
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended September 30, 2004

OR

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

For the transition period from _____ to _____

Commission file number 0-32501

MacroPore Biosurgery, Inc.

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

Delaware

(State or other jurisdiction of incorporation or organization)

33-0827593

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

6740 Top Gun Street, San Diego, California

(Address of principal executive offices)

92121

(Zip code)

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES NO

As of October 25, 2004, there were 13,927,184 shares of MacroPore Biosurgery, Inc. common stock outstanding.

MACROPORE BIOSURGERY, INC.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Report of Independent Registered Public Accounting Firm

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

We have reviewed the accompanying consolidated condensed balance sheet of MacroPore Biosurgery, Inc. and subsidiaries as of September 30, 2004, and the related consolidated condensed statements of operations and comprehensive income (loss) for the three-month and nine-month periods ended September 30, 2004 and 2003, and consolidated condensed statements of cash flows for the nine month periods ended September 30, 2004 and 2003. These consolidated condensed financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with standards established by the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards of the Public Company Accounting Oversight Board (United States), 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 reviews, we are not aware of any material modifications that should be made to the consolidated condensed financial statements referred to above for them to be in conformity with U.S. generally accepted accounting principles.

We have previously audited, in accordance with standards established by the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of MacroPore Biosurgery, Inc. and subsidiaries as of December 31, 2003, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated February 20, 2004, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying consolidated condensed balance sheet as of December 31, 2003 is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

Note 1 of MacroPore Biosurgery, Inc.'s audited financial statements as of December 31, 2003 and for the year then ended, discloses that the Company derives a substantial portion of its revenues from a related party. Our auditors' report on those financial statements dated February 20, 2004, includes an explanatory paragraph referring to the matter in note 1 of those financial statements.

/s/ KPMG LLP

San Diego, California
October 29, 2004

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	As of September 30, 2004 (Unaudited)	As of December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,986,000	\$ 2,820,000
Short-term investments, available-for-sale	13,991,000	11,448,000
Accounts receivable, net of allowance for doubtful accounts of \$5,000 and \$62,000 in 2004 and 2003, respectively	178,000	1,291,000
Inventories	459,000	831,000
Milestone payment due from distribution agreement	1,250,000	—
Other current assets	940,000	526,000
	<u>19,804,000</u>	<u>16,916,000</u>
Total current assets	19,804,000	16,916,000
Property and equipment, net	3,396,000	3,822,000

Other assets	226,000	332,000
Intangibles, net	2,189,000	2,392,000
Goodwill	4,387,000	4,627,000
Total assets	\$ 30,002,000	\$ 28,089,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,248,000	\$ 3,767,000
Current portion of long-term obligations	958,000	717,000
Total current liabilities	3,206,000	4,484,000
Deferred gain on sale of assets, related party	—	7,539,000
Deferred gain on sale of assets	5,694,000	—
Deferred license fee revenue	1,500,000	—
Deferred development revenue	1,092,000	—
Long-term obligations, less current portion	1,347,000	1,157,000
Total liabilities	12,839,000	13,180,000
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2004 and 2003	—	—
Common stock, \$0.001 par value; 95,000,000 shares authorized; 16,800,018 and 16,777,644 shares issued and 13,927,184 and 14,195,062 shares outstanding in 2004 and 2003, respectively	17,000	17,000
Additional paid-in capital	74,734,000	74,698,000
Unearned compensation	—	(109,000)
Accumulated deficit	(47,159,000)	(49,385,000)
Treasury stock, at cost	(10,414,000)	(9,362,000)
Treasury stock receivable	—	(976,000)
Accumulated other comprehensive (loss) income	(15,000)	26,000
Total stockholders' equity	17,163,000	14,909,000
Total liabilities and stockholders' equity	\$ 30,002,000	\$ 28,089,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues:				
Sales to related party	\$ 298,000	\$ 4,230,000	\$ 3,113,000	\$ 8,421,000
Sales to third parties	1,189,000	265,000	2,166,000	906,000
Research grant	129,000	—	229,000	—
Development	158,000	—	158,000	—
	<u>1,774,000</u>	<u>4,495,000</u>	<u>5,666,000</u>	<u>9,327,000</u>
Cost of revenues:				
Cost of revenues (including stock based compensation expense of \$-0- and \$3,000 for the three months ended September 30, 2004 and 2003; \$3,000 and \$9,000 for the nine months ended September 30, 2004 and 2003, respectively)	1,184,000	1,438,000	2,375,000	2,864,000
Inventory provision	—	—	242,000	—
Gross profit	<u>590,000</u>	<u>3,057,000</u>	<u>3,049,000</u>	<u>6,463,000</u>
Operating expenses:				
Research and development, excluding stock based compensation expense of \$-0- and \$19,000 for the three months ended September 30, 2004 and 2003, respectively; \$32,000 and \$58,000 for the nine months ended September 30, 2004 and 2003, respectively	2,959,000	2,552,000	8,134,000	6,810,000
Sales and marketing, excluding stock based compensation expense of \$-0- and \$17,000 for the three months ended September 30, 2004 and 2003, respectively; \$22,000 and	454,000	1,055,000	2,066,000	3,354,000

\$53,000 for the nine months ended September 30, 2004 and 2003, respectively

General and administrative, excluding stock based compensation expense of \$-0- and \$411,000 for the three months ended September 30, 2004 and 2003, respectively; \$71,000 and \$761,000 for the nine months ended September 30, 2004 and 2003, respectively	1,502,000	1,426,000	4,303,000	3,425,000
Stock based compensation (excluding cost of revenues stock based compensation)	—	447,000	125,000	872,000
Restructuring charge	37,000	458,000	107,000	458,000
Total operating expenses	4,952,000	5,938,000	14,735,000	14,919,000
Total operating loss	(4,362,000)	(2,881,000)	(11,686,000)	(8,456,000)
Other income (expense):				
Gain on the sale of assets, related party	8,883,000	—	13,883,000	—
Interest income	68,000	88,000	180,000	335,000
Interest expense	(44,000)	(24,000)	(131,000)	(88,000)
Other income (expense)	1,000	18,000	(20,000)	71,000
Total other income (expense)	8,908,000	82,000	13,912,000	318,000
Net income (loss)	4,546,000	(2,799,000)	2,226,000	(8,138,000)
Other comprehensive income (loss): unrealized holding loss	9,000	(44,000)	(41,000)	(96,000)
Comprehensive income (loss)	\$ 4,555,000	\$ (2,843,000)	2,185,000	\$ (8,234,000)
Net income (loss) per common share:				
Basic	\$ 0.33	\$ (0.19)	\$ 0.16	\$ (0.56)
Diluted	\$ 0.31	\$ (0.19)	\$ 0.15	\$ (0.56)
Weighted average common shares:				
Basic	13,929,326	14,605,273	13,929,895	14,557,167
Diluted	14,661,303	14,605,273	14,779,478	14,557,167

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	<u>Nine Months Ended September 30,</u>	
	<u>2004</u>	<u>2003</u>
Cash flows from operating activities:		
Net income (loss)	\$ 2,226,000	\$ (8,138,000)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,302,000	1,215,000
Inventory provision	242,000	—
Bad debt provision (reduction)	(46,000)	—
Warranty charge	—	243,000
Restructuring charge	—	458,000
Amortization of gain on sale of assets, related party	(156,000)	(1,342,000)
Amortization of gain on sale of assets	(735,000)	—
Gain on sale of assets, related party	(13,883,000)	—
Stock based compensation	119,000	881,000
Increases (decreases) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisition:		
Accounts receivable	1,159,000	(1,585,000)
Inventories	(47,000)	163,000
Other current assets	(414,000)	189,000
Other assets	18,000	125,000
Accounts payable and accrued expenses	(515,000)	900,000
Deferred license fee revenue	1,500,000	—
Deferred development revenue	(158,000)	—
Net cash used in operating activities	(9,388,000)	(6,891,000)
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	38,221,000	38,029,000

Purchases of short-term investments	(40,805,000)	(32,790,000)
Proceeds from sale of assets, related party	6,500,000	—
Cost of sale of assets, related party	—	(38,000)
Proceeds from the sale of assets, net	6,934,000	—
Purchases of property and equipment	(673,000)	(1,013,000)
Acquisition costs	(28,000)	(644,000)
Proceeds from the sale of impaired assets	—	46,000
Net cash provided by investing activities	10,149,000	3,590,000
Cash flows from financing activities:		
Principal payments on long-term obligations	(608,000)	(275,000)
Proceeds from long-term obligations	1,039,000	490,000
Proceeds from the exercise of employee stock options	26,000	33,000
Purchase of treasury stock	(1,052,000)	(248,000)
Proceeds from sale of treasury stock	—	542,000
Net cash (used in) provided by financing activities	(595,000)	542,000
Net increase (decrease) in cash	166,000	(2,759,000)
Cash and cash equivalents at beginning of period	2,820,000	5,108,000
Cash and cash equivalents at end of period	<u>\$ 2,986,000</u>	<u>\$ 2,349,000</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 133,000	\$ 88,000
Taxes	7,000	12,000
Supplemental schedule of non-cash investing activities		
Increase in cost of acquisition	\$ —	\$ 319,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

MACROPORE BIOSURGERY, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
September 30, 2004
(UNAUDITED)

1. Basis of Presentation

The accompanying unaudited consolidated condensed financial statements as of September 30, 2004 and for the three and nine months ended September 30, 2004 and 2003 have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for audited financial statements. The consolidated condensed balance sheet at December 31, 2003 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States 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 Biosurgery, Inc. ("MacroPore" or the "Company") have been included. Operating results for the three and nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, refer to the consolidated financial statements for the year ended December 31, 2003 and footnotes thereto which were included in the Company's Annual Report on Form 10-K, dated March 30, 2004.

2. Use of Estimates

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

3. Stock Based Compensation

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

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

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

The weighted average estimated fair values of stock options granted during the nine months ended September 30, 2004 was \$3.26 per share. There were no stock options granted during the three months ended September 30, 2004. The weighted average estimated fair values of stock options granted during the three and nine months ended September 30, 2003 were \$2.86 and \$3.64 per share, respectively. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

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	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
Expected term	—	7 years	7 years	7 – 8 years
Interest rate	—	3.45 – 3.96%	3.31-4.35%	2.84% - 3.96%
Volatility	—	92.9%	86.4 – 89.3%	95.0% – 98.0%
Dividends	—	—	—	—

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss):				
As reported	\$ 4,546,000	\$ (2,799,000)	\$ 2,226,000	\$ (8,138,000)
Add: Stock based employee compensation expense included in reported net income (loss), net of related tax effects	—	450,000	96,000	881,000
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(764,000)	(986,000)	(1,991,000)	(3,490,000)
Pro forma	\$ 3,782,000	\$ (3,335,000)	\$ 331,000	\$ (10,747,000)
Basic income (loss) per share:				
Basic income (loss) per common share:				
As reported	\$ 0.33	\$ (0.19)	\$ 0.16	\$ (0.56)
Pro forma	\$ 0.27	\$ (0.23)	\$ 0.02	\$ (0.74)
Diluted income (loss) per common share:				
As reported	\$ 0.31	\$ (0.19)	\$ 0.15	\$ (0.56)
Pro forma	\$ 0.26	\$ (0.23)	\$ 0.02	\$ (0.74)

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

4. Short-Term Investments

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

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

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

At September 30, 2004, the excess of carrying cost over the fair value of the Company's short-term investments that are below carrying cost is immaterial.

5. Inventories

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

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

6. Long-Lived Assets

In accordance with SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets," the Company assesses certain of its long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recovered. An impairment occurs when the undiscounted cash flows expected to be generated by an asset are less than its then carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. During the nine months ended September 30, 2004 and 2003, the Company had no impairment losses.

7. Revenue Recognition

Product Sales

The Company sells its products to distributors, and before the sale of its Thin Film product line in May 2004, also sold products directly to hospitals. The Company has agreements with its distributors that title and risk of loss pass upon shipment of the products to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order. Before the sale of the Thin Film product line in May 2004, revenue from sales to hospitals was recognized upon delivery of the product. On occasion, the Company offers extended payment terms to customers. The Company does not recognize revenues under these arrangements until the payment becomes due or, if earlier, is received.

The Company warrants that its products are free from manufacturing defects at the time of shipment to its customers. The Company has recorded a reserve for the estimated costs it may incur under its warranty program.

Except for the third quarter of 2004, the majority of the Company's revenues are from Medtronic, under a Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002, as well as a Development and Supply Agreement dated January 5, 2000 and amended December 22, 2000 and September 30, 2002. These revenues are classified as revenues from related party in the consolidated condensed statements of operations.

Any upfront payments received from license/distribution agreements are recognized ratably over the term of the agreement, provided no significant obligations or deliverables remain, into revenues from related party or revenues from third parties depending upon the counterparty to the transaction. Refer to note 14 below for the Company's specific policies related to the upfront fees recognized associated with the Senko distribution agreement.

In September 2002, the Company entered into various agreements with Medtronic and a subsidiary of Medtronic for the sale of the Company's CMF implants product line. The net proceeds received were recorded as a deferred gain on sale of assets, related party. The Company recognized as revenue in 2002 and 2003, and during 2004, a portion of the deferred gain upon the sale of the CMF products to Medtronic under the Company's back-up supply arrangement, which provided for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized correlates to the gross margin normally realized by the Company on similar products. The remainder of the deferred gain of \$7,383,000 was recognized as a gain on the sale of assets, related party in the third quarter of 2004 when Medtronic acknowledged that the technology and know-how transfer had been completed pursuant to the contract terms.

In May 2004, the Company sold most, but not all, of its Thin Film product line. Refer to note 13 below for the Company's specific policies related to the recognition of revenues and gain on sale of assets associated with this transaction.

Research

The Company earns revenue for performing tasks under research agreements with both commercial enterprises and governmental agencies like the National Institutes of Health ("NIH"). Milestone payments are considered to be payments received for the

accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, the amount of the milestone payments appear reasonably commensurate with the effort expended and collection of the payment is reasonably assured.

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

- Qualifying costs incurred (and not previously recognized) for which the Company is entitled to funding from the NIH; or,

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

Revenue earned under development agreements is classified as research grant or development revenues in the Company's statements of operations. The costs associated with development agreements are recorded as research and development expense. During the three and nine months ended September 30, 2004, the Company recognized NIH grant revenue of \$129,000 and \$229,000 and incurred qualifying costs of \$93,000 and \$246,000, respectively. There were no comparable revenues or costs in 2003 for NIH grants. During the three and nine months ended September 30, 2004, the Company recognized development revenue of \$158,000 and incurred costs of \$134,000 (refer to note 14 below). There were no comparable development revenues or costs in 2003.

Additionally, the Company earns revenue from contracted development arrangements. These arrangements are generally time and material arrangements and accordingly any revenue is recognized as services are performed and recorded in revenues from related party or revenues from third parties based upon the nature of the transaction. Any costs related to these arrangements are recognized as cost of revenue as these costs are incurred. There were no revenues of this type during any periods presented in the accompanying consolidated condensed statements of operations.

Other revenues

The Company recognizes revenue from the collection and storage of regenerative cell rich adipose tissue. In its cell banking service, the Company recognizes revenue for collection services when (i) the collection procedure is performed, (ii) the adipose tissue is received by the Company, (iii) fees from the procedure are fixed and determinable and (iv) payment is probable. In accordance with Emerging Issues Task Force ("EITF") No. 00-21 "Accounting for Revenue Arrangements with Multiple Elements," the Company uses the residual method to recognize revenue when a procedure includes elements to be delivered at a future date if evidence of the fair value of all undelivered elements exists. If evidence of the fair value of the undelivered elements does not exist, revenue is deferred on all elements and recognized when all elements are delivered.

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

8. Warranty

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

The following summarizes the Company's warranty reserve at September 30, 2004 and 2003:

	Balance at January 1	Additions (charges to expenses)	Claims	Balance at September 30
2004:				
Warranty reserve	\$ 267,000	\$ 66,000	\$ (251,000)	\$ 82,000
2003:				
Warranty reserve	\$ —	\$ 243,000	\$ —	\$ 243,000

In August 2003, as part of our ongoing product monitoring process, the Company determined that some of the products sold to Medtronic did not meet certain expectations, based on criteria previously communicated by the Company to Medtronic. The Company agreed to a "no charge" replacement of the affected inventory in the possession of Medtronic. During the nine months ended September 30, 2004, the Company incurred claims of \$251,000 in the replacement of the product.

9. Earnings (Loss) Per Share

The Company computes income (loss) per share based on the provision of SFAS No. 128, "Earnings Per Share." Basic per share data is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common share equivalents that would have been outstanding if potential common shares had been issued using the treasury stock method.

The composition of the weighted average common shares are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Weighted average shares, basic	13,929,326	14,605,273	13,929,895	14,557,167
Dilutive effect of stock options	731,977	—	849,583	—
Weighted average shares, diluted	14,661,303	14,605,273	14,779,478	14,557,167

The following instruments were not included in the calculation of diluted net income (loss) per share because the effect of the instrument was anti-dilutive:

	Three months ended September 30,		Nine months ended September 31,	
	2004	2003	2004	2003
Common stock options	2,923,722	4,832,944	2,454,317	4,832,944

10. Long-term Debt

In September 2003, the Company entered into an Amended Master Security Agreement to provide financing for equipment purchases.

In March 2004, the Company issued a promissory note under this Amended Master Security Agreement in an aggregate principal amount of approximately \$594,000. This note is secured by equipment with a cost of \$594,000. This note bears interest at 8.18% per annum with principal and interest due in monthly payments of approximately \$16,000 for the first 36 months and \$9,000 for the remaining 12 months.

In April 2004, the Company issued a promissory note in an aggregate principal amount of approximately \$128,000 and it is secured by equipment with a cost of \$128,000. This note bears interest at 9.01% per annum with principal and interest due in monthly payments of approximately \$3,000 for the first 36 months and \$2,500 for the remaining 12 months.

In September 2004, the Company issued a promissory note in an aggregate principal amount of approximately \$317,000 and it is secured by equipment with a cost of \$317,000. This note bears interest at 8.97% per annum with principal and interest due in monthly payments of approximately \$9,000 for the first 36 months and \$4,000 for the remaining 12 months.

As of September 30, 2004, the future contractual principal payments on all of the Company's promissory notes are as follows:

For the years ended December 31,

2004	\$	238,000
2005		937,000
2006		614,000
2007		428,000
2008		88,000
	\$	<u>2,305,000</u>

The interest expense for the three and nine months ended September 30, 2004 was \$44,000 and \$131,000, respectively.

11. Restructuring Event

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

The Königstein, Germany office is rented under an operating lease. As of September 30, 2003, the Company had ceased using the office space, but continued to remain liable for monthly rent payments of approximately \$12,500 per month under a lease agreement that expires in February 2006 (the "Lease Agreement"). The Company sought to sublease the entire facility for the remaining term of the Lease Agreement. However, due to the unique nature of the office building and the depressed rental market in and around Frankfurt, Germany, the Company expected that a sublease of the entire facility (if one is successfully negotiated) would yield only approximately 65% of the Company's monthly rental obligation. Accordingly, the Company recorded a restructuring expense of \$169,000 in the year 2003.

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

was recorded as restructuring expense.

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

The following outlines the restructuring activity recorded to the liability account during the nine months ended September 30, 2004:

	<u>December 31, 2003</u>	<u>Charged to Expense*</u>	<u>Costs Paid</u>	<u>Adjustments to Liability**</u>	<u>September 30, 2004</u>
Lease termination	\$ 153,000	\$ 107,000	\$ (255,000)	\$ (5,000)	\$ —

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

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

12. Gain on Sale of Assets, Related Party

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

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

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

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

In January 2004, the Company received a \$5,000,000 milestone payment from Medtronic relating to the disposition of the Company’s CMF product line. As part of the disposition arrangement, the Company agreed to complete clinical research regarding Faster Resorbable Polymers, an area that directly relates to the CMF product line transferred to Medtronic. The Company became entitled to the \$5,000,000 payment after fulfilling the research requirements set out in the CMF sale agreement. The \$5,000,000 payment has been recognized as “gain on sale of assets, related party” in the accompanying consolidated condensed statements of operations.

13. Sale of Bioresorbable Thin Film Product Line

In May 2004, the Company sold most, but not all, of its intellectual property rights and tangible assets related to its Thin Film product line to MAST Biosurgery AG, a Swiss corporation (“MAST”) and a subsidiary of MAST.

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

- \$200,000, payable only upon receipt of 510K clearance from the U.S. Food and Drug Administration (“FDA”) for a hernia wrap product currently under development and subject to FDA clearance, and
- \$2,000,000 on or before the earlier of (i) May 31, 2005, known as the “Settlement Date,” or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer, provided the Chief Executive Officer has held that position for at least four months and meets other requirements specified in the sale agreement. Note that clause (ii) effectively means that the Company will not receive payment of \$2,000,000 before May 31, 2005 unless MAST has hired a Chief Executive Officer on or before January 31, 2005 (four months prior to the Settlement Date). Moreover, in the event that

MAST does not hire a Chief Executive Officer on or before January 31, 2005, MAST may (at its sole option and subject to the requirements of the sale agreement) alternatively provide the Company with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 in lieu of making the \$2,000,000 payment.

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

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

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

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

Because of these additional performance requirements, the Company did not initially recognize any gain on sale of the Thin Film assets in the accompanying statement of operations. Instead, at the time of the sale, the Company recorded approximately \$6,429,000 as deferred gain on sale of assets in the accompanying balance sheet. The amount recorded as deferred gain on sale of assets does not include the two potential elements of contingent consideration described above, which will only be recognized when the contingencies are resolved.

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

- MAST has stopped relying on the Company to provide product under the back-up supply agreement,
- Transfer of Thin Film tangible assets and rights to intangible assets, and
- Delivery of all requisite training.

In addition, the Company has been recognizing (and will continue to recognize) a portion of the deferred gain as revenues as and when the Company sells products to MAST under the back-up supply agreement. This is necessary to record revenues (and gross margin) at the amount the Company would normally charge for selling the same product in an unencumbered transaction. In the first nine months of 2004, the Company has recognized \$735,000 of the deferred gain as revenues.

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

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

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

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

- If MAST exercises its option on or before May 31, 2005, the purchase price will be \$3,000,000, although such amount

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could have been reduced if MAST exercised its option within forty-five days of the Company entering into a business arrangement in Japan that involves the Company receiving an upfront, non-refundable license fee. On July 16, 2004, the Company did enter into a business arrangement in Japan with Senko Medical Trading Co., and received an upfront license fee of \$1,500,000 (see note 14 below). However, the forty-five day time period in which MAST could have obtained a reduced exercise price has now expired.

- After May 31, 2005 and until May 31, 2007, the exercise price of the Purchase Right will be equal to the fair market value of the Japanese business, but in no event will be less than \$3,000,000. Moreover, if the Company receives an outside offer for the Japanese business after May 31, 2005 but prior to May 13, 2007, MAST will have a right of first refusal to match the terms of the outside offer.

The Purchase Right is a written option, which must be recognized as a liability, at fair value, in the accompanying financial statements. As of September 30, 2004, the value of this Purchase Right is de minimis.

If MAST exercises the Purchase Right, MAST becomes obligated to reimburse the Company for certain costs incurred by the Company related to product development and intellectual property prosecution in Japan. Moreover, as part of a Business Development Agreement ("BDA") entered into contemporaneously with the Thin Film disposition, MAST has agreed that if (i) MAST exercises the Purchase Right and (ii) the Company or MAST enters into a Japanese distribution agreement before February 13, 2005 then MAST must share certain upfront payment and milestone payments with the Company and the Company would be entitled to a 5% share in MAST's gross profits and royalties for three years once MAST begins marketing Thin Film products in Japan. The Company has not recognized any amounts related to these potential cash inflows and will not do so until the Company has completed the earnings process.

14. Distribution Agreement

In the third quarter of 2004, the Company entered into a Distribution Agreement with Senko Medical Trading Co. ("Senko").

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

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

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

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

At the inception of this arrangement, the Company received a \$1.5 million license fee revenue which was recorded as deferred license fee in the accompanying balance sheet. The Company will recognize the deferred license fee as revenue systematically over the term of the Distribution Agreement once Commercialization has been achieved. The Distribution Agreement contains certain provisions that could require the Company to return a portion of the upfront license fee. For instance, if it is determined in good faith by the Company and Senko that Commercialization of the Thin Film product is unobtainable, then 50% of the \$1,500,000 license fee will be returned to Senko. Also, if the Company terminates the Distribution Agreement at any time within the initial three years post-Commercialization, for any reason except for material breach by Senko, then a pro-rata share of the license fee will be returned to Senko.

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

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

- Upon the Company notifying Senko of completion of the initial regulatory application to MHLW for the Thin Film product, the Company is entitled to a nonrefundable payment of \$1,250,000. The Company so notified Senko on September 28, 2004, and has recorded as of September 30, 2004 a receivable (and deferred development revenue) for this entitlement. Of the amount deferred, the Company has recognized development revenues of \$158,000,

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representing the fair value of the completed milestones relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the MHLW.

- Upon the achievement of Commercialization, the Company is entitled to a nonrefundable payment of \$250,000.

