION

Executive officers of the Company are appointed by the Board of Directors annually at the first meeting of the Board of Directors following the annual meeting of stockholders and generally serve until their successors have been duly appointed and qualified.

The following table sets forth summary information concerning compensation awarded to, earned by,

or accrued for services by the Company's Chief Executive Officer and four additional officers for services rendered to the Company in all capacities during the years ended December 31, 1998, 1999 and 2000. Except as set forth below, no profit-sharing, allowances, insurance payments, commissions or other remuneration paid or benefits in kind were made to the Company's officers during such years.

				AWARDS	
NAME AND PRINCIPAL POSITION	YEAR	SALARY	BONUS	SECURITIES UNDERLYING OPTIONS/SARS (#)	ALL OTHER COMPENSATION (1)
Christopher L. CalhounCHIEF EXECUTIVE OFFICER AND SECRETARY	2000 1999 1998	\$ 177,303 145,750 10,008	\$ 50,760 41,086	62,500 250,000 0	\$ 12,845 7,385
Michael Simpson PRESIDENT	2000 1999 1998	168,299 165,000 55,000	46,530 41,086 30,000	68,750 55,000 220,000	9,600 9,600
Ari Bisimis (2) CHIEF FINANCIAL OFFICER	2000	120,000	36,000	275,000	2,400 7,200
Charles Galetto (3)	2000	102,885	38,125	100,000	6,600
Gary Sohngen (4)	2000	120,000	1,500	100,000	9,600

ANNUAL COMPENSATION

LONG TERM

COMPENSATION

NUMBER OF

VICE PRESIDENT, RESEARCH AND DEVELOPMENT

## OPTION GRANTS IN 2000

The following table sets forth, as to the named executive officers, information concerning stock options granted during the year ended December 31,

INDIV	GRANTS	
DCENT	OΓ	EVED

NAME	NUMBER OF SECURITIES UNDERLYING OPTION/SARS GRANTED	PERCENT OF TOTAL OPTIONS GRANTED	PRICE	RCISE E PER HARE	EXPIRATION	DATE	GRANT DATE PRESENT VALUE (1)	
Christopher Calhoun	62,500	4.0%	\$	3.00	January 1,	2010	\$ 150,312	
Michael Simpson	68,700	4.4		3.00	January 1,	2010	165,224	
Ari Bisimis	250,000	15.8		3.00	April 1,	2010	2,659,500	
	25,000	1.6		3.00	January 1,	2010	60,125	
Charles Galetto	100,000	6.3		3.00	April 24,	2010	1,063,600	
Gary Sohngen	100,000	6.3		3.00	January 1,	2010	240,500	

<sup>(1)</sup> The amounts in this column represent the car allowance given to each named executive officer.

(2) Mr. Bisimis began his employment with the Company in April 2000. He was

granted 10,000 options in May 1999 for consulting services he provided prior to joining the Company.

Mr. Galetto began his employment with the Company in April 2000.

<sup>(4)</sup> Mr. Sohngen began his employment with the Company in January 2000.

<sup>(1)</sup> The Company used the Black-Scholes option-pricing model to determine the grant date present value of the options set forth in this table. The Company's use of this model should not be construed as an endorsement of its accuracy at valuing options. The real value of the options depends upon the actual changes in the market price of the Company's common stock during the applicable period.

All stock option valuation models, including the Black-Scholes model, require a prediction about the future movement of the stock price. The following facts and assumptions were used in calculating grant date present value: exercise prices as indicated in the table above, fair market value of each option on the date of grant based on the best information available, a dividend yield of 0.0%, an expected stock option term of ten years and a stock price volatility of 60.0% based on the market

performance of the stock of similar medical device companies. The Company used an assumed risk-free interest rate in its calculations equivalent to the yield of a zero-coupon, ten-year Treasury bond on the date of the grants. The risk-free interest rate was 6.48% for options granted on January 1, 2000, 6.03% for options granted on April 1, 2000 and 6.00% for options granted on April 24, 2000. No other discounts or restrictions related to vesting or the likelihood of vesting of the stock options were applied.

#### AGGREGATED OPTIONS EXERCISES IN 2000 AND OPTION VALUES IN 2000

The following table sets forth information concerning options to purchase common stock held as of December 31, 2000 by each of the officers named in the summary compensation table that have stock options.

Amounts set forth as "value realized" in the following table represent hypothetical calculations based on the difference between the fair market value of the common stock underlying the options and the exercise price of the options. Prior to the Company's initial public offering in August 2000, there was no public market for the Company's stock. The value realized is therefore based on the best information available as to the fair market value of the Company's stock at the date of grant. The value realized does not necessarily represent any actual monetary gain to the option holder.

SHARES ACQUIRED ON EXERCISE (#)	VALUE REALIZED	0PT	SECURITIES UNEXERCISED IONS BER 31, 2000	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS		
NAME 		EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE	
Christopher Calhoun93,750 Michael Simpson130,625	\$1,093,125 1,394,406	218,750 213,125	-	\$1,425,313 1,366,269	-	
Ari Bisimis	248,750 -	213,125 260,000 100,000	- - -	1,366,269 1,164,800 448,000	- - -	
Gary Sohngen	-	100,000	-	448,000	-	

#### **EMPLOYMENT AGREEMENTS**

The Company has not entered into any written employment agreements with any of its executive officers or directors. The Company intends to enter into an employment agreement with Mr. Bisimis and into standard employment agreements with its other overseas employees.

## STOCK OPTION PLAN

In October 1997, the Board of Directors of the Company adopted, and the stockholders approved, the Stock Option Plan. The Stock Option Plan is administered by the Committee. The purpose of the Stock Option Plan is to provide the Company's designated employees, consultants and advisors who perform services for the Company, and non-employee members of the Company's Board of Directors, with the opportunity to receive grants of incentive stock options, nonqualified stock options and restricted stock. Awards under the Stock Option Plan may be made in the form of:

- o incentive stock options
- o nonqualified stock options (incentive and nonqualified stock options are collectively referred to as "options")

#### o direct awards or sales of stock

Awards may be made to such directors and employees of the Company, and to such consultants to the Company as the Committee shall, in its own discretion, select.

The Company is currently authorized to issue 5,000,000 shares under its Stock Option Plan. As of May 10, 2001, the Company had outstanding options to purchase 3,800,778 shares of the Company's common stock pursuant to the Stock Option Plan. As of May 10, 2001, options to acquire 1,112,905 shares of common stock had been exercised and 2,086,317 shares of common stock were available for grant under the Stock Option Plan. The Company's Board of Directors has authorized, and the Company expects the stockholders of the Company to approve, an increase in the number of shares authorized for issuance under the Stock Option Plan to 7,000,000.

Awards granted under the Stock Option Plan and shares acquired pursuant thereto are subject to a number of rights and restrictions, including provisions relating to the termination of employment of service of the grantee. The Committee may, without stockholder approval, adopt, amend or rescind rules, procedures, and terms of the Stock Option Plan at any time, or from time to time; provided, however, that stockholder approval shall be obtained for any amendment for which such approval is required by Section 422 of the United States Internal Revenue Code of 1986, as amended, or by other provisions of applicable law. Unless sooner terminated by the Committee or unless the employee's service terminates, the provisions of the Stock Option Plan relating to the grant of incentive stock options shall terminate on October 22, 2007. All awards made under the Stock Option Plan prior to its termination shall remain in effect until they are satisfied or terminated. Stock options awarded under the Plan are not transferable.

In general, the individual stock option agreements granted under the Stock Option Plan prior to January 1, 2001 provide the Company's option holders with the ability to exercise stock option grants which have not yet vested. Shares of common stock issued by the Company upon the exercise of unvested options are held in escrow with the Secretary of the Company. Such escrowed shares typically vest 25% at the end of the first year anniversary of the stock option agreement and then vest at the rate of 1/48th per month thereafter until fully vested. In the event of termination of employment, the Company typically has a right to purchase any shares of common stock issued to an employee pursuant to the exercise of an unvested stock option. Individual stock option agreements issued under the Stock Option Plan since January 1, 2001 generally do not allow the exercise of unvested stock options. Stock option accounting is consistent with fixed plan accounting under APB 25.

The Committee is authorized to construe, interpret and implement the provisions of the Stock Option Plan, to select the persons to whom awards will be granted, to determine the terms and provisions of such awards, including the vesting schedule and purchase price per share payable upon the exercise of an option, and to amend outstanding awards. The determinations of the Committee are made in its sole discretion and are binding and conclusive.

# COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Mr. Calhoun, who is a member of the Committee, is currently Vice-Chairman, Chief Executive Officer and Secretary and serves as a director of the Company. He also serves as a director of Artes Medical, Inc. Mr. Cox, who is also a member of the Committee, serves as an employee of the Company and as Chairman of the Board of Directors. Mr. Cox is also the Managing Director of Saratoga Boys Club and serves as a director for Internix, Artes Medical, Inc., Triscend Inc. and G2 Inc.

#### ITEM 7. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The following is a description of transactions since January 1998 to which the Company has been a party and in which any director, executive officer or holder of more than 5% of the Company's capital stock had or will have a direct or indirect material interest. All of the transactions disclosed below were duly authorized by the then-serving Board of Directors.

In November 1999, Mr. Simpson purchased 45,951 shares, Mr. Bisimis purchased 92,558 shares, Mr. Lane purchased 22,505 shares and Mr. Krix purchased 246,386 shares of the Company's Series C preferred stock at a purchase price of \$2.25 per share for a total cash consideration of approximately \$917,000.

In November 1999 and June and July 2000, the Company issued 59,707 shares of common stock to Mr. Bisimis in consideration of services rendered by Mr. Bisimis as a consultant to the Company prior to April 2000 when he became an employee of the Company.

Mr. Cox, the Chairman of the Company's Board of Directors, is the Managing Director of Saratoga Boys Club. During the period from September 1997 through November 1999, Saratoga Boys Club purchased an aggregate of 2,099,880 shares of the Company's Series A, B and C preferred stock for a total cash consideration of approximately \$1,978,000. In 1998 and 1999, the Company issued three warrants for a total of 22,223 shares of common stock to Mr. Cox as partial consideration for three loans made by Mr. Cox to the Company. The loans, which were made on September 28, 1998, November 27, 1998 and January 8, 1999 for \$99,000, \$50,000 and \$51,000, respectively, have been repaid in full. The loans were unsecured and bore interest at the rate of 10% per annum. The loans were short term loans which matured in less than a year and were used to provide working capital. See "Description of Capital Stock -Warrants" for a further description of these warrants. In November 1999, the Company issued 39,333 shares of common stock to Mr. Cox for total cash consideration of approximately \$59,000.

In 2000, the Company issued two loans to Ari Bisimis, one of the Company's directors and executive officers, in the aggregate amount of \$46,500, at an annual interest rate of 10.0%, for the purchase of a total of 25,000 shares of the Company's common stock. The loans were issued pursuant to the exercise of stock options granted to Mr. Bisimis. The loans were repaid in full on April 30, 2001.

In January 2000, the Company entered into a distribution agreement and a development and supply agreement with Medtronic. Medtronic paid a \$1,500,000 license fee to the Company for the exclusive worldwide distribution rights granted under the distribution agreement. In January 2000, Medtronic purchased 1,000,000 shares of the Company's Series D preferred stock for total cash consideration of \$3,500,000.

The Company believes that all of the transactions described above were made and are on terms no less favorable to the Company than those that could be obtained from independent third parties in arms-length negotiations.

ITEM 8. LEGAL PROCEEDINGS.

The Company is not currently a party to any material legal proceedings.

#### MARKET PRICES

The Company's common stock has been quoted on the NEUER MARKT of the Frankfurt Stock Exchange under the symbol "XMP" since its initial public offering on August 8, 2000. Prior to this time, there was no public market for the Company's stock. The Company's common stock is not currently traded on any United States exchange. The following table shows the high and low sales prices for the Company's common stock for the periods indicated, as reported on the NEUER MARKT. These prices do not include retail markups, markdowns or commissions. Average daily trading volume since the Company's shares were listed and began trading on the NEUER MARKT through September 30, 2000 was 136,674 shares per day. Average daily trading volume of the Company's shares was 19,517 shares per day for the quarter ended December 31, 2000 and 17,503 shares per day for the quarter ended March 31, 2001.

2000	HIGH	LOW
Quarter ended September 30, 2000	E27.2	E17.8
Quarter ended December 31, 2000	E20.0	E 6.8
2001		
Quarter ended March 31, 2001	E14.0	E 6.0

Substantially all of the Company's shares are represented by a global stock certificate issued in the name of Concord Effekten AG and deposited with Clearstream Banking AG ("Clearstream"), Frankfurt, Germany, the German securities depository. As of May 30, 2001, based on information provided by Clearstream, the Company estimates that the number of beneficial owners of its common stock held through the global stock certificate is approximately 5,500. As of May 30, 2001, there were an additional fifteen stockholders of record who held individual stock certificates.

The Company has issued and has outstanding options to purchase 3,800,778 shares of common stock and warrants to purchase 47,223 shares of common stock. All of the outstanding shares of common stock are deemed to be "restricted securities" as that term is defined in Rule 144. Of these restricted shares, 6,876,909 shares are available for sale in the public market pursuant to Rule 144, subject to compliance with Rule 144 volume and other requirements.

# DIVIDENDS

The Company has never declared or paid any dividends and currently intends to retain all available earnings generated by its operations for the development and growth of its business. It does not currently anticipate paying any cash dividends on its outstanding shares of common stock in the foreseeable future.

# THE GERMAN EQUITY MARKET

# GERMAN SECURITIES LAWS

As a United States company offering securities on a German stock exchange, the Company is subject to various laws and regulations in both jurisdictions. Some of these laws and regulations, in turn, can affect the ability of holders of the Company's 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 DM5,000 (E2,550 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 DM3.0 million, or E1.53 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 DM100,000, or E51,000 or the equivalent in a foreign currency.

There are no limitations imposed by German law or the Company's Certificate of Incorporation or Bylaws on the right of non-resident owners to hold or vote the shares.

#### THE FRANKFURT STOCK EXCHANGE AND THE NEUER MARKT

The Frankfurt Stock Exchange is one of nine German stock exchanges (including the Eurex Deutschland). The NEUER MARKT segment of the Frankfurt Stock Exchange is a new trading segment that was launched in March 1997. It is designed for innovative, small to mid-size companies in high growth industries or in traditional industries that have an international orientation and that are willing to provide active investor relations. Issuers are requested to provide investors on an ongoing basis with information such as annual and quarterly reports, including cash flow statements, and a corporate action timetable. This information is required to be submitted in English and German as well as in electronic form, thus enabling the stock exchange to disseminate corporate information via the Internet. The NEUER MARKT permits the Company to file its reports in English only.

## TRADING ON THE NEUER MARKT

Trading of shares on the NEUER MARKT takes place on the floor of the stock exchange, but is computer aided. Shares can also be traded on the Exchange Electronic Trading System (hereinafter referred to as "Xetra"). Trading takes place on every business day between 9:00 a.m. and 8:00 p.m., Central Europe Time. Trading within the Xetra system is done by financial services institutes and securities trading firms which have been admitted to trading on at least one of Germany's stock exchanges. Xetra is integrated into the Frankfurt Stock Exchange and is subject to its rules and regulations.

Markets in listed securities are generally of the auction type, but listed securities also change hands in inter-bank dealer markets off the Frankfurt Stock Exchange. Price formation is determined by open bid by state-appointed specialists who are themselves exchange members, but who do not, as a rule, deal with the public. Prices of shares traded on the NEUER MARKT are displayed continuously during trading hours. At the half-way point of each trading day, a single standard quotation is determined for all shares. The members' association of the Frankfurt Stock Exchange publishes a daily list of prices which contains the standard prices of all traded securities, as well as their highest and lowest quotation during the past year.

Transactions on the Frankfurt Stock Exchange, including transactions within the Xetra system, are settled on the second business day following trading. Transactions off the Frankfurt Stock Exchange, for large volumes or if one of the parties is foreign, are generally also settled on the second business day following trading, unless the parties have agreed upon a different date. Following a recent amendment to the conditions of German banks for securities trading, customers' orders to buy or sell listed securities must be executed on a stock exchange, unless the customer instructs otherwise. Trading can be suspended by the Frankfurt Stock Exchange if orderly stock exchange trading is temporarily endangered or if a suspension is in the public interest. A specific feature of the NEUER MARKT is the introduction of the obligatory "Designated Sponsor," an entity admitted for trading at the Frankfurt Stock Exchange which provides additional liquidity by quoting prices for the buying and selling of shares on request. Each issuer on the NEUER MARKT is required to nominate at least two Designated Sponsors which will not only ensure that there is sufficient liquidity for its shares, but also serve as consultants on all stock market related matters for the issuer for at least twelve months.

The Company's common stock has been admitted at the Frankfurt Stock Exchange with trading on the NEUER MARKT of the Frankfurt Stock Exchange. The NEUER MARKT is still a relatively new market. Accordingly, there can be no assurance that an active trading market for the shares will develop on the NEUER MARKT or that the NEUER MARKT will not experience problems in settlement or clearance as trading develops. Any such delays or problems could adversely affect the market price of the shares. Persons proposing to trade the shares on the NEUER MARKT should inform themselves about the potential costs of such trading.

During the last three years, the Company has sold and issued unregistered securities as follows.

In October 1998, the Company issued 1,032,583 shares of Series B preferred stock to seven accredited investors, including Saratoga Boys Club, an affiliate of Mr. Cox, one of the Company's directors. These shares were issued for total cash consideration of approximately \$1,549,000.

In September and November 1999, the Company issued 2,574,989 shares of Series C preferred stock to approximately eighty four accredited investors, including Messrs. Bisimis, Krix and Simpson, three of the Company's directors, Mr. Lane, a vice president of the Company, and Saratoga Boys Club, an affiliate of Mr. Cox, one of the Company's directors. These shares were issued for total cash consideration of approximately \$5,794,000 and the conversion of \$77,000 of interest that accrued on early payments made by some of the investors. For accounting purposes, the accrued interest was reflected on the financial statements of the Company as debt which was later converted to preferred stock. In May 2000, the Company issued an additional 2,777 shares of Series C preferred stock for total cash consideration of \$6,000 upon the exercise of warrants issued to Richard Christopher. In February 2000, Mr. Simpson converted 45,951 shares of Series C preferred stock into 45,951 shares of common stock.

In November 1999, the Company issued 132,666 shares of common stock to four accredited investors, including Mr. Cox, one of the Company's directors. These shares were issued for total cash consideration of approximately \$304,000. From March through June 1999 and June and July 2000, the Company also issued 79,707 shares of common stock in consideration of services rendered to five employees and consultants, including Mr. Bisimis, who became a director of the Company in May 2000.

In December 1999 and March 2000, the Company issued an aggregate of 2,000,000 shares of Series D preferred stock to approximately sixty accredited investors. These shares were issued for total cash consideration of \$7,000,000.

In 1998 and 1999, the Company issued warrants to Mr. Cox and Richard Christopher to purchase an aggregate of 25,000 shares of the Company's Series C preferred stock at an exercise price of \$2.25 per share. The warrants were issued in connection with loans made to the Company by Mr. Cox and Mr. Christopher. In July 2000, the Company also issued one warrant to Surgical Science to purchase 25,000 shares of the Company's common stock at an exercise price of \$12.00, in connection with the termination of Surgical Science's distribution agreement with the Company.

The securities described in the foregoing paragraphs were issued in reliance on the exemption from the registration requirements under the Securities Act provided by Section 4(2) under the Securities Act or Regulation D promulgated thereunder. The Company believes that these transactions are exempt from registration because the subject securities were sold to limited groups of persons, each of whom was believed to have been a sophisticated investor or to have had a pre-existing business or personal relationship with the Company or the Company's management and to have been purchasing for investment without a view to further distribution.

In August 2000, the Company issued 3,500,000 shares of common stock to non-U.S. investors in a transaction completed outside the United States pursuant to an underwritten offering for total cash consideration of approximately \$47,201,000. The Company paid approximately \$2,478,000 in underwriting commissions to Concord Effekten AG, the Company's principal underwriter, in connection with this offering. These shares were listed on the NEUER MARKT. The shares were issued in reliance on the exemption from the registration requirements under the Securities Act provided by Section 4(2) under the Securities Act or Regulations S promulgated thereunder.

In August 2000, all of the outstanding 6,831,398 shares of the Company's preferred stock, including 1,267,000 shares of Series A preferred stock, 1,032,583 shares of Series B preferred stock, 2,531,815 shares of Series C preferred stock, and 2,000,000 shares of Series D preferred stock, were converted into 6,831,398 shares of common stock.

Pursuant to the Stock Option Plan and an exemption from the registration requirements under the Securities Act provided by Rule 701, since October 1997 and as of May 10, 2001, the Company has granted options to some of its employees, directors, officers and advisors to purchase a total of 5,210,476 shares of the Company's common stock, at a weighted average exercise price of

#### ITEM 11. DESCRIPTION OF CAPITAL STOCK.

#### AUTHORIZED AND OUTSTANDING CAPITAL STOCK

The Company's authorized capital stock consists of 95,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of May 10, 2001, 14,952,627 shares of common stock and no shares of preferred stock were outstanding.

#### COMMON STOCK

#### VOTING

Holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the Company's stockholders. Other than the election of directors by a plurality of votes cast, all other matters shall be decided by a majority of the votes cast.

#### **DIVIDENDS**

Holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors out of funds legally available therefor, subject to any preferential dividend rights of any outstanding Preferred Stock.

#### ADDITIONAL RIGHTS

Upon the liquidation, dissolution or winding up of the Company, the holders of common stock are entitled to receive ratably the net assets of the Company available after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of the common stock have no preemptive, subscription, redemption or conversion rights. Some of the rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any preferred stock which the Company may designate and issue in the future without further stockholder approval.

#### PREFERRED STOCK

The Company's Certificate of Incorporation provides that the Company's Board of Directors, without any further vote or action by the Company's stockholders, may authorize and issue, subject to limitations prescribed by law, up to an aggregate of 5,000,000 shares of preferred stock. The preferred stock may be issued in one or more series. The Company's Board of Directors may determine the designation and the number of shares, preferences, limitations and special rights of any series of preferred stock, including dividend rights, conversion rights, voting rights, redemption rights and liquidation preferences. Because of the rights that may be granted, the issuance of preferred stock may delay, defer or prevent a change of control of the Company.

#### SHARE CERTIFICATES

Shares in the Company are represented by one or more global certificates deposited with Clearstream. However, pursuant to the Delaware General Corporation Code, or DGCL, stockholders are entitled to individual certificates, in such form as may be prescribed by law and the Board of Directors, certifying the number and class of shares owned by the stockholder in the Company. Each such certificate shall be signed by, or in the name of the Company by the chairperson or vice-chairperson of the Board of

Directors, or the president or vice president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the Company.

#### WARRANTS

In September 1998, November 1998 and January 1999, the Company issued warrants to Marshall Cox providing Mr. Cox with options to purchase 11,000, 5,556 and 5,667 shares of the Company's Series C preferred stock, respectively. The warrants were issued in connection with three loans made to the Company by Mr. Cox, which have been paid in full and canceled. The warrants are each exercisable at an exercise price of \$2.25 per share. The warrants are exercisable in full. The warrants expire on the earliest to occur of:

- o ten years from their respective issue dates in September 2008, November 2008 and January 2009
- o upon a firmly underwritten public offering of the Company's common stock under the securities laws of the United States
- o upon the sale of all or substantially all of the Company's assets or a change in control of the Company

In July 2000, the Company issued a warrant to Surgical Science Systems in connection with the termination of the distribution agreement between the two companies. The warrant to purchase 25,000 shares of the Company's common stock is exercisable in full at an exercise price of \$12.00 per share. The warrant expires on the earliest to occur of:

- o July 31, 2004
- o upon a firmly underwritten public offering of the Company's common stock under the securities laws of the United States
- o  $\,$  upon the sale of all or substantially all of the Company's assets or a change in control of the Company

The fair value of the warrant on the grant date was determined by using the Black-Scholes option-pricing model, resulting in expense of approximately \$33,000 being recorded in conjunction with the issuance of the warrant.