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

As discussed in Note 13 above, the Company has granted MAST a Purchase Right to acquire the Company's Thin Film-related interests and rights for Japan for \$3,000,000 or, in some circumstances, a higher amount.

The Company has agreed to provide back-up supply of products to Senko subject to the terms of the Distribution Agreement in the event that (a) MAST exercises its Purchase Right and (b) MAST materially fails to deliver product to Senko. In this circumstance, Senko will pay any amounts due for purchases of product, as well as payments in the nature of royalties, directly to MacroPore. MacroPore will be obliged to remit 5% of the gross margin to MAST on any products sold to Senko. The Company believes that it is unlikely in practice that this contingency will materialize. Accordingly, the Company estimates the fair value of this guarantee to be de minimis as of the end of the current reporting period.

15. Composition of Certain Financial Statement Captions

Inventories

	September 30, 2004 (Unaudited)	December 31, 2003
Raw materials	\$ 241,000	\$ 399,000
Finished goods	218,000	432,000
	<u>\$ 459,000</u>	<u>\$ 831,000</u>

Other Current Assets

	September 30, 2004 (Unaudited)	December 31, 2003
Prepaid expenses	\$ 696,000	\$ 316,000
Other receivables.	86,000	53,000
Accrued interest receivable	158,000	157,000
	<u>\$ 940,000</u>	<u>\$ 526,000</u>

Property and Equipment, net

	September 30, 2004 (Unaudited)	December 31, 2003
Office and computer equipment	\$ 2,114,000	\$ 1,922,000
Manufacturing and development equipment	4,130,000	3,685,000
Leasehold improvements	1,941,000	1,905,000
	8,185,000	7,512,000
Less accumulated depreciation and amortization	<u>(4,789,000)</u>	<u>(3,690,000)</u>
	<u>\$ 3,396,000</u>	<u>\$ 3,822,000</u>

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Intangibles, net

September 30,

December 31,

	2004 (Unaudited)	2003
Intangibles	\$ 2,695,000	\$ 2,695,000
Less accumulated amortization	(506,000)	(303,000)
	<u>\$ 2,189,000</u>	<u>\$ 2,392,000</u>

The amortization expense of intangibles for the three and nine months ended September 30, 2004 was \$68,000 and \$203,000, respectively.

Estimated amortization of intangibles for the balance of 2004 and the years ended:

2004	\$ 67,000
2005	270,000
2006	270,000
2007	270,000
2008	270,000
Thereafter	1,042,000
	<u>\$ 2,189,000</u>

Accounts Payable and Accrued Expenses

	September 30, 2004 (Unaudited)	December 31, 2003
Accounts payable	\$ 235,000	\$ 520,000
Accrued bonus	630,000	631,000
Accrued vacation	538,000	468,000
Accrued expenses	763,000	752,000
Accrued restructuring expense	—	153,000
Warranty reserve	82,000	267,000
Share repurchase payable	—	976,000
	<u>\$ 2,248,000</u>	<u>\$ 3,767,000</u>

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed "forward-looking statements" within the meaning of United States securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. The forward-looking statements included in this report are also subject to a number of material risks and uncertainties, including but not limited to the risks described under the "Risk Factors" section in this Management's Discussion and Analysis of Financial Conditions and Results of Operations. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. Finally, we strongly emphasize that our reported net income for the three and nine months ended September 30, 2004 should **not** be considered predictive of future results. This is because we recognized \$13,883,000 as a gain on the sale of assets, related party during the nine months ended September 30, 2004 that related to our sale of our CMF product line to Medtronic in September 2002.

Overview

Our business is shifting toward a focus on discovering and developing therapies for cardiovascular disease, spine and orthopedic disorders and reconstructive surgery using adult stem cells from adipose tissue (body fat). Adipose tissue is the richest and most accessible known source for regenerative cells in the human body and includes a high concentration of adult stem cells. In order to use these cells therapeutically, we are developing a point-of-care system to isolate a patient's own regenerative cells in real-time.

Additionally, we have a line of surgical implants derived from our bioresorbable technology, which represent one of the latest advancements in spine and orthopedic medicine. We manufacture HYDROSORB™ surgical implants for spine and orthopedic applications and distribute these implants exclusively through Medtronic, Inc. ("Medtronic"). We also are preparing to distribute Thin Film bioresorbable implants in Japan through Senko Medical Trading Co. ("Senko").

During the quarter we continued to strategically transition the focus of our business toward regenerative cell technology. To date, we have been able to fund the research and development of this program by using cash generated from divested and licensed bioresorbable technology assets as well as revenues from the HYDROSORB™ product line. For the next several years we will fund these efforts through our cash reserve, entering into regenerative cell technology partnerships, and from potential HYDROSORB™ spinal implant profits. Additionally, it is possible that we may need to seek capital through the sale of equity securities, especially if we do not receive money from partnerships or positive cash flow from HYDROSORB™. During this time, we expect to incur increasing losses as we:

- Complete the engineering and design of our point-of-care regenerative cell technology system and seek relevant regulatory clearances;
- Continue pre-clinical development of regenerative cell therapies for cardiovascular disease, our primary focus, as well as spinal disc disease, orthopedic disorders, and reconstructive surgery, among others;
- Advance regenerative cell technology programs into clinical development;
- Seek partnerships for therapeutic applications outside the area of cardiovascular disease;
- Pursue available grant opportunities; and
- Continue to support Medtronic in growing HYDROSORB™ revenues and working with Senko to achieve regulatory clearance for the Thin Film product line in Japan.

Total revenues for the three months ended September 30, 2004 were \$1,774,000 compared to \$4,495,000 for the same period in 2003, a decrease of 60.5%. Of the total revenue in the third quarter, \$1,187,000 is attributable to sales of Thin Film to MAST Biosurgery AG (MAST) and \$298,000 is attributable to HYDROSORB™ sales. We expect our Thin Film sales to MAST to fall to zero in the near future. Total revenues for the nine months ended September 30, 2004 were \$5,666,000 compared to \$9,327,000 for the same period in 2003, a decrease of 39.3%.

The decrease in revenues for the three and nine months ended September 30, 2004 was primarily due to decreased orders for HYDROSORB™ by Medtronic during the second and third quarters of 2004 as a result of their stocking patterns, and their marketing efforts that have been significantly less vigorous than we had reasonably anticipated, which has resulted in slower than anticipated end-use market penetration. During the third and fourth quarters of 2003 and the first quarter of 2004, Medtronic placed initial stocking orders for newly released HYDROSORB™ products and they currently remain sufficiently stocked. While we perceive growing demand for HYDROSORB™ products in the market, we had expected a more rapid rate of growth and we cannot predict when the market demand will result in additional orders from Medtronic. This setback suggests a significant risk to our original strategy for financing our regenerative cell business, as we had expected the spine and orthopedics implants to quickly maintain and grow positive cash flow.

We are more closely monitoring the progress of the HYDROSORB™ business and are considering our various potential strategies in that regard.

Net income for the three and nine months ended September 30, 2004 was \$4,546,000 and \$2,226,000 respectively. This compares to a net loss of \$2,799,000 and \$8,138,000 respectively for the same periods in 2003. This income is not indicative of the level of earnings we expect to generate in the future, because it contains the following components:

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

Adjusted net loss for the three and nine months ended September 30, 2004 are outlined in the table below.

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net income (loss) GAAP	\$ 4,546,000	\$ (2,799,000)	\$ 2,226,000	\$ (8,138,000)
Less: Gain on the sale of assets, related party	(8,883,000)	—	(13,883,000)	—
Adjusted net loss (1)	\$ (4,337,000)	\$ (2,799,000)	\$ (11,657,000)	\$ (8,138,000)

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

The increase in the adjusted net loss for the three and nine months ended September 30, 2004 reflects our decrease in HYDROSORB™ revenues, which was particularly dramatic in this quarter, with a simultaneous increase in research and development expenses related to our regenerative cell technology program, compared to the same periods in 2003.

Developments during the third quarter of 2004 that reflect our transition toward regenerative cell technology program include the following:

- In July 2004 we were awarded up to \$850,000 of additional funding to continue with the second phase of our National Institutes of Health (NIH) Small Business Innovation Research (SBIR) grant subject to availability of NIH funds and satisfactory progress.
- In August 2004, an apparently fundamental patent from the U.S. Patent and Trademark Office (U.S. Patent No. 6,777,231), to which we are the exclusive, worldwide licensee, was issued to the University of California related to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types.
- In September 2004, we released data from a pre-clinical safety study, which demonstrated that infusion of adipose tissue-derived regenerative cells improved heart function following myocardial infarction (heart attack). This study, performed in pigs, confirms previous pre-clinical work by us and others suggesting that technology is safe and may be clinically useful.
- In September 2004, we received a 510(k) clearance from the U.S. Food and Drug Administration (FDA) for a point-of-care adipose tissue extraction system, which is designed to extract and collect adipose tissue. The clearance is one of multiple components that will require clearance or approval by the FDA prior to commercialization.

In addition, during the second quarter of 2004 we sold our bioresorbable Thin Film business to MAST (retaining rights to Japan). In this transaction we gained cash and avoided further cash burn during the early stages of that business.

For clarification, we have no involvement with embryonic stem cells, which is a politically controversial area.

Disposition of Product Line

In May 2004, we sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST Biosurgery AG, a Swiss corporation (“MAST”) and a subsidiary of MAST. We have received \$7,000,000 in cash and might receive the following additional contingent consideration:

- \$200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration for a hernia wrap product, and
- \$2,000,000 on or before the earlier of (i) May 31, 2005 or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer, provided the Chief Executive Officer has held that position for at least four months and meets other requirements specified in the sale agreement. If MAST does not hire a Chief Executive Officer by January 31, 2005, MAST may, at its sole option, provide us on May 31, 2005 with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 instead of making the \$2,000,000 cash payment.

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

Because of these and other additional performance requirements, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately \$6,429,000 as deferred gain on sale in the balance

sheet. The amount recorded as deferred gain on sale does not include the potential contingent consideration described above, which will only be added to the deferred gain on sale when the contingencies are resolved. However, we recorded the effect of the potential 19% interest that we will receive back in the Thin Film assets if certain events occur. Accordingly, we recorded 19% of the carrying value or \$124,000 of the assets transferred as “retained interest in transferred assets.” As of September 30, 2004, we classified this asset as a component of “other assets.”

We do not expect to complete our performance obligations until the second quarter of 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. However, in the second and third quarters of 2004 we recognized \$735,000 of the deferred gain as revenues related to the sale of Thin Film products to MAST under the back-up supply agreement at cost. This is necessary to state revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction.

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

- (a) Spinal field, exclusive until 2012, and
- (b) Field of regenerative medicine, non-exclusive on a perpetual basis

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

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

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

Distribution Agreement

In the third quarter of 2004, we entered into a Distribution Agreement with Senko Medical Trading Co., (“Senko”).

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

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

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

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

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

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

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

substantive effort and the fees received are commensurate with the level of effort expended. On September 28, 2004, we notified Senko of completion of the initial regulatory application to MHLW for the Thin Film product. As a result, we became entitled to a nonrefundable payment of \$1,250,000, which we received in October 2004. At September 30, 2004, we recorded a receivable (and deferred development revenue) for this entitlement. Of the amount deferred, we recognized \$158,000 as development revenues in the quarter ended September 30, 2004. The amount recognized as development revenues represents the relative fair value of the completed milestones as compared with the fair value of all milestones expected to be necessary to achieve regulatory approval by the MHLW.

As discussed above, we have granted MAST a Purchase Right to acquire our Thin Film-related interests and rights in Japan for \$3,000,000 or, in some circumstances, a higher amount.

Results of Operations

Three months and nine months ended September 30, 2004 compared to three months and nine months ended September 30, 2003

Revenues

The following table summarizes the components of our revenues for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Spine and orthopedics products	\$ 298,000	\$ 3,483,000	\$ (3,185,000)	(91.4)%	\$ 2,831,000	\$ 6,448,000	\$ (3,617,000)	(56.1)%
Thin film products:								
Product sales (non-MAST related)	—	262,000	(262,000)	—	559,000	898,000	(339,000)	(37.8)%
Product sales to MAST	641,000	—	641,000	—	864,000	—	864,000	—
Amortization of gain on sale (MAST)	546,000	—	546,000	—	735,000	—	735,000	—
Total thin film	1,187,000	262,000	925,000	353.1%	2,158,000	898,000	1,260,000	140.3%
Craniofacial (CMF) products:								
Product sales	—	193,000	(193,000)	—	126,000	631,000	(505,000)	(80.0)%
Amortization of gain on sale	—	554,000	(554,000)	—	156,000	1,342,000	(1,186,000)	(88.4)%
Total craniofacial	—	747,000	(747,000)	—	282,000	1,973,000	(1,691,000)	(85.7)%
Research grant (NIH)	129,000	—	129,000	—	229,000	—	229,000	—
Development (Senko)	158,000	—	158,000	—	158,000	—	158,000	—
Regenerative cell storage services	2,000	3,000	(1,000)	(33.3)%	8,000	8,000	—	—
Total	\$ 1,774,000	\$ 4,495,000	\$ (2,721,000)	(60.5)%	\$ 5,666,000	\$ 9,327,000	\$ (3,661,000)	(39.3)%
% attributable to Medtronic	16.8%	94.1%	(77.4)%		54.9%	90.3%	(35.4)%	

- Spine and orthopedic revenues represent sales of bioresorbable implants used in spine and orthopedic surgical procedures to maintain the relative position of bone graft material when used in conjunction with traditional rigid fixation. In the third and fourth quarters of 2003 and first quarter of 2004, Medtronic (our sole distributor of spine and orthopedic products) placed initial stocking orders for our newly developed HYDROSORB™ products. We had anticipated that demand for these products from Medtronic's customers would draw down these inventories sufficiently to require Medtronic to buy substantial additional amounts this year. In fact, sales to Medtronic through, and especially in, the third quarter of 2004 were well below our expectations. Note that Medtronic owns approximately 7.2% of our outstanding common stock. Refer to "The future" discussion below for our expectations regarding the outlook for fourth quarter and future spine and orthopedic revenues.
- Thin Film product revenues represent sales of SurgiWrap™ bioresorbable Thin Film used to support and reinforce soft tissues and to minimize tissue attachment to the device in case of contact with the viscera (organs of the body). Revenue increases in the 2004 periods primarily relate to initial stocking orders placed by MAST following the acquisition of Thin Film product rights from us in the second quarter of 2004. We are obliged by contract to sell these products to MAST at our manufacturing cost. Of the revenues reported during 2004, \$546,000 and \$735,000 relates to the recognition of a portion of the deferred gain related to sale of Thin Film assets to MAST, during the three-months and nine-months ended September 30, 2004, respectively. This recognition policy is necessary to state our revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction. Refer to "The future" discussion below for expected trends regarding fourth quarter and future Thin Film revenues.
- The CMF product revenues represent sales of the CMF line of products used for trauma and reconstructive procedures in the midface and craniofacial skeleton (the head and skull). As with the Thin Film products, we sold the products at cost under a contractual back-up supply agreement and we recognized a portion of the deferred gain related to sale of assets in order to reflect the gross margin which would otherwise have been associated with such sales. The decrease in CMF product revenue in the 2004 periods related to Medtronic transitioning the manufacturing of CMF products to their own facilities. During the third quarter of 2004, we completed all remaining performance obligations related to the 2002 sale of the CMF Product Line to Medtronic. Therefore, we do not expect to earn any CMF product revenue in the future.

- The research grant revenue relates to our agreement with the National Institutes of Health ("NIH"). Under this arrangement, the NIH reimburses us for "qualifying expenditures" relating to research on Adipose-Derived Cell Therapy for Myocardial Infarction. To receive funds under the grant

arrangement, we were required to: (i) demonstrate that we incurred “qualifying expenses,” as defined in the grant agreement between the NIH and us, (ii) maintain a system of controls, whereby we can accurately track and report all expenditures related solely to research on Adipose-Derived Cell Therapy for Myocardial Infarction, and (iii) file appropriate forms and follow appropriate protocols established by the NIH. As of June 30, 2004, we had completed Phase I of the research grant and incurred the full amount of qualifying expense for reimbursement of \$100,000. In the third quarter of 2004, the NIH authorized us to begin Phase II of the research grant which entitled us to receive up to \$850,000 (subject to availability of funds and satisfactory progress towards meeting the goals and objectives of our grant application). Our policy is to recognize revenues under the NIH grant arrangement as the lesser of (i) qualifying costs incurred (and not previously recognized) for which we are entitled to funding or (ii) the amount determined by comparing the outputs generated to date versus the total outputs expected to be achieved under the research arrangement. During the quarter ended September 30, 2004, we incurred \$129,000 in qualifying expenditures for reimbursement related to Phase II of the research grant, and have recorded revenues for the same amount.

- Under a Distribution Agreement with Senko we are entitled to earn payments based on achieving the following defined milestones:
 - Upon notifying Senko of completion of the initial regulatory application to MHLW for the Thin Film product, we are entitled to a nonrefundable payment of \$1,250,000. We so notified Senko on September 28, 2004, and have recorded as of September 30, 2004 a receivable (and deferred development revenue) for this entitlement. Of the amount deferred, we have recognized development revenues of \$158,000, representing the relative fair value of the completed milestones as compared with the fair value of all milestones expected to be necessary to achieve regulatory approval by the MHLW;
 - Upon the achievement of Commercialization, we are entitled to a nonrefundable payment of \$250,000.

The future: We sell our spine and orthopedic products exclusively to Medtronic at fixed selling prices that are subject to adjustment biannually (based on Medtronic’s selling prices to its customers) and our revenue from this product line is dependent upon the market’s adoption of our technology which is largely dependant upon Medtronic’s marketing efforts and pricing strategies. To increase our revenues from spine and orthopedic products we depend largely on Medtronic’s ability and commitment to expand HYDROSORB™ market share. Additionally, because our HYDROSORB™ products are relatively new to the market, and because our internal estimates of second quarter 2004 HYDROSORB™ sales were proven wrong, we have now concluded that we are currently unable to accurately forecast Medtronic’s, and Medtronic’s customers demand. Therefore, in July 2004, we retracted our previously stated revenue guidance for 2004 until more data becomes available. The extremely low sales in the third quarter of 2004 reinforced this conclusion. We continue to believe in the medical value of this product line, but there are serious risks regarding the vigor of Medtronic’s marketing efforts and the rate of adoption by physicians.

We expect revenue from Thin Film products to decline, and entirely disappear, as MAST begins to assume the manufacturing process. Specifically, MAST may begin their own manufacturing process as early as the fourth quarter of 2004.

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

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

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

Cost of revenues

Cost of revenues includes material, manufacturing labor, overhead costs and an inventory provision. The following table summarizes the components of our cost of revenues for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Cost of revenues:								
Cost of revenues	\$ 1,184,000	\$ 1,438,000	\$ (254,000)	(17.7)%	\$ 2,375,000	\$ 2,864,000	\$ (489,000)	(17.1)%
% of revenue	66.7%	32.0%	34.7%		41.9%	30.7%	11.2%	
Inventory provision	—	—	—	—	242,000	—	242,000	—
% of revenue	—	—	—	—	4.3%	—	—	—
Total	\$ 1,184,000	\$ 1,438,000	\$ (254,000)	(17.7)%	\$ 2,617,000	\$ 2,864,000	\$ (247,000)	(8.6)%
Cost of revenues as % of revenues	66.7%	32.0%	34.7%		46.2%	30.7%	15.5%	

- The cost of revenues, as a percent of revenues, increased 34.7% and 11.2% in the three and nine months ended September 30, 2004, as compared to the same period in 2003. This increase was due to higher cost of revenue associated with the Thin Film products than other product lines (product mix) as well as a lack of inventory production (generated by declining sales demand) to absorb fixed manufacturing and labor expense. Excess manufacturing capacity expensed in the three and nine months ended September 30, 2004 was \$458,000 and \$666,000, respectively.
- The \$242,000 inventory provision during the nine months ended September 30, 2004 with no comparable charges in 2003 related to excess inventory. Such inventory was produced in consideration of our responsibility to be a back-up supplier for CMF product line. We sold the assets related to this product line to a subsidiary of Medtronic in September 2002. In April of 2004, Medtronic indicated that it would no longer purchase CMF inventory from us under the back-up supply arrangement, leading to our determination that the remaining CMF inventory on hand would not be recoverable.

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

would require our spine and orthopedic product line sales to not only recover the ground lost in the third quarter of 2004, but to grow substantially beyond that.

Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and pre-clinical studies. It excludes related stock based compensation expenses. The following table summarizes the components of our research and development expenses for the three months and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Regenerative cell technology	\$ 2,120,000	\$ 1,261,000	\$ 859,000	68.1%	\$ 5,379,000	\$ 3,163,000	\$ 2,216,000	70.1%
Bioresorbable polymer implants	612,000	1,291,000	(679,000)	(52.6)%	2,375,000	3,647,000	(1,272,000)	(34.9)%
Research grants (NIH)	93,000	—	93,000	—	246,000	—	246,000	—
Development milestone-Senko	134,000	—	134,000	—	134,000	—	134,000	—
Total	\$ 2,959,000	\$ 2,552,000	\$ 407,000	15.9%	\$ 8,134,000	\$ 6,810,000	\$ 1,324,000	19.4%

- Regenerative cell technology expenses relate to the development of a technology platform that involves using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications. The increase in regenerative cell technology expense as compared with the same periods in 2003 results from the hiring of additional researchers, engineers and support staff. We incurred an additional \$299,000 and \$1,017,000 in labor related expenses in the three and nine months ended September 30, 2004, respectively, as compared with the same periods in 2003. The remainder of the increase related to increases in legal, research supplies, consulting fees and facility expenses of \$560,000 and \$1,199,000 in the three and nine month ended September 30, 2004, respectively, as compared to the same periods in 2003.
- Bioresorbable polymer surgical implants platform technology is used for development of spine and orthopedic products. The decrease in research and development costs associated with bioresorbable polymer implants in the 2004 periods as compared with the same periods in 2003 was a result of the successful completion of our bioresorbable Thin Film product line in late 2003, as well as a strategic decision to strongly focus our research and development efforts on our regenerative cell technology.
- In 2004, we entered into an agreement with the NIH to reimburse us for up to \$950,000 (Phase I \$100,000 and Phase II \$850,000) in “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. The funding under Phase II of the reimbursement was subsequently increased by the NIH to \$850,000 (subject to availability of funds and satisfactory progress) bringing the total reimbursement amount up to \$950,000. For the nine months ended September 30, 2004, we incurred a total of \$117,000 of direct qualifying expenses relating to Phase I and \$129,000 of direct qualifying expenses related to Phase II, for a total cost relating to NIH grants of \$246,000.
- Under a Distribution Agreement with Senko we are responsible for the completion of the initial regulatory application to the MHLW and Commercialization of the Thin Film product line in Japan. Commercialization occurs when one or more Thin Film product registrations are completed with the MHLW. To date, we have incurred \$134,000 of expense in this regulatory and registration process.

The future: We are developing a system to isolate autologous, homologous-use, regenerative cells. Simultaneously, we are generating scientific knowledge through internal research to support the clinical use of these cells and have made significant progress in understanding the potential clinical applications. Our most advanced research and development program is in the repair of cardiovascular tissues that are damaged after a heart attack. We are also researching applications in bone repair, spinal disc regeneration, and cosmetic and reconstructive surgery. Our strategy is to continue to increase our research and development efforts in this field and we anticipate expenditures in this area of research to be approximately \$2,400,000 to \$3,400,000 in the fourth quarter of 2004. The expenditures will primarily relate to conducting pre-clinical studies on harvesting therapeutically useful quantities of regenerative cells for cardiac tissue repair, bone regeneration, cosmetic and reconstruction surgery. Research and development expense in this area will further increase in 2005 and beyond.

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

We were successful with Phase I of the NIH research on Adipose-Derived Cell Therapy for Myocardial Infarction. Therefore, we were awarded Phase II of the NIH research grant. We expect research expenses to be incurred related to Phase II of this project for the remainder of 2004 and 2005.

Sales and marketing expenses

Sales and marketing expenses include costs of marketing personnel, tradeshow, and promotional activities and materials. It excludes related stock based compensation expenses. Medtronic is responsible for the distribution, marketing and sales support of our spine and orthopedic devices. Our bioresorbable Thin Film product line (before the sale of the non-Japan Thin Film business to MAST in May 2004) was distributed domestically through a dedicated sales force, independent sales representatives and internationally through independent distributors. After May 13, 2004, all Thin Film products (except for Japan) are sold exclusively to MAST under a back-up supply agreement. The following table summarizes the components of our sales and marketing expenses for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
General corporate marketing	\$ 248,000	\$ 53,000	\$ 195,000	367.9%	\$ 629,000	\$ 249,000	\$ 380,000	152.6%
Domestic sales and marketing	—	757,000	(757,000)	—%	846,000	2,387,000	(1,541,000)	(64.6)%
International sales and marketing	206,000	245,000	(39,000)	(15.9)%	591,000	718,000	(127,000)	(17.7)%
Total	\$ 454,000	\$ 1,055,000	\$ (601,000)	(57.0)%	\$ 2,066,000	\$ 3,354,000	\$ (1,288,000)	(38.4)%

- General corporate marketing expenditures relate to expenditures for maintaining our corporate image and reputation within the research and surgical communities. The increases in the 2004 periods as compared to the same periods in 2003 were due to an educational program which we voluntarily (and

not as a result of any commitment to Medtronic) created in 2004 to inform end-users and Medtronic's sale teams of the benefits and surgical applications for our biomaterials products.

- Domestic sales and marketing related to expenses associated with managing our domestic bioresorbable Thin Film product distribution, which included independent sales representatives and our domestic Thin Film sales consultants and marketing staff. The sharp decreases in 2004 as compared to the same periods in 2003 were due to the transfer of our sales force and marketing staff to MAST upon the sale of the Thin Film product line to MAST in May 2004.
- International marketing relates to costs associated with developing international bioresorbable Thin Film distributors and supporting a bioresorbable Thin Film sales office in Japan. The decrease spending in the three and nine months ended September 30, 2004 as compared to the same periods in 2003 related to the closure of our United Kingdom sales office.

The future: We project that corporate marketing as well as our international sales and marketing expenditures will remain stable for the balance of 2004.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. It excludes related stock based compensation expenses. The following table summarizes the general and administrative expenses for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
General and administrative expenses	\$ 1,502,000	\$ 1,426,000	\$ 76,000	5.3%	\$ 4,303,000	\$ 3,425,000	\$ 878,000	25.6%

- The primary reason for the increase in 2004 as compared to 2003 was the result of salary, administrative and professional services expenses rising due to economics of hiring and retaining a qualified management team to implement and manage our strategic plan. However, the three months ended September 30, 2004 benefited as compared to the same period in 2003 due to a

\$200,000 bonus accrual in the 2003 period. The increase in the nine months ended September 30, 2004 as compared to the same period in 2003 resulted from salary and bonus increases of \$564,000 and professional services and other general overall corporate expenditure increases of \$314,000.

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

Stock based compensation expenses

Stock based compensation expenses include charges related to options issued to employees, directors and non employees. The stock based compensation expenditures connected to options granted to employees and directors is the difference between the exercise price of the stock based awards and the deemed market value of the underlying common stock on the date of the grant. The stock based compensation expenditures connected to options granted to non employees is the fair value of the underlying common stock on the initial date of grant, as updated over the vesting period until meeting the performance commitment. Unearned stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four-year period from the date of grant. The following table summarizes the components of our stock based compensation expenses for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Research and development related	\$ —	\$ 19,000	\$ (19,000)	—%	\$ 32,000	\$ 58,000	\$ (26,000)	(44.8)%
Sales and marketing related	—	17,000	(17,000)	—%	22,000	53,000	(31,000)	(58.5)%
General and administrative related	—	411,000	(411,000)	—%	71,000	761,000	(690,000)	(90.7)%
Total	\$ —	\$ 447,000	\$ (447,000)	—%	\$ 125,000	\$ 872,000	\$ (747,000)	(85.7)%

- The decreases in stock based compensation expenses were primarily a result of the normal amortization of the stock based compensation expenses over the remaining vesting period, except for stock based compensation relating to research and development. In the three months ended June 30, 2004, we charged \$32,000 to research and development for options granted to a consultant. We determined the value of these options using the Black-Scholes option pricing model. There was no comparable charge in the same period in 2003. The options to the consultant were 100% vested and related to services fully rendered. The stock based compensation expense was fully amortized over the vesting period as of the second quarter of 2004. In the three months ended September 30, 2003, in addition to the normal amortization of stock based compensation, we also incurred \$234,000 in expense due to the modification of certain options granted to the Chief Financial Officer in his September 2003 separation agreement.

The future: We have expensed all unearned stock based compensation; therefore we do not anticipate any additional stock based compensation expense for the remainder of the year. However, we may from time to time award stock based compensation to consultants, in lieu of, or in addition to, cash compensation.

Restructuring charge

The following table summarizes the restructuring charge for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Restructuring charge	\$ 37,000	\$ 458,000	\$ (421,000)	(91.9)%	\$ 107,000	\$ 458,000	\$ (351,000)	(76.6)%

- In September 2003, we closed an administrative office in Königstein, Germany an effort to reduce costs and consolidate operation in the United States. The Königstein, Germany office was rented under an operating lease. During the third quarter of 2004, we negotiated a settlement of the remaining lease

payment with the lessor. As a result of the settlement, we recorded an additional provision of \$37,000 in the third quarter of 2004.

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

Other income

The following is a table summarizing the gain on the sale of assets, related party for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Gain on the sale of assets, related party	\$ 8,883,000	\$ —	\$ 8,883,000	—%	\$ 13,883,000	\$ —	\$ 13,883,000	—%

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

The future. We expect to be able to recognize in 2005 most of the deferred gain on the sale of the Thin Film assets to MAST, at the earliest, in the second quarter of 2005. This would result in a one-time gain of approximately \$5,680,000.

Financing items

The following table summarizes interest income, and interest and other expenses for the three and nine months ended September 30, 2004 and 2003:

	Three months ended:				Nine months ended:			
	September 30, 2004	September 30, 2003	Difference	%	September 30, 2004	September 30, 2003	Difference	%
Interest income	\$ 68,000	\$ 88,000	\$ (20,000)	(22.7)%	\$ 180,000	\$ 335,000	\$ (155,000)	(46.3)%
Interest expense	(44,000)	(24,000)	20,000	83.3%	(131,000)	(88,000)	43,000	48.9
Other income (expense)	\$ 1,000	\$ 18,000	\$ (17,000)	(94.4)%	\$ (20,000)	\$ 71,000	\$ (91,000)	(128.2)%

- Interest income decreased in 2004 as compared to the same period in 2003 because of a decrease in the funds we had available for investment and lower interest rates.
- Interest expense increased due to \$1,039,000 in additional long-term obligations associated with the acquisition of new equipment in late 2003 and in 2004.
- Other income (expense) decreases resulted from foreign currency gains in 2003 turned into foreign currency losses in 2004.

Deferred gain on sale of assets, related party

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

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

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

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

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

Deferred gain on sale of assets

At September 30, 2004, we have reflected \$5,694,000 of unamortized “Deferred gain on sale of assets” on our balance sheet. This deferred gain related to our sale of our Thin Film product line to MAST in May 2004. Because of additional performance requirements, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately \$6,429,000 as deferred gain on sale in the balance sheet. These performance requirements include

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training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line, transfer of Thin Film tangible assets and rights to intangible assets and acting in the capacity of a back-up supplier to MAST for a period of one year. Under the back-up supply agreement, we have agreed to supply product ordered by MAST at our manufacturing cost.

We do not expect to complete our performance obligations until, at the earliest, the second quarter of 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. However, we have been recognizing a portion of the deferred gain as revenues as and when we sell products to MAST under the back-up supply agreement. This is necessary to state revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction. Through September 30, 2004 we have recognized \$735,000 in deferred gain as revenues.

Deferred license fee revenue

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

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

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

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

We do not expect Commercialization to be achieved until 2006 or 2007.

Milestone payment due from distribution agreement and deferred revenue

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

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

We notified Senko on September 28, 2004 regarding the completion of the initial regulatory application, and recorded as of September 30, 2004 an account receivable (and deferred development revenue) for \$1,250,000. Of the amount deferred, we have recognized development revenues of \$158,000, representing the fair value of the completed milestones relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the MHLW.

Liquidity and Capital Resources

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2004 and 2003 is summarized as follows:

For the nine months ended:	September 30, 2004	September 30, 2003
Net cash used in operating activities	\$ (9,388,000)	\$ (6,891,000)
Net cash provided by investing activities	10,149,000	3,590,000
Net cash (used in) provided by financing activities	\$ (595,000)	\$ 542,000

Operating activities

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

Net cash used in operating activities in the nine months ended 2003 primarily resulted from our net loss.

Investing activities

Net cash provided by investing activities in the nine months ended 2004 resulted from the receipt of non-recurring payments totaling \$6,500,000 for the completion of the CMF Faster Resorbable Polymer clinical research and the transfer of the know-how related to the 2002 sale of the CMF Product Line to Medtronic. In addition, we received net proceeds of \$6,934,000 from the sale of our Thin Film product line (except for the territory of Japan) to MAST.

The net cash provided by investing activities in the nine months ended 2003 primarily related to net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e. we cashed in short-term investments to fund our operating and financing activities).

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore, in the nine months of 2004 and 2003 we used cash to purchase \$673,000 and \$1,013,000, respectively, of property and equipment to support bioresorbable polymer implant manufacturing and research and development of the regenerative cell technology platform.

Financing Activities

The net cash used in financing activities in the nine months ended September 30, 2004 related to:

- The repurchase of 262,602 shares of our common stock for \$976,000 from a former director and officer of StemSource at a price of \$3.72 per share,
- The repurchase of 27,650 shares of our common stock for \$76,000 on the open market at a price of \$2.75 per share, and
- The payment of \$608,000 on our long-term obligations.

Net cash used in financing activities was offset by proceeds from loans secured under an amended Master Security Agreement we entered in September 2003 to provide financing for equipment purchasing. In the first quarter of 2004, in connection with this agreement, we issued a promissory note in an aggregate principal amount of approximately \$594,000, secured by equipment with a cost of \$594,000. In the second quarter of 2004, we issued a promissory note in an aggregate principal amount of approximately \$128,000, secured by equipment with a cost of \$128,000. In the third quarter of 2004, we issued a promissory note in an aggregate principal amount of approximately \$317,000, secured by equipment with a cost of \$317,000.

The net cash provided by financing activities in the nine months ended September 30, 2003 related to:

- Proceeds from loans secured under an amended Master Security Agreement we entered in September 2003 to provide financing for equipment purchasing. In the third quarter of 2004, in connection with this agreement, we issued two promissory notes in an aggregate principal amount of approximately \$490,000, secured by equipment with a cost of \$567,000 and
- Proceeds of approximately \$542,000 from the sale of 150,500 shares of our common stock held in treasury at a price of \$3.60 per share.

Net cash provided by financing activities in 2003 was offset by our purchase of 63,499 shares of our common stock on the open market at an average price of \$3.90 per share or approximately \$248,000 and \$275,000 for payment of long term obligations.

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at September 30, 2004 and December 31, 2003:

	September 30, 2004	December 31, 2003	Difference	%
Cash and cash equivalents	\$ 2,986,000	\$ 2,820,000	\$ 166,000	5.9%
Short-term investments, available for sale	13,991,000	11,448,000	2,543,000	22.2%
Total cash and cash equivalents and short-term investments, available for sale	\$ 16,977,000	\$ 14,268,000	\$ 2,709,000	19.0%
Current assets	\$ 19,804,000	\$ 16,916,000	\$ 2,888,000	17.1%
Current liabilities	3,206,000	4,484,000	(1,278,000)	(28.5)%
Working capital	\$ 16,598,000	\$ 12,432,000	\$ 4,166,000	33.5%

We believe that existing funds, cash generated by operations, and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditures and debt service requirements at least through September 30, 2005. However, in order to provide greater financial flexibility and liquidity, and in view of the substantial cash needs of our regenerative cell business during its development stage, we will need to raise additional capital.

From inception to September 30, 2004, we have financed our operations primarily by:

- Issuing our stock,
- Generating revenues,
- Selling, in September 2002, the CMF product line,
- Selling, in May 2004 the Thin Film product line (except for the territory of Japan),
- Signed, in July 2004, a Distribution Agreement for the distribution rights to Thin Film in Japan and received an upfront license fee, and
- Obtaining a modest amount of capital equipment long-term financing.

As a result of the non-recurring receipt of \$6,500,000 for the completion of CMF clinical research and know-how transfer, long-term financing of \$1,039,000 and the sale of our non-Japan bioresorbable Thin Film product line for net proceeds of \$6,934,000 and the upfront license fee for the distribution rights to Thin Film product line of \$1,500,000, our liquidity metrics as of September 30, 2004 appear superior to those as of December 31, 2003. We increased our cash and short-term investment position by \$2,709,000 or 19.0% and working capital by \$4,166,000 or 33.5% in comparison to December 31, 2003. However, the improved metrics mask the cash losses we have been incurring in the business which we still retain. Also, acquiring cash through the sale of product lines is fundamentally non-recurring; once sold, they cannot be sold again to cover a future period's operating losses.

We believe that our near-term borrowing requirements and debt repayments will continue to involve a relatively small amount of cash. To fund the rest of 2004 expected capital expenditures of \$300,000 to \$600,000, we intend to borrow under our Amended Master Security Agreement, which has an available credit facility of approximately \$461,000.

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

Our capital requirements for the rest of 2004 and 2005 and beyond will depend on numerous factors, including the resources we devote to developing and supporting our products, Medtronic's marketing efforts, market acceptance of our developed products, regulatory approvals and other factors. We have positioned ourselves to expand our cash position through actively pursuing co-development and marketing agreements, research grants, and licensing agreements related to our technology platforms. Moreover, we are committed to increasing revenues from our bioresorbable products and reinvesting the profits into our regenerative cell therapy research. The revenue generated from our bioresorbable products will depend in large part on the success of Medtronic's (our sole distributor of spine and orthopedics implants) marketing efforts in the bioresorbable spine and orthopedics arena.

We expect to incur research and development expenses, well beyond our current level, in our regenerative cell platform for an extended time, even if our spine and orthopedics biomaterials business returns to profitability, and even more so if it does not, we will need to seek partnerships or additional sources of financing, such as, through the sale of equity securities.

The following summarizes our contractual obligations and other commitments at September 30, 2004, and the effect such obligations could have on our liquidity and cash flow in future periods:

Contractual Obligations	Payments due by period				
	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Long-term debt obligations	\$ 2,305,000	\$ 958,000	\$ 1,343,000	\$ 4,000	\$ —
Operating lease obligations	2,468,000	657,000	1,811,000	—	—
Research study obligations	394,000	394,000	—	—	—
Total	\$ 5,167,000	\$ 2,009,000	\$ 3,154,000	\$ 4,000	\$ —

Critical Accounting Policies and Significant Estimates

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

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

Revenue recognition

Product sales

We have agreements with our distributors that title and risk of loss pass upon shipment of the products to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order. On occasion, we offer extended payment terms to customers. We do not recognize revenues under these arrangements until the payment becomes due or, if earlier, is received.

We warrant that our products are free from manufacturing defects at the time of shipment to our customers.

In most fiscal quarters a majority of our revenues are from Medtronic, under our Development and Supply Agreement with Medtronic dated January 5, 2000 and amended December 22, 2000 and September 30, 2002, as well as our Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002. These revenues are classified as revenues from related party in the consolidated condensed statements of operations.

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

Research

We earn revenue for performing services under development agreements with both commercial enterprises and governmental agencies like the NIH. Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when (i) the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, (ii) the amount of the milestone payment appears reasonably commensurate with the effort expended and (iii) collection of the payment is reasonably assured.

When we are reimbursed for costs incurred under grant arrangements with the NIH, our policy is to recognize revenues under the NIH grant arrangement for the lesser of:

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

Income earned under development agreements is classified as research grant or development revenue in our statements of operations. The costs associated with development agreements are recorded as research and development expenses.

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

Inventory

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

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

Warranty provision

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

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

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

In the third quarter of 2003, we determined that some of the products we sold did not meet certain customer expectations, based on criteria previously communicated to our customer (Medtronic). After detecting this matter, we elected to replace all lots of affected inventory that were on hand at the customer, and we subsequently modified our procedures to alleviate similar occurrences in the future.

As a result, we recorded a warranty charge of \$243,000 in the third quarter of 2003. We have incorporated this new historical warranty data into our determination of appropriate warranty reserves to record prospectively and will continue to evaluate the adequacy and accuracy of our warranty obligations on a quarterly basis. There have been no material warranty claims since the third quarter of 2003.

Accounting for income taxes

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

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

Unearned Compensation

We record unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair market value of our common stock on the date of grant. Unearned compensation is amortized to stock based compensation expense and reflected as such in the Statements of Operations and Comprehensive Income (Loss). As of September 30, 2004 there was no outstanding amount related to unearned compensation.

Risk Factors

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this quarterly report on Form 10-Q. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part I, Item 2 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this quarterly report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

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

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

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced fields such as the medical device and biotechnology field. Due to our limited operating history, comparisons of our year-to-year operating results are not necessarily meaningful and the results for any periods should not necessarily be relied upon as an indication for future performance. Since our limited operating history makes the prediction of future results difficult or impossible, our recent revenue growth should not be taken as an indication of any future growth or of a sustainable level of revenue. This was demonstrated by our revenue decline in both the second and third quarter of 2004.

Moreover, our operating results can vary substantially from our previously published financial guidance (such as happened in the second quarter of 2004), from analyst expectations and from previous periodic results for many reasons, including the timing of product introductions and distributor purchase orders. Also, the 2002 sale of our craniomaxillofacial “CMF” bone fixation implant and accessory product line, which had represented a large portion of our revenues, plus the 2004 sale of our non-Japan bioresorbable Thin Film surgical implants for separation of soft tissues, will distort quarterly and annual earning comparisons through 2004 and 2005. Earnings surprises can have a disproportionate effect on the stock prices of emerging companies such as ours. Also, our stock price is likely to be disproportionately affected by changes which generally affect the economy, the stock market or the medical device and biotechnology industries.

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

Medtronic, we withdrew our previously issued guidance on July 19, 2004 and will not be issuing further guidance until after visibility improves. Our inability to sustain and provide guidance will make us more subject to the stock-price effects of any future operating volatility.

We have never been profitable on an operational basis

We have incurred net losses in each year since we started doing business. These losses have resulted primarily from expenses associated with our research and development activities, and general and administrative expenses. We anticipate that our recurring operating expenses will increase for the next several years, as our research and development expenses may increase in order to develop and market new products and fund additional pre-clinical research and possibly clinical trials. We expect to continue to incur operational losses at least through the end of 2004, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Development-stage losses related to our development of regenerative cell technology are expected to keep us in a loss position on a consolidated basis for several years.

We are adopting a high-risk strategy

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

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

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

We rely on Medtronic to distribute our products

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

We remain significantly dependent on Medtronic to generate sales revenues for all of our spine and orthopedics bioresorbable products. The amount and timing of resources which may be devoted to the performance of Medtronic's contractual responsibilities are not within our control. There can be no guarantee that Medtronic will perform its obligations as expected, pay us any additional option or license fees or market any new products under the distribution agreements, or that we will derive any significant revenue from such arrangements. Medtronic's sale of our products to end customers in the nine months ended September 30, 2004, and its rate of product orders placed with us in the same period disappointed our expectations. Third quarter results were exceptionally weak, and we are significantly disappointed with the marketing efforts of Medtronic for our products at this time.

Our dependence upon Medtronic to market and sell our bioresorbable products places us in a position where we cannot accurately predict the extent to which our products will be actively and effectively marketed, depriving us of some of the reliable data we need to make optimal operational and strategic decisions. The consequent lack of visibility resulted in our second quarter 2004 financial performance falling short of our own and the market's expectations and compelled us to, on July 19, 2004, withdraw our

previously announced financial guidance for the remainder of 2004. Third-quarter 2004 sales were even worse, further demonstrating the lack of control and visibility.

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

Medtronic owns more than 7.2% of our stock, which may limit our ability to negotiate commercial arrangements optimally with Medtronic. Although Medtronic has exclusive distribution rights to our co-developed spinal implants, Medtronic also distributes other products that are competitive to ours, and it might choose to develop and distribute existing or alternative technologies in preference to our technology in the spine.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that disagreement over rights or technology or other proprietary interests will not occur, and the loss of the marketing services provided by Medtronic, or the loss of revenues generated by Medtronic, could have a substantial negative effect on the results of our operations and financial condition.

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

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

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

We also compete with manufacturers of traditional non-bioresorbable implants, such as titanium implants. Doctors have historically been slow to adopt new technologies such as ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires other very significant marketing expenditures or definitive product superiority. Such inertia may be one reason why demand for the HYDROSORB™ implants we sell through Medtronic has been lower in 2004 than we had expected.

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

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

We are in a relatively early stage of commercialization with many of our products although we have derived revenue from sales of certain products to our distributors, particularly Medtronic. We believe that our long-term viability and growth will depend in large part on receiving additional regulatory clearances or approvals for our products and expanding our sales and marketing for our spine and orthopedics implants and other new products that may result from our research and development activities. We are presently pursuing product opportunities in spine and orthopedics and other tissue repair and regeneration throughout the body that will require extensive additional capital investment, research, development, clinical testing and regulatory clearances or approvals prior to commercialization. There can be no assurance that our product development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all. The path to commercial profit from our regenerative cell technology is unclear even if we demonstrate the medical benefit of our regenerative cell technology in various applications, there is no proven path for commercializing the technology in a way to earn a durable profit commensurate with the medical benefit. Most of our cell related products and/or services are at least three to five years away.

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

We will need to raise more cash in the future

As of September 30, 2004, we had \$16,977,000 of cash, cash equivalents and short-term investments; we have always had

negative cash flow from operations. Our regenerative cell business will continue to result in a substantial requirement for research and development expenses for several years, during which it will bring in no significant revenues. Other than our current equipment financing lines of credit, we currently have no commitments for any additional debt or equity financing, and there can be no guarantee that adequate funds for our operations from any additional debt or equity financing, our operating revenues, arrangements with distribution partners or from other sources will be available when needed or on terms attractive to us. The inability to obtain sufficient funds may require us to delay, scale back or eliminate some or all of our research or product development programs, manufacturing operations, clinical studies or regulatory activities or to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, and could have a substantial negative effect on the results of our operations and financial condition.

We do not have much manufacturing experience

We have a limited manufacturing history and limited experience in manufacturing some of our products. Our future success is dependent in significant part on our ability to manufacture products in commercial quantities, in compliance with regulatory requirements and in a cost-effective manner. Production of some of our products in commercial-scale quantities may involve unforeseen technical challenges and may require significant scale-up expenses for additions to facilities and personnel. There can be no guarantee that we will be able to achieve large-scale manufacturing capabilities for some of our products or that we will be able to manufacture these products in a cost-effective manner or in quantities necessary to allow us to achieve profitability. Our 2002 sale of CMF production assets to Medtronic and our 2004 sale of the non-Japan bioresorbable Thin Film product line deprive us of some economies of scale in manufacturing. Current demand for spine and orthopedics products from Medtronic is so low that economies of scale are lacking as to that product line as well.

If we are unable to sufficiently meet Medtronic's requirements for certain products as set forth under their agreement, Medtronic may itself then manufacture and sell such product and only pay us royalties on the sales. The resulting loss of payments from Medtronic for the purchase of these products would have a substantial negative effect on the results of our operations and financial condition.

We have to maintain quality assurance certification and manufacturing approvals

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

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

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

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

We may not be able to protect our proprietary rights

Our success depends in part on whether we can obtain additional patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. We have various U.S. patents for the design of our bioresorbable plates and high torque screws and devices and we have filed applications for numerous additional U.S. patents, as well as certain corresponding patent applications outside the United States, relating to our technology. However, we believe we cannot patent the use of our lactic acid

copolymer for surgical implants, nor are many of our particular implants generally patentable. There can be no assurance that any of the pending patent applications will be approved, or that we will develop additional proprietary products that are patentable, or that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products or design around our patents.

Our regenerative cell technology license agreement with the Regents of the University of California contains certain developmental milestones, which if not achieved could result in the loss of exclusivity or loss of the license rights. The loss of such rights could significantly impact our ability to continue the development of the regenerative cell technology and/or commercialize related products. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested. In addition, further legal risk arises from a lawsuit, just filed by the University of Pittsburgh, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. We are the exclusive, worldwide licensee from the University of California under this patent, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. If the University of Pittsburgh wins the lawsuit, our license rights could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, and our regenerative cell strategy could be materially adversely affected.

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

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

Any such litigation or interference proceeding, regardless of outcome, could be expensive and time consuming. We may incur substantial legal costs as a result of the University of Pittsburgh lawsuit, and our president Marc Hedrick is a named individual defendant in that lawsuit because he is one of the inventors identified on the patent. Litigation could subject us to significant liabilities to third parties and require disputed rights to be licensed from third parties or require us to cease using certain technology.

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

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

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

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

We are subject to intensive FDA regulation

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

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

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

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

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

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

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

We depend on a few key officers

Our performance is substantially dependent on the performance of our executive officers and other key scientific staff, including Christopher J. Calhoun, our Chief Executive Officer, Marc Hedrick, MD, our President and John Fraser, PhD, our Vice President of Research and Technology. We rely upon them for strategic business decisions and guidance. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

We may not have enough product liability insurance

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

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

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

The trading market for our stock in the United States is not liquid and our European stock exchange listing might not avail United States investors

In the United States, our stock is traded through the Pink Sheets, which results in an illiquid market. Investors trading in this market may be disadvantaged in comparison to investors trading in our stock in Europe. Our stock had been traded on the Neuer Markt segment of the Frankfurt Stock Exchange, but the Neuer Markt closed in March 2003. Our shares have since been listed on the "Prime Standard" segment of the Frankfurt Stock Exchange, but we cannot assure that this will result in a satisfactory trading market, particularly for United States investors. We cannot assure you that we will achieve our goal of listing our common stock on Nasdaq or a major United States stock exchange.