ITEM 12. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

#### LIMITATION OF LIABILITY

The Certificate of Incorporation provides that the Company's directors will not be personally liable to the Company or its stockholders for monetary damages resulting from a breach of fiduciary duty except for:

- o any breach of the duty of loyalty to the Company or its stockholders
- o acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law
- o liability under Section 174 of the DGCL
- o any transaction from which the director derived an improper personal benefit

This limitation of liability does not apply to the responsibility or liability of the Company's directors pursuant to any criminal statute nor does it relieve the directors from payment of taxes pursuant to federal, state or local law.

#### INDEMNIFICATION

The Certificate of Incorporation provides that the liability of the directors will be limited to the fullest extent permitted by Delaware law. The Bylaws provide that the Company will indemnify its directors and executive officers and may indemnify other corporate agents, to the fullest extent permitted by Delaware law. Section 145 of DGCL provides a corporation with the power to indemnify any officer or director acting in his capacity as the corporation's representative who was, is or is threatened to be made, a party to any action or proceeding for expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action or proceeding. The indemnity provisions apply whether the action was instituted by a third party or arose by or in the Company's right. Generally, the only limitation on the Company's ability to indemnify its officers and directors is if their actions violate a criminal statute or if their actions or failures to act are finally determined by a court to have constituted willful misconduct or recklessness.

The Company currently has directors' and officers' liability insurance to provide its directors and officers with insurance coverage for losses arising from claims based on breaches of duty, negligence, errors and other wrongful acts. At present, there is no pending litigation or proceeding involving any director, officer, employee or agent as to which indemnification will be required or permitted. The Company is not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

#### ITEM 13. FINANCIAL STATEMENTS.

INDEX TO FINANCIAL STATEMENTS	PAGE
Review Report of Arthur Andersen LLP, Independent Public Accountants	36
Condensed Balance Sheets as of March 31, 2001 (unaudited) and December 31, 2000	37
Condensed Statements of Operations and Comprehensive Income for the three months ended March 31, 2001 and 2000 (unaudited)	38
Condensed Statements of Cash Flows for the three months Ended March 31, 2001 and 2000 (unaudited)	39
Notes to Condensed Financial Statements (unaudited)	40
Report of Arthur Andersen LLP, Independent Public Accountants	43
Report of PricewaterhouseCoopers LLP, Independent Accountants	44
Balance Sheets as of December 31, 2000 and 1999	45
Statements of Operations and Comprehensive Income for the Years Ended December 31, 2000, 1999 and 1998	46
Statements of Stockholders' Equity and Convertible Redeemable Preferred Stock for the Years Ended December 31, 2000, 1999 and 1998	47
Statements of Cash Flows for the Years Ended December 31, 2000, 1999 and 1998	48
Notes to Financial Statements	49

To MacroPore, Inc.

We have reviewed the accompanying condensed balance sheet of MacroPore, Inc. (a Delaware corporation) as of March 31, 2001 and 2000, and the related condensed statements of operations and comprehensive income and cash flows for each of the three-month periods then ended. These financial statements are the responsibility of the company's management.

We conducted our review in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with generally accepted auditing standards, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the financial statements referred to above for them to be in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

San Diego, California May 2, 2001

#### MACROPORE, INC. CONDENSED BALANCE SHEETS

	MARCH 31, 2001 (UNAUDITED)	DECEMBER 31, 2000
ASSETS Current assets: Cash and cash equivalents Short-term investments, available for sale Accounts receivable, related party, net of allowance for bad debts of \$35,000 and \$75,000 in 2001 and	\$ 7,296,000 34,238,000	\$ 7,476,000 37,008,000
2000, respectively Inventories Prepaids and other current assets	1,196,000 2,812,000 1,019,000	693,000 2,278,000 882,000
Total current assets		48,337,000
Property and equipment, net Deposits	4,657,000 141,000	3,691,000 241,000
Total assets	\$ 51,359,000	
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable and accrued expenses Current portion of capital lease obligations	\$ 1,454,000 115,000	\$ 1,364,000 115,000
Total current liabilities	115,000  1,569,000	
Deferred revenue, related party Capital lease obligations, less current portion	1,125,000 227,000	1,200,000 255,000
Total liabilities	2,921,000	2,934,000
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 in 2001 and 2000; 14,952,127 and 14,814,346	-	-
issued and outstanding in 2001 and 2000, respectively Additional paid-in capital Unearned compensation Accumulated deficit	(2,883,000)	68,126,000
Other accumulated comprehensive income	333,000	180,000
Total stockholders' equity	48,438,000	
Total liabilities and stockholders' equity	\$ 51,359,000	\$ 52,269,000

See notes to condensed financial statements.

# MACROPORE, INC. CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
Revenues: Sales to related party Sales to distributors and end-users	\$ 1,999,000 30,000	\$ 880,000 379,000
Costs directly related to revenues, net of stock based compensation expense of \$5,000 and \$2,000 for the three months ended March 31, 2001 and 2000,	2,029,000	1,259,000
respectively	665,000	595,000
Gross profit	1,364,000	
Operating expenses:  Research and development, net of stock based compensation expense of \$30,000 and \$431,000 for the three months ended March 31, 2001		
and 2000, respectively Sales and marketing, net of stock based compensation expense of (\$52,000) and \$1,806,000 for the three months ended March 31, 2001	1,184,000	350,000
and 2000, respectively General and administrative, net of stock based compensation expense of \$160,000 and \$189,000 for the three months ended March 31, 2001	1,012,000	390,000
and 2000, respectively Stock based compensation	927,000 143,000	599,000 2,428,000
Total operating expenses	3,266,000	3,767,000
Other income (expenses):		
Interest income Interest expense and other	676,000 12,000	90,000 (28,000)
Net loss	(1,214,000)	
Other comprehensive income: Unrealized holding gains arising during period	153,000	-
Comprehensive loss	\$ (1,061,000)	\$ (3,041,000)
Basic and diluted net loss per share	\$ (0.08)	\$ (0.82)
Shares used in calculating basic and diluted net loss per share	14,917,376	3,704,270

See notes to condensed financial statements.

# MACROPORE, INC. CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss Adjustments to reconcile net loss to net cash (used in) provided by operating activities:	\$ (1,214,000)	. , , ,
Depreciation and amortization Stock based compensation Increases (decreases) in cash caused by changes in operating assets and liabilities:	226,000 143,000	
Accounts receivable Inventories Prepaids and other current assets	(503,000) (534,000) (137,000)	(29,000) (143,000) (65,000)
Deposits Accounts payable and accrued expenses Deferred revenue	100,000 90,000 (75,000)	(62,000) 85,000 1,425,000
Net cash (used in) provided by operating activities	(1,904,000)	
CASH FLOWS FROM INVESTING ACTIVITIES: Proceeds from the sale and maturity of short-term investments	29,876,000	_
Purchase of short-term investments Purchases of property and equipment	(26,953,000) (1,192,000)	(2,000) (310,000)
Net cash provided by (used in) investing activities	1,731,000	(312,000)
CASH FLOWS FROM FINANCING ACTIVITIES: Principal payments on capital leases Proceeds from sale of Common Stock Proceeds from sale of Series D	(28,000) 21,000	21,000
Preferred Stock, net of issuance costs	-	4,087,000
Net cash (used in) provided by financing activities	(7,000)	4,080,000
Net (decrease) increase in cash	(180,000)	4,456,000
Cash and cash equivalents at beginning of period	7,476,000	2,471,000
Cash and cash equivalents at end of period	\$ 7,296,000	\$ 6,927,000
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION: Cash paid during period for: Interest	\$ 14,000	\$ 28,000
Taxes SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:	800	-
Equipment acquired under capital leases	\$ -	\$ 81,000

See notes to condensed financial statements.

### NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED) MARCH 31, 2001

#### 1. BASIS OF PRESENTATION

The accompanying unaudited financial statements for the three months ended March 31, 2001 and 2000 have been prepared in accordance with generally accepted accounting principles for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for audited financial statements. The condensed balance sheet at December 31, 2000 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of MacroPore, Inc. ("MacroPore" or "the Company") have been included. Operating results for the three months ended March 31, 2001, are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. For further information, refer to the financial statements for the year ended December 31, 2000 and footnotes thereto which were included in the Company's Report on Form 10, dated March 30, 2001.

#### 2. 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 estimates.

#### 3. 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.

#### 4. INVENTORIES

Inventories are valued at the lower of average cost (determined on a FIFO basis) or market. Provisions, when necessary, are made to reduce excess and obsolete inventories to their estimated net realizable values.

#### 5. REVENUE RECOGNITION

The Company sells its products to distributors. The Company has agreements with its distributors which provide 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.

#### 6. EMPLOYEE STOCK-BASED COMPENSATION

The Company measures compensation expense for its employee stock-based compensation plans using the intrinsic value method in accordance with APB 25. Accordingly, compensation cost for stock awards is measured as the excess, if any, of the deemed market value for financial reporting purposes of the Company's common stock at the date of grant over the amount an employee must pay to acquire the stock. Compensation cost is amortized using the straight-line method over the related vesting periods. Earned compensation costs for awards that are forfeited are reversed against compensation expense in the period of forfeiture.

#### 7. SEGMENT INFORMATION

The Company follows the provisions of Statement of Financial Accounting Standards 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.

#### 8. NON-EMPLOYEE STOCK-BASED COMPENSATION

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.

#### 9. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing earnings (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 earnings (loss) per share is computed by dividing net earnings (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 shares 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 earnings (loss) per share by application of the treasury stock method. Potentially dilutive securities have been excluded from the computations as their inclusion would be antidilutive.

#### 10. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

#### ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	MARCH 31, 2001	DECEMBER 31, 2000
		(AUDITED)
Accounts payable Accrued expenses Accrued vacation	\$ 851,000 444,000 159,000	\$ 784,000 459,000 121,000
	\$1,454,000	\$1,364,000

#### 11. SUBSEQUENT EVENT

On May 2, 2001, the Company invested \$1,000,000 in cash in the Series A preferred stock of a company principally engaged in biomedical research. The Company will account for this investment under the equity method of accounting.

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

We have audited the accompanying balance sheet of MacroPore, Inc. as of December 31, 2000 and the related statements of operations and comprehensive income, stockholders' equity and convertible redeemable preferred stock and cash flows for the year 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 audit.

We conducted our audit 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 audit provides 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, 2000, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

San Diego, California February 23, 2001 To the Board of Directors of MacroPore, Inc.  $\,$ 

In our opinion, the accompanying balance sheet and the related statements of operations and comprehensive income, of stockholders' equity and convertible redeemable preferred stock and of cash flows present fairly, in all material respects, the financial position of MacroPore, Inc. at December 31, 1999, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 1999, in conformity with accounting principles generally accepted in the United States of America. 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 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 audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Diego, California June 30, 2000

		BER 31,
	2000	1999
ASSETS		
Current assets: Cash and cash equivalents Short-term investments, available for sale Accounts receivable, related party, net of allowance for bad debts of \$75,000 (Note 10)	\$ 7,476,000 37,008,000 693,000	\$ 2,471,000 110,000
Accounts receivable, net of allowance for bad debts of \$53,000 Inventories Prepaids and other current assets	2,278,000 882,000	492,000 1,135,000 31,000
Total current assets	48,337,000	31,000 4,239,000
Property and equipment, net Deposits	3,691,000 241,000	1,318,000 18,000
Total assets	\$ 52,269,000	\$ 5,575,000 ======
LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) Current liabilities:		
Accounts payable and accrued expenses Current portion of capital lease obligations	\$ 1,364,000 115,000	\$ 640,000 89,000
Total current liabilities	1,479,000	729,000
Deferred revenue, related party Capital lease obligations, less current portion	1,200,000 255,000	304,000  1,033,000
Total liabilities	2,934,000	1,033,000
Commitments (Note 5)		
Convertible redeemable preferred stock:  Series A non-cumulative, convertible preferred stock; \$0.001 par value; -0- and 1,267,000 shares authorized, issued and outstanding in 2000 and 1999, respectively; liquidation preference of \$0 and \$634,000 in 2000		
<pre>and 1999, respectively Series B non-cumulative, convertible preferred stock; \$0.001 par value; -0- and 1,032,583 shares authorized, issued and outstanding in 2000 and 1999, respectively; liquidation preference of \$0 and \$1,549,000 in 2000</pre>	-	630,000
and 1999, respectively Series C non-cumulative, convertible preferred stock; \$0.001 par value; -0- and 2,600,000 shares authorized in 2000 and 1999, respectively; -0- and 2,574,989 shares issued and outstanding in 2000 and 1999, respectively; liquidation preference of \$0 and \$5,696,000 in 2000 and	-	1,547,000
1999, respectively Series D non-cumulative, convertible preferred stock; \$0.001 par value; -0- and 2,000,000 shares authorized in 2000 and 1999, respectively; -0- and 832,226 issued and outstanding in 2000 and 1999, respectively; liquidation preference of \$0 and \$7,000,000 in 2000 and 1999,	-	5,657,000
respectively	-	2,855,000
Stockholders' equity (deficit): Preferred stock; \$0.001 par value; 5,000,000 authorized; -0- shares	-	10,689,000
issued and outstanding in 2000 Common stock; \$0.001 par value; 95,000,000 and 17,000,000 shares authorized in 2000 and 1999, respectively; 14,814,346 and 3,639,505 issued and outstanding in 2000 and 1999, respectively	- 15,000	4,000
Additional paid-in capital Unearned compensation Accumulated deficit	68,126,000 (3,094,000) (15,892,000)	2,381,000 (1,285,000) (7,247,000)
Other accumulated comprehensive income  Total stockholders' equity (deficit)	180,000  49,335,000	(6,147,000)
Total liabilities, convertible redeemable preferred stock and		
stockholders' equity (deficit)	\$ 52,269,000 ======	\$ 5,575,000 =======

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

### MACROPORE, INC. STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

YEAR ENDED DECEMBER 31, ------2000 1999 1998 Revenues: Sales to related party (Note 10) \$ 6,092,000 \$ 159,000 Sales to distributors and end-users 1,513,000 6,251,000 1,513,000 Costs directly related to revenues, net of stock based compensation expense of \$18,000, \$5,000 and \$0 for the years ended December 31, 2000, 1999 and 1998, respectively 2,376,000 481,000 Gross profit 3,875,000 1,032,000 Operating expenses: Research and development, net of stock based compensation expense of \$2,239,000, \$70,000 and \$40,000 for the years ended December 31, 2000, 1999 and 1998, respectively Sales and marketing, net of stock based compensation expense of \$1,852,000, \$231,000 and \$0 for the years 2,584,000 1,172,000 1,175,000 ended December 31, 2000, 1999 and 1998, respectively General and administrative, net of stock based compensation expense of \$1,607,000, \$360,000 and \$32,000 for the years ended December 31, 2000, 1999 2,629,000 2,356,000 202,000 and 1998, respectively Stock based compensation 2,555,000 1,313,000 604,000 666,000 5,716,000 76,000 Total operating expenses 13,484,000 5,507,000 2,057,000 Other income (expenses): Interest income 10,000 1,315,000 68,000 Interest and other expenses (351,000) (164,000) (43,000) Net loss (8,645,000) (4,571,000) (2,090,000) -----Other comprehensive income: Unrealized holding gains arising during period 180,000 Comprehensive loss \$ (8,465,000) \$ (4,571,000) \$ (2,090,000) ========= ========== Basic and diluted net loss per share (1.05)\$ (1.32)(0.64)========== Shares used in calculating basic and diluted net loss per share 8,201,739 3,458,292 3,250,000

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

### ${\tt MACROPORE,\ INC.}$ STATEMENTS OF STOCKHOLDERS' EQUITY AND CONVERTIBLE REDEEMABLE PREFERRED STOCK

		PREFE	ERRED A	PREFER	RED B	PREF	ERRED C	PREFER	RED D
	PREFERRED STOCK	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT
	SUBSCRIBED								
Balance at December 31, 1997 Compensatory stock options Issuance of Series B Preferred shares for cash, at \$1.50 per share, net of issuance costs of \$2,000 Preferred stock subscribed Net loss for the year ended December 31, 1998	\$ 425,000 (253,000) 347,000	1,267,000	\$630,000	1,032,583		-	- \$ -	-	\$ -
Balance at December 31, 1998 Issuance of common stock for services rendered Issuance of common stock under stock option plan Issuance of common stock for cash Compensatory stock options Issuance of Series C Preferred shares for cash, at \$2.25 per share, net of issuance costs of	(172,000)	1,267,000	630,000	1,032,583	1,547,000				
\$137,000  Issuance of Series D Preferred shares for cash, at \$3.50 per share, net of issuance costs of \$58,000  Net loss for the year ended December 31, 1999	(347,000)					2,574,989	5,657,000	832,226	2,855,000
Balance at December 31, 1999 Issuance of common stock under stock option plan	-	1,267,000	630,000	1,032,583	1,547,000	2,574,989	5,657,000	832,226	2,855,000
Conversion of Series C Preferred shares to common stock Issuance of Series C Preferred shares for cash, at \$2.25 per share						(45, 951 2, 777		)	
Issuance of Series D Preferred shares for cash, at \$3.50 Issuance of common stock for service rendered Issuance of common stock in initial public offering, net of issuance costs of \$3,957,000 Conversion of preferred stock in connection with initial public offering Compensatory stock options Unrealized income on investments Net loss for the year ended December 31, 2000		(1,267,000)	)(630,000)	(1,032,583)	<b>(1,547,000</b> )	)(2,531,815	5)(5,560,000		4,087,000 (6,942,000)
Balance at December 31, 2000	\$ -		\$ -		\$ -		\$ -	-	\$ -
Balance at December 31, 1997 Compensatory stock options Issuance of Series B Preferred shares for cash, at \$1.50 per	TOTAL \$ 1,055,000 -	COMMC SHARES 3,250,000	ON STOCK  AMOUNT  3,0	PAID CAPI 00 \$ 9,	TAL COMPE	EARNED A ENSATION - \$ 216,000)	ACCUMULATED ( DEFICIT (586,000)	INCOME	
share, net of issuance costs of \$2,000 Preferred stock subscribed Net loss for the year ended December 31, 1998	1,294,000 347,000				-		(2,090,000)	(	2,090,000)
Balance at December 31, 1998 Issuance of common stock for services rendered Issuance of common stock under stock option plan	2,696,000	3,250,000 66,339 190,500	3,0	13 14	,000	216,000)	(2,676,000)	- (	2,588,000) 13,000
Issuance of common stock for cash Compensatory stock options Issuance of Series C Preferred shares for cash, at \$2.25 per share, net of issuance costs of \$137,000	(172,000) - 5,310,000	132,666	1,0	00 303 1,750	,000 ,000 (1,0	969,000)			304,000 681,000

•	========	========	========	=========	=========	=======================================	=======	========
Balance at December 31, 2000	\$ -	14,814,346	\$ 15,000	\$68,126,000	\$(3,094,000)	\$(15,892,000)	\$180,000	\$49,335,000
December 31, 2000	-	-				(8,645,000)		(8,645,000)
Net loss for the year ended							100,000	100,000
Unrealized income on investments	- -			7,410,000	(1,000,000)		180,000	180,000
Compensatory stock options	(14,079,000)	0,001,000	7,000	7,413,000	(1,809,000)			5,604,000
connection with initial public offering	(14,679,000)	6 831 398	7,000	14,672,000				14,679,000
Conversion of preferred stock in								
of issuance costs of \$3,957,000	-	3,500,000	4,000	43,240,000				43,244,000
initial public offering, net		0 500 000	4 000	40.040.000				40 044 000
Issuance of common stock in		-,		. , , , , ,				- ,
service rendered	-	13,368	-	161,000				161,000
Issuance of common stock for	4,001,000							
shares for cash, at \$3.50	4,087,000			_				_
Issuance of Series D Preferred	6,000			-				-
shares for cash, at \$2.25 per share	6,000							
Issuance of Series C Preferred								
shares to common stock	(103,000)	45,951	-	103,000				103,000
Conversion of Series C Preferred								
stock option plan	-	784,124	-	156,000				156,000
Issuance of common stock under		• •	•		. , , ,			. , , ,
Balance at December 31, 1999	10,689,000	3,639,505	4,000	2,381,000	(1,285,000)	(7,247,000)	_	(6,147,000)
December 31, 1999	-	-	-	-		(4,571,000)		(4,571,000)
Net loss for the year ended						( . ==		( . ==)
\$58,000	2,855,000			-				-
share, net of issuance costs of	•							
shares for cash, at \$3.50 per								
Issuance of Series D Preferred								

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

#### MACROPORE, INC. STATEMENTS OF CASH FLOWS

YEAR ENDED DECEMBER 31,

	2000	1999	1998
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (8,645,000)	\$ (4,571,000)	\$(2,090,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	441,000	235,000	113,000 76,000 9,000
Stock based compensation	5,716,000	666,000	76,000
Loss from sale of equipment	-	-	9,000
Increases (decreases) in cash caused by changes in			
operating assets and liabilities: Accounts receivable	(201,000)	(492,000)	_
Inventories	(1,143,000)	(1,097,000)	(38,000)
Prepaids and other current assets	(851,000)	1,000	(30,000)
Deposits	(223,000)	1,000 (6,000)	(12,000)
Accounts payable and accrued expenses	724,000	157,000	449,000
Deferred revenue	1,200,000	157,000´ -	-
Net cash used in operating activities		(5,107,000)	
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from the sale and maturity of short-term			
investments	85,610,000	- (5.000)	(5.000)
Purchase of short-term investments Purchases of property and equipment	(122,328,000)	(5,000) (376,000)	(5,000) (503,000)
runchases of property and equipment	(2,732,000)	(5,000) (376,000)	(393,000)
Net cash used in investing activities	(39,450,000)	(381,000)	(598,000)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Principal payments on capital leases	(105,000)	(73,000)	(15,000)
Proceeds from sale of equipment to leasing company	•	-	37,000
Proceeds from short-term debt	-	51,000	174,000
Proceeds from stock subscriptions of Series C Preferred Stock			347,000
Proceeds from sale of Common Stock	205,000	146,000	347,000
Proceeds from sale of Series B, Series C and Series D	,	=,	
Preferred Stock, net of issuance costs	4,093,000	7,800,000	1,294,000
Proceeds from initial public offering, net of offering	42 244 000		
cost	43,244,000		-
Net cash provided by financing activities	47,437,000	7,924,000	1,837,000
Net increase (decrease) in cash	5 005 000		
Cash and cash equivalents at beginning of period	2,471,000	2,436,000 35,000	319,000
Cash and cash equivalents at end of period	\$ 7,476,000 	\$ 2,471,000 ======	\$ 35,000 ======
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:			
Cash paid during period for:		<b>A</b> 444 000	
Interest Taxes	\$ 82,000 800	\$ 111,000 800	\$ 8,000 800
Tunes	000	000	000
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING			
ACTIVITIES:			40-0
Equipment acquired under capital leases Conversion of bridge loan to Series B preferred	\$ 82,000	\$ 211,000	\$270,000
stock (Note 6)	_	_	425,000
Conversion of bridge loan to Series C preferred			0,000
stock (Note 6)	-	225,000	-
Issuance of Series C preferred stock for purchase of		140 000	
equipment Issuance of Common Stock for services rendered	112,000	140,000	-
133dance of Common Stock for Services relidered	112,000	_	-

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

#### .. 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 biodegradable surgical implants to aid in the reconstruction, repair and regeneration of bone. The Company's resorbable 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 is largely dependent 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.