We pay no dividends

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Exposure

Our exposure to market risk due to fluctuations in interest rates relates primarily to short-term investments. These short-term investments, reported at an aggregate fair market value of \$13,991,000 as of September 30, 2004, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to (minor) market rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at September 30, 2004, for example, and assuming average investment duration of seven months, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. While we do not always have the intent, we do currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows. Changes in interest rates would, of course, affect the interest income we earn on our cash balances after re-investment.

Foreign Currency Exchange Rate Exposure

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our cash balances in Europe and Japan. Although we transacted business in various foreign countries before the May 2004 sale of our non-Japan Thin Film business to MAST, settlements were usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the three months ended September 30, 2004, a hypothetical 10% adverse change in the Euro or Yen against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

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

Under our Japanese Thin Film agreement with Senko, we would receive payments in the nature of royalties based on Senko's net sales, which would be Yen denominated. We do not expect any such sales or royalties in 2004 or perhaps even in 2005.

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

Item 4. Controls and Procedures

Christopher J. Calhoun, our Chief Executive Officer, and Mark E. Saad, our Chief Financial Officer and Principal Financial Officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in Securities Exchange Act Rule 13a-15(e)), have concluded that as of September 30, 2004, our disclosure controls and procedures are effective.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company has been involved in routine litigation incidental to the conduct of its business. As of September 30, 2004 we were not a party to any material legal proceeding.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer purchase of equity securities

Period	Total number of shares repurchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plan or programs
July 1 – 31, 2004	—	\$ —	—	—
August 1 – 31, 2004	3,650(1)	\$ 2.48	3,650	29,268
September 1 – 30, 2004	—	\$ —	—	—
Total	3,650	\$ 2.48	3,650	—(1)

(1) Under a program first authorized by our Board of Directors on April 3, 2001, and amended on April 9, 2002, September 17, 2002 and August 11, 2003, we were authorized to repurchase up to 3,000,000 shares of common stock. The expiration date of this program was August 10, 2004.

Item 3. Defaults Upon Senior Securities

None

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

We held our annual meeting of stockholders on August 24, 2004. Of the 13,930,834 shares of our common stock which could be voted at the annual meeting, 5,256,495 shares of our common stock were represented at the annual meeting in person or by proxy, which constituted a quorum. Voting results were as follows:

- a. Election of the following persons to our Board of Directors to hold office until the next annual meeting of stockholders:

	For	Withheld
Christopher J. Calhoun	5,242,069	12,926
Marshall G. Cox	5,240,293	14,702
Marc H. Hedrick, MD	5,240,893	14,102
Ronald D. Henriksen	5,241,893	13,102
E. Carmack Holmes, MD	5,241,876	13,119
David M. Rickey	5,243,136	11,859

- b. The proposal to ratify the selection of KPMG LLP as the Company's independent auditors for the fiscal year ending December 31, 2004, received the following votes:

For	Against	Abstain
5,138,093	9,240	107,662

Item 5. Other Information

Properties and Facilities

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

- 14,000 square feet, of which approximately 4,000 square feet is for research and development and 10,000 square feet is office space, at 6749 Top Gun Street, San Diego, California for a five-year term expiring in 2006. We currently sublease 6,000 square feet of this office and warehouse space at the rate charged per square foot in our current lease agreement. We sublease approximate 5,000 square feet to MAST and the remainder to another unrelated party.
- 16,000 square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five-year term expiring 2007.

We pay an aggregate of approximately \$66,000 in rent per month for our properties.

Staff

As of September 30, 2004, we had 95 full-time employees, comprised of 57 employees in research and development, 9 employees in manufacturing, 22 employees in management and finance and administration and 7 employees in sales and marketing. From time to time, we also employ independent contractors to support our administrative organizations. Our employees are not represented by any collective bargaining unit and we have never experienced a work stoppage.

Item 6. Exhibits and Reports on Form 8-K

a. Exhibits

- 10.19 Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory)
- 10.20 Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory) with Cliff
- 10.21 Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive)
- 10.22 Notice and Agreement for Stock Options Grant Pursuant to MacroPore Biosurgery, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive) with Cliff
- 10.23 Form of Options Exercise and Stock Purchase Agreement Relating to the 2004 Equity Incentive Plan
- 10.24 Form of Notice of Stock Options Grant Relating to the 2004 Equity Incentive Plan
- 10.25* Exclusive Distribution Agreement, Effective July 16, 2004 by and between the Company and Senko Medical Trading Co.
- 15.1 Letter re unaudited interim financial information
- 31.1 Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Section 302 of the Sarbanes-Oxley Act of 2002

- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

b. Reports on Form 8-K

We filed, on August 27, 2004 a Form 8-K to report the 2004 Equity Incentive Plan of MacroPore Biosurgery, Inc. (covering 3,000,000 shares) became effective upon approval by the Board of Directors. (Items 1.01 and 9.01).

We filed on July 19, 2004, a Form 8-K to report entering into a distribution agreement with Senko Medical Trading Co. for the distribution of bioresorbable Thin Film products in Japan. This Form 8-K also reported the withdrawal of previously-given financial guidance. (Items 5, 7 and 12).

We furnished, on Form 8-K, during this fiscal quarter, disclosure of announcement of historical financial results. Pursuant to SEC staff guidance, such furnished Form 8-K information need not be listed in this Item 6(b) of Form 10-Q.

*Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text (the "Mark"). This exhibit has been filed separately with the Secretary of the Commission without the Mark pursuant to our Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in San Diego, California, on November 15, 2004.

MACROPORE BIOSURGERY, INC.

Dated: November 15, 2004

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

Dated: November 15, 2004

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

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EXHIBIT INDEX

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THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS IS NOT REQUIRED.

**MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN**

**NONSTATUTORY STOCK OPTION AGREEMENT
Four Year Vesting - Month to Month**

MacroPore Biosurgery, Inc., a Delaware corporation (the "Company"), hereby grants an option to purchase shares of its Common Stock (the "Shares") to the optionee named below. The terms and conditions of the option are set forth in this cover sheet, in the attachment and in the Company's 1997 Stock Option and Stock Purchase Plan (the "Plan").

Date of Option Grant:

Name of Optionee (print):

Optionee's Social Security Number:

Shares of Common Stock Covered by Option:

Exercise Price per Share:

Vesting Start Date:

By signing this cover sheet, you agree to all of the terms and conditions described in the attached Agreement and in the Plan, a copy of which is also enclosed.

Optionee: _____

MacroPore Biosurgery: _____
Christopher J. Calhoun, Chief Executive Officer

Attachment

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**MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN**

**NONSTATUTORY STOCK OPTION AGREEMENT
Four Year Vesting –Month to Month**

Nonstatutory Stock Option

This option is not intended to be an incentive stock option under section 422 of the Internal Revenue Code and will be interpreted accordingly.

Exercise and Vesting

This option becomes exercisable to the extent as shown in the schedule below: This option shall vest as to 1/48th of the Shares on the one-month anniversary of the Vesting Start Date and 1/48th of the Shares each full month of Service thereafter. The Shares shall be one hundred percent (100%) vested on the fourth anniversary of the Vesting Start Date.

Notwithstanding the foregoing vesting schedule, upon a Change in Control, the vesting schedule shall be accelerated so that you shall acquire a vested interest in all then remaining unvested Shares.

No additional Shares shall vest after your Service to the Company has been terminated for any reason or no reason.

Term

Your option will expire in any event at the close of business at Company headquarters on the day before the 10th anniversary of the Date of Option Grant, as shown on the cover sheet. (It will expire earlier if your Service to the Company terminates, as described below.)

Regular Termination

If your Service to the Company terminates for any reason except death or Disability, then your option will expire at the close of business at Company headquarters on the 90th day after your termination date.

Death

In the event of your death while in Service, then your option will expire at the close of business at Company headquarters on the date six (6) months after the date of death. During that six (6) month period, your estate or heirs may exercise your option.

Disability

If your Service terminates because of your Disability, then your option will expire at the close of business at Company headquarters on the date six (6) months after your termination date.

“Disability” means that you are unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment.

Leaves of Absence

For purposes of this option, your Service does not terminate when you go on a *bona fide* leave of absence, that was approved by the Company in writing, if the terms of the leave provide for continued service crediting, or when continued service crediting is required by applicable law. Your Service terminates in any event when the approved leave ends, unless you immediately return to active work.

The Company determines which leaves count for this purpose, and when your Service terminates for all purposes under the Plan.

Restrictions on Exercise

The Company will not permit you to exercise this option if the issuance of Shares at that time would violate any law or regulation.

Notice of Exercise

When you wish to exercise this option, you must notify the Company by filing the proper notice of exercise form at the address given on the form, a copy of which is attached hereto. Your notice must specify how many Shares you wish to purchase. Your notice must also specify how your Shares should be registered (in your name only or in your and your spouse’s names as community property or as joint tenants with right of survivorship). The notice will be effective when it is received by the Company.

If someone else wants to exercise this option after your death, that person must prove to the Company’s satisfaction that he or she is entitled to do so.

Periods of Nonexercisability

Any other provision of this Agreement notwithstanding, the Company shall have the right to designate one or more periods of time, each of which shall not exceed one hundred eighty (180) days in length, during which this option shall not be exercisable if the Company determines (in its sole discretion) that such limitation on exercise could in any way facilitate a lessening of any restriction on transfer pursuant to the Securities Act of 1933, as amended (the “Securities Act”) or any state securities laws with respect to any issuance of securities by the Company, facilitate the registration or qualification of any securities by the Company under the Securities Act or any state securities laws, or facilitate the perfection of any exemption from the registration or qualification requirements of the Securities Act or any applicable state securities laws for the issuance or transfer of any securities. Such limitation on exercise shall not alter the vesting schedule set forth in this Agreement other than to limit the periods during which this option shall be exercisable.

Form of Payment

When you submit your notice of exercise, you must include payment of the option price for the Shares you are purchasing. Payment may be made in one (or a combination) of the following forms:

- Your personal check, a cashier’s check or a money order.
- Common Stock which has already been owned by you any time period specified by the Committee and which is surrendered to the Company. The value of the Stock, determined as of the effective date of the option exercise, will be applied to the option price.
- To the extent that a public market for the Shares exists as determined by the Company, by delivery (on a form prescribed by the Committee) of an irrevocable direction to a securities broker to sell Shares and to deliver all or part of the sale proceeds to the Company in payment of the aggregate Exercise Price.

Withholding Taxes

You will not be allowed to exercise this option unless you make acceptable arrangements to pay any withholding or other taxes that may be due as a result of the option exercise or the sale of Shares acquired upon exercise of this option.

Market Stand-Off Agreement

In connection with any underwritten public offering by the Company of its equity securities pursuant to an effective registration statement filed under the Securities Act, including the Company’s initial public offering, you shall not sell, make any short sale of, loan, hypothecate, pledge, grant any option for the purchase of, or otherwise dispose or transfer for value or agree to engage in any of the foregoing transactions with respect to any Shares without the prior written consent of the Company or its underwriters, for such period of time after the effective date of such registration statement, not to exceed one hundred eighty (180) days, as may be requested by the Company or such underwriters.

In order to enforce the provisions of this paragraph, the Company may impose stop-transfer instructions with respect to the Shares until the end of the applicable stand-off period.

Restrictions on Resale

By signing this Agreement, you agree not to sell any option Shares at a time when applicable laws, regulations or Company or underwriter trading policies prohibit a sale.

You represent and agree that the Shares to be acquired upon exercising this option will be acquired for investment, and

not with a view to the sale or distribution thereof.

In the event that the sale of Shares under the Plan is not registered under the Securities Act of 1933 but an exemption is available which requires an investment representation or other representation, you shall represent and agree at the time of exercise to make such representations as are deemed necessary or appropriate by the Company and its counsel as a condition of issuance of the Shares to you by the Company.

The Company's Right of First Refusal

In the event that you propose to sell, pledge or otherwise transfer to a third party any Shares acquired under this Agreement, or any interest in such Shares, the Company shall have the "Right of First Refusal" with respect to all (and not less than all) of such Shares. If you desire to transfer Shares acquired under this Agreement, you must give a written notice to the Company describing fully the proposed transfer, including the number of Shares proposed to be transferred, the proposed transfer price and the name and address of the proposed transferee (the "Transfer Notice"). The Transfer Notice shall be signed both by you and by the proposed new transferee and must constitute a binding commitment of both parties to the transfer of the Shares. The Company shall have the right to purchase all, and not less than all, of the Shares on the terms of the proposal described in the Transfer Notice (subject, however, to any change in such terms permitted in the next paragraph) by delivery of a notice of exercise of the Right of First Refusal within thirty (30) days after the date when the Transfer Notice was received by the Company.

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If the Company fails to exercise its Right of First Refusal before or within thirty (30) days after the date when it received the Transfer Notice, you may, not later than ninety (90) days following receipt of the Transfer Notice by the Company, conclude a transfer of the Shares subject to the Transfer Notice on the terms and conditions described in the Transfer Notice. Any proposed transfer on terms and conditions different from those described in the Transfer Notice, as well as any subsequent proposed transfer by you, shall again be subject to the Right of First Refusal and shall require compliance with the procedure described in the paragraph above. If the Company exercises its Right of First Refusal, the parties shall consummate the sale of the Shares on the terms set forth in the Transfer Notice within sixty (60) days after the date when the Company received the Transfer Notice (or within such longer period as may have been specified in the Transfer Notice); provided, however, that in the event the Transfer Notice provided that payment for the Shares was to be made in a form other than lawful money paid at the time of transfer, the Company shall have the option of paying for the Shares with lawful money equal to the present value of the consideration described in the Transfer Notice.

The Company's Right of First Refusal shall inure to the benefit of its successors and assigns, shall be freely assignable in whole or in part and shall be binding upon any transferee of the Shares.

The Company's Right of First Refusal shall terminate in the event that Stock is listed on an established stock exchange or is quoted regularly on the Nasdaq Stock Market.

Transfer of Option

Prior to your death, only you may exercise this option. You cannot transfer or assign this option. For instance, you may not sell this option or use it as security for a loan. If you attempt to do any of these things, this option will immediately become invalid. You may, however, dispose of this option in your will, or you may designate a beneficiary to exercise this option.

Regardless of any marital property settlement agreement, the Company is not obligated to honor a notice of exercise from your spouse or former spouse, nor is the Company obligated to recognize such individual's interest in your option in any other way.

No Retention Rights

Your option or this Agreement do not give you the right to be retained by the Company (or any subsidiaries) in any capacity. The Company (and any subsidiaries) reserve the right to terminate your Service at any time and for any reason.

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Shareholder Rights

You, or your estate or heirs, have no rights as a shareholder of the Company until a certificate for your option Shares has been issued. No adjustments are made for dividends or other rights if the applicable record date occurs before your stock certificate is issued, except as described in the Plan.

Adjustments

In the event of a stock split, a stock dividend or a similar change in the Company stock, the number of Shares covered by this option and the exercise price per share may be adjusted pursuant to the Plan. Your option shall be subject to the terms of the agreement of merger, liquidation or reorganization in the event the Company is subject to such corporate activity.

Legends

All certificates representing the Shares issued upon exercise of this option shall, where applicable, have endorsed thereon the following legends:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD, TRANSFERRED, ENCUMBERED OR IN ANY MANNER DISPOSED OF, EXCEPT IN COMPLIANCE WITH THE TERMS OF A WRITTEN AGREEMENT BETWEEN THE COMPANY AND THE INITIAL HOLDER HEREOF. SUCH AGREEMENT PROVIDES FOR CERTAIN TRANSFER RESTRICTIONS, INCLUDING RIGHTS OF FIRST REFUSAL UPON AN ATTEMPTED TRANSFER OF THE SECURITIES AND CERTAIN REPURCHASE RIGHTS IN FAVOR OF THE COMPANY UPON TERMINATION OF SERVICE WITH THE COMPANY. THE SECRETARY OF THE COMPANY WILL UPON WRITTEN REQUEST FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER HEREOF WITHOUT CHARGE."

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS ARE NOT REQUIRED.”

Applicable Law	This Agreement will be interpreted and enforced under the laws of the State of California without regard to conflicts of laws provisions thereof.
The Plan and Other Agreements	<p>The text of the Plan is incorporated in this Agreement by reference. Certain capitalized terms used in this Agreement are defined in the Plan.</p> <p>This Agreement and the Plan constitute the entire understanding between you and the Company regarding this option. Any prior agreements, commitments or negotiations concerning this option are superseded.</p>
Special Notice to California Residents	MacroPore Biosurgery’s Plan does not allow for transferability by instrument to an inter vivos or testamentary trust, or by gift to immediate family as defined in 17 CFR 240.16a-1(e), of options that are granted pursuant to the Plan, nor does MacroPore Biosurgery’s Plan allow for transferability by will or the laws or descent or distribution of rights to purchase MacroPore Biosurgery’s common stock that are granted pursuant to the Plan.

By signing the cover sheet of this Agreement, you agree to all of the terms and conditions described above and in the Plan.

NOTICE OF EXERCISE OF STOCK OPTION

MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121
Attn: Chief Financial Officer

Re: Exercise of Stock Option to Purchase Shares of Company Stock

Ladies and Gentlemen:

Pursuant to the Stock Option Agreement dated _____, 199____ (the “Stock Option Agreement”), between MacroPore Biosurgery, Inc., a Delaware corporation (the “Company”), and the undersigned, I hereby elect to purchase _____ shares of the common stock of the Company (the “Shares”), at the price of \$ _____ per Share. My check in the amount of \$ _____ and the executed Assignment Separate from Certificate are enclosed. The Shares are to be issued and registered in the name(s) of:

The undersigned understands there may be tax consequences as a result of the purchase or disposition of the Shares. The undersigned represents that he/she has received and reviewed the Plan’s federal tax information and consulted with any tax consultants he/she deems advisable in connection with the purchase or disposition of the Shares and the undersigned is not relying on the Company for any tax advice.

The undersigned acknowledges that he/she has received, read and understood the Stock Option Agreement and agrees to abide by and be bound by their terms and conditions. The undersigned represents that the Shares are being acquired solely for his/her own account and not as a nominee for any other party, or for investment, and that the undersigned purchaser will not offer, sell or otherwise dispose of any such Shares except under circumstances that will not result in a violation of the Securities Act of 1933, as amended, or any state securities laws.

Dated: _____

(Signature)

(Please Print Name)

Social Security No. _____

(Full Address)

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS IS NOT REQUIRED.

**MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN**

**NONSTATUTORY STOCK OPTION AGREEMENT
Four Year Vesting With One Year Cliff**

MacroPore Biosurgery, Inc., a Delaware corporation (the "Company"), hereby grants an option to purchase shares of its Common Stock (the "Shares") to the optionee named below. The terms and conditions of the option are set forth in this cover sheet, in the attachment and in the Company's 1997 Stock Option and Stock Purchase Plan (the "Plan").

Date of Option Grant:

Name of Optionee (print):

Optionee's Social Security Number:

Shares of Common Stock Covered by Option:

Exercise Price per Share:

Vesting Start Date:

By signing this cover sheet, you agree to all of the terms and conditions described in the attached Agreement and in the Plan, a copy of which is also enclosed.

Optionee: _____

MacroPore Biosurgery: _____

Christopher J.
Calhoun,
Chief
Executive
Officer

Attachment

**MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN**

**NONSTATUTORY STOCK OPTION AGREEMENT
Four Year Vesting With One Year Cliff**

Nonstatutory Stock Option This option is not intended to be an incentive stock option under section 422 of the Internal Revenue Code and will be interpreted accordingly.

Exercise and Vesting This option becomes exercisable to the extent of the vesting schedule. This option shall vest as to 12/48th of the Shares on the one-year anniversary of the Vesting Start Date and 1/48th of the Shares each full month of Service thereafter. The Shares shall be one hundred percent (100%) vested on the fourth anniversary of the Vesting Start Date.

Notwithstanding the foregoing vesting schedule, upon a Change in Control, the vesting schedule shall be accelerated so that you shall acquire a vested interest in all then remaining unvested Shares.

No additional Shares shall vest after your Service to the Company has been terminated for any reason or no reason.

Term Your option will expire in any event at the close of business at Company headquarters on the day before the 10th anniversary of the Date of Option Grant, as shown on the cover sheet. (It will expire earlier if your Service to the Company terminates, as described below.)

Regular Termination If your Service to the Company terminates for any reason except death or Disability, then your option will expire at the close of business at Company headquarters on the 90th day after your termination date.

Death In the event of your death while in Service, then your option will expire at the close of business at Company headquarters on the date six (6) months after the date of death. During that six (6) month period, your estate or heirs may exercise your option.

Disability If your Service terminates because of your Disability, then your option will expire at the close of business at Company headquarters on the date six (6) months after your termination date.

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“Disability” means that you are unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment.

Leaves of Absence For purposes of this option, your Service does not terminate when you go on a *bona fide* leave of absence, that was approved by the Company in writing, if the terms of the leave provide for continued service crediting, or when continued service crediting is required by applicable law. Your Service terminates in any event when the approved leave ends, unless you immediately return to active work.

The Company determines which leaves count for this purpose, and when your Service terminates for all purposes under the Plan.

Restrictions on Exercise The Company will not permit you to exercise this option if the issuance of Shares at that time would violate any law or regulation.

Notice of Exercise When you wish to exercise this option, you must notify the Company by filing the proper notice of exercise form at the address given on the form, a copy of which is attached hereto. Your notice must specify how many Shares you wish to purchase. Your notice must also specify how your Shares should be registered (in your name only or in your and your spouse’s names as community property or as joint tenants with right of survivorship). The notice will be effective when it is received by the Company.

If someone else wants to exercise this option after your death, that person must prove to the Company’s satisfaction that he or she is entitled to do so.

Periods of Nonexercisability Any other provision of this Agreement notwithstanding, the Company shall have the right to designate one or more periods of time, each of which shall not exceed one hundred eighty (180) days in length, during which this option shall not be exercisable if the Company determines (in its sole discretion) that such limitation on exercise could in any way facilitate a lessening of any restriction on transfer pursuant to the Securities Act of 1933, as amended (the “Securities Act”) or any state securities laws with respect to any issuance of securities by the Company, facilitate the registration or qualification of any securities by the Company under the Securities Act or any state securities laws, or facilitate the perfection of any exemption from the registration or qualification requirements of the Securities Act or any applicable state securities laws for the issuance or transfer of any securities. Such limitation on exercise shall not alter the vesting schedule set forth in this Agreement other than to limit the periods during which this option shall be exercisable.

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Form of Payment When you submit your notice of exercise, you must include payment of the option price for the Shares you are purchasing. Payment may be made in one (or a combination) of the following forms:

- Your personal check, a cashier’s check or a money order.
- Common Stock which has already been owned by you any time period specified by the Committee and which is surrendered to the Company. The value of the Stock, determined as of the effective date of the option exercise, will be applied to the option price.
- To the extent that a public market for the Shares exists as determined by the Company, by delivery (on a form prescribed by the Committee) of an irrevocable direction to a securities broker to sell Shares and to deliver all or part of the sale proceeds to the Company in payment of the aggregate Exercise Price.

Withholding Taxes You will not be allowed to exercise this option unless you make acceptable arrangements to pay any withholding or other taxes that may be due as a result of the option exercise or the sale of Shares acquired upon exercise of this option.

Market Stand-Off Agreement In connection with any underwritten public offering by the Company of its equity securities pursuant to an effective registration statement filed under the Securities Act, including the Company’s initial public offering, you shall not sell, make any short sale of, loan, hypothecate, pledge, grant any option for the purchase of, or otherwise dispose or transfer for value or agree to engage in any of the foregoing transactions with respect to any Shares without the prior written consent of the Company or its underwriters, for such period of time after the effective date of such registration statement, not to exceed one hundred eighty (180) days, as may be requested by the Company or such underwriters.

In order to enforce the provisions of this paragraph, the Company may impose stop-transfer instructions with respect to the Shares until the end of the applicable stand-off period.

Restrictions on Resale

By signing this Agreement, you agree not to sell any option Shares at a time when applicable laws, regulations or Company or underwriter trading policies prohibit a sale.

You represent and agree that the Shares to be acquired upon exercising this option will be acquired for investment, and not with a view to the sale or distribution thereof.

In the event that the sale of Shares under the Plan is not registered under the Securities Act of 1933 but an exemption is available which requires an investment representation or other representation, you shall represent and agree at the time of exercise to make such representations as are deemed necessary or appropriate by the Company and its counsel as a condition of issuance of the Shares to you by the Company.

The Company's Right of First Refusal

In the event that you propose to sell, pledge or otherwise transfer to a third party any Shares acquired under this Agreement, or any interest in such Shares, the Company shall have the "Right of First Refusal" with respect to all (and not less than all) of such Shares. If you desire to transfer Shares acquired under this Agreement, you must give a written notice to the Company describing fully the proposed transfer, including the number of Shares proposed to be transferred, the proposed transfer price and the name and address of the proposed transferee (the "Transfer Notice"). The Transfer Notice shall be signed both by you and by the proposed new transferee and must constitute a binding commitment of both parties to the transfer of the Shares. The Company shall have the right to purchase all, and not less than all, of the Shares on the terms of the proposal described in the Transfer Notice (subject, however, to any change in such terms permitted in the next paragraph) by delivery of a notice of exercise of the Right of First Refusal within thirty (30) days after the date when the Transfer Notice was received by the Company.