### 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 estimates.

#### CONCENTRATION OF CREDIT RISK

The Company's financial instruments that are subject to concentration of credit risk consist primarily of cash and cash equivalents, certificates of deposit and money market accounts. The balances in excess of FDIC insured amounts are \$3,274,000 and \$2,611,000 as of December 31, 2000 and 1999, respectively.

#### 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 \$4,522,000 as of December 31, 2000. There were no investments classified as cash equivalents as of December 31, 1999.

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

#### SHORT-TERM INVESTMENTS

The Company invests its excess cash in debt instruments of financial institutions, corporations with strong credit ratings, and in U.S. 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 FASB Statement 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 premium 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 such investments down to estimated fair value by a charge to operations when such review results in management's determination that an investment's impairment is considered to be other than temporary. The cost of securities sold is based on the specific identification method.

#### FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of the Company's cash and cash equivalents, accounts receivable and accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances. The carrying amounts of the Company's short-term debt and capital lease 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 are valued at the lower of average cost (determined on a FIFO basis) or market. Provisions, when necessary, are made to reduce excess and obsolete inventories to their estimated net realizable values.

#### 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, the

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

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 which provide 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.

#### RESEARCH AND DEVELOPMENT

Research and development expenditures are charged to expense in the period incurred.  $\,$ 

#### INCOME TAXES

Deferred income taxes are recognized for the expected tax consequences in future years of temporary differences between the tax bases of assets and liabilities and their financial reporting amounts at each year end as well as the expected future tax benefit from tax loss and tax credit carryforwards, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount more likely than not to be realized in future tax returns. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and liabilities.

#### EMPLOYEE STOCK-BASED COMPENSATION

The Company measures compensation expense for its employee stock-based compensation plans using the intrinsic value method and provides pro forma disclosures of net loss and net loss per share as if fair value methods had been applied in measuring compensation expense. Accordingly, compensation cost for stock awards is measured as the excess, if any, of the deemed market value for financial reporting purposes of the Company's Common Stock at the date of grant over the amount an employee must pay to acquire the stock. 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.

#### NON-EMPLOYEE STOCK-BASED COMPENSATION

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)

In accordance with FASB Statement No. 130, Reporting Comprehensive Income, the Company displays comprehensive income (loss) and its components in a financial statement that is displayed with the same prominence as other financial statements.

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

#### SEGMENT INFORMATION

The Company follows the provisions of Statement of Financial Accounting Standards 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.

#### EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing earnings (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 earnings (loss) per share is computed by dividing net earnings (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 shares 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 earnings (loss) per share by application of the treasury stock method.

The Company has excluded all convertible Preferred Stock and outstanding stock options from the calculation of diluted loss per share attributable to Common Stockholders for the periods ended December 31, 2000, 1999 and 1998 because all such securities are antidilutive. The number of potential common shares excluded from the calculations of diluted loss per share for the years ended December 31, 2000, 1999 and 1998 was 2,750,000, 5,907,420 and 2,431,977, respectively.

#### RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 is effective for fiscal years beginning after June 15, 2000. SFAS No. 133 requires that all derivative instruments be recorded on the balance sheet at their fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, unless specific hedge accounting criteria are met. The Company does not expect that the adoption of SFAS No. 133 will have a material impact on its financial statements because it does not currently hold any derivative instruments and does not engage in any hedging activities.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 ("SAB 101") "Revenue Recognition in Financial Statements." SAB 101 summarizes the SEC's views regarding the application of generally accepted principles to revenue recognition in financial statements. The Company believes that its revenue recognition principles comply with SAB 101.

In March 2000, the FASB issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation" (FIN 44). This interpretation clarifies the application of APB Opinion No. 25 for certain issues related to stock based compensation, including the definition of employee for the purposes of applying APB 25, the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequences of modifications to the terms of a previously fixed stock option award, and the accounting for an exchange of stock compensation awards in a business combination. FIN 44 is effective July 1, 2000, but covers certain events that occur either after December 15, 1998 or January 12, 2000. The Company has

applied the interpretations set forth in FIN 44 for the recognition of certain stock based compensation during the year ended December 31,

#### 3. SHORT-TERM INVESTMENTS

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

	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
	\$36,828,000	\$ 180,000	\$37,008,000
	======	======	=======

	AMORTIZED COST	ESTIMATED FAIR VALUE
Corporate notes and bonds:		
with maturity of less than 1 year	\$17,594,000	\$17,639,000
Agency securities:		
with maturity of less than 1 year	5,639,000	5,677,000
with maturity of 1 to 2 years	12,101,000	12,196,000
Treasury note:		
with maturity of less than 1 year	1,494,000	1,496,000
	\$36,828,000	\$37,008,000

As of December 31, 1999, investments consisted of a corporate note which was classified as held to maturity with the amortized cost and estimated fair value approximately equal with a value of \$110,000. The investment was due within one year.

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

#### 4. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

INVENTORIES

	DECEMBER 31,		
	2000	1999	
Raw Materials Finished goods	\$ 706,000 1,572,000	\$ 97,000 1,038,000	
	\$ 2,278,000 ======	\$ 1,135,000 ======	

PROPERTY AND EQUIPMENT, NET

	DECEMBER 31,		
	2000	1999	
Office and computer equipment Manufacturing and development equipment	\$ 845,000 2,684,000	\$ 356,000 874,000	
Leasehold improvements	916,000	423,000	
Less accumulated depreciation and amortization	4,445,000 (754,000)	1,653,000 (335,000)	
	\$ 3,691,000 ======	\$ 1,318,000 ======	

ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	DECE	MBER 31,
	2000	1999
Accounts payable Accrued expenses Accrued vacation	\$ 784,000 459,000 121,000	\$ 334,000 251,000 55,000
	\$ 1,364,000 =======	\$ 640,000 ======

#### . COMMITMENTS

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

YEAR ENDING DECEMBER 31,	CAPITAL LEASES	OPERATING LEASES
2001 2002 2003 2004 2005 Thereafter	\$ 164,000 152,000 116,000 37,000	\$ 322,000 341,000 57,000 - -
Total minimum lease payments Less amounts representing interest	469,000 (99,000)	\$ 720,000 ======
Present value of minimum capital lease obligations Less current portion	370,000 (115,000)	
Long term portion of capital lease obligations	\$ 255,000 ======	

Equipment acquired under capital leases included in property and equipment amount to \$588,000 (\$446,000 net of accumulated depreciation and amortization) as of December 31, 2000. The Company's capital lease obligations mature at various dates through 2004 with interest rates ranging from 12.42% to 30.46%.

Rent expense for the years ended December 31, 2000, 1999 and 1998 was \$369,000, \$210,000 and \$102,000, respectively.

The Company has entered into a long-term supply agreement with B.I. Chemical. The Company has agreed to purchase at least 50 kilograms of the product 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.

#### S. SHORT-TERM DEBT

In 1998, the Company executed two bridge notes with a 10% annual interest rate with certain stockholders in the amount of \$174,000. The principal and accrued interest was paid during 1999. In conjunction with the bridge notes, warrants to purchase 19,333 shares of Series C preferred stock were issued. The fair value of the warrants was calculated using the minimum value method and was determined to be diminimis.

In 1999, the Company executed a bridge note with a 10% annual interest rate with a stockholder in the amount of \$51,000. The principal and accrued interest was paid during 1999. In conjunction with the bridge note, warrants to purchase 5,667 shares of Series C preferred stock were issued. The fair value of the warrants was calculated using the minimum value method and was determined to be di minimis.

In 1999, the Company had available up to \$100,000 under an irrevocable letter of credit agreement with a bank. Interest was payable monthly at the bank's prime rate plus 0.5% with a maturity date of December 15, 1999. The agreement was collateralized by a certificate of deposit held at the bank in the amount of \$100,000. At December 31, 1999, the Company had \$100,000

#### INCOME TAXES

7.

Due to the Company's net loss position for the years ended December 31, 2000, 1999 and 1998 and as the Company has recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded.

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

		YEAR ENDED DECEMBER 31,	
	2000	1999	1998
Tax provision (benefit) at			
statutory rate	-34.00%	-34.00%	-34.00%
State tax, net of federal tax			
benefit	-3.00%	-5.95%	-6.89%
Stock based compensation		3.43%	0.50%
Research credits and other credits	-5.44%	-0.68%	-2.42%
Other permanent differences	0.14%	0.66%	-0.85%
Change in valuation allowance	42.30%	36.54%	43.66%
·			
	0.00%	0.00%	0.00%

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

	DECEMBER 31,		
	2000	1999	1998
DEFERRED TAX ASSET			
Accrued expenses	\$ 42,000	\$ 22,000	\$ 15,000
Accounts receivable	30,000	72,000	-
Deferred expenses	136,000	188,000	241,000
Deferred revenue	480,000	-	-
Property and equipment	(173,000)	(41,000)	(6,000)
Stock based compensation	2,376,000	89,000	21,000
Net operating loss			
carryforwards	3,051,000	2,247,000	725,000
Research credits	310,000	143,000	94,000
California manufacturer's			
credits	160,000	36,000	18,000
	6,412,000	2,756,000	1,108,000
Less valuation allowance	(6,412,000)	(2,756,000)	(1,108,000)
Net deferred tax asset	\$ -	\$ -	\$ -
	=======	========	=======

The Company has established a valuation allowance against its deferred tax assets 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, 2000, the Company had federal net operating loss carryforwards of approximately \$7,789,000, and state net operating loss carryforwards of approximately \$6,710,000, which may be available to offset future taxable income for tax purposes. The federal net operating loss carryforwards begin to expire, if unused, in 2012. The state net operating loss carryforwards begin to expire in 2005.

At December 31, 2000, the Company also had a research tax credit carryforward of approximately \$170,000 for federal tax purposes and \$141,000 for state tax purposes. The federal carryforward will begin expiring, if unused, in 2012. The Company also has a California manufacturer's credit carryforward of approximately \$160,000 at December 31, 2000, which will begin to expire, if unused, in 2007.

The Internal Revenue Code (the "Code") limits the availability of net operating losses and certain tax credits that arose prior to certain cumulative changes in a corporation's ownership resulting in a change of control of the Company. Due to an ownership change during 1997 and 2000, as defined in IRC Section 382, a portion of the net operating losses is limited in their annual utilization.

#### 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 2000 and 1999.

#### 9. EOUITY

#### 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 preferred stock into 45,951 shares of Common Stock. In August 2000, all outstanding shares of Series A, Series B, Series C and Series 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 currently has authorized 5,000,000 shares of preferred stock, with no shares outstanding. 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.

Ouring 1997, the Company adopted a 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 ISO's 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.

#### YEAR ENDED DECEMBER 31,

	2000	9	199	9	199	98
	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISED PRICE
Options outstanding at beginning of period	2,151,000	\$0.19	1,035,000	\$0.11	485,000	\$ 0.05
Granted Exercised Forfeited	1,577,000 (784,000) (194,000)	\$5.92 \$0.20 \$0.65	1,306,000 (190,000) -	\$0.25 \$0.07 -	550,000 - - 	\$ 0.15 - -
Options outstanding at end of period	2,750,000 ======	\$3.44	2,151,000 ======	\$0.19	1,035,000 ======	\$ 0.11
Options vested at end of period	840,000 ======	\$1.41	499,000 ======	\$0.13	349,000 ======	\$ 0.09

The following table summarizes information about options outstanding under the 1997 Plan as of December 31, 2000:

		WEIGHTED AVERAGE REMAINING	
EXERCISE	OPTIONS	CONTRACTUAL LIFE	OPTIONS
PRICES	OUTSTANDING	(IN YEARS)	VESTED
\$ 0.05 - \$ 0.45	1,182,000	7.9	480,000
\$ 1.90 - \$ 3.00	1,075,000	9.1	355,000
\$ 10.56 - \$12.00	425,000	9.6	5,000
\$ 13.88 - \$15.14	57,000	9.8	· -
\$ 16.30 - \$17.26	11,000	9.7	-
	2,750,000		840,000
	=======================================		

The weighted-average grant date fair value (minimum value for the periods prior to the initial public offering) per share of options granted under the 1997 Plan for the years ended 2000, 1999 and 1998 was \$6.40, \$1.42 and \$0.55, respectively.

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

#### EMPLOYEE STOCK-BASED COMPENSATION

Employee stock-based compensation is recognized using the intrinsic value method. In connection with the grant of stock options to employees and directors, the Company recorded unearned stock-based compensation within stockholders' equity of \$4,980,000, \$1,480,000 and \$247,000 during the years ended December 31, 2000, 1999 and 1998, 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 \$3,171,000, \$411,000 and \$31,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

In January 2000, employee stock options previously granted to MacroPore's sales force were modified upon the termination of those employees. The modification extended the expiration date of the options to ten years, upon termination of employment. As the services related to these options were deemed completed, approximately \$1,775,000 of unearned compensation was recognized in conjunction with the modification.

The remaining unearned stock-based compensation of \$3,094,000 at December 31, 2000 will be amortized as follows: \$1,020,000 in 2001, \$989,000 in 2002, \$860,000 in 2003 and \$225,000 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.

#### PRO FORMA COMPENSATION

The Company has computed the value of all options granted to employees using a fair value method. Under this method, the Company used the risk-free interest rate at the date of grant, expected volatility, expected dividend yield and the expected life of the options to determine the fair value of options granted. The risk-free interest rates ranged from 4.65% to 6.71%, expected volatility was assumed to be 60%, expected dividend yield of 0%, and the expected life of the options was assumed to be 4 years.

The following pro forma information is determined as if the Company had accounted for its employee stock options using the fair value methodology.

	DI	ECEMBER 31,	
	2000	1999	1998
Net loss: As reported Pro forma	\$(8,645,000) (9,456,000)	\$ (4,571,000) (4,962,000)	\$(2,090,000) (2,125,000)
Loss per common share: As reported Pro forma	\$ (1.05) (1.15)	\$ (1.32) (1.43)	\$ (0.64) (0.65)

For purposes of pro forma disclosures, the estimated fair value of options is amortized to expense over the options' vesting period. The pro forma compensation expense may not be representative of such expense in future years.

#### NON-EMPLOYEE STOCK-BASED COMPENSATION

The Company issued 298,000, 226,000 and 35,000 stock options to non-employees for consulting services for the years ended December 31, 2000, 1999 and 1998, respectively. As a result, the Company recorded stock-based compensation expense of \$2,545,000, \$255,000 and \$45,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

The weighted-average grant-date fair value per share of stock options issued to non-employees for the years ended December 31, 2000, 1999 and 1998 was \$9.42, \$1.49 and \$0.55, 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, 2000, 1999 and 1998: expected dividend yield of 0.0%, risk-free interest rate ranging from 5.33% to 6.52%, expected volatility ranging from 60% to 100% and expected life of 2 years.

#### WARRANTS

The Company, in connection with the convertible bridge loan financing in 1998 and 1999, issued warrants to purchase 25,000 shares of Series C convertible preferred stock with an exercise price of \$2.25 per share. All of the warrants are exercisable, and begin to expire in September 2008. As of December 31, 2000, 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.

The Company, in connection with a termination of a sales distribution agreement in 2000, 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.

#### 10. RELATED PARTY TRANSACTIONS

Included in research and development expenses are consulting fees, manufacturing and out-of-pocket expenses paid to various stockholders and employees. These expenses amounted to \$19,000, \$151,000 and \$146,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

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 other 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. For the year ended December 31, 2000, the Company had sales to the distributor of \$6,092,000 which represented 97% of total revenue. At December 31, 2000, the Company had amounts due from the distributor of \$693,000. The terms of the sale of the Series D preferred stock were equivalent to the terms and price paid by unaffiliated third parties who also purchased shares of Series D preferred stock.

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.

#### 11. 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. The quarterly information is restated due to an adjustment of approximately \$1.8 million to stock based compensation for certain employee stock options

accelerated in January 2000. The effects of this adjustment are reflected in all appropriate quarters.  $\,$ 

	FIRST	SECOND	THIRD	FOURTH
	QUARTER	QUARTER	QUARTER	QUARTER
YEAR 2000				
Revenues	\$1,259,000	\$ 2,206,000	\$ 1,114,000	\$ 1,672,000
Gross profit	664,000	1,673,000	766,000	772,000
Operating expenses, excluding				
stock based compensation	1,339,000	1,702,000	2,076,000	2,651,000
Stock based compensation	2,428,000	1,431,000	1,745,000	112,000
Other income	62,000	84,000	81,000	737,000
Net loss	(3,041,000)	(1,376,000)	(2,974,000)	(1,254,000)
Basis and diluted net loss per	\$ (0.82)	\$ (0.36)	\$ (0.50)	\$ (0.15)
share	=======================================	==========	==========	=========
YEAR 1999				
Revenues	\$ 54,000	\$ 243,000	\$ 601,000	\$ 615,000
Gross profit	38,000	165,000	410,000	419,000
Operating expenses, excluding				
stock based compensation	594,000	1,502,000	1,338,000	1,407,000
Stock based compensation	61,000	169,000	237,000	199,000
Other expenses	(58,000)	(25,000)	(9,000)	(4,000)
Net loss	(675,000)	(1,531,000)	(1,174,000)	(1,191,000)
Basis and diluted net loss per	\$ (0.21)	\$ (0.46)	\$ (0.35)	\$ (0.34)
share	==========	=========	=======================================	=========

ITEM 14. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

On December 12, 2000, PricewaterhouseCoopers LLP ("PWC") resigned as independent accountants for the Company.

PWC's report on the Company's financial statements for the fiscal years ended December 31, 1998 and 1999 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

In connection with PWC's audit of the Company's fiscal years ended December 31, 1998 and 1999 and through December 12, 2000, there were no disagreements with PWC on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to PWC's satisfaction, would have caused PWC to make reference to the subject matter of the disagreement(s) in connection with PWC's report.

During the Company's fiscal years ended December 31, 1998 and 1999 and through December 12, 2000, there were no reportable events (as defined in Item 304(a)(1)(v) of Regulation S-K).

The Company engaged Arthur Andersen, LLP as its independent accountants on December 15, 2000. The Company's Audit Committee participated in and approved the decision to engage Arthur Andersen.

The Company has provided PWC with a copy of the disclosures contained in Item 14 of this registration statement and has requested that PWC furnish to the Company a letter addressed to the SEC stating whether or not it agrees with the statements made therein.

ITEM 15. FINANCIAL STATEMENTS AND EXHIBITS.

#### INDEX TO FINANCIAL STATEMENTS

See the Index to the Company's financial statements included in Item  ${\tt 13}$  of this registration statement.

#### **EXHIBITS**

EXHIBIT NO.	DESCRIPTION OF EXHIBITS
* 3.1	Amended and Restated Certificate of Incorporation of MacroPore, Inc. (the "Company")
* 3.2	Bylaws of the Company
*10.1	Amended and Restated Stock Option and Stock Repurchase Plan
10.2+	Distribution Agreement, made and entered into as of January 5, 2000, between the Company and Medtronic, Inc. ("Medtronic")
10.3+	Amendment No. 1 to Distribution Agreement, effective as of December 22, 2000, by and between the Company and Medtronic
10.4+	Development and Supply Agreement, made and entered into as of January 5, 2000, by and between the Company and Medtronic
10.5+	Amendment No. 1 to Development and Supply Agreement, effective as of December 22, 2000, by and between the Company and Medtronic
16.1	Letter from PricewaterhouseCoopers LLP re: change in certifying accountant

<sup>\*</sup> Previously filed.

 $<sup>\</sup>mbox{+}$  Portions of these exhibits have been omitted pursuant to a request for confidential treatment.

#### SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the Company has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on June 1, 2001.

MACROPORE, INC.

By: /S/ CHRISTOPHER J. CALHOUN

Christopher J. Calhoun VICE-CHAIRMAN, CHIEF EXECUTIVE OFFICER AND SECRETARY

#### DISTRIBUTION AGREEMENT

THIS DISTRIBUTION AGREEMENT (the "AGREEMENT") is made and entered into as of January 5, 2000 (the "EFFECTIVE DATE"), between MACROPORE, INC. ("MACROPORE"), a Delaware corporation, and MEDTRONIC, INC. (as defined below, "MEDTRONIC"), a Minnesota corporation.

#### WITNESSETH:

WHEREAS, MacroPore has developed bioabsorbable surgical implants for use in, among other areas, bone fixation and reconstruction in the craniofacial skeleton; and

WHEREAS, MacroPore and Medtronic's Affiliate, Medtronic Asset Management, Inc. ("MAMI"), intend to enter into a Series D Preferred Stock Purchase Agreement (the "INVESTMENT AGREEMENT") pursuant to which MAMI will purchase Series D Preferred Stock of MacroPore and receive various rights; and

WHEREAS, it is a condition to MAMI's willingness to purchase such MacroPore Series D Preferred Stock that the parties enter into this Agreement.

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

### ARTICLE 1 DEFINITIONS

1.1 SPECIFIC DEFINITIONS. As used in this Agreement, the following terms shall have the meanings set forth or as referenced below:

"AFFILIATE" of a specified person (natural or juridical) means a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. "CONTROL" shall mean ownership of more than 50% of the shares of stock entitled to vote for the election of directors in the case of a corporation, and more than 50% of the voting power in the case of a business entity other than a corporation.

"AGREEMENT" means this Agreement and all Exhibits and Schedules hereto.

"CONFIDENTIAL INFORMATION" means know-how, trade secrets, and unpublished information disclosed (whether before or during the term of this Agreement) by one of the parties (the "disclosing party") to the other party or such other party's designee pursuant to Section 13.5 (the "receiving party"), and which is marked as proprietary or confidential as provided below, excluding information that:

 (a) was already in the possession of receiving party prior to its receipt from the disclosing party (provided that the receiving party is able to provide the disclosing party with reasonable documentary proof thereof);

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

- (b) is or becomes part of the public domain by reason of acts not attributable to the receiving party;
- (c) is or becomes available to receiving party from a source other than the disclosing party which source, to the best of receiving party's knowledge, has rightfully obtained such information and has no obligation of nondisclosure or confidentiality to the disclosing party with respect thereto;
- (d) is made available by the disclosing party to a third party unaffiliated with the disclosing party on an unrestricted basis;
- (e) is independently developed by the receiving party completely without reference to any Confidential Information of the disclosing party, as evidenced by the receiving party's written records; or
- (f) has been or must be publicly disclosed by reason of legal, accounting or regulatory requirements beyond the reasonable control, and despite the reasonable efforts, of the receiving party.

All Confidential Information disclosed by one party to the other under this Agreement shall be in writing and bear a legend "Proprietary," "Confidential" or words of similar import or, if disclosed in any manner other than writing, shall be followed by confirmation that such information is confidential by the disclosing party within 30 days.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain merely because the aspects or details of the Confidential Information is embraced by general disclosures in the public domain. In addition, any combination of Confidential Information shall not be considered in the public domain or in the prior possession of the receiving party merely because individual elements thereof are in the public domain or in the prior possession of the receiving party unless the combination and its principles are in the public domain or in the prior possession of the receiving party.

"CRANIAL FIELD" means the reconstruction or fixation of the cranial or facial skeleton, including but not limited to cranial, cranial-facial, mid-facial and mandibular applications.

"EXISTING DISTRIBUTION AGREEMENT" means: the Exclusive Sales Distribution Agreement dated as of July 15, 1999, by and between MacroPore, Inc. and Normed GmbH; the Exclusive Sales Agency Agreement dated as of July 15, 1999, by and between MacroPore, Inc. and Medsource; and the Exclusive Sales Distribution Agreement dated as of October 15, 1999, by and between MacroPore, Inc. and Surgical Science Systems.

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

"FAILURE OF SUPPLY" means (i) MacroPore's failure, for any reason other than Force Majeure, to deliver any Product ordered in accordance with the provisions of Article 5 by the date scheduled for delivery thereof, including but not limited to a failure to deliver Product which conforms to the Specifications therefor, which failure is not cured within one month after MacroPore is notified of such failure, or (ii) MacroPore's failure due to Force Majeure to deliver any Product

ordered in accordance with the provisions of Article 5 by the date scheduled for delivery thereof, including but not limited to a failure to deliver Product which conforms to the Specifications therefor, which failure is not cured within three months after MacroPore is notified of such failure.

"FORCE MAJEURE" means any event or condition, not existing as of the date of this Agreement, not reasonably foreseeable as of such date and not reasonably within the control of either party, which prevents in whole or in material part the performance by one of the parties of its obligations hereunder, such as an act of government, war or related actions, civil insurrection, riot, sabotage, strike, epidemic, fire, flood, windstorm, and similar events.

"FOREIGN DEVICE REGULATORY AUTHORITIES" means foreign regulatory authorities, the function and purpose of which include regulating the design, manufacture, quality and/or sale of medical devices.

"INTELLECTUAL PROPERTY" means letters patent and patent applications; trademarks, service marks and registrations thereof and applications therefor; copyrights and copyright registrations and applications; mask works and registrations thereof; all inventions, discoveries, ideas, technology, know-how, trade secrets, data, information, processes, formulas, drawings and designs, licenses, computer programs and software; and all amendments, modifications, and improvements to any of the foregoing.

"KNOWLEDGE" means actual knowledge of a fact or the knowledge that such person could reasonably be expected to have based on reasonable inquiry. The "knowledge" of an entity shall include the knowledge of such entity's employees.

"LICENSED INTELLECTUAL PROPERTY" means, with respect to a Failure of Supply of a particular Product, all Intellectual Property used by MacroPore in connection with the manufacture or sale of such Product at the time of such Failure of Supply.

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

"MEDTRONIC" means Medtronic, Inc. and its Affiliates.

"NET SALES" of Products for purposes of Article 13 with respect to a particular period means the amounts that Medtronic or any Affiliate of Medtronic receives from third parties (eliminating transactions among Affiliates of Medtronic and/or Medtronic) for net sales of Products during such period, excluding sales, use or excise tax, freight, duty or insurance included therein, returns, discounts and allowances, credits or repayments due to rejections, defects or returns, provided that if Medtronic or any Affiliate of Medtronic sells at a single price or rate a packaged combination of products, not all of which if sold individually would be Products, then "Net Sales" with respect to such sales of packaged products shall equal the number of units of Products sold as part of such packaged products (less rejections, defects and returns) multiplied by either (i) the respective average net selling price during such period of the same type of Product sold individually, or (ii) the average net selling price during such period for a comparable product (if the same type of Product is not sold individually), in either case excluding sales, use or excise tax, freight, duty or insurance included therein.

"NON-CRANIAL FIELD" means uses outside of the Cranial Field.

"PRODUCTS" means all products, devices, systems and instruments now or hereafter during the Term (as defined in Section 12.1) of this Agreement developed, manufactured, produced or sold by MacroPore that may be used in the Cranial Field, including but not limited to MacroPore's MacroSorb(TM) product line, including all components thereof and accessories thereto, and any modifications, improvements, substitutions and future generations of such products made by or under the authority of MacroPore during the Term.

"PRODUCT LIABILITY DAMAGES" means any liability, claim or expense, including but not limited to reasonable attorneys' fees and medical expenses, arising in whole or in part out of claims of third parties for personal injury or loss of or damage to property relating to or arising out of the Products, whether based on strict liability in tort, negligent manufacture of product, or any other allegation of liability arising directly from the design, testing, manufacture, packaging, labeling (including instructions for use), or sale of the Products.

"SPECIFICATIONS" means MacroPore's current specifications for the Products, as the same may be amended from time to time by MacroPore in compliance with this Agreement.

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

#### 1.3 DEFINITIONAL PROVISIONS.

- (a) The words "hereof," "herein," and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provisions of this Agreement.
- (c) References to an "Exhibit" or to a "Schedule" are, unless otherwise specified, to one of the Exhibits or Schedules attached to or referenced in this Agreement, and references to an "Article" or a "Section" are, unless otherwise specified, to one of the Articles or Sections of this Agreement.
- (d) The term "person" includes any individual, partnership, joint venture, corporation, trust, unincorporated organization or government or any department or agency thereof.
- (e) The term "dollars" or " $\$  shall refer to the currency of the United States of America.
- (f) All references to time shall refer to Minneapolis, Minnesota time.

### ARTICLE 2 APPOINTMENT; ADDITIONAL RIGHTS OF FIRST OFFER

- 2.1 SCOPE. Subject to the terms and conditions of this Agreement, MacroPore hereby appoints Medtronic, and Medtronic hereby accepts appointment, as MacroPore's exclusive worldwide distributor during the Term with the right to sell and distribute Products solely for use in the Cranial Field. Except as provided in Section 2.5, Medtronic shall not have any right to distribute Products for use outside the Cranial Field.
- 2.2 PAYMENT FOR DISTRIBUTION RIGHTS. In consideration of Medtronic's rights hereunder, Medtronic shall, within two business days after the date hereof, pay MacroPore the sum of One Million Five Hundred Thousand Dollars (\$1,500,000).

#### 2.3 EXCLUSIVITY.

- (a) Medtronic's distribution rights under this Agreement shall be exclusive throughout the United States and, except for the Existing Distribution Agreements throughout the world. MacroPore represents and warrants to Medtronic that, except for the Existing Distribution Agreements, MacroPore has not entered into any other distributorship agreements or sales representative agreements, written or oral, with any third party permitting the sale of Products for use in the Cranial Field, and, to the extent it has entered into such agreements in the past, that all such agreements have been terminated without liability to MacroPore or Medtronic. MacroPore covenants and agrees that during the Term, MacroPore will not enter into any such agreement or itself sell or distribute any Products for use in the Cranial Field. MacroPore will use its reasonable best efforts to negotiate the termination of the Existing Distribution Agreements or, if such termination is not commercially feasible, to convert such existing distributors to sub-distributors of Medtronic.
- (b) Except as set forth in Article 13, during the term of this Agreement, Medtronic shall not purchase or resell any poly-lactic acid implantable reconstruction or fixation products for use in the Cranial Field (excluding however, applications in the nose, sinus or ears) except those purchased from MacroPore hereunder.
- 2.4 SUBDISTRIBUTORS. Medtronic may appoint subdistributors for the sale or distribution of Products for use in the Cranial Field; provided that Medtronic gives MacroPore written notice of the identity of such subdistributors, and uses commercially reasonable efforts to ensure that such subdistributors comply with the applicable provisions of this Agreement. Notwithstanding such appointment of subdistributors, Medtronic shall remain fully responsible for the performance of all of its covenants and obligations hereunder, and any shipments by MacroPore to such Medtronic subdistributors shall be billed by MacroPore to Medtronic directly. Medtronic shall indemnify and hold MacroPore harmless from and against any claim, loss, damage or expense (including reasonable attorneys' fees) suffered or incurred by MacroPore relating to any claim in connection with this Agreement that is threatened or initiated by any subdistributor or sub-agent appointed by Medtronic, except for claims for which Medtronic is entitled to indemnification from MacroPore under Section 11.1.

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- (a) MacroPore shall not enter into any definitive agreement with respect to the grant by MacroPore of distribution or sales representative rights with respect to any MacroPore products, devices, systems and instruments now or hereafter during the Term developed, manufactured, produced or sold by MacroPore (such proposed grant of such rights referred to as a "PROPOSED TRANSACTION") unless Medtronic is given MacroPore's Notice (as defined below) with respect thereto and MacroPore complies with the terms of this Section 2.5.
- (b) If (i) MacroPore receives a bona fide offer or written indication of interest from a third party to enter into a Proposed Transaction which MacroPore is willing to accept, or (ii) MacroPore determines to seek a third party to enter into a Proposed Transaction, then, in either such event MacroPore shall, within ten (10) days after such event, notify Medtronic in writing of MacroPore's receipt of such offer or indication of interest described in (i) above or of MacroPore's determination described in (ii) above ("MACROPORE'S NOTICE"). MacroPore's Notice shall include a copy of such offer or indication of interest and any other terms of such Proposed Transaction proposed by such third party, in the case of (i) above, or all material terms and provisions upon which MacroPore proposes to seek a third party to enter into a Proposed Transaction, in the case of (ii) above. For a period of 45 days following Medtronic's receipt of MacroPore's Notice with respect to such Proposed Transaction (referred to in this Section 2.5 as the "EXCLUSIVE PERIOD"), Medtronic shall have the exclusive right to negotiate with MacroPore regarding the material terms of such Proposed Transaction and, with respect to a Proposed Transaction initiated by MacroPore pursuant to (ii) above, the irrevocable right and option to enter into the Proposed Transaction on the terms and provisions specified in MacroPore's Notice. In the event Medtronic proposes, in the course of negotiation with MacroPore during the Exclusive Period, terms and provisions more favorable to MacroPore than those contained in Medtronic's initial proposal to MacroPore, then Medtronic shall memorialize such revised proposed terms and provisions in writing prior to the end of the Exclusive Period.
- (c) During the Exclusive Period, MacroPore shall negotiate in good faith exclusively with Medtronic regarding the material terms of such Proposed Transaction or any comparable transaction. During the Exclusive Period, MacroPore shall not solicit offers from, negotiate with, or provide information to any third party regarding the Proposed Transaction or any comparable transaction. Nothing in this section shall prohibit MacroPore from consulting with or providing information to its attorneys, accountants, investment bankers or other consultants or advisors.
- (d) If during the Exclusive Period MacroPore and Medtronic fail to reach agreement in principal upon the material terms for such Proposed Transaction and, in the event of a Proposed Transaction initiated by MacroPore pursuant to (b)(ii) above, Medtronic fails to exercise its option to enter into such Proposed Transaction, then MacroPore shall have 120 days after the expiration of the Exclusive Period in which to complete such Proposed Transaction with the third party whose bona fide offer or indication of interest was described in MacroPore's Notice (with respect to a Proposed

Transaction described in (b)(i) above) or with any third party (with respect to a Proposed Transaction described in (b)(ii) above); provided that MacroPore may not complete such Proposed Transaction unless the terms and provisions thereof are, in the aggregate, (with respect to a Proposed Transaction described in (b)(i) above) more favorable to MacroPore (as reasonably and in good faith determined by MacroPore's Board of Directors) than the terms and provisions most favorable to MacroPore that were proposed by Medtronic in its negotiations with MacroPore, or (with respect to a Proposed Transaction described in (b)(ii) above) at least as favorable to MacroPore as the terms and provisions specified in MacroPore's Notice. If MacroPore fails to complete such particular Proposed Transaction within such 120-day period, then Medtronic's rights under this Section 2.5 shall be reinstated and MacroPore may not enter into such Proposed Transaction without first giving Medtronic a new MacroPore's Notice and complying with the terms of this Section 2.5.

2.6 RESERVATION OF RIGHTS. Except as expressly provided herein, no right, title, or interest is granted, whether express or implied by MacroPore to Medtronic, and nothing in this Agreement shall be deemed to grant to Medtronic rights in any products or technology other than the Products.

## ARTICLE 3 GENERAL OBLIGATIONS OF MEDTRONIC

- 3.1 MARKETING AND DISTRIBUTION. Medtronic shall use reasonable best efforts to further the promotion, marketing, sale and/or other distribution of Products for use in the Cranial Field. Without limiting the generality of the foregoing, Medtronic shall maintain adequate sales channels to market and distribute the Products for use in the Cranial Field.
- 3.2 QUALITY CONTROL. Medtronic agrees to follow reasonable quality control standards with respect to the storage, preservation, sale and use of the Products purchased under this Agreement. Medtronic shall make no representations or warranties concerning such Products other than as made to Medtronic by MacroPore or as otherwise may be agreed by the parties.
- 3.3 SALES AND SERVICE; TRAINING. Medtronic shall be solely responsible for marketing and selling all Products for use in the Cranial Field.
- 3.4 INVENTORY. Medtronic shall use commercially reasonable efforts to maintain sufficient quantities of each Product as reasonably necessary to meet the demand of customers for the Products in the Cranial Field.
- 3.5 MARKETING MATERIALS. Subject to Section 4.4, Medtronic shall be responsible for the preparation of sales and marketing materials for the marketing and sale of Products for use within the Cranial Field, including the translation, adaptation and/or modification of MacroPore's sales and marketing materials, as deemed appropriate by Medtronic, to reflect the culture or business practices and languages of the particular regions and to reflect Medtronic as the exclusive distributor of the Products for use in the Cranial Field. Medtronic shall provide to MacroPore for purposes of review and approval (such approval not to be unreasonably withheld

or delayed) all such sales and marketing materials relating to Products at least ten (10) days prior to the commercial release of such materials.

3.6 RECORDS AND RECALL. Medtronic shall maintain complete and accurate records of all Products sold by Medtronic and its subdistributors in sufficient detail to enable MacroPore to conduct an effective recall of Products if MacroPore determines that such a recall is required or otherwise necessary or appropriate. Medtronic shall not initiate a recall of Products without MacroPore's prior written consent, which consent shall not be unreasonably withheld. In the event of a recall of any of the Products, Medtronic will cooperate with and assist MacroPore in effecting such recall, including promptly contacting any purchasers that MacroPore reasonably desires to be contacted and promptly communicating to such purchasers the information or instructions MacroPore reasonably desires to be transmitted relating to such recall, all of which customer contact and communication shall be conducted by Medtronic at its own expense. Notwithstanding the foregoing, MacroPore shall pay, or reimburse Medtronic, for all other costs of effecting such recall, including any shipping costs related to returning recalled Products to MacroPore and replacing such recalled Products with new Products at MacroPore's expense.

In addition, upon MacroPore's request, Medtronic shall provide MacroPore with access to Medtronic's records of sales of Products in the event of Product recall or other quality related issue. During the Term of this Agreement, Medtronic also shall promptly forward all Product complaints which it receives to MacroPore. Medtronic shall make available to MacroPore for inspection Medtronic's process and records for adverse events and other regulatory reporting purposes at mutually agreed upon time and further shall ensure that Medtronic's processes comply with all applicable laws and regulations.

- 3.7 IMPORT APPROVALS. Except for (i) the CE Mark, which MacroPore shall be responsible for obtaining, and (ii) existing import licenses, which MacroPore shall assign or transfer to Medtronic, Medtronic shall be responsible for obtaining all import licenses and permits as may be required to import the Products into countries as selected by Medtronic in accordance with then prevailing laws and regulations of such countries. All such filings and registrations of the Products shall be owned by Medtronic and shall be obtained and maintained in the name of Medtronic, whenever feasible in accordance with prevailing laws and regulations. MacroPore shall cooperate fully with Medtronic in its efforts to obtain any such approvals.
- 3.8 EUROPEAN AUTHORIZED REPRESENTATIVE. Medtronic agrees to act as MacroPore's European Authorized Representative as required by the Medical Device Directive and as MacroPore's representative for Products for use within the Cranial Field in the countries outside the European Common Market. Medtronic shall, as soon as reasonably practicable, notify, document and forward to MacroPore or MacroPore's authorized representative all customer complaints received by Medtronic such that MacroPore can comply with Medical Device Reporting (MDR) regulations and vigilance. Medtronic shall notify Competent Authorities of clinical investigations as required, and shall represent MacroPore if a Competent Authority decides to: (i) refuse to allow the marketing of a Product in the Cranial Field, (ii) restrict the marketing of Product in the Cranial Field, or (iii) withdraw a Product from the market in the Cranial Field. Medtronic agrees to provide the competent authorities and notified bodies with access to the table of contents for the Technical File. In addition, Medtronic shall authorize

MacroPore to list Medtronic as the Authorized European Representative on product labeling, outer packaging, and instructions for use.

## ARTICLE 4 GENERAL OBLIGATIONS OF MACROPORE

4.1 MANUFACTURE AND SUPPLY OF PRODUCTS. MacroPore shall use commercially reasonable efforts to manufacture, or have manufactured, Products in accordance with the Specifications and to ship such Products to Medtronic in the quantities ordered by Medtronic pursuant to Article 5 of this Agreement. MacroPore shall be responsible for packaging in accordance with packaging specifications to be mutually agreed upon by Medtronic and MacroPore, and for any necessary sterilization of Products purchased under this Agreement in accordance with the Specifications.

#### 4.2 REGULATORY APPROVALS.

- (a) CLINICALS. MacroPore shall be responsible for all clinical study design, investigator selection, data analysis in connection with clinical trials of the Products. Medtronic shall assist MacroPore in such clinical study activities such as investigator selection, and such other clinical matters as the parties may agree.
- (b) DEVICE APPROVALS. MacroPore shall be responsible, on a timely basis and at its expense, for filing, obtaining and maintaining regulatory approvals in the Territory. To the extent permitted by law, all foreign regulatory approvals, including those processed by Medtronic, shall be owned by MacroPore and shall be in the name of MacroPore. Except as otherwise required by law or agreed by the parties, MacroPore will be responsible for the content of its own labeling. In connection with obtaining Device Approvals, MacroPore shall bear the expenses of meeting any applicable Product design and manufacturing facility requirements applicable to its then current manufacturing facility, and shall take all steps as are necessary to meet the EMD Directive.
- (c) EXPORT. MacroPore shall be responsible for obtaining all export licenses and permits as may be required to export the Products from the country of manufacture into the particular countries where such Products are delivered. Medtronic shall cooperate fully with MacroPore in its efforts to obtain any such approvals.
- (d) GOOD MANUFACTURING PRACTICES/QUALITY SYSTEMS REGULATIONS. MacroPore shall be responsible for compliance with present and future applicable statutes, laws, ordinances and regulations of national, federal, state and local governments now or hereafter in effect relating to the design, manufacture and/or quality of Products. Without limitation of the foregoing, MacroPore represents and warrants to Medtronic that all Products sold and delivered to Medtronic under this Agreement will have been designed, manufactured and labeled in accordance with all applicable requirements. MacroPore shall cause Medtronic's regulatory personnel to be provided with reasonable access from time to time to the facilities and records of MacroPore for the purpose of confirming MacroPore's compliance with this Section 4.2(d).

- 4.3 TRAINING. MacroPore at its expense will provide Medtronic with surgical procedure manuals and a reasonable level of sales and technical training for Medtronic's dedicated sales personnel for Products and other appropriate Medtronic personnel. If requested by Medtronic, MacroPore at its expense will also provide training for up to fifty (50) physicians per annum.
- 4.4 PRODUCT LITERATURE AND PACKAGING. MacroPore will work jointly with Medtronic in the preparation of mutually acceptable Product packaging, labeling and operations and technical manuals for use with the Products, and will not unreasonably refuse to incorporate any changes thereto reasonably requested by Medtronic. MacroPore at its expense shall provide Medtronic from time to time as requested by Medtronic with a reasonable supply of Product sales and marketing materials in the English language. Pursuant to Section 3.5, Medtronic shall be responsible for the translation, adaptation and/or modification of MacroPore's sales and marketing materials as deemed appropriate by Medtronic, and MacroPore shall supply any artwork or other materials reasonably requested by Medtronic for use solely in connection therewith.
- $4.5\ \text{SALES}\ \text{LEADS}.$  MacroPore shall forward to Medtronic all leads for sales of Products in the Cranial Field.

### ARTICLE 5 ORDERS FOR PRODUCTS

- 5.1 PURCHASE ORDERS. Medtronic shall submit purchase orders for Products to MacroPore in writing, whether by mail, telecopier, telegram or otherwise, at the time that each forecast is delivered to MacroPore pursuant to Section 5.2. Each purchase order shall, at a minimum, set forth the product numbers, quantities (subject to Section 5.3), delivery dates, and shipping instructions and shipping addresses for all Products ordered. Each purchase order shall be subject to and governed by the terms of this Agreement. Purchase orders shall be binding upon MacroPore unless and to the extent the quantities specified therein exceed the amounts specified in the Plan. No partial shipment of an order shall constitute the acceptance of the entire order, absent the written acceptance of such entire order. The terms and conditions of this Agreement shall so govern and supersede any additional or contrary terms set forth in Medtronic's purchase order or any MacroPore or Medtronic acceptance, confirmation, invoice or other document unless duly signed by an officer of Medtronic and an officer of MacroPore and expressly stating and identifying which specific additional or contrary terms shall supersede the terms and conditions of this Agreement. Upon the execution of this Agreement, Medtronic will place a three-month purchase order for deliveries in January, February and March 2000. Subsequently, Medtronic will place orders for the next succeeding months on a monthly basis, at the time that it provides its forecast described in Section 5.2, with all such subsequent purchase orders submitted at least 60 days in advance of the earliest scheduled delivery date for such order.
- 5.2 MEDTRONIC'S FORECASTS. At the time that Medtronic places its order for the first month following the three months covered by the initial purchase order, Medtronic shall provide MacroPore with a six-month sales plan to be mutually agreed upon (but subject to Section 5.3 and Exhibit A) indicating by month the number of Products anticipated to be sold by Medtronic

or purchased by Medtronic for use as demonstration units (as updated as provided herein, the "Plan") in the Territory. The Plan shall be updated by Medtronic on a quarterly basis (on or before the first day of each subsequent quarter) for a rolling successive six-month period. Each Plan shall be used for purposes of facilitating Medtronic's marketing plans, MacroPore's manufacturing plans, and meeting the lead times required by certain of MacroPore's suppliers, but are not legally-binding on Medtronic or MacroPore in any manner.

- 5.3 ORDER LIMITATIONS. During the first 12 months of the Term, MacroPore shall maintain the ability to supply at least the "Guaranteed Supply Quantities" specified on Exhibit A hereto. Except as provided in the immediately proceeding sentence, MacroPore shall not be required to deliver quantities in excess of 100% of forecasted requirements, provided, however, that MacroPore shall use all commercially reasonable efforts to supply such excess.
- 5.4 MODIFICATION OF ORDERS. Medtronic may cancel or reschedule purchase orders for products only with MacroPore's prior written approval. Notwithstanding the foregoing, any purchase order may be cancelled by Medtronic as to any Products that are not delivered within 60 days after the delivery date requested by Medtronic pursuant to a purchase order, and any such cancellation shall not limit or affect any contract remedies available to Medtronic with respect thereto. Any such cancellation by Medtronic must be by written notice to MacroPore given within 10 business days after such 60th day.
- 5.5 DELIVERY TERMS. Subject to MacroPore's obligations in Section 4.2 above, all deliveries of Products shall be F.O.B. MacroPore's facility in California. Except as otherwise provided in Article 9 or Article 11 below, MacroPore shall have no further responsibility for risk of damage to or loss or delay of Products after their delivery at the aforesaid F.O.B point. All Product deliveries shall be made by a common carrier specified by Medtronic or, in the event that no carrier shall have been specified by Medtronic on or before the date 15 days prior to the requested shipment date, a reputable common carrier selected by MacroPore.
- 5.6 PRODUCT CHANGES. MacroPore shall not, without Medtronic's prior written consent, modify the Specifications for a Product in a manner that materially affects the performance or regulatory approval status of the Product or materially increases Medtronic's costs or expenses. Subject to the foregoing, MacroPore may modify the Specifications for the Product without the consent of Medtronic, provided that MacroPore notifies Medtronic of such modifications within 30 days. If such modifications affect the performance or applicable regulatory approvals of the Product, Medtronic shall not be obligated to purchase such altered Product.
- 5.7 CUSTOM PRODUCTS. In the event Medtronic is requested by a customer to provide customized Products, Medtronic shall provide the specifications for the customized Product to MacroPore. MacroPore will determine and provide to Medtronic the additional cost, if any, and the feasibility of providing the customized Product. Medtronic will thereafter notify MacroPore if it intends to provide such customer with the customized Product.
- 5.8 REPORTS. Medtronic shall provide MacroPore, on a quarterly basis, with reports reflecting Medtronic's sales of the Products (on a product-by-product basis).