If the Company fails to exercise its Right of First Refusal before or within thirty (30) days after the date when it received the Transfer Notice, you may, not later than ninety (90) days following receipt of the Transfer Notice by the Company, conclude a transfer of the Shares subject to the Transfer Notice on the terms and conditions described in the Transfer Notice. Any proposed transfer on terms and conditions different from those described in the Transfer Notice, as well as any subsequent proposed transfer by you, shall again be subject to the Right of First Refusal and shall require compliance with the procedure described in the paragraph above. If the Company exercises its Right of First Refusal, the parties shall consummate the sale of the Shares on the terms set forth in the Transfer Notice within sixty (60) days after the date when the Company received the Transfer Notice (or within such longer period as may have been specified in the Transfer Notice); provided, however, that in the event the Transfer Notice provided that payment for the Shares was to be made in a form other than lawful money paid at the time of transfer, the Company shall have the option of paying for the Shares with lawful money equal to the present value of the consideration described in the Transfer Notice.

The Company's Right of First Refusal shall inure to the benefit of its successors and assigns, shall be freely assignable in whole or in part and shall be binding upon any transferee of the Shares.

The Company's Right of First Refusal shall terminate in the event that Stock is listed on an established stock exchange or is quoted regularly on the NASDAQ Stock Market.

Transfer of Option

Prior to your death, only you may exercise this option. You cannot transfer or assign this option. For instance, you may not sell this option or use it as security for a loan. If you attempt to do any of these things, this option will immediately become invalid. You may, however, dispose of this option in your will, or you may designate a beneficiary to exercise this option.

Regardless of any marital property settlement agreement, the Company is not obligated to honor a notice of exercise from your spouse or former spouse, nor is the Company obligated to recognize such individual's interest in your option in any other way.

No Retention Rights

Your option or this Agreement does not give you the right to be retained by the Company (or any subsidiaries) in any capacity. The Company (and any subsidiaries) reserve the right to terminate your Service at any time and for any reason.

Shareholder Rights

You, or your estate or heirs, have no rights as a shareholder of the Company until a certificate for your option Shares has been issued. No adjustments are made for dividends or other rights if the applicable record date occurs before your stock certificate is issued, except as described in the Plan.

Adjustments

In the event of a stock split, a stock dividend or a similar change in the Company stock, the number of Shares covered by this option and the exercise price per share may be adjusted pursuant to the Plan. Your option shall be subject to the terms of the agreement of merger, liquidation or reorganization in the event the Company is subject to such corporate activity.

Legends

All certificates representing the Shares issued upon exercise of this option shall, where applicable, have endorsed thereon the following legends:

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD, TRANSFERRED, ENCUMBERED OR IN ANY MANNER DISPOSED OF, EXCEPT IN COMPLIANCE WITH THE TERMS OF A WRITTEN AGREEMENT BETWEEN THE COMPANY AND THE INITIAL HOLDER HEREOF. SUCH AGREEMENT PROVIDES FOR CERTAIN TRANSFER RESTRICTIONS, INCLUDING RIGHTS OF FIRST REFUSAL UPON AN ATTEMPTED TRANSFER OF THE SECURITIES AND CERTAIN REPURCHASE RIGHTS IN FAVOR OF THE COMPANY UPON TERMINATION OF SERVICE WITH THE COMPANY. THE SECRETARY OF THE COMPANY WILL UPON WRITTEN REQUEST FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER HEREOF WITHOUT CHARGE.”

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS ARE NOT REQUIRED.”

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Applicable Law

This Agreement will be interpreted and enforced under the laws of the State of California without regard to conflicts of laws provisions thereof.

The Plan and Other Agreements

The text of the Plan is incorporated in this Agreement by reference. Certain capitalized terms used in this Agreement are defined in the Plan.

This Agreement and the Plan constitute the entire understanding between you and the Company regarding this option. Any prior agreements, commitments or negotiations concerning this option are superseded.

Special Notice to California Residents

MacroPore Biosurgery’s Plan does not allow for transferability by instrument to an inter vivos or testamentary trust, or by gift to immediate family as defined in 17 CFR 240.16a-1(e), of options that are granted pursuant to the Plan, nor does MacroPore Biosurgery’s Plan allow for transferability by will or the laws of descent or distribution of rights to purchase MacroPore Biosurgery’s common stock that are granted pursuant to the Plan.

By signing the cover sheet of this Agreement, you agree to all of the terms and conditions described above and in the Plan.

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NOTICE OF EXERCISE OF STOCK OPTION

MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121
Attn: Chief Financial Officer

Re: Exercise of Stock Option to Purchase Shares of Company Stock

Ladies and Gentlemen:

Pursuant to the Stock Option Agreement dated _____, 199 (the “Stock Option Agreement”), between MacroPore Biosurgery, Inc., a Delaware corporation (the “Company”), and the undersigned, I hereby elect to purchase _____ shares of the common stock of the Company (the “Shares”), at the price of \$ _____ per Share. My check in the amount of \$ _____ and the executed Assignment Separate from Certificate are enclosed. The Shares are to be issued and registered in the name(s) of:

The undersigned understands there may be tax consequences as a result of the purchase or disposition of the Shares. The undersigned represents that he/she has received and reviewed the Plan’s federal tax information and consulted with any tax consultants he/she deems advisable in connection with the purchase or disposition of the Shares and the undersigned is not relying on the Company for any tax advice.

The undersigned acknowledges that he/she has received, read and understood the Stock Option Agreement and agrees to abide by and be bound by their terms and conditions. The undersigned represents that the Shares are being acquired solely for his/her own account and not as a nominee for any other party, or for investment, and that the undersigned purchaser will not offer, sell or otherwise dispose of any such Shares except under circumstances that will not result in a violation of the Securities Act of 1933, as amended, or any state securities laws.

Dated: _____

(Signature)

(Please Print Name)

Social Security No. _____

(Full Address)

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS IS NOT REQUIRED.

**MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN**

**INCENTIVE STOCK OPTION AGREEMENT
4 Year Vesting – Month to Month**

MacroPore Biosurgery, Inc., a Delaware corporation (the “Company”), hereby grants an option to purchase shares of its Common Stock (the “Shares”) to the optionee named below. The terms and conditions of the option are set forth in this cover sheet, in the attachment and in the Company’s 1997 Stock Option and Stock Purchase Plan (the “Plan”).

Date of Option Grant:

Name of Optionee:

Optionee Social Security Number:

Shares of Common Stock Covered by Option:

Exercise Price per Share:

Vesting Start Date:

Check here if Optionee is a 10% owner (so that exercise price must be 110% of fair market value and the Option term will not exceed 5 years).

By signing this cover sheet, you agree to all of the terms and conditions described in the attached Agreement and in the Plan, a copy of which is also enclosed.

Optionee: _____

Company: _____
Christopher J. Calhoun, Chief Executive Officer

Attachment

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**MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN**

**INCENTIVE STOCK OPTION AGREEMENT
4 Year Vesting – Month to Month**

Incentive Stock Option

This option is intended to be an incentive stock option under section 422 of the Internal Revenue Code and will be interpreted accordingly.

Exercise and Vesting

This option becomes exercisable to the extent as shown in the schedule below. This option shall vest as to 1/48th of the Shares on the one-month anniversary of the Vesting Start Date and 1/48th of the Shares each full month of Service thereafter. The Shares shall be one hundred percent (100%) vested on the fourth anniversary of the Vesting Start Date.

Notwithstanding the foregoing vesting schedule, upon a Change in Control, the vesting schedule shall be accelerated so that you shall acquire a vested interest in all then remaining unvested Shares.

No additional Shares shall vest after your Service to the Company has been terminated for any reason or no reason.

Your Service shall cease when you cease to be actively employed by, or a consultant or adviser to, the Company as determined in the sole discretion of the Committee. A leave of absence, regardless of the reason, shall be deemed to constitute the cessation of your Service unless such leave is authorized by the Company, and you return within the time specified in such authorization.

Term

Your option will expire in any event at the close of business at Company headquarters on the day before the 10th anniversary of the Date of Option Grant, as shown on the cover sheet. (It will expire earlier if your Service to the Company terminates, as described below.)

Regular Termination

If your Service to the Company terminates for any reason except death or Disability, then your option will expire at the close of business at Company headquarters on the 90th day after your termination date.

Death	In the event of your death while in Service, then your option will expire at the close of business at Company headquarters on the date six (6) months after the date of death. During that six (6) month period, your estate or heirs may exercise your option.
Disability	<p>If your Service terminates because of your Disability, then your option will expire at the close of business at Company headquarters on the date six (6) months after your termination date.</p> <p>However, for purposes of determining whether your option is entitled to ISO status, unless your Disability satisfies the definition set forth in section 22(e)(3) of the Code (as cited below), ISO status will terminate three (3) months after your termination date.</p> <p>“Disability” means that you are unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment.</p>
Leaves of Absence	<p>For purposes of this option, your Service does not terminate when you go on a <i>bona fide</i> leave of absence, that was approved by the Company in writing, if the terms of the leave provide for continued service crediting, or when continued service crediting is required by applicable law. However, for purposes of determining whether your option is entitled to ISO status, your Service will be treated as terminating ninety (90) days after you went on leave, unless your right to return to active work is guaranteed by law or a contract. Your Service terminates in any event when the approved leave ends, unless you immediately return to active work.</p> <p>The Company determines which leaves count for this purpose, and when your Service terminates for all purposes under the Plan.</p>
Restrictions on Exercise	The Company will not permit you to exercise this option if the issuance of Shares at that time would violate any law or regulation.

Notice of Exercise	<p>When you wish to exercise this option, you must notify the Company by filing the proper notice of exercise form at the address given on the form, a copy of which is attached hereto. Your notice must specify how many Shares you wish to purchase. Your notice must also specify how your Shares should be registered (in your name only or in your and your spouse's names as community property or as joint tenants with right of survivorship). The notice will be effective when it is received by the Company.</p> <p>If someone else wants to exercise this option after your death, that person must prove to the Company's satisfaction that he or she is entitled to do so.</p>
Periods of Nonexercisability	Any other provision of this Agreement notwithstanding, the Company shall have the right to designate one or more periods of time, each of which shall not exceed one hundred eighty (180) days in length, during which this option shall not be exercisable if the Company determines (in its sole discretion) that such limitation on exercise could in any way facilitate a lessening of any restriction on transfer pursuant to the Securities Act of 1933, as amended (the “Securities Act”) or any state securities laws with respect to any issuance of securities by the Company, facilitate the registration or qualification of any securities by the Company under the Securities Act or any state securities laws, or facilitate the perfection of any exemption from the registration or qualification requirements of the Securities Act or any applicable state securities laws for the issuance or transfer of any securities. Such limitation on exercise shall not alter the vesting schedule set forth in this Agreement other than to limit the periods during which this option shall be exercisable.
Form of Payment	<p>When you submit your notice of exercise, you must include payment of the option price for the Shares you are purchasing. Payment may be made in one (or a combination) of the following forms:</p> <ul style="list-style-type: none"> • Your personal check, a cashier's check or a money order. • Common Stock which has already been owned by you for any time period specified by the Committee and which is surrendered to the Company. The value of the Stock, determined as of the effective date of the option exercise, will be applied to the option price.

Withholding Taxes	<ul style="list-style-type: none"> • To the extent that a public market for the Shares exists as determined by the Company, by delivery (on a form prescribed by the Committee) of an irrevocable direction to a securities broker to sell Shares and to deliver all or part of the sale proceeds to the Company in payment of the aggregate Exercise Price. <p>You will not be allowed to exercise this option unless you make acceptable arrangements to pay any withholding or other taxes that may be due as a result of the option exercise or the sale of Shares acquired upon exercise of this option.</p>
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Market Stand-Off Agreement

In connection with any underwritten public offering by the Company of its equity securities pursuant to an effective registration statement filed under the Securities Act, including the Company's initial public offering, you shall not sell, make any short sale of, loan, hypothecate, pledge, grant any option for the purchase of, or otherwise dispose or transfer for value or agree to engage in any of the foregoing transactions with respect to any Shares without the prior written consent of the Company or its underwriters, for such period of time after the effective date of such registration statement, not to exceed one hundred eighty (180) days as may be requested by the Company or such underwriters.

In order to enforce the provisions of this paragraph, the Company may impose stop-transfer instructions with respect to the Shares until the end of the applicable stand-off period.

Restrictions on Resale

By signing this Agreement, you agree not to sell any option Shares at a time when applicable laws, regulations or Company or underwriter trading policies prohibit a sale.

You represent and agree that the Shares to be acquired upon exercising this option will be acquired for investment, and not with a view to the sale or distribution thereof.

In the event that the sale of Shares under the Plan is not registered under the Securities Act but an exemption is available which requires an investment representation or other representation, you shall represent and agree at the time of exercise to make such representations as are deemed necessary or appropriate by the Company and its counsel as a condition of issuance of the Shares to you by the Company.

5

The Company's Right of First Refusal

In the event that you propose to sell, pledge or otherwise transfer to a third party any Shares acquired under this Agreement, or any interest in such Shares, the Company shall have the "Right of First Refusal" with respect to all (and not less than all) of such Shares. If you desire to transfer Shares acquired under this Agreement, you must give a written notice to the Company describing fully the proposed transfer, including the number of Shares proposed to be transferred, the proposed transfer price and the name and address of the proposed transferee (the "Transfer Notice"). The Transfer Notice shall be signed both by you and by the proposed new transferee and must constitute a binding commitment of both parties to the transfer of the Shares. The Company shall have the right to purchase all, and not less than all, of the Shares on the terms of the proposal described in the Transfer Notice (subject, however, to any change in such terms permitted in the next paragraph) by delivery of a notice of exercise of the Right of First Refusal within thirty (30) days after the date when the Transfer Notice was received by the Company.

If the Company fails to exercise its Right of First Refusal before or within thirty (30) days after the date when it received the Transfer Notice, you may, not later than ninety (90) days following receipt of the Transfer Notice by the Company, conclude a transfer of the Shares subject to the Transfer Notice on the terms and conditions described in the Transfer Notice. Any proposed transfer on terms and conditions different from those described in the Transfer Notice, as well as any subsequent proposed transfer by you, shall again be subject to the Right of First Refusal and shall require compliance with the procedure described in the paragraph above. If the Company exercises its Right of First Refusal, the parties shall consummate the sale of the Shares on the terms set forth in the Transfer Notice within sixty (60) days after the date when the Company received the Transfer Notice (or within such longer period as may have been specified in the Transfer Notice); provided, however, that in the event the Transfer Notice provided that payment for the Shares was to be made in a form other than lawful money paid at the time of transfer, the Company shall have the option of paying for the Shares with lawful money equal to the present value of the consideration described in the Transfer Notice.

The Company's Right of First Refusal shall inure to the benefit of its successors and assigns, shall be freely assignable in whole or in part and shall be binding upon any transferee of the Shares.

The Company's Right of First Refusal shall terminate in the event that Stock is listed on an established stock exchange or is quoted regularly on the Nasdaq Stock Market.

6

Transfer of Option

Prior to your death, only you may exercise this option. You cannot transfer or assign this option. For instance, you may not sell this option or use it as security for a loan. If you attempt to do any of these things, this option will immediately become invalid. You may, however, dispose of this option in your will, or you may designate a beneficiary to exercise this option.

Regardless of any marital property settlement agreement, the Company is not obligated to honor a notice of exercise from your spouse or former spouse, nor is the Company obligated to recognize such individual's interest in your option in any other way.

No Retention Rights

Your option or this Agreement do not give you the right to be retained by the Company (or any subsidiaries) in any capacity. The Company (and any subsidiaries) reserve the right to terminate your Service at any time and for any reason.

Shareholder Rights

You, or your estate or heirs, have no rights as a shareholder of the Company until a certificate for your option Shares has been issued. No adjustments are made for dividends or other rights if the applicable record date occurs before your stock certificate is issued, except as described in the Plan.

Adjustments

In the event of a stock split, a stock dividend or a similar change in the Company stock, the number of Shares covered by this option and the exercise price per share may be adjusted pursuant to the Plan. Your option shall be subject to the terms of the agreement of merger, liquidation or reorganization in the event the Company is subject to such corporate activity.

7

Legends

All certificates representing the Shares issued upon exercise of this option shall, where applicable, have endorsed thereon the following legends:

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD, TRANSFERRED, ENCUMBERED OR IN ANY MANNER DISPOSED OF, EXCEPT IN COMPLIANCE WITH THE TERMS OF A WRITTEN AGREEMENT BETWEEN THE COMPANY AND THE INITIAL HOLDER HEREOF. SUCH AGREEMENT PROVIDES FOR CERTAIN TRANSFER RESTRICTIONS, INCLUDING RIGHTS OF FIRST REFUSAL UPON AN ATTEMPTED TRANSFER OF THE SECURITIES AND CERTAIN REPURCHASE RIGHTS IN FAVOR OF THE COMPANY UPON TERMINATION OF SERVICE WITH THE COMPANY. THE SECRETARY OF THE COMPANY WILL UPON WRITTEN REQUEST FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER HEREOF WITHOUT CHARGE.”

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS ARE NOT REQUIRED.”

Applicable Law

This Agreement will be interpreted and enforced under the laws of the State of California without regard to conflicts of laws provisions thereof.

8

The Plan and Other Agreements

The text of the Plan is incorporated in this Agreement by reference. Certain capitalized terms used in this Agreement are defined in the Plan.

This Agreement and the Plan constitute the entire understanding between you and the Company regarding this option. Any prior agreements, commitments or negotiations concerning this option are superseded.

Special Notice to California Residents

MacroPore’s Plan does not allow for transferability by instrument to an inter vivos or testamentary trust, or by gift to immediate family as defined in 17 CFR 240.16a-1(e), of options that are granted pursuant to the Plan, nor does MacroPore’s Plan allow for transferability by will or the laws or descent or distribution of rights to purchase MacroPore’s common stock that are granted pursuant to the Plan.

By signing the cover sheet of this Agreement, you agree to all of the terms and conditions described above and in the Plan.

9

NOTICE OF EXERCISE OF STOCK OPTION

MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121
Attn: Chief Financial Officer

Re: Exercise of Stock Option to Purchase Shares of Company Stock

Ladies and Gentlemen:

Pursuant to the Stock Option Agreement dated _____ (the “Stock Option Agreement”), between MacroPore Biosurgery, Inc., a Delaware corporation (the “Company”), and the undersigned, I hereby elect to purchase _____ shares of the common stock of the Company (the “Shares”), at the price of \$ _____ per Share. My check in the amount of \$ _____ and the executed Assignment Separate from Certificate are enclosed. The Shares are to be issued and registered in the name(s) of:

The undersigned understands there may be tax consequences as a result of the purchase or disposition of the Shares. The undersigned represents that he/she has received and reviewed the Plan’s federal income tax information and consulted with any tax consultants he/she deems advisable in connection with the purchase or disposition of the Shares and the undersigned is not relying on the Company for any tax advice.

The undersigned acknowledges that he/she has received, read and understood the Stock Option Agreement and agrees to abide by and be bound by their terms and conditions. The undersigned represents that the Shares are being acquired solely for his/her own account and not as a nominee for any other party, or for investment, and that the undersigned purchaser will not offer, sell or otherwise dispose of any such Shares except under circumstances that will not result in a violation of the Securities Act of 1933, as amended, or any state securities laws.

Dated: _____

(Signature)

(Please Print Name)

Social Security No. _____

(Full Address)

Internal Revenue Service Center

Re: Protective Election Under Section 83(b) of the Internal Revenue Code of 1986

Ladies and Gentlemen:

I hereby make a protective election under section 83(b) of the Internal Revenue Code of 1986 to include in gross income on the date of transfer any excess of fair market value over purchase price with respect to the transfer of the property described below if such property is sold in a disqualifying disposition under section 422 of the Code:

1. Name: _____
2. Address: _____
3. Social Security Number: _____
4. Tax Year of Election: Calendar Year of _____ .
5. Description of Property: _____ shares of Common Stock of MacroPore Biosurgery, Inc., a Delaware corporation (the "Company").
6. Date of Property Transfer: _____ .
7. Nature of Property Restrictions: Property is subject to the Company's right to repurchase the stock at the undersigned's original purchase price if the undersigned ceases to be associated with the Company, which right will generally lapse over a designated four (4) year period.
8. Fair Market Value at the Time of Transfer: \$ _____ per share for an aggregate of \$ _____. The Fair Market Value at the time of transfer was determined without regard to any lapse restrictions as defined in section 1.83-3(i) of the Income Tax Regulations.
9. Amount Paid for Property: \$ _____ per share for an aggregate of \$ _____ .
10. A copy of this election has been furnished to the Company, the person for whom the services are performed.

Sincerely,

Signature

Date

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS IS NOT REQUIRED.

MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN

INCENTIVE STOCK OPTION AGREEMENT
Four Year Vesting with One Year Cliff

MacroPore Biosurgery, Inc., a Delaware corporation (the "Company"), hereby grants an option to purchase shares of its Common Stock (the "Shares") to the optionee named below. The terms and conditions of the option are set forth in this cover sheet, in the attachment and in the Company's 1997 Stock Option and Stock Purchase Plan (the "Plan").

Date of Option Grant:

Name of Optionee:

Optionee Social Security Number:

Shares of Common Stock Covered by Option:

Exercise Price per Share:

Vesting Start Date:

Check here if Optionee is a 10% owner (so that exercise price must be 110% of fair market value and the Option term will not exceed 5 years).

By signing this cover sheet, you agree to all of the terms and conditions described in the attached Agreement and in the Plan, a copy of which is also enclosed.

Optionee: _____

Company: _____
Christopher J. Calhoun, Chief Executive Officer

Attachment

MACROPORE BIOSURGERY, INC.
1997 STOCK OPTION AND STOCK PURCHASE PLAN

INCENTIVE STOCK OPTION AGREEMENT
Four Year Vesting with One Year Cliff

Incentive Stock Option

This option is intended to be an incentive stock option under section 422 of the Internal Revenue Code and will be interpreted accordingly.

Exercise and Vesting

This option becomes exercisable to the extent as shown in the schedule below. This option shall vest as to 12/48th of the Shares on the one-year anniversary of the Vesting Start Date and 1/48th of the Shares each full month of Service thereafter. The Shares shall be one hundred percent (100%) vested on the fourth anniversary of the Vesting Start Date.

Notwithstanding the foregoing vesting schedule, upon a Change in Control, the vesting schedule shall be accelerated so that you shall acquire a vested interest in all then remaining unvested Shares.

No additional Shares shall vest after your Service to the Company has been terminated for any reason or no reason.

Your Service shall cease when you cease to be actively employed by, or a consultant or adviser to, the Company as determined in the sole discretion of the Committee. A leave of absence, regardless of the reason, shall be deemed to constitute the cessation of your Service unless such leave is authorized by the Company, and you return within the time specified in such authorization.

Term

Your option will expire in any event at the close of business at Company headquarters on the day before the 10th anniversary of the Date of Option Grant, as shown on the cover sheet. (It will expire earlier if your Service to the Company terminates, as described below.)

Regular Termination

If your Service to the Company terminates for any reason except death or Disability, then your option will expire at the close of business at Company headquarters on the 90th day after your termination date.

Death	In the event of your death while in Service, then your option will expire at the close of business at Company headquarters on the date six (6) months after the date of death. During that six (6) month period, your estate or heirs may exercise your option.
Disability	<p>If your Service terminates because of your Disability, then your option will expire at the close of business at Company headquarters on the date six (6) months after your termination date.</p> <p>However, for purposes of determining whether your option is entitled to ISO status, unless your Disability satisfies the definition set forth in section 22(e)(3) of the Code (as cited below), ISO status will terminate three (3) months after your termination date.</p> <p>“Disability” means that you are unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment.</p>
Leaves of Absence	<p>For purposes of this option, your Service does not terminate when you go on a <i>bona fide</i> leave of absence, that was approved by the Company in writing, if the terms of the leave provide for continued service crediting, or when continued service crediting is required by applicable law. However, for purposes of determining whether your option is entitled to ISO status, your Service will be treated as terminating ninety (90) days after you went on leave, unless your right to return to active work is guaranteed by law or a contract. Your Service terminates in any event when the approved leave ends, unless you immediately return to active work.</p> <p>The Company determines which leaves count for this purpose, and when your Service terminates for all purposes under the Plan.</p>
Restrictions on Exercise	The Company will not permit you to exercise this option if the issuance of Shares at that time would violate any law or regulation.

Notice of Exercise	<p>When you wish to exercise this option, you must notify the Company by filing the proper notice of exercise form at the address given on the form, a copy of which is attached hereto. Your notice must specify how many Shares you wish to purchase. Your notice must also specify how your Shares should be registered (in your name only or in your and your spouse’s names as community property or as joint tenants with right of survivorship). The notice will be effective when it is received by the Company.</p> <p>If someone else wants to exercise this option after your death, that person must prove to the Company’s satisfaction that he or she is entitled to do so.</p>
Periods of Nonexercisability	Any other provision of this Agreement notwithstanding, the Company shall have the right to designate one or more periods of time, each of which shall not exceed one hundred eighty (180) days in length, during which this option shall not be exercisable if the Company determines (in its sole discretion) that such limitation on exercise could in any way facilitate a lessening of any restriction on transfer pursuant to the Securities Act of 1933, as amended (the “Securities Act”) or any state securities laws with respect to any issuance of securities by the Company, facilitate the registration or qualification of any securities by the Company under the Securities Act or any state securities laws, or facilitate the perfection of any exemption from the registration or qualification requirements of the Securities Act or any applicable state securities laws for the issuance or transfer of any securities. Such limitation on exercise shall not alter the vesting schedule set forth in this Agreement other than to limit the periods during which this option shall be exercisable.
Form of Payment	<p>When you submit your notice of exercise, you must include payment of the option price for the Shares you are purchasing. Payment may be made in one (or a combination) of the following forms:</p> <ul style="list-style-type: none"> • Your personal check, a cashier’s check or a money order. • Common Stock which has already been owned by you for any time period specified by the Committee and which is surrendered to the Company. The value of the Stock, determined as of the effective date of the option exercise, will be applied to the option price.

Withholding Taxes	<ul style="list-style-type: none"> • To the extent that a public market for the Shares exists as determined by the Company, by delivery (on a form prescribed by the Committee) of an irrevocable direction to a securities broker to sell Shares and to deliver all or part of the sale proceeds to the Company in payment of the aggregate Exercise Price. <p>You will not be allowed to exercise this option unless you make acceptable arrangements to pay any withholding or other taxes that may be due as a result of the option exercise or the sale of Shares acquired upon exercise of this option.</p>
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Market Stand-Off Agreement

In connection with any underwritten public offering by the Company of its equity securities pursuant to an effective registration statement filed under the Securities Act, including the Company's initial public offering, you shall not sell, make any short sale of, loan, hypothecate, pledge, grant any option for the purchase of, or otherwise dispose or transfer for value or agree to engage in any of the foregoing transactions with respect to any Shares without the prior written consent of the Company or its underwriters, for such period of time after the effective date of such registration statement, not to exceed one hundred eighty (180) days as may be requested by the Company or such underwriters.

In order to enforce the provisions of this paragraph, the Company may impose stop-transfer instructions with respect to the Shares until the end of the applicable stand-off period.

Restrictions on Resale

By signing this Agreement, you agree not to sell any option Shares at a time when applicable laws, regulations or Company or underwriter trading policies prohibit a sale.

You represent and agree that the Shares to be acquired upon exercising this option will be acquired for investment, and not with a view to the sale or distribution thereof.

In the event that the sale of Shares under the Plan is not registered under the Securities Act but an exemption is available which requires an investment representation or other representation, you shall represent and agree at the time of exercise to make such representations as are deemed necessary or appropriate by the Company and its counsel as a condition of issuance of the Shares to you by the Company.

5

The Company's Right of First Refusal

In the event that you propose to sell, pledge or otherwise transfer to a third party any Shares acquired under this Agreement, or any interest in such Shares, the Company shall have the "Right of First Refusal" with respect to all (and not less than all) of such Shares. If you desire to transfer Shares acquired under this Agreement, you must give a written notice to the Company describing fully the proposed transfer, including the number of Shares proposed to be transferred, the proposed transfer price and the name and address of the proposed transferee (the "Transfer Notice"). The Transfer Notice shall be signed both by you and by the proposed new transferee and must constitute a binding commitment of both parties to the transfer of the Shares. The Company shall have the right to purchase all, and not less than all, of the Shares on the terms of the proposal described in the Transfer Notice (subject, however, to any change in such terms permitted in the next paragraph) by delivery of a notice of exercise of the Right of First Refusal within thirty (30) days after the date when the Transfer Notice was received by the Company.

If the Company fails to exercise its Right of First Refusal before or within thirty (30) days after the date when it received the Transfer Notice, you may, not later than ninety (90) days following receipt of the Transfer Notice by the Company, conclude a transfer of the Shares subject to the Transfer Notice on the terms and conditions described in the Transfer Notice. Any proposed transfer on terms and conditions different from those described in the Transfer Notice, as well as any subsequent proposed transfer by you, shall again be subject to the Right of First Refusal and shall require compliance with the procedure described in the paragraph above. If the Company exercises its Right of First Refusal, the parties shall consummate the sale of the Shares on the terms set forth in the Transfer Notice within sixty (60) days after the date when the Company received the Transfer Notice (or within such longer period as may have been specified in the Transfer Notice); provided, however, that in the event the Transfer Notice provided that payment for the Shares was to be made in a form other than lawful money paid at the time of transfer, the Company shall have the option of paying for the Shares with lawful money equal to the present value of the consideration described in the Transfer Notice.

The Company's Right of First Refusal shall inure to the benefit of its successors and assigns, shall be freely assignable in whole or in part and shall be binding upon any transferee of the Shares.

The Company's Right of First Refusal shall terminate in the event that Stock is listed on an established stock exchange or is quoted regularly on the Nasdaq Stock Market.

6

Transfer of Option

Prior to your death, only you may exercise this option. You cannot transfer or assign this option. For instance, you may not sell this option or use it as security for a loan. If you attempt to do any of these things, this option will immediately become invalid. You may, however, dispose of this option in your will, or you may designate a beneficiary to exercise this option.

Regardless of any marital property settlement agreement, the Company is not obligated to honor a notice of exercise from your spouse or former spouse, nor is the Company obligated to recognize such individual's interest in your option in any other way.

No Retention Rights

Your option or this Agreement do not give you the right to be retained by the Company (or any subsidiaries) in any capacity. The Company (and any subsidiaries) reserve the right to terminate your Service at any time and for any reason.

Shareholder Rights

You, or your estate or heirs, have no rights as a shareholder of the Company until a certificate for your option Shares has been issued. No adjustments are made for dividends or other rights if the applicable record date occurs before your stock certificate is issued, except as described in the Plan.

Adjustments

In the event of a stock split, a stock dividend or a similar change in the Company stock, the number of Shares covered by this option and the exercise price per share may be adjusted pursuant to the Plan. Your option shall be subject to the terms of the agreement of merger, liquidation or reorganization in the event the Company is subject to such corporate activity.

7

Legends

All certificates representing the Shares issued upon exercise of this option shall, where applicable, have endorsed thereon the following legends:

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD, TRANSFERRED, ENCUMBERED OR IN ANY MANNER DISPOSED OF, EXCEPT IN COMPLIANCE WITH THE TERMS OF A WRITTEN AGREEMENT BETWEEN THE COMPANY AND THE INITIAL HOLDER HEREOF. SUCH AGREEMENT PROVIDES FOR CERTAIN TRANSFER RESTRICTIONS, INCLUDING RIGHTS OF FIRST REFUSAL UPON AN ATTEMPTED TRANSFER OF THE SECURITIES AND CERTAIN REPURCHASE RIGHTS IN FAVOR OF THE COMPANY UPON TERMINATION OF SERVICE WITH THE COMPANY. THE SECRETARY OF THE COMPANY WILL UPON WRITTEN REQUEST FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER HEREOF WITHOUT CHARGE.”

“THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY BE OFFERED AND SOLD ONLY IF REGISTERED AND QUALIFIED PURSUANT TO THE RELEVANT PROVISIONS OF FEDERAL AND STATE SECURITIES LAWS OR IF THE COMPANY IS PROVIDED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION AND QUALIFICATION UNDER FEDERAL AND STATE SECURITIES LAWS ARE NOT REQUIRED.”

Applicable Law

This Agreement will be interpreted and enforced under the laws of the State of California without regard to conflicts of laws provisions thereof.

8

The Plan and Other Agreements

The text of the Plan is incorporated in this Agreement by reference. Certain capitalized terms used in this Agreement are defined in the Plan.

This Agreement and the Plan constitute the entire understanding between you and the Company regarding this option. Any prior agreements, commitments or negotiations concerning this option are superseded.

Special Notice to California Residents

MacroPore’s Plan does not allow for transferability by instrument to an inter vivos or testamentary trust, or by gift to immediate family as defined in 17 CFR 240.16a—1(e), of options that are granted pursuant to the Plan, nor does MacroPore’s Plan allow for transferability by will or the laws or descent or distribution of rights to purchase MacroPore’s common stock that are granted pursuant to the Plan.

By signing the cover sheet of this Agreement, you agree to all of the terms and conditions described above and in the Plan.

9

NOTICE OF EXERCISE OF STOCK OPTION

MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121
Attn: Chief Financial Officer

Re: Exercise of Stock Option to Purchase Shares of Company Stock

Ladies and Gentlemen:

Pursuant to the Stock Option Agreement dated _____ (the “Stock Option Agreement”), between MacroPore Biosurgery, Inc., a Delaware corporation (the “Company”), and the undersigned, I hereby elect to purchase _____ shares of the common stock of the Company (the “Shares”), at the price of \$ _____ per Share. My check in the amount of \$ _____ and the executed Assignment Separate from Certificate are enclosed. The Shares are to be issued and registered in the name(s) of:

The undersigned understands there may be tax consequences as a result of the purchase or disposition of the Shares. The undersigned represents that he/she has received and reviewed the Plan’s federal income tax information and consulted with any tax consultants he/she deems advisable in connection with the purchase or disposition of the Shares and the undersigned is not relying on the Company for any tax advice.

The undersigned acknowledges that he/she has received, read and understood the Stock Option Agreement and agrees to abide by and be bound by their terms and conditions. The undersigned represents that the Shares are being acquired solely for his/her own account and not as a nominee for any other party, or for investment, and that the undersigned purchaser will not offer, sell or otherwise dispose of any such Shares except under circumstances that will not result in a violation of the Securities Act of 1933, as amended, or any state securities laws.

Dated: _____

(Signature)

(Please Print Name)

Social Security No. _____

(Full Address)

Internal Revenue Service Center

Re: Protective Election Under Section 83(b) of the Internal Revenue Code of 1986

Ladies and Gentlemen:

I hereby make a protective election under section 83(b) of the Internal Revenue Code of 1986 to include in gross income on the date of transfer any excess of fair market value over purchase price with respect to the transfer of the property described below if such property is sold in a disqualifying disposition under section 422 of the Code:

1. Name: _____
2. Address: _____
3. Social Security Number: _____
4. Tax Year of Election: Calendar Year of _____ .
5. Description of Property: _____ shares of Common Stock of MacroPore Biosurgery, Inc., a Delaware corporation (the "Company").
6. Date of Property Transfer: _____ .
7. Nature of Property Restrictions: Property is subject to the Company's right to repurchase the stock at the undersigned's original purchase price if the undersigned ceases to be associated with the Company, which right will generally lapse over a designated four (4) year period.
8. Fair Market Value at the Time of Transfer: \$ _____ per share for an aggregate of \$ _____ . The Fair Market Value at the time of transfer was determined without regard to any lapse restrictions as defined in section 1.83-3(i) of the Income Tax Regulations.
9. Amount Paid for Property: \$ _____ per share for an aggregate of \$ _____ .
10. A copy of this election has been furnished to the Company, the person for whom the services are performed.

Sincerely,

Signature

Date

MacroPore Biosurgery, Inc.

2004 Equity Incentive Plan of MacroPore Biosurgery, Inc.

OPTION EXERCISE
AND
STOCK PURCHASE AGREEMENT

Instructions

1. Read the entire Agreement carefully. This is a legally binding agreement between you and the Company.
2. **Items A – C:** insert your name and identifying information.
3. **Items D-G:** identify the stock option you want to exercise.
4. **Item H:** identify how many shares you want to purchase.
5. **Item I:** Calculate the Option Price by multiplying the share number in Item H by the purchase price per share in Item E.
6. **Item J:** Confirm with the Company whether a tax withholding amount should be entered in this space.
7. **Item K:** Add the Option Price in Item I to the tax withholding amount, if any, in Item J. Insert the resulting Purchase Price in Item K.
8. **Item L:** Identify your approved method of payment for the Shares.
9. **Signatures:** Sign the Agreement in the space provided on page 10. **Important note:** If you are married, your spouse also is required to sign.
10. Submit the fully completed and signed Agreement, together with payment of the Purchase Price, to Sally Davis, Director of Human Resources and Administration.

MacroPore Biosurgery, Inc.

2004 Equity Incentive Plan of MacroPore Biosurgery, Inc.

OPTION EXERCISE AND
STOCK PURCHASE AGREEMENT

Date:

OPTIONHOLDER / PURCHASER

- (A) Name:
- (B) Employee number:
- (C) Residence address:

STOCK OPTION

- (D) Option Shares (total) subject to this Option:
- (E) Purchase Price per Share:
- (F) Grant Date:
- (G) Option Control Number:

OPTION SHARES PURCHASED UNDER THIS AGREEMENT

- (H) Shares purchased:
- (I) Option Price [(E) x (H)]:
- (J) Tax withholding (if applicable):
(to be calculated by Company)
- (K) Purchase Price [(I) + (J)]:

PAYMENT METHOD (select one or more)

(L) Cash or check (enclosed):

Wire transfer:

(Identify sending bank and wire transfer number)

“Cashless exercise”:

(Identify approved NASD broker-dealer and attach agreement)

Other:

(Attach Company approval for other form of payment)

2

1. Exercise of Option.

1.1. I am exercising my right to purchase the number of shares of common stock of MacroPore Biosurgery, Inc. indicated on Line (H) by exercising the option identified on Lines (D) through (G). The per share purchase price of the option is indicated on Line (E) and the aggregate purchase price of the shares I am purchasing is indicated on Line (I). I acknowledge that I may be responsible for tax withholding on the shares, in which case the aggregate purchase price would be as indicated on Line (K) (which the Company will complete). The shares that I am purchasing by exercising my option are referred to in this agreement as the “Shares”. The total purchase price of the shares is referred to in this agreement as the “Purchase Price”. I acknowledge that the option I am exercising was issued under and is subject to the rules of the 2004 Equity Incentive Plan of MacroPore Biosurgery, Inc. (the “Plan”).

1.2. With this signed agreement, I have submitted either (a) cash or a check for the amount of the Purchase Price or (b) irrevocable wire transfer instructions for the Purchase Price, or (c) a certificate or certificates (or designation of such certificates if permitted by the Plan) representing shares of MacroPore Biosurgery, Inc. common stock that I have owned for at least six months if the shares were acquired by me through exercise of an option, and that have a fair market value (as determined in accordance with the Plan) as of this date equal to the Purchase Price. I recognize that other forms of payment may be permitted by the written approval of the Administrator.

2. Representations

2.1. **Taxes.** The Company has made no warranties or representations to me with respect to the income tax consequences of the transactions contemplated by this Agreement and I am not relying on the Company or its representatives for an assessment of such tax consequences. I have had adequate opportunity to consult with my personal tax advisor prior to submitting this Agreement to the Company.

2.2. **Repurchase.** If the Shares are subject to a right of repurchase in favor of the Company at their original purchase price when I cease to provide services for the Company, or if I could be subject to suit under Section 16(b) of the Securities Exchange Act of 1934 with respect to the purchase of the Shares, I will execute and deliver to the Company a copy of the Acknowledgment and Statement of Decision Regarding Election Pursuant to Section 83(b) of the Internal Revenue Code (the “Acknowledgment”) attached as Exhibit A. I acknowledge that I am primarily responsible for filing any Section 83(b) elections although the Company will, as an accommodation to me and without assuming any liability, file a duplicate election if I promptly provide an executed form with the Acknowledgment and Statement of Decision Regarding Section 83(b). I will consult with my own tax advisor to determine if there is a comparable election to file in the state of where I reside and whether filing a federal or state Section 83(b) election is desirable under my circumstances.

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3. Miscellaneous Provisions.

3.1. **Successors and Assigns.** Subject to the limitations set forth in this Agreement, the benefits and obligations of this Agreement will be binding on the executors, administrators, heirs, legal representatives, successors, and assigns of the parties.

3.2. **Costs.** I will repay the Company for all costs and damages, including incidental and consequential damages and attorney’s fees, resulting from any transfer of the Shares which is not in compliance with the provisions of this Agreement.

3.3. **Governing Law.** This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware excluding those laws that direct the application of the laws of another jurisdiction.

3.4. **Notices.** All notices and other communications under this Agreement shall be in writing. Unless and until I am notified in writing to the contrary, all notices, communications, and documents directed to the Company and related to the Agreement, if not delivered by hand, shall be mailed, addressed to:

MacroPore Biosurgery, Inc.
Attention: Sally B. Davis, Director of Human
Resources and Administration

at the Company’s published principal office location.

3.5. **Communications.** Unless and until I notify the Company in writing to the contrary, all notices, communications, and documents intended for me and related to this Agreement, if not delivered by hand, shall be mailed to my last known address as shown on the Company’s books. Notices and communications shall be mailed by first class mail, postage prepaid; documents shall be mailed by registered mail, return receipt requested, postage prepaid.

All mailings and deliveries related to this Agreement shall be deemed received when actually received, if by hand delivery, and three business days after mailing, if by mail.

3.6. **Arbitration.** All disputes arising out of this Agreement will be finally settled by arbitration in accordance with the then existing rules of the American Arbitration Association. The arbitration will be conducted in the county of San Diego. Judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction over it; provided that nothing in this Agreement shall prevent a party from applying to a court of competent jurisdiction to obtain temporary relief pending resolution of the dispute through arbitration. The parties agree that service of any notices in the course of such arbitration at their respective addresses as provided for in this agreement shall be valid and sufficient.

3.7. **This is not an employment contract.** This Agreement is not to be interpreted as a guarantee or contract of continuing employment.

MACROPORE BIOSURGERY, INC.

By: _____

Title: _____

I hereby agree to be bound by all of the terms and conditions of this Agreement and the Plan.

Purchaser's signature

Printed name

The purchaser's spouse indicates by the execution of this Agreement his or her consent to be bound by the terms herein as to his or her interests, whether as community property or otherwise, if any, in the Shares hereby purchased.

Purchaser's Spouse



[Date]
[Name]
[Address]

Re: Grant of Nonstatutory Stock Option

Option Shares:	Grant Date:
Price per share:	Vesting Start Date:
	Fully-Vested Date:
Option control no.:	Expiration Date:

Dear [Name]:

I am pleased to confirm that the Company has granted you an option to purchase shares of our common stock under the 2004 Equity Incentive Plan of MacroPore Biosurgery, Inc (the "**Plan**"). To accept your stock option, please sign the enclosed copy of this letter and return it to the Human Resources Department in the envelope provided.

General terms

Your option is intended to be a nonstatutory option. The basic terms of your option grant are identified in the information block at the top of this offer letter, but other important terms and conditions are described in the Plan. We encourage you to carefully review the Plan, a copy of which is enclosed.

Purchase and payment

Subject to the Plan, your option vests (becomes exercisable) **[insert vesting schedule]**, calculated to the closest whole share, so that all shares will become purchasable on the Fully-Vested Date shown above.

If you decide to purchase shares under this option, you will be required to submit a completed Option Exercise and Stock Purchase Agreement in the form attached, or in another form approved by the Company, together with payment for the shares. You may pay for the shares (plus any associated withholding taxes) using cash, a check, a wire transfer or any other form of payment listed in section 6.4(c) of the Plan and permitted by

the Administrator at the time you wish to exercise. Shares available under this option must be purchased, if at all, no later than the Expiration Date.

We value your efforts and look forward to your continued contribution.

Sincerely,

Christopher J. Calhoun
Chief Executive Officer

I accept this option and agree to the terms of this offer letter and the Plan.

_____, 200
Optionee signature Date

CONFIDENTIAL TREATMENT REQUESTED**EXCLUSIVE DISTRIBUTION AGREEMENT**

between

MACROPORE BIOSURGERY, INC

a Delaware Corporation

("MacroPore")

and

SENKO MEDICAL TRADING CO.

a Japanese Corporation

("Senko")

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

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EXCLUSIVE DISTRIBUTION AGREEMENT

THIS EXCLUSIVE DISTRIBUTION AGREEMENT (this “Agreement”) is made and entered into effective as of the date the last party hereto signs as shown on the signature page (“Effective Date”), and is by and between MacroPore Biosurgery, Inc., a Delaware corporation (“MacroPore”), and Senko Medical Trading Co., a Japanese Corporation (“Senko”).

RECITALS:

WHEREAS, MacroPore desires to have Senko develop demand for and sell Products (as defined herein) within the Territory (as defined herein), and to appoint Senko to act as the exclusive distributor of Products in the Territory; and

WHEREAS, Senko desires to engage in the sale and distribution of Products within the Territory and to be designated as the exclusive distributor of Products in the Territory and has the expertise, staff, experience and has made the necessary investments to carry out the terms of this Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, MacroPore and Senko hereby agree as follows:

1. **Certain Definitions.** As used in this Agreement, the terms set forth below shall have the following meanings:

1.1 “**Affiliate of Senko**” shall mean any (natural or legal) person that directly, or indirectly through one or more intermediaries, controls, or is controlled by Senko, or is under common control with, the person specified. “Control” shall mean ownership of more than 20% of the shares of stock entitled to vote for the election of directors in the case of a corporation, and more than 20% of the voting power in the case of a business entity other than a corporation.

1.2 “**Commercialization**” shall mean the formal listing of registration and reimbursement points for the first Product (defined below) so listed with the Japanese Ministry of Health, Labour and Welfare (“MHLW”) as specially defined in Section 6.1(a) of this Agreement.

1.3 “**Commercialization Date**” shall mean the date upon which Commercialization has occurred as specially defined in Section 6.1(a) of this Agreement.

1.4 “**Field of Use**” shall mean the MacroPore Thin film technology (SurgiWrap/CardioWrap) for use in anti-adhesion, soft tissue support and minimizing the attachment of soft tissues through out the body. Field of Use does not include applications in the Spinal Field.

1.5 “**Gross Sales**” shall mean the total amount of money and/or the value of other consideration received by Senko and/or Senko Medical Instrument Mfg. Co., Ltd. for the sale and/or distribution of Product (excluding the amount and/or value received by Senko from Senko Medical Instrument Mfg. Co., Ltd.); provided, however, that in case the Product is sold by Senko or Senko Medical Instrument Mfg. Co., Ltd. to any Affiliate of Senko (other than these two companies), the Gross Sales shall be calculated on the basis of 70% of the reimbursement points which shall be deemed to be the fair market price rather than the actual transfer price. .

1.6 “**Product(s)**” shall mean the specialized bioresorbable polymeric thin film medical products manufactured or marketed by MacroPore on the date of this Agreement including the “SurgiWrap” and “CardioWrap” products, and such additional items as may be added to the definition of “Products” by mutual agreement in writing between the parties hereto.

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

1.8 “Territory” shall mean the country of Japan.

2. Distributorship.

2.1 Exclusive Appointment. Upon the terms and subject to the conditions contained herein, MacroPore hereby appoints Senko as its exclusive distributor of Products in the Territory for the Field of Use. By said appointment, MacroPore (a) grants Senko the exclusive right to purchase Products from MacroPore for resale and distribution in the Territory within the Field of Use, (b) agrees not to sell, distribute or otherwise make available (for remuneration or gratuitously) Products directly into the Territory other than to Senko, and (c) agrees not to knowingly, directly, or indirectly, sell, distribute or otherwise make available (for remuneration or gratuitously) Products to persons outside the Territory for the purpose of resale into the Territory within the Field of Use.

2.2 Acceptance of Exclusive Appointment. Senko hereby accepts appointment as MacroPore’s exclusive distributor of Products in the Territory, as provided in Section 2.1 above, and agrees fully and faithfully to perform and discharge all of its duties, obligations and responsibilities as set forth in this Agreement. Senko agrees that it shall not purchase Products for resale into or distribution in the Territory from any source beside MacroPore. Senko agrees that it shall not directly or indirectly sell, distribute or otherwise make available (for remuneration or gratuitously) Products outside the Territory or outside the Field of Use, or sell, distribute or otherwise make

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available (for remuneration or gratuitously) Products to persons for the purpose of active resale or distribution (whether for remuneration or gratuitously) outside the Territory or outside the Field of Use. SENKO ACKNOWLEDGES AND AGREES THAT SALES AND DISTRIBUTION OF PRODUCTS OUTSIDE OF THE TERRITORY OR OUTSIDE THE FIELD OF USE MAY RESULT IN THE LOSS OF ALL RIGHTS GRANTED TO IT BY THIS AGREEMENT AS PRESCRIBED IN SECTIONS 19 & 20 BELOW.

2.3 Payment for Distribution Rights. In consideration of Senko’s rights hereunder, Senko shall, within ten Japanese business days after the date hereof, pay MacroPore the sum of One Million Five Hundred Thousand Dollars (\$1,500,000). This distribution rights fee is fully earned after the initial three (3) years after the Commercialization Date. In addition:

(a) If it is determined in good faith by the parties that Commercialization of the Products is unobtainable, then 50% of the distribution rights fee will be returned to Senko.

(b) If MacroPore terminates the Agreement at any time within the initial three (3) years post Commercialization, for any reason except for a material breach by Senko, a pro-rata share of the distribution rights fee will be returned.