### ARTICLE 6

- 6.1 DETERMINATION OF QUOTE. During the first 12-month period of the Term, Medtronic shall submit purchase orders to purchase at least the minimum amount set forth on Exhibit A (the "Quota"). By the end of each quarter of such initial 12-month period, Medtronic shall have submitted purchase orders for at least the cumulative percentage of the Quota set forth on Exhibit A.
- 6.2 REDUCTIONS IN QUOTA. Notwithstanding Section 6.1, the Quota for any period shall be reduced (a) in the case of subpart (i) below by an amount equal to 1.5 times the aggregate transfer price of Products not supplied by MacroPore against purchase orders issued by Medtronic in accordance with Article 5, (b) in the case of subpart (ii) below, by an amount equal to 1.5 times the aggregate transfer price of Products affected by such recall or withdrawal, and (c) in the case of subpart (iii) below, by a pro rata amount of the Quota for the applicable period based upon the number of days of such period that have transpired prior to the removal of the restriction on sale referenced in such subpart:
  - (i) If MacroPore materially and substantially fails for any reason to deliver ordered Products by the date scheduled for delivery thereof pursuant to purchase orders issued by Medtronic in accordance with Article 5, including but not limited to a failure to deliver Products that conform to the then current Specifications and such failure is not cured within 30 days;
  - (ii) If a Product covered by this Agreement is recalled from the market or withdrawn from sale for reasons of product safety or quality as determined by any applicable governmental authority or by the mutual agreement of the parties; or
  - (iii) If Medtronic is restricted in the sale of Products in a market within the European Common Market that affects the CE Mark by any applicable regulatory authority because approval to sell the Product is pending, denied or revoked therein.
- 6.3 TERMINATION OF AGREEMENT. If Medtronic does not order at least the applicable Quota, as it may be modified as provided herein, and does not elect to make the Shortfall payment described below, MacroPore shall have the right, at its option, to terminate this Agreement. Notice of MacroPore's election to terminate this Agreement (the "Termination Notice") must be given by MacroPore in writing within 30 days following the period for which Medtronic has not satisfied the Quota, specifying the amount by which Medtronic's purchases for such period were below the Quota (the "Shortfall"). If within 30 days after such Termination Notice Medtronic either (i) places orders for the purchase of sufficient quantities of Products to make up the Shortfall and agrees to pay for such Products within 10 days after shipment thereof, or (ii) Medtronic pays MacroPore cash in the amount of 75% of the Shortfall, then MacroPore's Termination Notice will be deemed to be automatically withdrawn. If Medtronic pays MacroPore cash in the amount of 75% of the Shortfall, such payment shall be treated as a prepayment for Products to be ordered by Medtronic in the future and shall be applied toward the

purchase price of such future Product purchase orders as Medtronic directs. Termination of this Agreement shall be MacroPore's sole and exclusive remedy for any failure by Medtronic to purchase the applicable Quota.

### ARTICLE 7 PRICES AND PAYMENTS

- 7.1 PRICES. Unless and until otherwise mutually agreed by the parties in writing, the purchase prices per unit of Products to Medtronic under this Agreement shall equal [\*\*\*] of MacroPore's average selling price per unit for such Product, excluding any sales, use or excise tax, freight duty or insurance included therein, during the six-month period immediately prior to the date of this Agreement (the "Transfer Price"). Separate Transfer Prices will be established for sales in the United States and for each major international market. If MacroPore's sales were inadequate for purposes of establishing such average price, then the Transfer Price shall equal [\*\*\*] of Medtronic's average selling price per unit for such Products, excluding any sales, use or excise tax, freight duty or insurance included therein, in such market during the initial twelve-month period after commencement of commercial sales of such Products in such market (the "Medtronic Pricing Period"). If the Transfer Price is to be based on the Medtronic Pricing Period, then during the Medtronic Pricing Period Medtronic shall pay MacroPore [\*\*\*] of Medtronic's published list price as the estimated Transfer Price, and within 90 days after the end of the Medtronic Pricing Period, Medtronic or MacroPore, respectively, shall pay the other party the aggregate amount by which the estimated Transfer Price for Products purchased during the Medtronic Pricing Period is less than, or more than, respectively, the actual Transfer Price. Any prices referred to in any information provided to Medtronic by MacroPore (other than the transfer Prices for Products) are recommended prices only and Medtronic has no obligation to comply with any such recommendations.
- 7.2 PAYMENT TERMS. Payments made by Medtronic for Products purchased hereunder shall be due and payable in full within 30 days after the date of invoice by MacroPore. Any payments due hereunder which are not paid on the date such payments are due shall bear interest at the lesser of one and one-half percent (1 1/2%) per month or the maximum rate permitted by law, calculated on the number of days such payment is delinquent. This Section 7.2 shall in no way limit any other remedies available to MacroPore.
- 7.3 TAXES. The transfer prices for Products established pursuant to this Article 7 do not include any sales, use, value added or similar taxes, customs, duties, or tariffs imposed by any governmental authority or agency on Products or any components thereof that are imported by Medtronic into any country (other than taxes on the net income of MacroPore), and Medtronic shall bear all such taxes and duties. MacroPore shall be required to take appropriate steps to minimize imposition of such taxes by filing sales exemption certificates and taking similar actions where applicable to the seller. When MacroPore has the legal obligation to collect and/or pay such taxes, the appropriate amount shall be added to Medtronic's invoice and paid by Medtronic, unless Medtronic provides MacroPore with a valid tax exemption certificate authorized by the appropriate taxing authority. Medtronic shall not be obligated to pay or reimburse MacroPore for taxes that are not imposed on the sale of Product to Medtronic.

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

### ARTICLE 8

- 8.1 OFFERS OF EMPLOYMENT. Medtronic shall have the right to interview and offer employment to some or all of MacroPore's sales organization. Those employees of MacroPore that accept such employment with Medtronic are referred to herein as "Hired Employees." The employment of all Hired Employees will be at will. Medtronic will set its own initial terms and conditions of employment for Hired Employees and others it may hire, including without limitation work rules, benefits and salary and wage structure, all as permitted by law.
- 8.2 COBRA. MacroPore will be responsible for satisfying obligations under Section 601 et seq. of ERISA and Section 4980B of the Code and any applicable similar state laws, to provide continuation coverage to or with respect to any MacroPore employee in accordance with law with respect to any "qualifying event" occurring up to the date of hiring such employee by Medtronic. Medtronic will be responsible for satisfying obligations under Section 601 et seq. of ERISA and Section 4980B of the Code and any applicable similar state laws, to provide continuation coverage to or with respect to any Hired Employee in accordance with law with respect to any "qualifying event" which occurs following the date of hire.
- 8.3 VACATION. Medtronic will assume all obligations to Hired Employees for any vacation entitlement and vacation pay entitlement as of the date of hire and MacroPore shall reimburse Medtronic for the amount of accrued vacation assumed.
- 8.4 WORKERS' COMPENSATION. MacroPore shall be responsible for all workers' compensation benefits, occupational diseases claims and employer liability claims payable to MacroPore employees with respect to (i) claims filed through the date such employee is hired by Medtronic and (ii) claims filed after such date resulting from a discrete event or injury occurring through such date. Medtronic shall be responsible for all workers' compensation benefits, and employer liability claims payable to Hired Employees with respect to a discrete event or injury occurring after the date of hire.
- 8.5 SEVERANCE. MacroPore shall be responsible for paying to any employee of its sales organization all termination or severance benefits, if any, that MacroPore is required to pay, pursuant to its contracts or policies or pursuant to law, to such employee.
- 8.6 NO THIRD PARTY BENEFICIARY. The provisions of this Article 8 are not intended to and shall not be construed as granting rights to or vesting rights in any party or creating any third party beneficiary, including, without limitation, any Affected Employee or any Hired Employee.

# ARTICLE 9 INSPECTION, WARRANTY AND SERVICE

9.1 INSPECTION OF PRODUCT. Medtronic shall inspect all Products promptly upon receipt thereof, and in the event of any shortage, damage or discrepancy in or to a shipment of Products or in the event any of the Products fail to comply with the then current Specifications for the Products (except for latent defects not readily observable by Medtronic), Medtronic shall report the same to MacroPore within 60 days after delivery thereof to Medtronic and furnish such written evidence or other documentation as MacroPore reasonably may deem appropriate. If the

substantiating evidence delivered by Medtronic reasonably demonstrates that such shortage, damage or discrepancy or nonconformity with Specifications existed at the time of delivery of the Products, Medtronic may return the Products to MacroPore, at MacroPore's expense, and, at Medtronic's request, MacroPore shall use all reasonable efforts to deliver promptly replacement Products to Medtronic in accordance with the delivery procedures set forth herein. Any Products not rejected by Medtronic by written notice given to MacroPore within such 60-day period (other than Products containing latent defects not readily observable by Medtronic) shall be deemed to have been accepted by Medtronic. Following any such acceptance, the sole remedies of Medtronic with respect to damage to or defects in the Products shall be those set forth in Sections 9.2 and 11.1.

#### 9.2 WARRANTY.

- (a) MacroPore represents and warrants to Medtronic that all Products sold under this Agreement will have been designed, manufactured, labeled, packaged and sold to Medtronic in accordance with all applicable laws and regulations, including (as applicable) FDA GMP requirements, European Medical Device Directive requirements, ISO 9001 certification or successor requirements, and all other applicable manufacturing requirements. Upon prior written notice, MacroPore shall cause Medtronic's regulatory personnel to be provided with reasonable access from time to time to the facilities and records of MacroPore for the purpose of confirming MacroPore's and the Product's compliance with all applicable laws and regulations.
- (b) MacroPore warrants to Medtronic and to Medtronic's customers that Products shall, when delivered to Medtronic, meet the Specifications and, for a period of 2 years (shelf life) after delivery of the Product to the customer, be free from defects in materials and workmanship. The foregoing express warranty is contingent upon proper use of the Products in the applications for which they were intended as indicated in the Product label claims. Medtronic shall invoice MacroPore for, and MacroPore shall promptly pay, all shipping, transportation, insurance and other expenses actually incurred in replacing defective Products that were under warranty. MacroPore will repair, replace or credit Medtronic's account for any Product that it reasonably determines was defective at the time of shipment to Medtronic or that does not conform to the express warranties herein; provided, however, that MacroPore shall have no obligation under this warranty to repair, make replacements, or grant credits necessitated in whole or in part by accidents; failure to maintain in accordance with any transportation, storage, handling, or maintenance, instructions supplied by MacroPore; damage by acts of nature, vandalism, burglary neglect or misuse; or other fault or negligence of Medtronic or (except for any strict liability of MacroPore) the customer or user. Prior to returning any Product alleged to be defective, Medtronic shall notify MacroPore in writing of the claimed defect and shall include the model and lot/serial number of such Product, as well as the number and date of the invoice therefor. No Product shall be returned without first obtaining a returned goods authorization from MacroPore, which authorization shall not be unreasonably withheld.

9.3 LIMITED WARRANTY. THE EXPRESS WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY

SPECIFICALLY DISCLAIMED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE. IN NO EVENT SHALL MACROPORE'S LIABILITY FOR PRODUCT WARRANTY INCLUDE ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

### ARTICLE 10 CERTAIN REPRESENTATIONS, WARRANTIES AND INDEMNITIES

#### 10.1 REPRESENTATIONS AND WARRANTIES.

- (a) MacroPore represents and warrants to Medtronic that the execution and delivery by MacroPore of this Agreement and the performance by MacroPore of its obligations hereunder have been duly authorized by all requisite corporate action and will not violate any provision of law, any order of any court or other agency of government, the Articles of Incorporation or Bylaws of MacroPore, as amended, or any provision of any indenture, agreement or other instrument to which MacroPore or any of its properties or assets is bound, or conflict with, result in a breach of or constitute (with due notice or lapse of time or both) a default under any such indenture, agreement or other instrument, or result in the creation or imposition of any lien, charge, restriction, claim or encumbrance of any nature whatsoever upon any of the properties or assets of MacroPore. This Agreement has been duly executed and delivered by MacroPore and constitutes the legal, valid and binding obligation of MacroPore, enforceable in accordance with its terms, subject, as to the enforcement of remedies, to the discretion of the courts in awarding equitable relief and to applicable bankruptcy, reorganization, insolvency, moratorium and similar laws affecting the rights of creditors generally.
- (b) Medtronic represents and warrants to MacroPore that the execution and delivery by Medtronic of this Agreement and the performance by Medtronic of its obligations hereunder have been duly authorized by all requisite corporate action and will not violate any provision of law, any order of any court or other agency of government, the Articles of Incorporation or Bylaws of Medtronic, as amended, or any provision of any indenture, agreement or other instrument to which Medtronic or any of its properties or assets is bound, or conflict with, result in a breach of or constitute (with due notice or lapse of time or both) a default under any such indenture, agreement or other instrument, or result in the creation or imposition of any lien, charge, restriction, claim or encumbrance of any nature whatsoever upon any of the properties or assets of Medtronic. This Agreement has been duly executed and delivered by Medtronic and constitutes the legal, valid and binding obligation of Medtronic, enforceable in accordance with its terms, subject, as to the enforcement of remedies, to the discretion of the courts in awarding equitable relief and to applicable bankruptcy, reorganization, insolvency, moratorium and similar laws affecting the rights of creditors generally.

### ARTICLE 11 INDEMNIFICATION

- 11.1 MACROPORE'S LIABILITY. MacroPore shall indemnify, defend and hold harmless Medtronic and each of its subsidiaries, officers, directors, employees, shareholders and distributors from and against and in respect of any and all demands, claims, actions or causes of action, assessments, losses, damages, liabilities, interest and penalties, costs and expenses (including, without limitation, reasonable legal fees and disbursements incurred in connection therewith and in seeking indemnification therefor, and any amounts or expenses required to be paid or incurred in connection with any action, suit, proceeding, claim, appeal, demand, assessment or judgment) finally awarded ("Indemnifiable Losses"), resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of (i) any breach of representation, warranty, or agreement on the part of MacroPore under this Agreement, (ii) Product Liability Damages with respect to the Products, or (iii) other negligence or intentional misconduct of MacroPore; provided that in no event shall MacroPore be liable for matters for which Medtronic is responsible under Section 11.2 below or for punitive or exemplary damages. MacroPore shall maintain product liability insurance or self-insurance in such amounts as ordinary good business practice for its type of business would make advisable and shall provide Medtronic with evidence of this coverage.
- 11.2 MEDTRONIC'S LIABILITY. Medtronic shall indemnify, defend and hold harmless MacroPore and each of its subsidiaries, officers, directors, employees, shareholders and suppliers from and against and in respect of any and all Indemnifiable Losses resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of (i) any breach of representation, warranty, or agreement on the part of Medtronic under this Agreement, (ii) product claims whether written or oral, made or alleged to be made, by Medtronic in its advertising, publicity, promotion, or sale of any Products where such product claims were not provided by or approved by MacroPore, (iii) negligent handling by Medtronic of the Products or changes, additions or modifications to the Products by Medtronic, or (iv) other negligence or intentional misconduct of Medtronic; provided that in no event shall Medtronic be liable for matters for which MacroPore is responsible under Section 11.1 above or for punitive or exemplary damages. Medtronic shall maintain product liability insurance or self-insurance in such amounts as ordinary good business practice for its type of business would make advisable and shall provide MacroPore with evidence of this coverace.
- 11.3 PROCEDURE. If a claim by a third party is made and a party (the "Indemnitee") intends to claim indemnification under this Article 11, the Indemnitee shall promptly notify the other party (the "Indemnitor") in writing of any claim in respect of which the Indemnitee or any of its subsidiaries, directors, officers, employees, shareholders, suppliers or distributors intends to claim such indemnification and the Indemnitor shall have sole control of the defense and/or settlement thereof, provided that the Indemnitee may participate in any such proceeding with counsel of its choice at its own expense. The indemnity agreement in this Article 11 shall not apply to amounts paid in settlement of any Indemnifiable Losses if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if adversely prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 11, but the

omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may otherwise have to any Indemnitee other than under this Article 11. If the Indemnitor fails to provide defense of the claim, and diligently defend or settle the same after receipt of notice from Indemnitee of, and a reasonable opportunity to cure such failure, the Indemnitee may defend or settle the claim without prejudice to its rights to indemnification hereunder, provided that the Indemnitee does so diligently and in good faith and further does not enter into any settlement or agree to any stipulation that would adversely affect the rights of the Indemnitor or impose any additional obligation on the Indemnitor without the Indemnitor's prior written consent (which consent will not be unreasonably withheld). The Indemnitee under this Article 11, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives and provide full information in the investigation of any Indemnifiable Losses, in order to be covered by this indemnification.

## ARTICLE 12 TERM AND TERMINATION

- 12.1 TERM. This Agreement shall take effect as of the date hereof and shall continue in force until the fifth anniversary of the date hereof, and shall automatically renew for successive five-year periods unless either party gives the other party written notice of non-renewal at least 180 days prior to such renewal date (the "Term").
- 12.2 TERMINATION. Notwithstanding the provisions of Section 12.1 above, this Agreement may be terminated in accordance with the following provisions:
  - (a) MacroPore may terminate this Agreement in the manner described in Section 6.3 hereof:
  - (b) Except as described in Section 6.3, a party may terminate this Agreement by giving notice in writing to the other party if the other party is in breach of any material representation, warranty or covenant of this Agreement and, except as otherwise provided herein, shall have failed to cure such breach within 60 days after receipt of written notice thereof from the first party;
  - (c) A party may terminate this Agreement at any time by giving notice in writing to the other party, which notice shall be effective upon dispatch, should the other party become insolvent, make an assignment for the benefit of creditors, go into liquidation or receivership or otherwise lose legal control of its business; or
  - (d) A party may terminate this Agreement by giving notice in writing to the other party should an event of Force Majeure preventing performance by such other party continue for more than 180 consecutive days as provided in Article 13 below.
- 12.3 RIGHTS AND OBLIGATIONS ON TERMINATION. In the event of termination of this Agreement for any reason, the parties shall have the following rights and obligations:

- (b) The terminating party shall have the right, at its option, to cancel any or all purchase orders that provide for delivery after the effective date of termination.
- (c) Medtronic shall have the right, at its option, to require MacroPore to repurchase from Medtronic all of Medtronic's inventory of Products (excluding demonstration units and Products with less than 6 months shelf life remaining as of the effective date of termination) as of the termination date at MacroPore's invoiced price (and inclusive of any shipping charges or taxes, but net of any price adjustments, credits or other allowances) to Medtronic for such Products. Medtronic may exercise its option under this Section 12.3(c) by notifying MacroPore in writing no later than 30 days after the effective termination date. Medtronic shall be permitted to resell any such inventory of Products that MacroPore does not repurchase from Medtronic.
- (d) The parties' obligations pursuant to Articles 9, 11 and 14 and Sections 3.6, 12.3, 12.4, and 15.1 hereof shall survive termination of this Agreement. All other provisions of this Agreement shall terminate upon termination of this Agreement.
- (e) Upon expiration or termination of this agreement, Medtronic shall use reasonable best efforts to transfer ownership to MacroPore of all Product authorizations, registrations, permits and approvals of any kind with respect to Products and applications therefor, including without limitation, marketing approval applications, and other governmental approvals, registrations and the like, at MacroPore's cost and expense, and shall execute such documents and perform such acts as may be necessary, useful or convenient to perfect such transfer.
- (f) For a period of one year following expiration or termination of this Agreement, neither party shall solicit or cause to be solicited for employment any employees of the other party; provided that, if this Agreement is terminated pursuant to Section 6.3, MacroPore may, for a period of 60 days from and after such termination, interview and offer employment to former MacroPore employees hired by Medtronic pursuant to Section 8.1.
- 12.4 TERMINATION OF SUBDISTRIBUTORS. If MacroPore terminates this Agreement in accordance with its rights under Section 12.2, Medtronic shall have sole responsibility for termination of any subdistributor, including any costs or expenses associated therewith, and shall indemnify and hold MacroPore harmless from and against any claim, loss, damage or expense (including reasonable attorneys' fees) suffered or incurred by MacroPore relating to the termination of any subdistributor appointed by Medtronic.

## ARTICLE 13 FAILURE TO SUPPLY AND FORCE MAJEURE

13.1 NOTICE OF FORCE MAJEURE. Upon giving notice to the other party, a party affected by an event of Force Majeure shall be released without any liability on its part from the performance of its obligations under this Agreement, except for the obligation to pay any amounts due and owing hereunder, but only to the extent and only for the period that its performance of such obligations is prevented by the event of Force Majeure.

- 13.2 SUSPENSION OF PERFORMANCE. Subject to Section 13.3 below, during the period that the performance by one of the parties of its obligations under this Agreement has been suspended by reason of an event of Force Majeure, the other party may likewise suspend the performance of all or part of its obligations hereunder (except for the obligations to pay any amounts due and owing hereunder) to the extent that such suspension is commercially reasonable.
- 13.3 EXERCISE OF LICENSE UPON FAILURE OF SUPPLY. Upon a Failure of Supply, Medtronic shall have the right to exercise its license rights granted pursuant to Section 13.4 below to manufacture and sell such Product (but not any other Product) itself or have such Product manufactured by others.

#### 13.4 LICENSE GRANT.

- (a) MacroPore hereby grants Medtronic (i) an exclusive, sublicensable, worldwide, license to the Licensed Intellectual Property to make, have made, use, distribute, sell, offer for sale, have sold, import and otherwise commercialize and exploit Products in the Cranial Field during the Term. Medtronic may not exercise such license unless and until the occurrence of a Failure of Supply.
- (c) Within sixty (60) days after the end of each Medtronic fiscal quarter, Medtronic shall provide MacroPore with a written report indicating the amount of Net Sales of Products during such quarter and the amount of the royalties due for such quarter. Simultaneously with making such report, Medtronic shall pay to MacroPore the amount of royalties then due.
- (d) Medtronic agrees to keep accurate written records sufficient in detail to enable the royalties payable under this Agreement by Medtronic to be determined and verified. Such records for a particular quarter shall be retained by Medtronic for a period of not less than three years after the end of such quarter.
- (e) Upon reasonable notice and during regular business hours, Medtronic shall from time to time (but no more frequently than once annually) make available the records referred to in subsection (d) above for audit at MacroPore's expense by independent representatives selected by MacroPore to verify the accuracy of the reports provided to MacroPore. Such representatives shall execute a suitable confidentiality agreement reasonably acceptable to Medtronic prior to conducting such audit. Such representatives may disclose to MacroPore only their conclusions regarding the accuracy and completeness of royalty payments and of records related thereto, and shall not disclose Medtronic's confidential business information to MacroPore without the prior written consent of Medtronic.