2.4 Competing Products. During the term of this Agreement, Senko shall not, and shall cause its officers, directors, employees, agents or representatives including Senko Medical Instrument Mfg. Co., Ltd (collectively, “Agents”), and any entity in which Senko has a controlling ownership interest, directly or indirectly, not to, directly or indirectly, promote, sell or distribute products within the Territory which are competitive with the Products so long as the Products are competitive in the Field of Use in the Territory.

2.5 Independent Contractor. The relationship of MacroPore and Senko established by this Agreement is that of independent contractors, and nothing contained in this Agreement shall be construed to (a) give either party hereto the power to direct and control the day-to-day activities of the other, or (b) constitute the parties as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking. Neither party hereto nor any of its Agents is the representative of the other party for any purpose except as expressly set forth in this Agreement, and has no power or authority as agent, employee or in any other capacity to represent, act for, bind or otherwise create or assume an obligation on behalf of the other for any purpose whatsoever. All financial obligations associated with Senko’s business are the sole responsibility of Senko. All sale and other agreements between Senko and its customers are Senko’s exclusive responsibility and shall have no effect on Senko’s obligations under this Agreement.

2.6 Promotional Duties.

(a) Senko shall (i) exert its best efforts to introduce and diligently promote, sell and service the Products within the Territory, including, without

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limitation, the full and complete attainment of the Minimum Purchase Guarantee as set forth below in Section 3.1, (ii) make use of, and disseminate to its customers, all promotional materials supplied by MacroPore, and (iii) cooperate with MacroPore in activities directed toward the promotion, sales and servicing of the Products, including but not limited to Senko’s translation of product literature for the Products in the Japanese language and attaching Product updates, literature, etc. with Products sold in the Territory as reasonably requested by MacroPore or required by the responsible governmental authorities, provided that MacroPore shall be allowed final review of all product translations and modified marketing literature prior to distribution of such materials, and (iv) support interest in the Products by representing the Products at major trade shows in the Territory selected by Senko where similarly applicable products are promoted.

(b) Senko and its staff shall be conversant with the technology and language relating to the Products, and shall develop sufficient knowledge of the industry of MacroPore, the Products (including their specifications, features and benefits) and products competitive with the Products, so as to be able to explain in detail to potential customers the differences between the Products and such competitive products. Senko shall conduct such sales training of its personnel as may be necessary to impart such knowledge, and shall extend commercially reasonable cooperation to MacroPore in any product education programs which it may establish.

(c) Senko shall be obligated to attend training sessions held by MacroPore at mutually agreed locations not more than once annually. Travel, lodging and related expenses shall be borne by Senko. Senko shall train and maintain a sufficient number of capable personnel (i) to service

the demands and needs for marketing and supporting the Products within the Territory, and (ii) to otherwise carry out the obligations and responsibilities of Senko under this Agreement.

(d) Senko shall at all times display, demonstrate and otherwise represent the Products fairly in comparison with competitive products from other manufacturers, shall make no false or misleading representations to customers or other persons with regard to the Products or MacroPore, and shall not make any representations with respect to the specifications, features or capabilities of the Products which are not consistent with those described in literature distributed by MacroPore.

3. Minimum Purchases and Sales of Products.

3.1 Minimum Purchase Requirements.

(a) During the first three years after the Commercialization Date, Senko shall purchase a minimum of ***** units of Product from MacroPore (the "Minimum Purchase Guarantee").

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

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(b) Within the first year after Commercialization, both parties agree to have an opportunity to assess the Minimum Purchase Guarantee in relation to the second and third year, and in good faith, mutually agree to at the time of such assessment make any indicated upward or downward correction in the Minimum Purchase Guarantee for observed market response to the Products, changes of reimbursement points, changes in the \$/Yen exchange rate.

(c) For each year following the third year after Commercialization the parties shall reach a mutually agreed minimum purchase guarantee prior to the commencement of that year.

3.2 Minimum Product Sales. Notwithstanding Section 3.1 (a) and (b), if Senko fails to sell ***** units of Product in the Territory in the first three (3) years after Commercialization (the "Minimum Sales Guarantee"), Senko agrees that MacroPore may, in its sole discretion, elect to reduce the distribution rights of Senko to non-exclusive in the Territory for the remainder of the Term of Senko's distribution rights under this Agreement. In the event that such rights reduction occurs, MacroPore may then sell Products in the Territory through other distribution channels in parallel to Senko.

3.3 Reductions in Quota. Notwithstanding the provisions of Sections 3.1 and 3.2, the Minimum Purchase Guarantee and the Minimum Sales Guarantee for any period shall be reduced (a) in the case of subpart (i) below, by an amount equal to 1.5 times the aggregate number of units of Product not supplied by MacroPore against purchase orders issued by Senko in accordance with Section 4.3, and (b) in the case of subpart (ii) below, by an amount equal to 1.5 times the aggregate number of units of Product affected by such recall or withdrawal:

(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 Senko in accordance with Section 4.3, 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; or

(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.

3.4 Samples. MacroPore will provide Senko with an appropriate number of samples at mutually agreed upon sample prices, for assisting Senko in mutually agreed upon sales activities. A formula of supply will be determined in good faith discussions between the parties.

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

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4. Payment for Products, Terms & Restrictions.

4.1 Product Prices. Product will be transferred at a transfer price of FOB (San Diego) \$***** (USD) per sheet for 130mm x 200mm and FOB (San Diego) \$***** (USD) for 100mm x 130mm. In the event of reasonably unforeseen substantial changes in terms of the USD/Yen exchange rate, reimbursement rates, or manufacturing costs which substantially influence the business of either party, both parties agree to discuss in good faith and mutually determine an equitable price adjustment formula to moderate the negative effects to the party so impacted by such changes. The application of such formula may result in a higher or lower transfer price. In addition to such transfer price, Senko must also make the payments in the form of a Royalty as described in Section 5.

4.2 Payment Terms. All payments by Senko under this Agreement shall be made in United States Dollars, free of all withholdings, and shall not be reduced by any exchange or collection charges or by any taxes imposed under the laws of any country other than the United States of America, and shall be due and payable within forty-five (45) days of invoice.

4.3 Purchase Orders. Senko shall submit purchase orders for Products to MacroPore in writing, whether by mail, telecopier, telegram or otherwise. Each purchase order shall, at a minimum, set forth the product numbers, quantities, delivery dates, 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 Senko and MacroPore to the extent that they comply with all of the terms of the Agreement. The terms and conditions of this Agreement shall so govern and supersede any additional or contrary terms set forth in Senko's purchase order or any MacroPore or Senko acceptance, confirmation, invoice or other

document unless duly signed by an officer of Senko 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. Senko will place orders at least sixty (60) days in advance of the earliest scheduled delivery date. Senko 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 Senko as to any Products that are not delivered within 60 days after the delivery date requested by Senko pursuant to a purchase order, and any such cancellation shall not limit or affect any contract remedies available to Senko with respect thereto. Any such cancellation by Senko must be by written notice to MacroPore given within 10 business days after such 60th day.

4.4 Senko's Forecasts. Senko shall provide MacroPore with a six-month sales plan to be mutually agreed upon indicating by month the number of Products

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anticipated to be sold by Senko or purchased by Senko for use as samples in the Territory. The Plan shall be updated by Senko twice per year, for a rolling successive six-month period. Each Plan shall be used for purposes of facilitating Senko'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 Senko or MacroPore in any manner.

4.5 Invoices. MacroPore shall invoice Senko for the purchase price of the Products upon MacroPore's delivery FOB (San Diego) of such Products to Senko's carrier.

4.6 Late Payment. If Senko fails to pay to MacroPore any amount when due, in addition to any other remedies of MacroPore, Senko agrees to pay interest on the overdue balance at the rate of eight and one-half (8.5%) per annum or, if such rate exceeds the maximum rate permitted by law, Senko shall pay interest on such overdue balance at the maximum rate permitted by law. Payments received from Senko when any overdue balance exists shall be applied first against accrued interest.

4.7 Exchange Control Restrictions. If, because of exchange control restrictions in the Territory, Senko is unable to make any payment when due in United States Dollars and free of any exchange or collection charges and of any taxes imposed under the laws of any country other than the United States of America, Senko shall, upon written instructions from MacroPore, deposit such payment in the name of MacroPore or its nominee in such bank or other institution in the Territory and in such type of account as shall be specified by MacroPore. MacroPore shall be entitled to all interest earned on such deposited amounts.

4.8 Production and Supply of Products. During the term of this Agreement or thereafter, MacroPore reserves the right, without obligation or liability to Senko, to manufacture, produce, assemble, warehouse or source the Products at any worldwide location, including locations outside of the United States of America and locations within or outside the Territory unless it may adversely affect the regulatory status of Products under the Shonin (as defined in Section 6.1(a)) and/or the incessant supply of the Products to Senko.

4.9 Product Packaging. MacroPore agrees to cause the Products to be packed pursuant to its standard export procedure and to deliver the Products to Senko in accordance with the terms of each purchase order in so far as such purchase order complies with the terms of this Agreement. The above notwithstanding, it is the obligation of the Senko to inform and assist MacroPore in complying with regulations on this and other requirements relating to the importation of Products into the Territory.

4.10 Title and Risk of Loss. Title to Products and all risk of loss shall pass from MacroPore to Senko at the time and place of MacroPore's delivery of Products to Senko, FOB Shipping Point with a carrier specified by or reasonably acceptable to

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Senko. Senko shall be solely responsible for insuring Products after shipment to Senko, FOB Shipping Point.

4.11 United States Export Controls. MacroPore's obligation to sell and deliver Products to Senko shall be subject in all respects to such laws and regulations of the United States of America as shall from time to time govern the sale and delivery of goods abroad by persons subject to the jurisdiction of the United States of America. Senko shall not directly or indirectly export, re-export or transship any of the Products, even though otherwise permitted by this Agreement or by subsequent authorization from MacroPore, except as shall be permitted by the laws and regulations of the United States of America in effect from time to time. (MacroPore shall endeavor to keep Senko informed of changes in such laws and regulations, but assumes no obligation to do so.) Upon the reasonable request by MacroPore, Senko shall give written assurances against such export, re-export or transshipment.

4.12 Product Changes. MacroPore shall not, without Senko'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 Senko's costs or expenses.

5. Payments in the Form of a Royalty.

5.1 Payments in the Form of a Royalty. In consideration for MacroPore's sale of products and grant of exclusivity and other rights to Senko hereunder, Senko agrees to pay to MacroPore, in addition to the transfer price in Section 4, payments in the form of a royalty (hereafter "royalty" or "royalties") in the amount of 5% of Senko's Gross Sales for a period of three (3) years from the Commercialization Date.

5.2 Quarterly Royalty Reports. Beginning on Commercialization, and covering the period of the royalty obligation provided in Section 5.1, Senko will make quarterly fee reports to MacroPore on or before each January 21 (for the quarter ending December 31), April 21 (for the quarter ending March 31), July 21 (for the quarter ending June 30) and October 21 (for the quarter ending September 30) of each year. Each fee report will cover Senko's most recently completed calendar quarter and will, at a minimum, show:

(a) The gross invoice prices for all Products sold in the Territory and any payments thereon and other income (received by Senko and/or Senko Medical Instrument Mfg. Co., Ltd.) for those Products sold during the reporting period;

(b) The total royalty fees due, in Japanese Yen, payable to MacroPore for the quarter being reported;

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(c) The amount of the cash and the amount of the cash equivalent of the non-cash consideration including the method used to calculate the non-cash consideration; and

(d) Any other information reasonably necessary to confirm Senko's calculation of its royalty obligations hereunder.

5.3 Quarterly Royalty Fee Payments. All fees payable to MacroPore pursuant to this Section 5 shall be paid simultaneously with the delivery of the quarterly report with which they correspond in Japanese YEN unless otherwise specified in writing.

5.4 Document Retention. Senko will keep accurate books and records showing all Products sold in or for the Territory sufficient to verify the quarterly reports required in Section 5.2. Such books and records will be preserved for at least three (3) years after the date of the payment to which they pertain.

5.5 Document Inspection. The books and records required to be maintained pursuant to Section 5.4 will be open to inspection by experts appointed by MacroPore and bound by their obligation to professional secrecy not more than once per calendar year, upon reasonable notice, at reasonable times and in a manner that is not disruptive to the conduct of operations of Senko, to determine their accuracy and assess Senko's compliance with the terms of this Agreement. MacroPore shall bear the fees and expenses of such examination. If, however, an error in fees is discovered in any examination, and the correction of such error would result in an additional payment to MacroPore of more than five percent (5%) of the total fees due for any year, then Senko shall bear the fees and expenses related to such examination.

6. Regulatory Matters.

6.1 MacroPore Responsibilities.

(a) MacroPore will be responsible to obtain regulatory approval ("Shonin") under Manufacturing Approval of Foreign Manufactured Medical Devices and retain In-Country Caretaker (ICC). MacroPore shall be responsible for all preparation and translation of the regulatory application materials as well as any necessary product testing, pre-clinical and/or clinical trials. MacroPore will apply for the Shonin and reimbursement points as a bioresorbable barrier for adhesion prevention, adhesion control and adhesion reduction. The application will cover general, OB/GYN and cardiac surgeries. Nevertheless, the product registration/reimbursement will be considered complete (or "formally listed") if one or more of the above specified surgical areas (general, OB/GYN and cardiac) are approved with a regulatory clearance for adhesion prevention, or, adhesion control and adhesion reduction, or, with a clearance equal to or greater than the 510 K clearance received by MacroPore on September 22, 2003 for the minimization of attachment of soft tissue ("MAST") in the U.S. and reimbursement points are established based upon the clearance achieved; provided,

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however, that MacroPore agrees that the Minimum Purchase Guarantee and the Minimum Sales Guarantee shall be reduced appropriately by consultation with Senko, in good faith, taking into account the market size for each area in the Territory if any one of the three surgical areas fails to be approved or reimbursement points are not established for any one of said surgical areas as of the Commercialization Date.

(b) MacroPore shall be responsible for obtaining all necessary export licenses and permits as may be required to export the Products from the country of manufacture into the Territory. Senko shall cooperate fully with MacroPore in its efforts to obtain any such approvals.

(c) 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 Senko that all Products sold and delivered to Senko under this Agreement will have been designed, manufactured and labeled in accordance with all applicable requirements. MacroPore shall inform Senko of all serious and relevant adverse experience outside the Territory as soon as possible whenever MacroPore becomes aware of such experiences. MacroPore also shall inform Senko of any matters required so that Senko will be able to observe the Good Manufacturing Practice for Import (GMPI) imposed in the Territory. The GMPI agreement shall be otherwise discussed and signed by both parties, but it is expressly agreed and understood that the terms of this Agreement shall supercede and be controlling over any conflicting or contrary terms found in the GMPI Agreement.

(d) MacroPore at its expense will provide Senko with any applicable surgical procedure manuals and a reasonable and agreed level of sales and technical training for Senko's dedicated sales personnel for Products and other appropriate Senko personnel. MacroPore and Senko will work together to provide training to Physicians in the Territory at least once annually at a location reasonably satisfactory to the parties. Each party shall bear their own expenses for the provision of such training, and the training sessions shall accommodate up to (50) Physicians. MacroPore shall not be required to pay any attending Physicians expenses (e.g. travel, accommodations, compensation etc...) related to attending such training.

(e) MacroPore will work jointly with Senko in the preparation of mutually acceptable Product packaging and labeling. MacroPore will provide its standard operations and technical manuals to be modified by Senko for use with the Products. MacroPore at its expense shall provide Senko from time to time as requested by Senko with samples of Product sales and marketing materials. Senko shall be responsible for reproduction and distribution of such materials. Senko shall be responsible for the translation, adaptation and/or modification of MacroPore's sales and marketing materials as deemed appropriate by Senko, and MacroPore shall supply any available artwork or other materials reasonably requested by Senko for use solely in connection therewith. Notwithstanding the foregoing, MacroPore shall have final review of all product

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translations, modified marketing materials and literature prior to distribution in the Territory.

6.2 Senko Responsibilities. Senko agrees to be designated and act as MacroPore's importer and distributor for the Products in the Territory (and to obtain any necessary licenses and permits for such importation and distribution). Senko agrees to act as the Appointed Marketing Approval Holder for the Products in the Territory and shall be responsible for compliance with any and all applicable Pharmaceutical Affairs Laws (PAL) and with any such other laws which an importer or distributor of medical implants in the Territory must comply. In addition, Senko shall obtain all (other than MacroPore responsibilities in Section 6.1 above) necessary government approvals, consents, licenses and permits in the Territory or any governmental or political subdivisions thereof (collectively, "Approvals"), and for complying, and/or assisting MacroPore with complying with any and all applicable statutory, administrative or regulatory requirements of the Territory or any governmental or political subdivisions thereof (collectively, "Laws"), that are necessary for the importation, sale and storage of the Products within the Territory. These responsibilities include, or may include, without limitation, testing, warehousing, and tracking, product labeling and packaging, periodic evaluations of products, adverse event reporting, product documentation such as traceability, samples, sales literature and records, and documentation and reporting of recalls, which documentation shall be maintained by the Senko for 15 years after termination or expiration of this Agreement, any product registrations with any government agency or health authority, or any registration, approvals, or filing of this Agreement. Without limiting the generality of the foregoing:

(a) Senko shall bear all costs, fees and expenses associated with obtaining Approvals, as well as any other fees related to complying with laws of the Territory (other than MacroPore responsibilities in Section 6.1 above, all costs, fees and expenses associated with which shall be borne by MacroPore). MacroPore shall bear all costs, fees and expenses associated with obtaining any approvals or complying with the laws of the United States and all other countries, if any, of manufacture of the Products.

(b) The Shonin (and/or any other Product registration and approval necessary for the importation and sale of Products in the Territory) issued by any governmental agency or health authority which are necessary to import and sell the Products within the Territory shall be the sole property of MacroPore and shall be issued to, and in the name of, MacroPore. In the event that any right, title, or interest in and to any such Shonin should be obtained by Senko in contravention hereof, Senko shall hold the same on behalf of MacroPore and shall transfer the same to MacroPore or its designee upon request and without expense to MacroPore.

(c) Senko shall maintain complete and accurate records of all Products sold by Senko, any Affiliate of Senko and any 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. In the event of a recall of any of the Products initiated by MacroPore, or by Senko if directed by MHLW,

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Senko and/or MacroPore will cooperate with and assist the other party in effecting a recall, including promptly contacting any purchasers that either party reasonably desires to be contacted, and Senko shall promptly communicate to such purchasers the information or instructions reasonably necessary to be transmitted relating to a recall, all of which customer contact and communication shall be conducted by Senko. Notwithstanding the foregoing, MacroPore shall pay, or reimburse Senko, for all other costs of effecting a recall, including any shipping costs related to returning recalled Products to MacroPore and replacing such recalled Products with new Products at MacroPore's expense, unless such recall is caused by Senko's (including any of its Affiliates and subdistributors) translations or modification of product labeling or marketing materials and MacroPore has not approved such translation or modification.

6.3 Regulatory Filing Milestone. Senko shall pay MacroPore the nonrefundable amount of \$1,250,000 (One Million Two Hundred and Fifty Thousand US Dollars) within two (2) weeks of MacroPore notifying Senko of completion of filing of the initial regulatory application to MHLW for the Products as a bioresorbable barrier for adhesion prevention, adhesion control and adhesion reduction for applications in general, OB/GYN and cardiac surgeries. Photocopies of the application documents submitted to MHLW are to be provided to Senko.

6.4 Regulatory Clearance Milestone. Senko shall pay MacroPore the nonrefundable amount of \$250,000 (Two Hundred and Fifty Thousand US Dollars) within two (2) weeks of MacroPore's notice to Senko of the achievement of Commercialization.

7. Examination and Audit of Senko Information. Senko (a) shall maintain for at least three (3) years its books, records, contracts and accounts relating to the marketing and sale of the Products, including, without limitation, information concerning customer accounts, inventory levels, unit sales, Product prices, Product margins, competitor information, market trends and strategies, and promotional activities (collectively, "Senko Information"), and (b) shall permit examination thereof at all reasonable times and upon reasonable notice (in no event shall such notice be less than ten (10) Japanese business days) by MacroPore. Senko shall allow representatives of MacroPore at any reasonable time to audit all relevant Product Information owned or controlled by Senko. Senko shall provide MacroPore with copies of any documents reasonably requested by MacroPore as a result of such examination or audit.

7.1 Accounting Cooperation. From time to time MacroPore may need assistance from Senko in complying with various accounting rules and regulations in keeping with its status as a publicly traded entity in the U.S. Occasionally MacroPore requires information that cannot always be gleaned from publicly available records. Accordingly, Senko agrees to make commercially reasonable efforts to provide requested information about its operations at MacroPore's expense, provided that Senko shall be entitled to withhold any information it deems, in its sole discretion, to be compromising to its interests.

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8. Representations and Warranties of Senko. Senko represents and warrants to MacroPore that it:

(a) Has full and unrestricted authority to enter into this Agreement and, by entering into or performing under this Agreement, it will not breach any agreement to which it is currently a party;

(b) Has the legal right, free of any right or interest of any third party, to disclose all information disclosed to the other party hereunder; and

(c) Currently is in compliance with all Laws.

9. Representations and Warranties of MacroPore. MacroPore represents and warrants to Senko that it:

- (a) Has full and unrestricted authority to enter into this Agreement and by entering into or performing under this Agreement, it will not breach any agreement to which it is currently a party, and
- (b) Has the legal right, free of any right or interest of any third party, to disclose all information disclosed to the other party hereunder; and
- (c) Currently is in compliance with all Laws.

10. Confidential Information.

10.1 Definition. Each of the parties hereto recognizes that the relationship created by this Agreement may involve access by Senko and MacroPore to information of substantial value to the other party, including, but not limited to, designs, drawings, plans, software, programs, material and manufacturing specifications, devices, trade secrets, applications, formulae, know-how, methods, techniques, and processes (whether related to MacroPore's Patents, as defined herein, or otherwise), as well as financial, business, marketing and product development information, and customer lists relating to the Products (collectively, "Confidential Information"), provided that Confidential Information shall not include information (a) in the public domain or which subsequently falls into the public domain, (b) specifically intended by MacroPore for disclosure to customers of Senko, (c) which the non-disclosing party can prove was already known to it prior to the date of this Agreement, or (d) disclosed to the non-disclosing party in good faith by a third party having a legal right to do so.

10.2 Non-Disclosure. Each of the parties hereto acknowledges and agrees that the other party owns all right, title and interest in and to such party's Confidential Information. Each of the parties hereto further agrees that it shall (a) maintain the secrecy and confidentiality of all Confidential Information which comes to its attention, (b) take all necessary precautions to prevent any disclosure of Confidential Information by any person within its control having access to said Confidential

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Information, and (c) during the term of this Agreement and for so long as Confidential Information does not enter into the public domain through an act or omission of the disclosing party, neither publish, disclose nor disseminate any part of such Confidential Information in any manner (except as required by law), or use the same, without the prior written consent of the disclosing party.

10.3 Injunctive Relief. Each of the parties hereto understands and agrees that the Confidential Information has special value, the loss of which cannot be reasonably or adequately compensated in damages or in an action at law, and therefore, in the event of any breach or violation of the provisions of this Section 10 by MacroPore or Senko, the non-breaching party shall be entitled to equitable relief by way of injunction without the necessity of proving actual damages, which relief shall be in addition to, and not in limitation of, any other relief or rights to which such party may be entitled. The terms and provisions of this Section 10 shall survive any termination or expiration of this Agreement.

11. Warranty.

(a) MacroPore represents and warrants to Senko that all Products sold under this Agreement will have been designed, manufactured, labeled, packaged and sold to Senko in accordance with all applicable laws and regulations, including (as applicable) FDA GMP requirements, ISO 13485 certification or successor requirements. Upon prior written notice, MacroPore shall cause Senko'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 Senko and to Senko's customers that Products shall, when delivered to Senko, meet the specifications and, for a period of two (2) years after delivery of the Product to Senko, 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. Senko shall invoice MacroPore for, and MacroPore shall promptly pay, all shipping, transportation, insurance and other expenses actually incurred in replacing Products that were under warranty. MacroPore will repair, replace or credit Senko's account for any Product that MacroPore reasonably determines does not comply with this warranty at the time of shipment to Senko or that otherwise 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 Senko or (except for any strict liability of MacroPore) the customer or user. Prior to returning any Product alleged to be defective, Senko 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

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returned goods authorization from MacroPore, which authorization shall not be unreasonably withheld. 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.

12. Trademarks.

12.1 MacroPore's Marks. MacroPore owns or has the right to use the trademarks, service marks and/or trade names listed on Schedule 12 in connection with the sale of the Products in the Territory ("MacroPore's Marks"), Certain of MacroPore's Marks may be registered in the

jurisdiction(s) which comprise the Territory.