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

- 13.5 TECHNOLOGY TRANSFER. Upon Medtronic's request any time after a Failure of Supply, MacroPore shall promptly provide to Medtronic, or a third party designated by Medtronic, as applicable, copies of such technical documentation and related know-how and trade secrets, and training as is reasonably necessary for a skilled manufacturer to make such Product; provided that any such third party shall agree to maintain the confidentiality of all such information to the same extent that Medtronic is obligated to do so under this Agreement, and Medtronic will reimburse MacroPore for salary and reasonable travel and lodging expenses for MacroPore personnel with respect to training requested by Medtronic at a location other than MacroPore's facility to the extent such expenses are substantiated by expense receipts.
- 13.6 MAINTAIN LICENSES IN FORCE. MacroPore shall comply with all of the provisions of, and shall maintain in full force and effect, all license agreements with third parties pursuant to which MacroPore is licensee of intellectual property included in the Licensed Intellectual Property. MacroPore shall promptly notify Medtronic if any such third party licensor alleges any breach by MacroPore of any such license agreement. Medtronic shall be entitled, but not obligated, to cure any alleged breach by MacroPore of such license agreement and set-off the cost of such cure against amounts otherwise owed to MacroPore hereunder.
- 13.7 NO LIABILITY. MacroPore shall have no obligation or any liability under Sections 9.2 or 11.1(ii) with respect to any Products produced by Medtronic or its third party designee pursuant to the license granted in this Article 13.

## ARTICLE 14 INTELLECTUAL PROPERTY

- 14.1 TRADEMARK LICENSE. MacroPore hereby grants Medtronic a royalty-free license to use all trademarks, trade names and logotypes of MacroPore relating to the Products solely in connection with the sale or other distribution, promotion, advertising and/or maintenance of the Products in the Cranial Field. Medtronic shall acquire no right, title or interest in such MacroPore trademarks, trade names and logotypes, other than the license provided for above, and Medtronic shall not use any MacroPore trademarks, trade names and logotypes as part of Medtronic's corporate, trade name, trademark or logotype or permit any third party under Medtronic's control to do so without the prior written consent of MacroPore. To the extent permitted by local law, any statutory powers which would be granted to Medtronic by virtue of its local use of MacroPore's trademarks or its licensee status are excluded. Medtronic shall in addition have the right to promote and sell the Products under trademarks, trade names and logotypes of Medtronic selected by Medtronic, which trademarks, trade names and logotypes shall be and shall remain the property of Medtronic, provided however, that Medtronic agrees to use reasonable efforts to credit MacroPore as the manufacturer, and to include the brand name, on packaging, brochures and advertisements specific to the Products.
- 14.2 TRADEMARK INFRINGEMENT. Medtronic shall promptly notify MacroPore of any use by any third party of MacroPore's trademarks, trade names or logotypes or any use by such third parties of similar marks that may constitute an infringement or passing off of MacroPore's trademarks, trade names or logotypes of which Medtronic has knowledge. MacroPore reserves the right in its sole discretion to institute any proceedings against such third-party infringers and Medtronic shall refrain from doing so. Medtronic agrees to cooperate fully with MacroPore in

any action taken by MacroPore against such third parties, provided that all expenses of such action shall be borne by MacroPore and all damages that may be awarded or agreed upon in settlement of such action shall accrue to MacroPore.

14.3 TERMINATION OF USE OF TRADEMARKS. Medtronic acknowledges MacroPore's proprietary rights in and to MacroPore's trademarks, trade names and logotypes, and Medtronic hereby waives all right to any trademarks, trade names and logotypes now or hereafter originated by MacroPore. Medtronic shall not after the date of this Agreement adopt, use or register any words, phrases or symbols that are identical to or confusingly similar to any of MacroPore's trademarks. Upon termination of this Agreement, Medtronic shall cease using MacroPore's trademarks, trade names and logotypes in any manner, subject to Medtronic's right, if any, to continue to sell Products under Section 12.3(c).

### 14.4 PATENT RIGHTS.

- (a) DEFENSE OF CLAIMS. MacroPore shall defend, or at its option settle, any suit instituted against Medtronic that is based on an allegation that any Product constitutes an infringement of any patent or any other intellectual property right. MacroPore shall have sole control of defense of any such action, including any appeals and negotiations for the settlement or compromise thereof and shall have full authority to enter into a binding settlement or compromise; provided that MacroPore shall not enter into any settlement or compromise that may adversely affect Medtronic without Medtronic's consent, which consent shall not be unreasonably withhold. MacroPore shall indemnify, subject to the limitations set forth herein, Medtronic against any final award of damages and costs made against Medtronic and any settlement amounts as a result of any such action. In order to qualify for such indemnification, Medtronic shall notify MacroPore promptly in writing of such claim, suit or proceeding and give MacroPore such information and assistance as MacroPore may reasonably request to settle and defend any such claim; provided the failure to give such notice, information and assistance shall only relieve MacroPore of liability under this subsection to the extent such failure adversely affects MacroPore's ability to defend such action.
- (b) LIMITATION OF LIABILITY. MacroPore shall have no liability of any kind to Medtronic under Section 14.4(a) or based upon any other claim Medtronic may have to the extent any such claim is based upon or arises out of (a) the use of any Product in combination with an apparatus or device not manufactured, supplied or approved by MacroPore, (b) the use of any Product in a manner for which it was not designed or intended to be used, or (c) any modification of any Product by Medtronic or any third party that causes it to become infringing.
- (c) REPLACEMENT PRODUCT. Notwithstanding the foregoing, if it is adjudicatively determined that any Product infringes, or in MacroPore's sole opinion, may be found to infringe a third party's patent or other intellectual property rights, or if the sale or use of the Products is, as a result, enjoined, then MacroPore shall, at its option and expense, either: (i) procure for Medtronic the right under such patent to sell or use, as appropriate, the Products; or (ii) replace the Products with other noninfringing functionally equivalent products; or (iii) modify the Products to make the Products

functionally equivalent and noninfringing, remove any prior version of the Products in Medtronic's inventory and refund the aggregate payments made therefor by Medtronic; or (iv) if the use of the Products is prevented by injunction, discontinue Product sales under the Agreement and remove any Products in Medtronic's inventory and refund the aggregate payments paid therefor by Medtronic, in which event MacroPore shall promptly refund to Medtronic a pro rata portion (based on the portion of the original Term remaining) of the \$1,500,000 paid by Medtronic pursuant to Section 2.2.

14.5 OWNERSHIP. MacroPore represents and warrants to Medtronic the following: MacroPore owns or possesses licenses or other rights to use all Intellectual Property used in the research, design, development, manufacture or sale of the Products (the "MacroPore Intellectual Property"), free and clear of any liens, charges, security interests, mortgages, pledges, restrictions, or any other encumbrances of any kind which are inconsistent with the rights granted to Medtronic hereunder. To the knowledge of MacroPore, the MacroPore Intellectual Property is valid and has not been challenged in any judicial or administrative proceeding. MacroPore has taken all necessary steps or appropriate actions to record its interests, or to protect its rights, in the MacroPore Intellectual Property. To the knowledge of MacroPore, no person or entity nor such person's or entity's business or products has infringed, misused, misappropriated or conflicted with the MacroPore Intellectual Property or currently is infringing, misusing, misappropriating or conflicting with the MacroPore Intellectual Property. To the knowledge of MacroPore, all proprietary technical information developed by and belonging to MacroPore that has not been patented has been kept confidential.

14.6 PROTECTION OF MACROPORE'S INTELLECTUAL PROPERTY AND IMPROVEMENTS. MacroPore shall be responsible for filing, prosecuting and maintaining all US and foreign patents and copyrights and applications therefor to the extent it deems necessary or appropriate to protect the MacroPore Intellectual Property.

### ARTICLE 15 MISCELLANEOUS

- 15.1 NONDISCLOSURE. The parties agree not to disclose or use (except as permitted or required for performance by the party receiving such Confidential Information of its rights or duties hereunder) any Confidential Information of the other party obtained during the during the term of this Agreement until the expiration of five years after the receiving party's receipt of such Confidential Information. Each party further agrees to take appropriate measures to prevent any such prohibited disclosure of Confidential Information by its present and future employees, officers, agents, subsidiaries, or consultants during such period.
- 15.2 PUBLIC ANNOUNCEMENT. In the event any party proposes to issue any press release or public announcement concerning any provisions of this Agreement or the transactions contemplated hereby, such party shall so advise the other parties hereto, and the parties shall thereafter use their best efforts to cause a mutually agreeable release or announcement to be issued. Neither party will publicly disclose or divulge any provisions of this Agreement or the transactions contemplated hereby without the other party's written consent, except as may be required by applicable law or stock exchange regulation, and except for communications to such

party's employees or customers or investors or prospective investors (subject to appropriate confidentiality obligations).

- 15.3 COMPLETE AGREEMENT. This Agreement, the Investment Agreement, the Investors' Rights Agreement, the Supplemental Rights Agreement, the Supply Agreement, and the Schedules and Exhibits hereto and thereto, constitute the entire agreement between the parties hereto with respect to the subject matter hereof and supersede all prior agreements whether written or oral relating hereto.
- 15.4 WAIVER, DISCHARGE, AMENDMENT, ETC. The failure of any party hereto to enforce at any time any of the provisions of this Agreement shall not, absent an express written waiver signed by the party making such waiver specifying the provision being waived, be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of the party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. Any amendment to this Agreement shall be in writing and signed by the parties hereto.
- 15.5 SUCCESSORS AND ASSIGNS. This Agreement shall be binding upon and inure to the benefit of the parties hereto and the successors or assigns of the parties hereto; provided, that (i) the rights and obligations of MacroPore herein may not be assigned except to any person who succeeds to substantially all of the assets and business of MacroPore to which this Agreement relates, and (ii) the rights and obligations of Medtronic herein may not be assigned except to any person who succeeds to substantially all of that portion of Medtronic's business to which this Agreement relates.
- 15.6 NOTICES. All notices or other communications to a party required or permitted hereunder shall be in writing and shall be delivered personally or by facsimile (receipt confirmed electronically) to such party (or, in the case of an entity, to an executive officer of such party) or shall be sent by a reputable express delivery service or by certified mail, postage prepaid with return receipt requested, addressed as follows:

### if to Medtronic, to:

Medtronic, Inc. Corporate Center 7000 Central Avenue N.E. Minneapolis, MN 55432 Attention: General Counsel FAX (612) 572-5459

with a copy to:

Medtronic, Inc.
Corporate Center
7000 Central Avenue N.E.
Minneapolis, MN 55432
Attention: Vice President and Chief Development Officer
FAX (612) 572-5404

if to MacroPore, to:

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

with a copy to:

MacroPore, Inc. 6740 Top Gun Street San Diego, CA 92121 Attention: Vice President of Finance FAX (858) 458-0994

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

- 15.7 EXPENSES. Except as expressly provided herein, MacroPore and Medtronic shall each pay their own expenses incident to this Agreement and the preparation for, and consummation of, the transactions provided for herein.
- 15.8 GOVERNING LAW. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Minnesota, including all matters of construction, validity, performance and enforcement, without giving effect to principles of conflict of laws.
- 15.9 TITLES AND HEADINGS; CONSTRUCTION. The titles and headings to the Articles and Sections herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.
- 15.10 ILLEGALITY: SEVERABILITY. In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 15.11 RELATIONSHIP. This Agreement does not make either party the employee, agent or legal representative of the other for any purpose whatsoever. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party. In fulfilling its obligations pursuant to this Agreement, each party shall be acting as an independent contractor.
- 15.12 BENEFIT. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties hereto or their respective successors or assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

- 15.13 SURVIVAL. All of the representations, warranties, and covenants made in this Agreement, and all terms and provisions hereof intended to be observed and performed by the parties after the termination hereof, shall survive such termination and continue thereafter in full force and effect.
- 15.14 COUNTERPARTS. This Agreement may be executed in any number of counterparts, each of which shall be deemed as original and all of which together shall constitute one instrument.
- 15.15 EXECUTION OF FURTHER DOCUMENTS. Each party agrees to execute and deliver without further consideration any further applications, licenses, assignments or other documents, and to perform such other lawful acts as the other party may reasonably require to fully secure and/or evidence the rights or interests herein.

MACROPORE, INC.

By: /s/ Christopher J. Calhoun

Its: Vice Chairman, Chief Executive Officer

MEDTRONIC, INC.

By: /s/ Michael D. Ellwein

Its: Vice President and Chief Development Officer

## EXHIBIT A QUOTA

During the first 12-month of the Term, Medtronic shall submit purchase orders for at least [\*\*\*\*\*\*\*\*] of Product (based on Transfer Price to Medtronic) (the "Quota"). By the end of each three-month quarter of such initial 12-month period, Medtronic shall have ordered at least the following cumulative percentage of the Quota, and MacroPore shall supply all Products so ordered up to the following cumulative percentage of the Quota:

Quarter 	Medtronic Cumulative Minimum Order (as % of Quota)	MacroPore Cumulative Guaranteed Supply (as % of Quota)
First Second Third Fourth	[*****] [*****] [*****]	[*****] [*****] [*****]

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

### AMENDMENT NO. 1 TO DISTRIBUTION AGREEMENT

This Amendment No. 1, effective as of December 22, 2000, is to that certain Distribution Agreement (the "Agreement"), dated as of January 5, 2000, by and between MacroPore, Inc., a Delaware corporation ("MacroPore") and Medtronic, Inc. ("Medtronic"), a Minnesota corporation.

WHEREAS, MacroPore and Medtronic desire to amend the Agreement as set forth below.

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

1. Section 7.1 (Prices) of the Agreement is hereby amended by deleting Section 7.1 in its entirety and inserting the following in its place.

### "Section 7.1) PRICES

- (a) Unless and until otherwise mutually agreed upon by the parties in writing, the purchase price per unit to Medtronic (the "Transfer Price") under this Agreement shall be based on the price list in effect at the time of MacroPore's receipt of the order from Medtronic (the "Price List") as set forth on Exhibit B; PROVIDED, HOWEVER, that the Transfer Price for all Product sales from MacroPore to Medtronic from January 5, 2000 to the date hereof shall be the Transfer Price as set forth on Exhibit B. MacroPore established the attached Price List based on [\*\*\*] of the average selling price per unit for each Product, excluding any sales, use or excise tax, freight, duty or insurance included therein, during the six-month period immediately prior to the date of the Price List.
- (b) The Price List shall be reviewed by MacroPore and Medtronic on the six month anniversary of the date hereof and every six months thereafter (the "Six Month Review"), with any changes in these prices to take effect upon delivery of the revised Price List to Medtronic. MacroPore shall prepare the revised Price List, to be prepared after each Six Month Review, on the same basis as the initial Price List.
- (c) New products may be added to the Price List at any time by 30 day prior written notice to Medtronic. In the event that a new Product is added to the Price List, the Transfer Price shall be based on [\*\*] of the estimated selling price per unit for such Product until the next Six Month Review.

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

- (d) In the event sales of a Product already on the Price List were inadequate to establish an average selling price during the previous six month period, MacroPore shall set the Transfer Price based on [\*\*\*] of the estimated selling price per unit for such Product, which price may be based on the Transfer Price for that Product from the previous Price List.
- (e) In the event MacroPore and Medtronic's review of the Price List results in a change to the Transfer Price for any of the Products on the Price List, all such changes will apply to the Transfer Price of future sales of that Product and shall not be applied retroactively to previous sales of that Product to Medtronic. Separate Transfer Prices will be established for sales in the United States and for sales in the international market. The prices for customized products are not included in the Price List but shall be determined in accordance with Section 5.7 herein."
- 2. The Agreement is hereby amended by inserting Exhibit B attached hereto immediately after Exhibit A to the Agreement.
- 3. Except as amended hereby, the Agreement shall remain unchanged and in full force and effect.
- 4. This Amendment No. 1 and the Agreement constitute the entire agreement among the parties hereto with respect to the subject matter hereof, and supersede any and all prior agreements and undertakings, oral or written, concerning the subject matter hereof. This Agreement may not be changed or terminated orally, and may only be changed or terminated by a writing signed by the party against whom such change or termination is sought.
- 5. This Amendment No. 1 may be executed in any number of counterparts and by facsimile, each of which, when executed, shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

\* \* \* \* \* \*

IN WITNESS WHEREOF, this Amendment No. 1 has been duly executed by the parties as of the date first set forth above.

MACROPORE, INC., a Delaware corporation

By: /s/ Charles E. Galetto Name: Charles E. Galetto Its: VP - Finance

MEDTRONIC, INC., a Minnesota corporation

By: /s/ Michael D. Ellwein

Name: Michael D. Ellwein Its: VP and Chief Development Officer

### EXHIBIT B PRICE LIST

MacroPore, Inc. Master Product Library - Pricing

Version - 1 - 12/22/00

CATALOG NUMBER	DESCRIPTION	UNIT OF MEASURE	SYSTEM	MEDTRONIC LIST PRICE	U.S.A. TRANSFER PRICE	INTERNATIONAL TRANSFER PRICE	SAMPLE CATALOG NUMBER	SAMPLE PRICE
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

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#### DEVELOPMENT AND SUPPLY AGREEMENT

THIS DEVELOPMENT AND SUPPLY AGREEMENT (the "AGREEMENT") is made and entered into as of January 5, 2000 (the "EFFECTIVE DATE") between MACROPORE, INC. ("MACROPORE"), a Delaware corporation, and MEDTRONIC, INC. (as defined below, "MEDTRONIC"), a Minnesota corporation.

#### WITNESSETH:

WHEREAS, MacroPore has developed bioabsorbable surgical implants for use in, among other areas, bone fixation and reconstruction in the craniofacial skeleton and, on even date herewith, MacroPore and Medtronic have entered into a Distribution Agreement (the "DISTRIBUTION AGREEMENT") pursuant to which Medtronic is granted exclusive worldwide distribution rights with respect to such products; and

WHEREAS, the parties desire MacroPore to develop bioabsorbable spinal implants and [\*\*\*\*\*\*\*\*\*\*\*] pursuant to Medtronic's designs and specifications and to manufacture and supply such developed products to Medtronic; and

WHEREAS, MacroPore and Medtronic's Affiliate, Medtronic Asset Management, Inc. ("MAMI"), intend to enter into a Series D Preferred Stock Purchase Agreement (the "INVESTMENT AGREEMENT") pursuant to which MAMI will purchase Series D Preferred Stock of MacroPore and receive various rights; and

WHEREAS, it is a condition to MAMI's willingness to purchase such MacroPore Series D Preferred Stock that the parties enter into this Agreement.

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

### ARTICLE 1 DEFINITIONS

1.1 SPECIFIC DEFINITIONS. As used in this Agreement, the following terms shall have the meanings set forth or as referenced below:  $\frac{1}{2} \left( \frac{1}{2} \right) = \frac{1}{2} \left( \frac{1}{2} \right) \left( \frac$ 

"AFFILIATE" of a specified person (natural or juridical) means a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. "Control" shall mean ownership of more than 50% of the shares of stock entitled to vote for the election of directors in the case of a corporation, and more than 50% of the voting power in the case of a business entity other than a corporation.

"AGREEMENT" means this Agreement and all Exhibits and Schedules hereto.

"CONFIDENTIAL INFORMATION" means know-how, trade secrets, and unpublished information disclosed (whether before or during the term of this Agreement) by one of the parties (the "disclosing party") to the other party or such other party's designee pursuant to Section 11.5 (the

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"receiving party"), and which is marked as proprietary or confidential as provided below, excluding information that:

- (a) was already in the possession of receiving party prior to its receipt from the disclosing party (provided that the receiving party is able to provide the disclosing party with reasonable documentary proof thereof);
- (b) is or becomes part of the public domain by reason of acts not attributable to the receiving party;
- (c) is or becomes available to receiving party from a source other than the disclosing party which source, to the best of receiving party's knowledge, has rightfully obtained such information and has no obligation of nondisclosure or confidentiality to the disclosing party with respect thereto;
- (d) is made available by the disclosing party to a third party unaffiliated with the disclosing party on an unrestricted basis;
- (e) is independently developed by the receiving party completely without reference to any Confidential Information of the disclosing party, as evidenced by the receiving party's written records; or
- (f) has been or must be publicly disclosed by reason of legal, accounting or regulatory requirements beyond the reasonable control, and despite the reasonable efforts, of the receiving party.
- All Confidential Information disclosed by one party to the other under this Agreement shall be in writing and bear a legend "Proprietary," "Confidential" or words of similar import or, if disclosed in any manner other than writing, shall be followed by confirmation that such information is confidential by the disclosing party within 30 days.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain merely because the aspects or details of the Confidential Information is embraced by general disclosures in the public domain. In addition, any combination of Confidential Information shall not be considered in the public domain or in the prior possession of the receiving party merely because individual elements thereof are in the public domain or in the prior possession of the receiving party unless the combination and its principles are in the public domain or in the prior possession of the receiving party.

"DEVELOPED PRODUCTS" means as defined in Section 2.3.

"FAILURE OF SUPPLY" means (i) MacroPore's failure, for any reason other than Force Majeure, to deliver any Developed Product ordered in accordance with the provisions of Article 5 by the date scheduled for delivery thereof, including but not limited to a failure to deliver Developed Products which conforms to the Specifications therefor, which failure is not cured within two months after MacroPore is notified of such failure, (ii) MacroPore's failure due to Force Majeure to deliver any Developed Product ordered in accordance with the provisions of Article 5 by the date scheduled for delivery thereof, including but not limited to a failure to deliver Developed Product which

conforms to the Specifications therefor, which failure is not cured within three months after MacroPore is notified of such failure, or (iii) MacroPore's failure on any five occasions within any 24-month period, for any reason other than Force Majeure, to deliver any Developed Product ordered in accordance with the provisions of Article 5 within 30 days after the respective dates scheduled for delivery thereof, including but not limited to a failure to deliver Developed Product which conforms to the Specifications therefor.

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

"FORCE MAJEURE" means any event or condition, not existing as of the date of this Agreement, not reasonably foreseeable as of such date and not reasonably within the control of either party, which prevents in whole or in material part the performance by one of the parties of its obligations hereunder, such as an act of government, war or related actions, civil insurrection, riot, sabotage, strike, epidemic, fire, flood, windstorm, and similar events.

"GMP" means Good Manufacturing Practices as defined in 21 CFR Parts 210 through 226 and Parts 600 through 680.

"INTELLECTUAL PROPERTY" means letters patent and patent applications; trademarks, service marks and registrations thereof and applications therefor; copyrights and copyright registrations and applications; mask works and registrations thereof, all inventions, discoveries, ideas, technology, know-how, trade secrets, data, information, processes, formulas, drawings and designs, licenses, computer programs and software; and all amendments, modifications, and improvements to any of the foregoing.

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

"KNOWLEDGE" means actual knowledge of a fact or the knowledge that such person could reasonably be expected to have based on reasonable inquiry. The "knowledge" of an entity shall include the knowledge of such entity's employees.

"LICENSED INTELLECTUAL PROPERTY" means, with respect to a Failure of Supply of a particular Developed Product, all Intellectual Property used by MacroPore in connection with the manufacture or sale of such Developed Product at the time of such Failure of Supply.

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

"MEDTRONIC" means Medtronic, Inc. and its Affiliates.

"NET SALES" of Developed Products for purposes of Article 11 with respect to a particular period means the amounts that Medtronic or any Affiliate of Medtronic receives from third parties (eliminating transactions among Affiliates of Medtronic and/or Medtronic) for net sales of

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Developed Products during such period, excluding sales, use or excise tax, freight, duty or insurance included therein, returns, discounts and allowances, credits or repayments due to rejections, defects or returns, provided that if Medtronic or any Affiliate of Medtronic sells at a single price or rate a packaged combination of products, not all of which if sold individually would be Developed Products, then "Net Sales" with respect to such sales of packaged products shall equal the number of units of Developed Products sold as part of such packaged products (less rejections, defects and returns) multiplied by either (i) the respective average net selling price during such period of the same type of Developed Product sold individually, or (ii) the average net selling price during such period for a comparable product (if the same type of Developed Product is not sold individually), in either case excluding sales, use or excise tax, freight, duty or insurance included therein.

"PMA" means a Premarket Approval Application as defined in 21 CFR Part 814.

"PRODUCT LIABILITY DAMAGES" means any liability, claim or expense, including but not limited to reasonable attorneys' fees and medical expenses, arising in whole or in part out of claims of third parties for personal injury or loss of or damage to property relating to or arising out of the Developed Products, whether based on strict liability in tort, negligent manufacture of product, or any other allegation of liability arising directly from the design, testing, manufacture, packaging, labeling (including instructions for use), or sale of the Developed Products.

"SAFETY" means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time. This definition of "safety" is essentially the definition of "safety" as used in 21 CFR part 600.

"SPECIFICATIONS" means the specifications for the Developed Products as determined by Medtronic.

"SPINAL IMPLANTS" means those medical devices (other than [\*\*\*\*\*\*\*\*\*\*\*\*]) designed to be implanted in the human body for the treatment of spinal disease, deformity or trauma as the parties may agree to develop hereunder.

"STATEMENT OF WORK" means, with respect to each Spinal Implant and/or [\*\*\*\*\*\*\*\*\*\*], the mutually-agreed upon and signed written description of the development process for such product, and shall include unless otherwise agreed between the parties: a detailed description of such product; a description of each phase in such development; a list of goals (or "milestones") and target dates for achievement of such milestones and completion of each phase; and such other details as the parties may agree in writing. A Statement of Work shall include any mutually agreed-upon written amendments thereto.

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

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#### 1.3 DEFINITIONAL PROVISIONS.

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

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

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

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

The term "dollars" or "\$" shall refer to the currency of the United States of America.

### ARTICLE 2 LICENSE AND DEVELOPMENT OF PRODUCTS

- 2.2 EXCLUSIVITY. During the term of this Agreement, MacroPore shall not develop manufacture or sell any products or devices for use in the field of spinal fixation, stabilization and/or fusion, except for Developed Products to be supplied to Medtronic hereunder.
- 2.3 DEVELOPMENT EFFORTS. MacroPore shall be responsible for developing the ability, equipment and processes to manufacture Spinal Implants and [\*\*\*\*\*\*\*\*\*\*\*\*\*\*] from poly-lactic acid (or other resorbable materials as agreed to by Medtronic) pursuant to Statements of Work. Those Spinal Implants and [\*\*\*\*\*\*\*\*\*\*\*\*\*] which MacroPore demonstrates to Medtronic's reasonable satisfaction can be manufactured from poly-lactic acid on a commercially feasible scale and without any material adverse effect on the functionality thereof (versus the functionality of a product manufactured in the same design but from other materials) are referred to as "Developed Products". If either Medtronic or MacroPore notifies the other party in writing of a proposal for a potential Developed Product, MacroPore and Medtronic shall, within thirty (30) days thereafter, each designate the appropriate personnel to meet and/or correspond with the appropriate personnel of the other party with a view to evaluating the technical and commercial feasibility of such proposed Developed Product. Attached hereto as Exhibit A is notice of proposed potential Development Products to be initiated at the signing of this Agreement. If the parties mutually determine in their discretion that research and/or development of such proposed

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Developed Product appears to be desirable and technically and commercially feasible, MacroPore and Medtronic shall each use good faith reasonable efforts to agree upon a Statement of Work for such proposed Developed Product. Such Statement of Work shall, when signed by each of Medtronic and MacroPore, become subject to the general terms and provisions of this Agreement. Subject to the terms and conditions of this Agreement, Medtronic and MacroPore shall each use good faith reasonable efforts to perform their respective responsibilities under each Statement of Work within the timeframes specified in such Statement of Work. Any changes to a Statement of Work will require mutual written agreement by the parties.

### 2.4 REGULATORY APPROVALS.

- (a) Medtronic shall be responsible obtaining all necessary regulatory approvals for the commercial sale of the Developed Products, including the preparation of the clinical study protocols, selection of investigational sites, preparation of the investigator's brochures, instruction and training of clinical investigators, monitoring the performance of clinical trials, data collection and analysis, reporting of adverse events, preparation and prosecution of regulatory submissions, and post approval clinical studies All regulatory approvals for the Developed Products will be in Medtronic's name and owned by Medtronic.
- (b) MacroPore shall supply to Medtronic such quantities of Developed Products as is reasonably required by Medtronic to obtain necessary regulatory approvals. Medtronic shall pay MacroPore an amount equal to MacroPore's direct cost of materials and labor for such Developed Products used in clinical trials.
- (c) MacroPore will grant Medtronic the right of reference to MacroPore's regulatory files with the FDA or other appropriate government agencies as necessary or helpful for support of Medtronic's regulatory submissions with respect to Developed Products and, upon Medtronic's request participate in any discussions with the FDA or clinical investigators with respect thereto. MacroPore represents and warrants to Medtronic that MacroPore's poly-lactic acid material has been approved by the FDA for Safety in long term implantable devices.
- 2.5 TERMINATION OF DEVELOPMENT STATEMENT OF WORK. Medtronic shall be entitled to terminate any Statement of Work for a Developed Product or potential Developed Product if Medtronic, in its sole discretion, determines that such Developed Product will not be technically or commercially feasible or will have only limited commercial value to Medtronic.

### ARTICLE 3 GENERAL OBLIGATIONS OF MEDTRONIC

- 3.1 SALES OF DEVELOPED PRODUCTS. Medtronic shall be solely responsible for marketing and selling all Developed Products.
- 3.2 QUALITY CONTROL. Medtronic agrees to follow reasonable quality control standards with respect to the storage, preservation, sale and use of the Developed Products purchased under this Agreement.
- 3.3 RECORDS AND RECALL. Medtronic shall maintain complete and accurate records of all Developed Products sold by Medtronic and its subdistributors in sufficient detail to enable

Medtronic to conduct an effective recall of Developed Products if Medtronic determines that such a recall is required or otherwise necessary or appropriate. In the event of a recall of any of the Developed Products, MacroPore will cooperate with and assist Medtronic in effecting such recall.

#### 3.4 REGULATORY APPROVALS.

- (a) CLINICALS. Medtronic shall be responsible for all clinical study design, investigator selection, and data analysis in connection with clinical trials of the Developed Products. MacroPore shall give Medtronic such assistance in connection with such clinical studies as Medtronic may reasonably request.
- (b) DEVICE APPROVALS. Medtronic shall be responsible for filing, obtaining and maintaining all necessary regulatory approvals for the importation and sale of Developed Products. To the extent permitted by law, all foreign regulatory approvals shall be owned by Medtronic and shall be in the name of Medtronic.
- (c) EXPORT. Medtronic shall be responsible for obtaining all export licenses and permits as may be required to export the Developed Products from the country of manufacture into the particular countries where such Developed Products are delivered. MacroPore shall cooperate fully with Medtronic in its efforts to obtain any such approvals.

# ARTICLE 4 GENERAL OBLIGATIONS OF MACROPORE

- 4.1 MANUFACTURE AND SUPPLY OF DEVELOPED PRODUCTS. MacroPore shall use commercially reasonable efforts to manufacture, or have manufactured, Developed Products in accordance with the Specifications and to ship such Developed Products to Medtronic in the quantities ordered by Medtronic pursuant to Article 5 of this Agreement. MacroPore shall be responsible for packaging in accordance with packaging specifications to be mutually agreed upon by Medtronic and MacroPore, and for any necessary sterilization of Developed Products purchased under this Agreement in accordance with the Specifications.
- 4.2 GOOD MANUFACTURING PRACTICES/QUALITY SYSTEMS REGULATIONS. MacroPore shall be responsible for compliance with present and future applicable statutes, laws, ordinances and regulations of national, federal, state and local governments now or hereafter in effect relating to the [design,] manufacture and/or quality of Developed Products. Without limitation of the foregoing, MacroPore represents and warrants to Medtronic that all Developed Products sold and delivered to Medtronic under this Agreement will have been manufactured in accordance with all applicable requirements. MacroPore shall cause Medtronic's regulatory personnel to be provided with reasonable access from time to time to the facilities and records of MacroPore for the purpose of confirming MacroPore's compliance with this Section 4.2.
- 4.3 TRAINING. MacroPore shall provide Medtronic with such training as Medtronic may reasonably request in connection with the sale of Developed Products. Medtronic shall reimburse MacroPore for travel and other out-of-pocket costs reasonably incurred by MacroPore in connection with such training upon submission by MacroPore of appropriate documentation thereof.

4.4 PRODUCT LITERATURE AND PACKAGING. MacroPore will give Medtronic such assistance in connection with the preparation of Developed Product packaging, labeling and operations and technical manuals for use with the Developed Products as reasonably requested by Medtronic. Medtronic shall be responsible for the preparation of sales and marketing materials as deemed appropriate by Medtronic, and MacroPore shall supply any artwork or other materials reasonably requested by Medtronic in connection therewith.

### ARTICLE 5 ORDERS FOR PRODUCTS

- 5.1 PURCHASE ORDERS. Medtronic shall submit purchase orders for Developed Products to MacroPore in writing, whether by mail, telecopier, telegram or otherwise, at the time that each forecast is delivered to MacroPore pursuant to Section 5.3. Each purchase order shall, at a minimum, set forth the product numbers, quantities (subject to Section 5.3), delivery dates, and shipping instructions and shipping addresses for all Developed Products ordered. Purchase orders shall be binding upon MacroPore unless and to the extent the quantities specified therein exceed the amounts specified in the Plan. Each purchase order shall be subject to and governed by the terms of this Agreement. No partial shipment of an order shall constitute the acceptance of the entire order, absent the written acceptance of such entire order. The terms and conditions of this Agreement shall so govern and supersede any additional or contrary terms set forth in Medtronic's purchase order or any MacroPore or Medtronic acceptance, confirmation, invoice or other document unless duly signed by an officer of Medtronic and an officer of MacroPore and expressly stating and identifying which specific additional or contrary terms shall supersede the terms and conditions of this Agreement.
- 5.2 FIRST ORDER. The first purchase order for a Developed Product will be placed by Medtronic approximately 90 days prior to commercial release of the Developed Product. Subsequently, Medtronic will place orders for the next succeeding months on a monthly basis, at the time that it provides its forecast described in Section 5.3, with all such subsequent purchase orders submitted at least 60 days in advance of the earliest scheduled delivery date for such order.
- 5.3 MEDTRONIC'S FORECASTS. At the time that Medtronic places its first order for a Developed Product, Medtronic shall provide MacroPore with a six-month sales plan to be mutually agreed upon indicating by month the number of such Developed Products anticipated to be sold by Medtronic or purchased by Medtronic for use as demonstration units (as updated as provided herein, the "Plan"). The Plan shall be updated by Medtronic on a quarterly basis (on or before the first day of each subsequent month) for a rolling successive six-month period. Each Plan shall be used for purposes of facilitating Medtronic's marketing plans, MacroPore's manufacturing plans, and meeting the lead times required by certain of MacroPore's suppliers, but are not legally binding on Medtronic or MacroPore in any manner.
- 5.4 ORDER LIMITATIONS. MacroPore shall not be required to deliver quantities in excess of 100% of forecasted requirements for the first three months of any Plan, provided, however, that MacroPore shall use all commercially reasonable efforts to supply such excess.

- 5.5 MODIFICATION OF ORDERS. Medtronic may cancel or reschedule purchase orders for products only with MacroPore's prior written approval. Notwithstanding the foregoing, any purchase order may be cancelled by Medtronic as to any Developed Products that are not delivered within 60 days after the delivery date requested by Medtronic pursuant to a purchase order, and any such cancellation shall not limit or affect any contract remedies available to Medtronic with respect thereto. Any such cancellation by Medtronic must be by written notice to MacroPore given within 15 business days after such 60th day.
- 5.6 DELIVERY TERMS. All deliveries of Developed Products shall be F.O.B. MacroPore's facility in California. Except as otherwise provided in Article 7 or Article 9 below, MacroPore shall have no further responsibility for risk of damage to or loss or delay of Developed Products after their delivery at the aforesaid F.O.B. point. All Product deliveries shall be made by a common carrier specified by Medtronic or, in the event that no carrier shall have been specified by Medtronic on or before the date 15 days prior to the requested shipment date, a reputable common carrier selected by MacroPore.
- 5.7 PRODUCT CHANGES. MacroPore shall not, without Medtronic's prior written consent, modify the Specifications for a Product in a manner that materially affects the performance or regulatory approval status of the Product or materially increases Medtronic's costs or expenses.
- 5.8 CUSTOM DEVELOPED PRODUCTS. In the event Medtronic is requested by a customer to provide customized Developed Products, Medtronic shall provide the specifications for the customized Product to MacroPore. MacroPore will determine and provide to Medtronic the additional cost, if any, and the feasibility of providing the customized Product. Medtronic will thereafter notify MacroPore if it intends to provide such customer with the customized Developed Product.

# ARTICLE 6 PRICES AND PAYMENTS

6.1 PRICES. Unless and until otherwise mutually agreed by the parties in writing, the purchase prices per unit of Developed Products to Medtronic under this Agreement (the "Transfer Price") shall be (i) for Developed Products that are Spinal Implants, [\*\*\*] of Medtronic's average net selling price per unit during the six-month period following commercial release of such Developed Product in such market, and (ii) for Developed Products that are [\*, [\*\*\*\*] of Medtronic's average net selling price per unit during the six-month period following commercial release of such Developed Product in such market; provided that in no event shall the Transfer Price for any Developed Products be less than [\*\*\*\*] of MacroPore's per unit direct cost of manufacturing. Separate Transfer Prices will be established for sales in the United States market and for each major international market. Until six months after commercial release of a Developed Product in a particular market, Medtronic's average net selling price per unit shall be based on Medtronic's catalog list price. If Medtronic sells the Developed Product as part of a packaged combination of products or instruments, then Medtronic's sale price of the Developed Product shall equal either (i) the respective average net selling price during such period of the same type of Developed Product is not period for a comparable product (if the same type of Developed Product is not

sold individually). Medtronic's net selling price shall exclude sales, use or excise tax, freight, duty or insurance included therein. MacroPore and Medtronic agree to review the Transfer Price at least annually to determine if adjustments are appropriate, taking into account then market conditions. Medtronic and MacroPore agree to keep accurate written records sufficient in detail to enable Medtronic's average selling price and MacroPore's direct cost of manufacturing, respectively, of Developed Products to be determined and verified. Such records for a particular quarter shall be retained for a period of not less than three years. Upon reasonable notice and during regular business hours, each party shall from time to time (but no more frequently than once annually) make available such records for audit at the other party's expense by independent representatives selected by such other party to verify the accuracy of the reports provided to such other party. Such representatives shall execute a suitable confidentiality agreement reasonably acceptable to the party whose records are being audited prior to conducting such audit. Such representatives may disclose to such other party only their conclusions regarding the accuracy and completeness of records related thereto, and shall not disclose confidential business information to such other party without the prior written consent of Medtronic.

- 6.2 PAYMENT TERMS. Payments made by Medtronic for Developed Products purchased hereunder shall be due and payable in full within 30 days after the date of invoice by MacroPore. Any payments due hereunder which are not paid on the date such payments are due shall be subject to interest at the rate of one and one-half percent (1 1/2%) per month calculated on the number of days such payment is delinquent.
- 6.3 TAXES. The transfer prices for Developed Products established pursuant to this Article 6 do not include any sales, use, value added or similar taxes, customs, duties, or tariffs imposed by any governmental authority or agency on Developed Products or any components thereof that are imported by Medtronic into any country (other than taxes on the net income of MacroPore), and Medtronic shall bear all such taxes and duties. MacroPore shall be required to take appropriate steps to minimize imposition of such taxes by filing sales exemption certificates and taking similar actions where applicable to the seller. When MacroPore has the legal obligation to collect and/or pay such taxes, the appropriate amount shall be added to Medtronic's invoice and paid by Medtronic, unless Medtronic provides MacroPore with a valid tax exemption certificate authorized by the appropriate taxing authority. Medtronic shall not be obligated to pay or reimburse MacroPore for taxes that are not imposed on the sale of Product to Medtronic.

# ARTICLE 7 INSPECTION, WARRANTY AND SERVICE

7.1 INSPECTION OF PRODUCT. Medtronic shall inspect all Developed Products promptly upon receipt thereof, and in the event of any shortage, damage or discrepancy in or to a shipment of Developed Products or in the event any of the Developed Products fail to comply with the then current Specifications for the Developed Products (except for latent defects not readily observable by Medtronic), Medtronic shall report the same to MacroPore within 60 days after delivery thereof to Medtronic and furnish such written evidence or other documentation as MacroPore reasonably may deem appropriate. If the substantiating evidence delivered by Medtronic reasonably demonstrates that such shortage, damage or discrepancy or nonconformity with Specifications existed at the time of delivery of the Developed Products, Medtronic may return the Developed Products to MacroPore, at MacroPore's expense, and, at Medtronic's

request, MacroPore shall use all reasonable efforts to deliver promptly replacement Developed Products to Medtronic in accordance with the delivery procedures set forth herein. Any Developed Products not rejected by Medtronic by written notice given to MacroPore within such 60-day period (other than Developed Products containing latent defects not readily observable by Medtronic) shall be deemed to have been accepted by Medtronic. Following any such acceptance, the sole remedies of Medtronic with respect to damage to or defects in the Developed Products shall be those set forth in Sections 7.2 and 9.1.

### 7.2 WARRANTY.

- (a) MacroPore represents and warrants to Medtronic that all Developed Products sold under this Agreement will have been manufactured and packaged in accordance with all applicable laws and regulations, including (as applicable) FDA GMP requirements, European Medical Device Directive requirements, ISO 9001 certification or successor requirements, and all other applicable manufacturing requirements. Upon prior written notice, MacroPore shall cause Medtronic's regulatory personnel to be provided with reasonable access from time to time to the facilities and records of MacroPore for the purpose of confirming MacroPore's and the Product's compliance with all applicable laws and regulations.
- (b) MacroPore warrants to Medtronic and to Medtronic's customers that Developed Products shall, when delivered to Medtronic, meet the Specifications and, for a period of one year after delivery of the Product to the customer but not more than two years after receipt by Medtronic, be free from defects in materials and workmanship. The foregoing express warranty is contingent upon proper use of the Developed Products in the applications for which they were intended as indicated in the Product label claims. Medtronic shall invoice MacroPore for, and MacroPore shall promptly pay, all shipping, transportation, insurance and other expenses actually incurred in replacing defective Developed Products that were under warranty. MacroPore will repair, replace or credit Medtronic's account for any Product that it reasonably determines was defective at the time of shipment to Medtronic or that does not conform to the express warranties herein; provided, however, that MacroPore shall have no obligation under this warranty to repair or make replacements or grant credits necessitated in whole or in part by accidents; failure to maintain in accordance with any transportation, storage, handling, or maintenance, instructions supplied by MacroPore; damage by acts of nature, vandalism, burglary neglect or misuse; or other fault or negligence of Medtronic or (except for any strict liability of MacroPore) the customer or user. Prior to returning any Product alleged to be defective, Medtronic shall notify MacroPore in writing of the claimed defect and shall include the model and lot/serial number of such Product, as well as the number and date of the invoice therefor. No Product shall be returned without first obtaining a returned goods authorization from MacroPore, which authorization shall not be unreasonably withheld.
- 7.3 LIMITED WARRANTY. THE EXPRESS WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY SPECIFICALLY DISCLAIMED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE. IN NO EVENT SHALL MACROPORE'S LIABILITY FOR PRODUCT WARRANTY INCLUDE ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

11

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### ARTICLE 8 CERTAIN REPRESENTATIONS, WARRANTIES AND INDEMNITIES

#### 8.1 REPRESENTATIONS AND WARRANTIES.

- (a) MacroPore represents and warrants to Medtronic that the execution and delivery by MacroPore of this Agreement and the performance by MacroPore of its obligations hereunder have been duly authorized by all requisite corporate action and will not violate any provision of law, any order of any court or other agency of government, the Articles of Incorporation or Bylaws of MacroPore, as amended, or any provision of any indenture, agreement or other instrument to which MacroPore or any of its properties or assets is bound, or conflict with, result in a breach of or constitute (with due notice or lapse of time or both) a default under any such indenture, agreement or other instrument, or result in the creation or imposition of any lien, charge, restriction, claim or encumbrance of any nature whatsoever upon any of the properties or assets of MacroPore. This Agreement has been duly executed and delivered by MacroPore and constitutes the legal, valid and binding obligation of MacroPore, enforceable in accordance with its terms, subject, as to the enforcement of remedies, to the discretion of the courts in awarding equitable relief and to applicable bankruptcy, reorganization, insolvency, moratorium and similar laws affecting the rights of creditors generally.
- (b) Medtronic represents and warrants to MacroPore that the execution and delivery by Medtronic of this Agreement and the performance by Medtronic of its obligations hereunder have been duly authorized by all requisite corporate action and will not violate any provision of law, any order of any court or other agency of government, the Articles of Incorporation or Bylaws of Medtronic, as amended, or any provision of any indenture, agreement or other instrument to which Medtronic or any of its properties or assets is bound, or conflict with, result in a breach of or constitute (with due notice or lapse of time or both) a default under any such indenture, agreement or other instrument, or result in the creation or imposition of any lien, charge, restriction, claim or encumbrance of any nature whatsoever upon any of the properties or assets of Medtronic. This Agreement has been duly executed and delivered by Medtronic and constitutes the legal, valid and binding obligation of Medtronic, enforceable in accordance with its terms, subject, as to the enforcement of remedies, to the discretion of the courts in awarding equitable relief and to applicable bankruptcy, reorganization, insolvency, moratorium and similar laws affecting the rights of creditors generally.
- (c) Medtronic represents and warrants to MacroPore that the requirements it specifies for Developed Products and the information or designs it provides to MacroPore for incorporation into Developed Products under this Agreement will not infringe any Intellectual Property rights of any third party. MacroPore represents and warrants to Medtronic that the Intellectual Property related to poly-lactic acid used by MacroPore in the manufacture of Developed Products under this Agreement will not infringe any Intellectual Property rights of any third party.

# ARTICLE 9 INDEMNIFICATION

9.1 MACROPORE'S LIABILITY. MacroPore shall indemnify, defend and hold harmless Medtronic and each of its subsidiaries, officers, directors, employees, shareholders and

distributors from and against and in respect of any and all demands, claims, actions or causes of action, assessments, losses, damages, liabilities, interest and penalties, costs and expenses (including, without limitation, reasonable legal fees and disbursements incurred in connection therewith and in seeking indemnification therefor, and any amounts or expenses required to be paid or incurred in connection with any action, suit, proceeding, claim, appeal, demand, assessment or judgment) finally awarded ("Indemnifiable Losses"), resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of (i) any breach of representation, warranty, or agreement on the part of MacroPore under this Agreement, or (ii) other negligence or intentional misconduct of MacroPore; provided that in no event shall MacroPore be liable for matters for which Medtronic is responsible under Section 9.2 below or for punitive or exemplary damages. MacroPore shall maintain product liability insurance or self-insurance in such amounts as ordinary good business practice for its type of business would make advisable and shall provide Medtronic with evidence of this coverage.

- 9.2 MEDTRONIC'S LIABILITY. Medtronic shall indemnify, defend and hold harmless MacroPore and each of its subsidiaries, officers, directors, employees, shareholders and suppliers from and against and in respect of any and all Indemnifiable Losses resulting from, arising out of, or imposed upon or incurred by any person to be indemnified hereunder by reason of (i) any breach of representation, warranty, or agreement on the part of Medtronic under this Agreement, (ii) Product Liability Damages with respect to the Developed Products (except to the extent Medtronic has a claim against MacroPore pursuant to Section 9.1 above) or (iii) other negligence or intentional misconduct of Medtronic; provided that in no event shall Medtronic be liable for matters for which MacroPore is responsible under Section 9.1 above or for punitive or exemplary damages. Medtronic shall maintain product liability insurance or self-insurance in such amounts as ordinary good business practice for its type of business would make advisable and shall provide MacroPore with evidence of this coverage.
- 9.3 PROCEDURE. If a claim by a third party is made and a party (the "Indemnitee") intends to claim indemnification under this Article 9, the Indemnitee shall promptly notify the other party (the "Indemnitor") in writing of any claim in respect of which the Indemnitee or any of its subsidiaries, directors, officers, employees, shareholders, suppliers or distributors intends to claim such indemnification and the Indemnitor shall have sole control of the defense and/or settlement thereof, provided that the Indemnitee may participate in any such proceeding with counsel of its choice at its own expense. The indemnity agreement in this Article 9 shall not apply to amounts paid in settlement of any Indemnifiable Losses if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if adversely prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 9 but the omission to so deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may otherwise have to any Indemnitee other than under this Article 9. If the Indemnitor fails to provide defense of the claim, and diligently defend or settle the same after receipt of notice from Indemnitee of, and a reasonable opportunity to cure, such failure, the Indemnitee may defend or settle the claim without prejudice to its rights to indemnification hereunder, provided that the Indemnitee does so diligently and in good faith and further does not enter into any settlement or agree to any stipulation that would adversely affect the rights of the Indemnitor or impose any additional obligation on the Indemnitor without the Indemnitor's prior

13

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written consent (which consent will not be unreasonably withheld). The Indemnitee under this Article 9, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives and provide full information in the investigation of any Indemnifiable Losses covered by this indemnification.

# ARTICLE 10 TERM AND TERMINATION

- 10.1 TERM. This Agreement shall take effect as of the date hereof and shall continue in force until the fifth anniversary of the date hereof, and shall automatically renew for successive five-year periods unless either party gives the other party written notice of non-renewal at least 180 days prior to such renewal date (the "Term").
- 10.2 TERMINATION. Notwithstanding the provisions of Section 10.1 above, this Agreement may be terminated in accordance with the following provisions:
- (a) A party may terminate this Agreement by giving notice in writing to the other party if the other party is in breach of any material representation, warranty or covenant of this Agreement and, except as otherwise provided herein, shall have failed to cure such breach within 60 days after receipt of written notice thereof from the first party;
- (b) A party may terminate this Agreement at any time by giving notice in writing to the other party, which notice shall be effective upon dispatch, should the other party become insolvent, make an assignment for the benefit of creditors, go into liquidation or receivership or otherwise lose legal control of its business; or
- (c) A party may terminate this Agreement by giving notice in writing to the other party should an event of Force Majeure preventing performance by such other party continue for more than 180 consecutive days as provided in Article 11 below.
- 10.3 RIGHTS AND OBLIGATIONS ON TERMINATION. In the event of termination of this Agreement for any reason, the parties shall have the following rights and obligations:
- (a) Termination of this Agreement shall not release either party from the obligation to make payment of all amounts previously due and payable.
- (b) The terminating party shall have the right, at its option, to cancel any or all purchase orders that provide for delivery after the effective date of termination.
- (c) The parties' obligations pursuant to Articles 7, 9 and 12 and Sections 3.3, 10.3 and 13.1 hereof and any and all other terms and provisions hereof intended to be observed and performed by the parties after the termination hereof, shall survive termination of this Agreement. All other provisions of this Agreement shall terminate upon termination of this Agreement.

### ARTICLE 11 FAILURE TO SUPPLY AND FORCE MAJEURE

- 11.1 NOTICE OF FORCE MAJEURE. Upon giving notice to the other party, a party affected by an event of Force Majeure shall be released without any liability on its part from the performance of its obligations under this Agreement, except for the obligation to pay any amounts due and owing hereunder, but only to the extent and only for the period that its performance of such obligations is prevented by the event of Force Majeure.
- 11.2 SUSPENSION OF PERFORMANCE. Subject to Section 11.3 below, during the period that the performance by one of the parties of its obligations under this Agreement has been suspended by reason of an event of Force Majeure, the other party may likewise suspend the performance of all or part of its obligations hereunder (except for the obligation to pay any amounts due and owing hereunder) to the extent that such suspension is commercially reasonable.
- 11.3 EXERCISE OF LICENSE UPON FAILURE OF SUPPLY. Upon a Failure of Supply, Medtronic shall have the right to exercise its license rights granted pursuant to Section 11.4 below to manufacture and sell such Developed Product (but not any other Developed Product) itself or have such Product manufactured by others.

### 11.4 LICENSE GRANT.

- (a) MacroPore hereby grants Medtronic (i) an exclusive, sublicensable, worldwide, license to the Licensed Intellectual Property to make, have made, use, distribute, sell, offer for sale, have sold, import and otherwise commercialize and exploit Developed Products during the Term. Medtronic may not exercise such license unless and until the occurrence of a Failure of Supply.
- (b) The license granted herein shall be royalty free with respect to any Developed Products manufactured or supplied to Medtronic by MacroPore or any Affiliate of MacroPore. If Medtronic exercises its right pursuant to Section 11.3 to make or have made by a third party a Developed Product, then subject to the terms of this Agreement, Medtronic shall pay to MacroPore a royalty equal to [\*\*\*\*\*\*\*\*\*\*\*\*\*\*] of Medtronic's Net Sales of such Developed Product.
- (c) Within sixty (60) days after the end of each Medtronic fiscal quarter, Medtronic shall provide MacroPore with a written report indicating the amount of Net Sales of Developed Products during such quarter and the amount of the royalties due for such quarter. Simultaneously with making such report, Medtronic shall pay to MacroPore the amount of royalties then due.
- (d) Medtronic agrees to keep accurate written records sufficient in detail to enable the royalties payable under this Agreement by Medtronic to be determined and verified. Such records for a particular quarter shall be retained by Medtronic for a period of not less than three years after the end of such quarter.
- (e) Upon reasonable notice and during regular business hours, Medtronic shall from time to time (but no more frequently than once annually) make available the records referred to in

subsection (d) above for audit at MacroPore's expense by independent representatives selected by MacroPore to verify the accuracy of the reports provided to MacroPore. Such representatives shall execute a suitable confidentiality agreement reasonably acceptable to Medtronic prior to conducting such audit. Such representatives may disclose to MacroPore only their conclusions regarding the accuracy and completeness of royalty payments and of records related thereto, and shall not disclose Medtronic's confidential business information to MacroPore without the prior written consent of Medtronic.

- 11.5 TECHNOLOGY TRANSFER. Upon Medtronic's request any time after a Failure of Supply, MacroPore shall promptly provide to Medtronic, or a third party designated by Medtronic, as applicable, copies of such technical documentation and related know-how and trade secrets, and training as is reasonably necessary for a skilled manufacturer to make such Product; provided that any such third party shall agree to maintain the confidentiality of all such information to the same extent that Medtronic is obligated to do so under this Agreement, and Medtronic will reimburse MacroPore for salary and reasonable travel and lodging expenses for MacroPore personnel with respect to training requested by Medtronic at a location other than MacroPore's facility to the extent such expenses are substantiated by expense receipts.
- 11.6 MAINTAIN LICENSES IN FORCE. MacroPore shall comply with all of the provisions of, and shall maintain in full force and effect, all license agreements with third parties pursuant to which MacroPore is licensee of intellectual property included in the Licensed Intellectual Property. MacroPore shall promptly notify Medtronic if any such third party licensor alleges any breach by MacroPore of any such license agreement. Medtronic shall be entitled, but not obligated, to cure any alleged breach by MacroPore of such license agreement and set-off the cost of such cure against amounts otherwise owed to MacroPore hereunder.
- 11.7 NO LIABILITY. MacroPore shall have no obligation or any liability under Section 7.2 with respect to any Developed Products produced by Medtronic or its third party designee pursuant to the license granted in this Article 11.

# ARTICLE 12 INTELLECTUAL PROPERTY

12.1 TRADEMARKS. MacroPore hereby grants Medtronic a royalty-free license to use all trademarks, trade names and logotypes of MacroPore relating to the Developed Products solely in connection with the sale or other distribution, promotion, advertising and/or maintenance of the Developed Products. Medtronic shall acquire no right, title or interest in such MacroPore trademarks, trade names and logotypes, other than the license provided for above, and Medtronic shall not use any MacroPore trademarks, trade names and logotypes as part of Medtronic's corporate or trade name, or trademark or logotype or permit any third party under Medtronic's control to do so without the prior written consent of MacroPore. To the extent permitted by local law, any statutory powers which would be granted to Medtronic by virtue of its local use of MacroPore's trademarks or its licensee status are excluded. Medtronic shall, in addition, have the right to promote and sell the Developed Products under trademarks, trade names and logotypes of Medtronic selected by Medtronic, which trademarks, trade names and logotypes shall be and shall remain the property of Medtronic.

- 12.2 TRADEMARK INFRINGEMENT. Each party shall promptly notify the other party of any use by any third party of such other party's trademarks, trade names or logotypes or any use by such third parties of similar marks that may constitute an infringement or passing off of such other party's trademarks, trade names or logotypes of which such first party has knowledge. The owner of such trademark(s) reserves the right in its sole discretion to institute any proceedings against such third-party infringers and the other party shall refrain from doing so. Each party agrees to cooperate fully with the other party in any action taken by such other party against such third parties, provided that all expenses of such action shall be borne by such other party and all damages that may be awarded or agreed upon in settlement of such action shall accrue to such other party.
- 12.3 TERMINATION OF USE OF TRADEMARKS. Medtronic acknowledges MacroPore's proprietary rights in and to MacroPore's trademarks, trade names and logotypes, and Medtronic hereby waives all right to any trademarks, trade names and logotypes now or hereafter originated by MacroPore. Medtronic shall not after the date of this Agreement adopt, use or register any words, phrases or symbols that are identical to or confusingly similar to any of MacroPore's trademarks. Upon termination of this Agreement, Medtronic shall cease using MacroPore's trademarks, trade names and logotypes in any manner, subject to Medtronic's right, if any, to continue to sell its remaining inventory of Developed Products.
- 12.4 MEDTRONIC PROPERTY. All tooling, patterns, dies, gauges, jobs, fixtures, and all specifications, drawings, samples, designs, software, firmware, programs, formulae, and other items and information, including, without limitations improvements to the Developed Product furnished by Medtronic to MacroPore in connection with this Agreement shall only be used in the performance of work for Medtronic; and shall remain the property of Medtronic; and together with all copies thereof shall be disposed of or returned in good repair, normal wear and tear excepted, by MacroPore to Medtronic at Medtronic's direction and expense upon Medtronic's request. MacroPore assumes risk of loss and damage to said items while in its possession or under its control. MacroPore shall notify Medtronic promptly whenever any items of Medtronic's tangible property are in need of repair or replacement. Medtronic's property shall be marked or otherwise adequately identified by MacroPore as property of Medtronic for use only under this Agreement and shall be safely stored. MacroPore waives any right it may have in law or equity to withhold Medtronic's property.

#### 12.5 PATENT RIGHTS.

(a) DEFENSE OF CLAIMS. Medtronic shall defend, or at its option settle, any suit instituted against Medtronic that is based on an allegation that any Developed Product constitutes an infringement of any patent or any other intellectual property right. Medtronic shall have sole control of defense of any such action, including any appeals and negotiations for the settlement or compromise thereof and shall have full authority to enter into a binding settlement or compromise; provided that Medtronic shall not enter into any settlement or compromise that may adversely affect MacroPore without MacroPore's consent, which consent shall not be unreasonably withheld. Medtronic shall indemnify, subject to the limitations set forth herein, MacroPore against any final award of damages and costs made against MacroPore and any settlement amounts as a result of any such action. MacroPore shall notify Medtronic promptly in

writing of such claim, suit or proceeding and give Medtronic such information and assistance as Medtronic may reasonably request to settle and defend any such claim.

- (b) LIMITATION OF LIABILITY. Medtronic shall have no liability of any kind to MacroPore under Section 10.5 or based upon any other claim MacroPore may have to the extent any such claim is based upon or arises out of the use of poly-lactic acid or any manufacturing or processing of Developed Product.
- 12.6 PROTECTION OF INTELLECTUAL PROPERTY. Each party shall be responsible for and have control of filing, prosecuting and maintaining all US and foreign patents and copyrights and applications therefor owned by it, and no party shall have any obligation to obtain or maintain any patent or copyright except as it deems necessary or appropriate to protect such party's Intellectual Property.
- 12.7 OWNERSHIP OF INVENTIONS. Subject to the terms of this Agreement, (a) any Invention conceived, reduced to practice or otherwise made, developed or acquired by one or more employees or agents of MacroPore shall be the property of MacroPore, (b) any Invention conceived, reduced to practice or otherwise made, developed or acquired by one or more employees or agents of Medtronic shall be the property of Medtronic, and (c) MacroPore and Medtronic shall each have an undivided one-half interest in any Invention jointly conceived, reduced to practice or otherwise made, developed or acquired by one or more employees or agents of MacroPore and one or more employees or agents of Medtronic; provided that neither party shall exploit such jointly-owned Invention without the written consent of the other party.

#### ARTICLE 13 MISCELLANEOUS

- 13.1 NONDISCLOSURE. The parties agree not to disclose or use (except as permitted or required for performance by the party receiving such Confidential Information of its rights or duties hereunder) any Confidential Information of the other party obtained during the during the term of this Agreement until the expiration of five years after the receiving party's receipt of such Confidential Information. Each party further agrees to take appropriate measures to prevent any such prohibited disclosure of Confidential Information by its present and future employees, officers, agents, subsidiaries, or consultants during such period.
- 13.2 PUBLIC ANNOUNCEMENT. In the event any party proposes to issue any press release or public announcement concerning any provisions of this Agreement or the transactions contemplated hereby, such party shall so advise the other parties hereto, and the parties shall thereafter use their best efforts to cause a mutually agreeable release or announcement to be issued. Neither party will publicly disclose or divulge any provisions of this Agreement or the transactions contemplated hereby without the other party's written consent, except as may be required by applicable law or stock exchange regulation, and except for communications to such party's employees or customers or investors or prospective investors (subject to appropriate confidentiality obligations).
- 13.3 COMPLETE AGREEMENT. This Agreement, the Investment Agreement, the Investors' Rights Agreement, the Supplemental Rights Agreement, the Distribution Agreement, and the

Schedules and Exhibits hereto and thereto, constitute the entire agreement between the parties hereto with respect to the subject matter hereof and supersede all prior agreements whether written or oral relating hereto.

- 13.4 WAIVER, DISCHARGE, AMENDMENT, ETC. The failure of any party hereto to enforce at any time any of the provisions of this Agreement shall not, absent an express written waiver signed by the party making such waiver specifying the provision being waived, be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of the party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach. Any amendment to this Agreement shall be in writing and signed by the parties hereto.
- 13.5 SUCCESSORS AND ASSIGNS. This Agreement shall be binding upon and inure to the benefit of the parties hereto and the successors or assigns of the parties hereto; provided, that (i) the rights and obligations of MacroPore herein may not be assigned except to any person who succeeds to substantially all of the assets and business of MacroPore to which this Agreement relates, and (ii) the rights and obligations of Medtronic herein may not be assigned except to any person who succeeds to substantially all of that portion of Medtronic's business to which this Agreement relates.
- 13.6 NOTICES. All notices or other communications to a party required or permitted hereunder shall be in writing and shall be delivered personally or by facsimile (receipt confirmed electronically) to such party (or, in the case of an entity, to an executive officer of such party) or shall be sent by a reputable express delivery service or by certified mail, postage prepaid with return receipt requested, addressed as follows:

### if to Medtronic, to:

Medtronic, Inc. Corporate Center 7000 Central Avenue N.E. Minneapolis, MN 55432 Attention: General Counsel Facsimile: (612) 572-5459

with a copy to:

Medtronic, Inc. Corporate Center 7000 Central Avenue N.E.

Minneapolis, MN 55432 Attention: Vice President and Chief Development Officer Facsimile: (612) 572-5404

if to MacroPore, to:

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

San Diego, CA 92121 Attention: Christopher J. Calhoun

Facsimile: (858) 458-0995

with a copy to:

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

San Diego, CA 92121 Attention: Vice President of Finance

Facsimile: (858) 458-0994

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

- 13.7 EXPENSES. Except as expressly provided herein, MacroPore and Medtronic shall each pay their own expenses incident to this Agreement and the preparation for, and consummation of, the transactions provided for herein.
- 13.8 GOVERNING LAW. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Minnesota, including all matters of construction, validity, performance and enforcement, without giving effect to principles of conflict of laws.
- 13.9 TITLES AND HEADINGS; CONSTRUCTION. The titles and headings to the Articles and Sections herein are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the party causing this Agreement to be drafted.
- 13.10 ILLEGALITY; SEVERABILITY. In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 13.11 RELATIONSHIP. This Agreement does not make either party the employee, agent or legal representative of the other for any purpose whatsoever. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party. In fulfilling its obligations pursuant to this Agreement, each party shall be acting as an independent contractor.
- 13.12 BENEFIT. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties hereto or their respective successors or assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

- 13.13 SURVIVAL. All of the representations, warranties, and covenants made in this Agreement, and all terms and provisions hereof intended to be observed and performed by the parties after the termination hereof, shall survive such termination and continue thereafter in full force and effect.
- 13.14 COUNTERPARTS. This Agreement may be executed in any number of counterparts, each of which shall be deemed as original and all of which together shall constitute one instrument.
- 13.15 EXECUTION OF FURTHER DOCUMENTS. Each party agrees to execute and deliver without further consideration any further applications, licenses, assignments or other documents, and to perform such other lawful acts as the other party may reasonably require to fully secure and/or evidence the rights or interests herein.

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

MACROPORE, INC.

By: /s/ Christopher J. Calhoun

Its: Vice-Chairman and Chief Executive Officer

MEDTRONIC, INC.

Its:

By: /s/ Michael D. Ellwein

VP and Chief Development Officer

### EXHIBIT A

### PROPOSED POTENTIAL DEVELOPMENT PRODUCTS

1.	[*	k *	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	]			
2.	[ *	* *	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	]
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# AMENDMENT NO. 1 TO DEVELOPMENT AND SUPPLY AGREEMENT

This Amendment No. 1, effective as of December 22, 2000, is to that certain Development and Supply Agreement (the "Agreement"), dated as of January 5, 2000, by and between MacroPore, Inc., a Delaware corporation ("MacroPore") and Medtronic, Inc. ("Medtronic"), a Minnesota corporation.

WHEREAS, MacroPore and Medtronic desire to amend the Agreement as set forth below.

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

1. Section 6.1 (Prices) of the Agreement shall be deleted in its entirety and the following inserted in its place.

### "Section 6.1) PRICES.

- (a) Unless and until otherwise mutually agreed upon by the parties in writing, the purchase price per unit of Developed Products to Medtronic (the "Transfer Price") under this Agreement shall be based on the price list in effect at the time of receipt of the order (the "Price List") to be set forth on Exhibit B to this Agreement. The Price List shall be reviewed by MacroPore and Medtronic on the six month anniversary of the date of the initial Price List and every six months thereafter, with any changes to the Price List to take effect upon delivery of the revised Price List to Medtronic. New Developed Products may be added to the Price List at any time by 30 day prior written notice to Medtronic. In the event MacroPore and Medtronic's review of the Price List results in a change to the Transfer Price for any of the Developed Products on the Price List, all such changes will apply to the Transfer Price of future sales and shall not be applied retroactively to previous sales of that Developed Product to Medtronic. Separate Transfer Prices will be established for sales in the United States and for sales in the international market. The prices for customized products are not included in the Price List but shall be determined in accordance with Section 5.8 herein.
- (b) MacroPore will establish the Price List (i) for Developed Products that are Spinal Implants based on [\*\*\*] of the

estimated average selling price per unit for each Product, excluding any sales, use or excise tax, freight, duty or insurance included therein and (ii) for Developed Products that are [\*\*\*\*\*\*\*\*\*\*\*\*\*\* based on [\*\*\*] of the estimated average selling price per unit for each Product, excluding any sales, use or excise tax, freight, duty or insurance included therein; provided that in no event shall the Transfer Price for any Developed Product be less than [\*\*\*] of MacroPore's per unit direct cost of manufacturing.

- (c) If Medtronic sells the Developed Product as part of a packaged combination of products or instruments, then Medtronic's sale price of the Developed product shall equal either (i) the respective average net selling price during such period of the same type of Developed Product sold individually, or (ii) the average net selling price during such period for a comparable product (if the same type of Developed Product is not sold individually).
- (d) Medtronic and MacroPore agree to keep accurate written records sufficient in detail to enable Medtronic's average selling price and MacroPore's direct cost of manufacturing, respectively, of Developed Products to be determined and verified. Such records for a particular quarter shall be retained for a period of not less than three years. Upon reasonable notice and during regular business hours, each party shall from time to time (but no more frequently than once annually) make available such records for audit at the other party's expense by independent representatives selected by such other party to verify the accuracy of the reports provided to such other party. Such representatives shall execute a suitable confidentiality agreement reasonable acceptable to the party whose records are being audited prior to conducting such audit. Such representatives may disclose to such other party only their conclusions regarding the accuracy and completeness of records related thereto, and shall not disclose confidential business information to such other party without the prior written consent of Medtronic.
- 2. The Agreement will be amended by inserting Exhibit B immediately after Exhibit A to the Agreement as soon as Exhibit B becomes available.
- 3. Except as amended hereby, the Agreement shall remain unchanged and in full force and effect.

PORTIONS OF THIS EXHIBIT MARKED AS [\*\*\*] HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SEC.

- 4. This Amendment No. 1 and the Agreement constitute the entire agreement among the parties hereto with respect to the subject matter hereof, and supersede any and all prior agreements and undertakings, oral or written, concerning the subject matter hereof. This Agreement may not be changed or terminated orally, and may only be changed or terminated by a writing signed by the party against whom such change or termination is sought.
- 5. This Amendment No. 1 may be executed in any number of counterparts and by facsimile, each of which, when executed, shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

IN WITNESS WHEREOF, this Amendment No. 1 has been duly executed by the parties as of the date first set forth above.

MACROPORE, INC., a Delaware corporation

/s/ Charles E. Galetto By:

Charles E. Galetto

Name:

VP - Finance Its:

MEDTRONIC, INC., a Minnesota corporation

By: /s/ Michael D. Ellwein

Michael D. Ellwein Name:

Vice President and Chief Development Officer Its:

June 1, 2001

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

### Commissioners:

We have read the statements made by MacroPore, Inc. (copy attached), which we understand will be filed with the Commission, pursuant to Item 14 of Form 10/A, as part of the Company's Form 10 report dated June 1, 2001. We agree with the statements concerning our Firm made in Item 14 of such Form 10.

Very truly yours,

/s/ PricewaterhouseCoopers LLP