12.2 Use of MacroPore's Marks by Senko. MacroPore hereby grants to Senko an exclusive right and license to use MacroPore's Marks solely in connection with the promotion, sale and distribution of the Products within the Territory. This right and license shall not be assignable or transferable by, or subject to any encumbrance of, Senko in any manner whatsoever. Senko shall have the right to grant any sublicenses in the Territory solely for use in connection to the Products for sale within the Field of Use without MacroPore's prior written consent. All rights with respect to MacroPore's Marks and all other trademarks, service marks and trade names used by MacroPore not specifically granted to Senko in this Agreement shall be and hereby are reserved to MacroPore. Nothing in this Agreement shall be deemed to constitute or result in an assignment of any of MacroPore's Marks to Senko or the creation of any equitable or other interests therein. Neither Senko nor any of its Affiliates or sublicensees shall use any of MacroPore's Marks in any manner as a part of its business, corporate or trade name or otherwise.

12.3 Acknowledgment of Ownership. Senko acknowledges that (a) MacroPore owns MacroPore's Marks and all goodwill associated with or symbolized by MacroPore's Marks, (b) Senko has no ownership right in or to any of MacroPore's Marks, and (c) Senko shall acquire no ownership interest in or to any of MacroPore's Marks by virtue of this Agreement. Senko shall do nothing inconsistent with MacroPore's ownership of MacroPore's Marks and related goodwill (such as using or registering any similar name or mark) and agrees that all use of MacroPore's Marks by Senko shall inure to the benefit of MacroPore.

12.4 Form of Use. Senko shall use MacroPore's Marks only in the form and manner prescribed from time to time by MacroPore. Senko shall mark each Product and all advertising, promotional or other materials bearing any of MacroPore's Marks with such notices as MacroPore may require, including, but not limited to, notices that MacroPore's Marks are trademarks of MacroPore and are being used with the permission of MacroPore.

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12.5 Submissions. Senko shall submit to MacroPore for its written approval before any use is made thereof, representative samples of all Products, stationery, invoices, catalogs, brochures, packages, containers, and advertising or promotional materials bearing any of MacroPore's Marks which Senko or its Agents prepare. Senko shall not make any use of MacroPore's Marks unless and until it receives MacroPore's prior written approval. MacroPore shall have the absolute right to approve or reject any proposed use of any of MacroPore's Marks, in its sole discretion.

12.6 Registration. MacroPore shall have the sole right to take such action as it deems appropriate to obtain trademark registration in the Territory for any of MacroPore's Marks. If it shall be necessary for Senko to be the applicant to effect any such registrations, Senko shall cooperate with MacroPore to effect any such registrations, and hereby does assign all of its right, title and interest in and to each such application, and any resulting registration, to MacroPore, and shall execute all papers and documents necessary to effectuate or confirm any such assignment. Senko shall perform all reasonable and necessary acts and execute all necessary documents to effect the registration of MacroPore's Marks as MacroPore may request, all at MacroPore's sole expense. Senko shall not obtain or attempt to obtain in the Territory, or elsewhere, any right, title or interest, registration, or otherwise, in or to MacroPore's Marks, or any of them. In the event that any such right, title or interest should be obtained by Senko in contravention hereof, Senko shall hold the same on behalf of MacroPore and shall transfer the same to MacroPore upon request and without expense to MacroPore.

12.7 Infringement Information. Senko shall notify MacroPore promptly of any unauthorized use of MacroPore's Marks or of any mark confusingly similar thereto which comes to its attention. MacroPore shall have the sole right to determine whether or not any action shall be taken against any such infringement, and Senko shall not institute any suit or take any action on account of any such infringement or imitation without first obtaining the written consent of MacroPore to do so. Senko shall provide MacroPore with all reasonable assistance, at MacroPore's expense, in any prosecution of any such action, including suits in which Senko is joined as plaintiff, MacroPore shall have the sole right to employ counsel and to direct the handling of the action and litigation and any settlement thereof, and Senko shall not share in any of the proceeds of judgment or settlement resulting from any such action.

12.8 Termination of Use. Upon expiration or earlier termination of this Agreement, Senko shall cease using MacroPore's Marks in any manner, either similar or dissimilar to the use enumerated above.

13. Patent Ownership and Rights to Inventions.

13.1 No Ownership By Senko. Subject to Section 13.2 below, Senko shall not be deemed by anything contained in this Agreement or done pursuant to it to acquire any right, title or interest in or to MacroPore's Patents (as defined in Section 15) or any patent now or hereafter covering or applicable to any Product, nor in or to any

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invention or improvement now or hereafter embodied in any Product, whether or not such invention or improvement is patentable under the laws of any country.

13.2 New Inventions/Improvements. If during the term of this Agreement or within one (1) year after the date of its termination, Senko, any of its Agents, or any person acting under contract with Senko, invents or designs any improved Product, whether or not patented or patentable in any jurisdiction, Senko shall make or cause a prompt and full disclosure to MacroPore of such invention, design, or improvement and shall grant, or cause the grant of a perpetual, irrevocable, non-exclusive, royalty-free worldwide license to MacroPore to use such invention, design or improvement, with an unlimited right in MacroPore to sublicense under such license. At MacroPore's request, Senko promptly shall supply or cause to be supplied to MacroPore such drawings, specifications, engineering data and shop practice information as may be reasonably necessary to enable MacroPore to use the invention, design or improvement. Senko's obligations under this Section 13.2 shall continue for so long after any termination of the Agreement as may be necessary for MacroPore to obtain effective use of the rights granted herein.

13.3 Obligations of Employees. Senko shall enter into appropriate contracts with its present and future Agents and with any persons acting under contract with Senko, obligating such Agents and other persons to grant the licenses and perform the other acts required under Section 13.2 above. All such information and rights of inventions shall be deemed Confidential Information of MacroPore.

14. Infringement of Third Party Rights.

14.1 Patent Rights.

(a) Defense of Claims. MacroPore shall defend (without substantial delay), or at its option settle, any suit instituted against Senko that is based on an allegation that any Product (as sold by Senko in and for the Territory within the Field of Use) 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 Senko without Senko's consent, which consent shall not be unreasonably withheld. MacroPore shall indemnify, subject to the limitations set forth herein, Senko against any final award of damages and costs made against Senko and any settlement amounts as a result of any such action. In order to qualify for such indemnification, Senko 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.

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(b) Limitation of Liability. MacroPore shall have no liability of any kind to Senko under Section 14.1(a) or based upon any other claim Senko 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 Senko 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 Senko 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 Senko's inventory and refund the aggregate payments made therefor by Senko; or (iv) if the use of the Products is prevented by injunction, discontinue Product sales under the Agreement and remove any Products in Senko's inventory and refund the aggregate payments paid therefor by Senko, in which event MacroPore shall promptly refund to Senko a pro rata portion (based on the portion of the original Term remaining) of the distribution rights fee paid by Senko pursuant to Section 2.3.

14.2 Ownership. MacroPore represents and warrants to Senko the following: MacroPore owns or possesses licenses or other rights to use all Intellectual Property (as defined below) used in the research, design, development, manufacture or sale of the Products in the Territory (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 Senko 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 extent that is necessary for Senko to exercise its rights under this Agreement. To the knowledge of MacroPore, no person or entity nor such person's or entity's business or products has infringed, misused, misappropriated or materially conflicted with the MacroPore Intellectual Property for use within the Territory, or currently is infringing, misusing, misappropriating or materially conflicting with the MacroPore Intellectual Property for use within the Territory. To the knowledge of MacroPore, all proprietary technical information developed by and belonging to MacroPore that has not been patented has been kept confidential (subject to the rights of MAST under the APA, each as defined in Section 22.1(b) below). "Intellectual Property" means letters patent and patent applications; trademarks, service marks and registrations thereof and applications thereof; copyrights and copyright registrations and applications; mask works and registrations thereof; all inventions, discoveries, ideas, technology, know-how, trade secrets, data, information, processes,

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formulas, drawings and designs, licenses, computer programs and software; and all amendments, modifications, and improvements to any of the foregoing.

14.3 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.

15. Third Party Infringers. If Senko becomes aware that a third party is or may be making unauthorized use of (a) any patent owned by MacroPore, or for which MacroPore has the exclusive right of use, which relates to the Products ("MacroPore's Patents"), or (b) any other intellectual property rights relating to the Products owned or controlled by MacroPore, Senko shall promptly give MacroPore written notice thereof. Senko shall not take any other action regarding such infringement without the prior written approval of MacroPore, which shall not be unreasonably delayed or withheld. Senko shall cooperate with MacroPore, at no out-of-pocket expense to Senko, in connection with any action taken by MacroPore to terminate the infringements. With respect to all claims and suits, including suits in which Senko is joined as plaintiff, MacroPore shall have the sole right to employ counsel and to direct the handling of the claim and litigation and any settlement thereof.

16. Claims.

16.1 Product Liability Claims. Senko shall immediately notify MacroPore in writing of any products liability claim or action brought with respect to the Products based on alleged defects in the design or manufacture of the Products or other adverse claim regarding the Products. Upon receiving such written notice, MacroPore shall assume and have sole control of the defense of any such claim or action, including the power to conduct and conclude any and all negotiations, compromises or settlements. Senko shall comply with all reasonable requests from MacroPore for information, materials or assistance, with respect to the conduct of such defense at MacroPore's expense. MacroPore shall be responsible for payment of all claims based on MacroPore's design or manufacture of the Products, and all legal expenses and costs incurred in that regard; provided, however, that MacroPore shall have no liability for any judgment, settlement, compromise, expenses or costs made or incurred by Senko without MacroPore's consent, which shall not be unreasonably delayed or withheld. Nothing in this section shall be construed as requiring MacroPore to conduct and/or assume Senko's independent defense against any claim or action, if such claim or action involves the independent conduct, acts or omissions of Senko.

16.2 Notice from Senko. Senko shall promptly notify MacroPore of any potential or actual litigation or governmental activity in the Territory relating to the Products or the business operations of Senko or MacroPore. Senko shall provide such notice with ten (10) Japanese business days from the time that Senko learns of such litigation or activity.

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16.3 Indemnification by Senko. Senko assumes sole responsibility for all acts performed by it pursuant to this Agreement and shall be solely responsible for all Claims (as defined herein) in connection therewith. Senko shall indemnify, defend and hold MacroPore harmless from any and all claims, actions, lawsuits, demands, costs, liabilities, losses, damages and/or expenses (including reasonable attorneys' fees and costs of litigation) by any other party resulting from or relating to any acts, omissions or misrepresentations of Senko, its Agents or any of them (collectively, "Claims").

16.4 Indemnification by MacroPore. MacroPore assumes sole responsibility for all acts performed by it pursuant to this Agreement and shall be solely responsible for all Claims (as defined herein) in connection therewith. MacroPore shall indemnify, defend and hold Senko harmless from any and all claims, actions, lawsuits, demands, costs, liabilities, losses, damages and/or expenses (including reasonable attorneys' fees and costs of litigation) by any other party resulting from or relating to any acts, omissions or misrepresentations of MacroPore, its Agents or any of them (collectively, "Claims").

17. Insurance. To the extent commercially available, each party shall maintain in full force and effect product liability insurance and property damage insurance on its operations, with reasonable coverage limitations and terms. Each party shall provide the other party with written notice of any cancellation of any insurance hereunder at least thirty (30) days prior to such cancellation.

18. Term. The term of this Agreement shall be for a period of five (5) years following Commercialization of the Product in Japan, and is renewable for an additional

five (5) year term conditioned upon reaching mutually agreed Minimum Purchase Guarantees following the initial term.

19. Termination. This Agreement shall remain in full force and effect as specifically set forth in Section 18 hereof, unless earlier terminated as follows:

- (a) By mutual consent of the parties in writing at any time;
- (b) By either party upon giving written notice to the other party if such other party is in default of any material term or provision hereunder (including, without limitation, Senko's failure to meet the Minimum Purchase Guarantee pursuant to Section 3.1 hereof), and such default is not cured within ninety (90) days of written notice of such default;
- (c) By either party upon giving written notice to the other party: (i) if ownership, management, or control of the other party or all or substantially all of the other party's assets are transferred to a person or entity other than the person or entity exercising ownership, management or control at the date of this Agreement which transfer materially adversely affects the performance of such other party's obligations hereunder; or (ii) if a court having jurisdiction shall enter a decree or order for relief in respect of the other party in an involuntary case under any applicable bankruptcy,

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insolvency or other similar law now or hereinafter in effect, or appoint a receiver, liquidator, assignee, custodian, trustee, sequestrator (or similar official) for such other party or for any substantial part of its property, or order the winding up or liquidation of its affairs, and such decree or order shall remain unstayed and in effect for a period of sixty (60) consecutive days; or (iii) if the other party shall commence a voluntary case under any applicable bankruptcy, insolvency or other similar law now or hereafter in effect, or consent to the entry of an order for relief in any involuntary case under any such law, or consent to the appointment of or taking possession by a receiver, liquidator, assignee, trustee, custodian, sequestrator (or similar official) for such other party for any substantial part of its property, or make any general assignment for the benefit of creditors, or fail generally to pay its debts as they become due or shall take any action in furtherance of any of the foregoing; 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. "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.

20. Effect of Termination.

20.1 Effect of Full Termination. Termination or expiration of this Agreement shall not extinguish debts and other obligations created or arising between the parties by virtue of contracts or arrangements entered into hereunder before the effective date of termination or expiration of this Agreement (the "Termination Date"). Without limiting the generality of the foregoing, upon the Termination Date:

(a) Senko shall not be relieved of its obligation to (i) pay for Products received by Senko prior to the Termination Date, or (ii) receive and pay for all Products covered by orders which have been received by MacroPore prior to the Termination Date, or (iii) make Section 5 royalty payments with regard to all Products received before or after the Termination Date by Senko; MacroPore shall be obligated to complete all Product orders which were received by MacroPore prior to the Termination date, provided that MacroPore receives adequate assurance of payment; and in each such case, Senko shall be permitted to distribute such Products as well as any Products in Senko's inventory within the Territory, subject to Section 20.1 (c).

(b) Senko shall cooperate with MacroPore to allow for the orderly transfer of operations within the Territory to MacroPore or its designee; Senko shall provide MacroPore with (i) full and immediate access to all marketing and sales information pertaining to the Products, including, without limitation, customer lists, past sales history and Product pricing information, and (ii) copies of any such information upon MacroPore's request. Furthermore, Senko shall transfer all MacroPore Product

registration and regulatory documentation necessary to facilitate transfer of the Territorial distribution to a third party as well as to transfer to MacroPore all of MacroPore's Marks, MacroPore's Patents which are then in the name of and/or held by Senko.

(c) In the event of a termination resulting from a material breach of this Agreement by MacroPore, Senko shall have the right, at its option, to require MacroPore to repurchase from Senko all of Senko'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 Senko for such Products. Senko may exercise its option under this Section 20.1(c) by notifying MacroPore in writing no later than 30 days after the effective termination date. Senko shall be permitted to resell any such inventory of Products that MacroPore does not repurchase from Senko.

(d) In the event of a termination resulting from a material breach of the Agreement by Senko, Senko shall submit to MacroPore within thirty (30) days after the Termination Date a list of all the Products owned by Senko which were purchased from MacroPore as of the Termination Date; MacroPore may, at its option, purchase any or all of such Products from Senko upon written notice of its intention to do so, at prices to be agreed upon between the parties but in no event greater than the respective prices paid by Senko to MacroPore for such products; after receipt of such Products from Senko, MacroPore will issue an appropriate credit to Senko's account.

(d) Senko shall cease to use any Confidential Information relating to or in connection with its continued business operations and shall promptly return to MacroPore any and all registrations of MacroPore's Marks and all physical, written and descriptive matter (including all reproductions and copies thereof) containing Confidential Information as MacroPore may specify.

(e) NEITHER PARTY HERETO SHALL BE LIABLE TO THE OTHER PARTY FOR DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, INCIDENTAL OR CONSEQUENTIAL DAMAGES, ARISING FROM THE TERMINATION OF THIS AGREEMENT IN ACCORDANCE WITH ITS TERMS.

20.2 Effect of Partial Termination. In the event that Senko's distribution rights are reduced as provided for in Section 3.2, Senko shall assist and cooperate with MacroPore by providing MacroPore at MacroPore's cost any regulatory materials related to the Territory and in executing any documents, if any, necessary to effectuate the distribution of the product through another distributor in parallel to Senko in the Territory.

21. Excusable Delays. MacroPore shall not be liable for any delay in the manufacture or delivery of Products pursuant to the terms and provisions of this Agreement, or for any damages suffered by Senko by reason of such delay, when such

delay is, directly or indirectly, caused by, or in any manner arises from, fires, floods, accidents, riots, acts of God, war, governmental interference or restrictions, strikes, labor difficulties, back-orders, material shortages, regulatory or business interruptions, acts of Senko or any other cause beyond the reasonable control of MacroPore, whether similar or dissimilar to the foregoing.

22. General Provisions.

22.1 Successors and Assigns.

(a) This Agreement shall inure to the benefit of, and be binding upon, the respective successors and assigns of the respective parties hereto; provided, however, that neither party shall have the right to assign any of its rights, delegate any of its duties, or subrep or contract out any of its duties under this Agreement without the prior written consent of the other party, which consent may not be unreasonably withheld. For avoidance of doubt, it is understood and agreed that Senko may withhold such consent if the assignment, delegation or subrep or contract may, in Senko's reasonable opinion, materially adversely affects the regulatory status of Products under the Shonin or application therefor, or may cause substantial delay in obtainment of the Shonin for Products, and/or materially effects the supply of the Products to Senko. Neither party hereto shall be relieved of its respective right or obligations hereunder upon any assignment, whether voluntary, involuntary or by operation of law. Subject to the preceding sentence, each term and provision of this Agreement shall be binding upon and enforceable against and inure to the benefit of any successors or assigns of the parties hereto. For purposes of this Agreement, any change of voting or management control of Senko or MacroPore or any transfer (whether by sale of stock, sale of assets, merger or otherwise) of any substantial part of its business (each a "Change in Control") shall constitute an assignment by Senko or MacroPore of its rights and interest in and to this Agreement. In the event of a Change in Control, each party agrees to notify the other party in writing no less than thirty (30) days prior to such Change in Control. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the parties hereto and their respective successors and assigns any rights or remedies under or by reason of this Agreement.

(b) Notwithstanding Section 22.1 (a), MacroPore shall have the express right (not subject to any prior consent of Senko) to assign all of its rights, interests and obligations in and to this Agreement in connection with the purchase rights of MAST Biosurgery AG ("MAST") granted to MAST in the May 7, 2004, Asset Purchase Agreement ("APA"), between MacroPore and MAST. The APA provides that MAST shall have the right to purchase all rights of MacroPore to the Products in the Territory, which would include the rights and obligations of MacroPore provided by this Agreement. Also, in the event of an assignment to MAST, MacroPore agrees to provide (i) a written notice with the detailed description of the assignment to Senko before the closing date of the assignment; and (ii) back-up supply of Product directly to Senko (and not through MAST) for the Term of this Agreement if MAST fails to supply Product to Senko in accordance with the terms of this Agreement, and such failure would otherwise

amount to a material breach on the part of MAST. The terms of the back-up supply shall be subject to all of the terms of this Agreement, except that the Product transfer price shall be established through good faith negotiations between the parties at the time of such failure, provided that such transfer price

shall not be higher than that under this Agreement. Upon MAST's provision of reasonably satisfactory assurances to Senko that it can and will resume the contractual supply of Product to Senko, MacroPore shall be relieved of this duty.

22.2 Notices. All notices, requests, demands and other communications which may be given or are required to be given under this Agreement shall be in writing and in the English language with certified translations as necessary. All notices shall be sent by facsimile transmission and confirmed by letter, certified mail return receipt requested, and shall be deemed given on the date of such facsimile transmission. All notices shall be addressed as set forth below in Schedule 22.2, hereto, or to such other address as each party hereto may from time to time designate by written notice to the other party as provided herein.

22.3 Governing Law. This Agreement shall be governed by, construed and enforced in accordance with the laws of the State of California and the United States of America. Any actions, suits or proceedings arising out of or related to this Agreement shall be brought in, and determined exclusively by the courts of the State of California and the United States of America. The United Nations Convention for the International Sale of Goods will not apply.

22.4 Resolution of Disputes. The parties hereto (a) mutually consent and submit to the jurisdiction of any state or federal court of competent jurisdiction located in the City of San Diego, State of California, in any action or proceeding arising out of or relating in any manner to this Agreement, (b) each waive any claim that any such state or federal court is an inconvenient forum, and (c) each irrevocably agree that any and all actions or proceedings arising out of or relating to this Agreement or from transactions contemplated herein shall be exclusively heard only in such state or federal court, provided that nothing in this Section 22.4 shall affect MacroPore's right to bring an action or proceeding against Senko in the courts of any other jurisdiction where the purpose of such action or proceeding is to (i) seek injunctive relief against Senko, or (ii) collect moneys due and owing from Senko to MacroPore on account of Senko's failure to pay for Products or services provided by MacroPore. Service of process in any such action or proceeding brought hereunder may be made by mailing copies of such process to the address of the parties provided for in Section 22.2 hereto, provided that nothing in this Section 22.4 shall affect the right of either party to serve legal process in any other manner permitted by law.

22.5 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement, and shall not be deemed to limit or affect any of the terms or provisions hereof.

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22.6. Construction. Whenever in this Agreement the context so requires, references to the masculine shall be deemed to include feminine and the neuter, references to the neuter shall be deemed to include the masculine and feminine, and references to the plural shall be deemed to include the singular and the singular to include the plural. Any references in this Agreement to either party hereto shall include such party's Agents.

22.7 Waiver and Amendment. No waiver, amendment, modification or change of any provision of this Agreement shall be effective unless and until made in writing and signed by all of the parties hereto. No waiver, forbearance or failure by any party hereto of its right to enforce any provision of this Agreement shall constitute a waiver or estoppel of such party's right to enforce any other provision of this Agreement or a continuing waiver by such party of compliance with any provision.

22.8 Severability. The provisions of this Agreement are intended to be interpreted and construed in a manner so as to make such provisions valid, binding and enforceable. In the event that any provision of this Agreement is determined to be partially or wholly invalid, illegal or unenforceable, then such provision shall be deemed to be modified or restricted to the extent necessary to make such provision valid, binding and enforceable, or, if such provision cannot be modified or restricted in a manner so as to make such provision valid, binding and enforceable, then such provision shall be deemed to be excised from this Agreement and the validity, binding effect and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any manner. Nothing in this Agreement shall be interpreted or construed as creating, expressly or by implication, a partnership, joint venture, agency relationship or employment relationship between the parties hereto or between a party hereto and the respective Agents of the other party.

22.9 Cooperation. Each party hereto shall cooperate with the other party hereto and shall take such further action and shall execute and deliver such further documents as may be necessary or desirable in order to carry out the provisions and purposes of this Agreement.

22.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

22.11 Entire Agreement. This Agreement (including any exhibits and schedules hereto, each of which is incorporated herein and made a part of this Agreement) constitutes the entire agreement and understanding of the parties hereto and terminates and supersedes any and all prior agreements, arrangements and understandings, both oral and written, express or implied, between the parties hereto concerning the subject matter of this Agreement.

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

MACROPORE BIOSURGERY, INC.

By: /s/ Christopher J. Calhoun

Title: CEO

Date: July 13, 2004

SENKO MEDICAL TRADING CO.

By: /s/ Tetsuo Sasaki

Title: President

Date: July 16, 2004

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EXCLUSIVE DISTRIBUTION AGREEMENT

SCHEDULES

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Schedule 12

TRADEMARKS

<u>Outside #</u>	<u>Title</u>	<u>Serial # or Registration #</u>	<u>Date Filed</u>	<u>Status</u>
MA9672JP (Japan)	SURGIWRAP	2003-015208	27-Feb-03	Pending
MA9644JP (Japan)	CARDIOWRAP	2005-015207		Pending

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Schedule 22.2

ADDRESSES

MACROPORE BIOSURGERY, INC.:

MACROPORE

Attention: Bruce Reuter

6740 Top Gun Street

San Diego, CA 92121

(858) 458- 0900 – Telephone

(858) 458- 0994 – Facsimile

With copy to:

Attention: Seijihiro Shirahama

SENKO MEDICAL TRADING CO.:

SENKO

Attention: Executive Director

20-12, 3-chome, Yushima

Bunkyo-ku, Tokyo, Japan

(813) 3836-9031 – Telephone

(813) 3836-9087 – Facsimile

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Letter Re Unaudited Interim Financial Information

November 15, 2004

MacroPore Biosurgery, Inc.
6740 Top Gun Street
San Diego, CA 92121
Re: Registration Statement No. 333-82074

With respect to the subject registration statement, we acknowledge our awareness of the use therein of our report dated October 29, 2004 related to our review of interim financial information.

Pursuant to Rule 436 under the Securities Act of 1933 (the Act), such report is not considered part of a registration statement prepared or certified by an accountant, or a report prepared or certified by an accountant within the meaning of Sections 7 and 11 of the Act.

/s/ KPMG LLP

San Diego, California

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

I, Christopher J. Calhoun, the Chief Executive Officer of MacroPore Biosurgery, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of MacroPore Biosurgery, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2004

/s/ Christopher J. Calhoun

Christopher J. Calhoun,
Chief Executive Officer

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

I, Mark Saad, the Chief Financial Officer of MacroPore Biosurgery, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of MacroPore Biosurgery, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2004

/s/ Mark E. Saad

Mark E. Saad,
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Macropore Biosurgery, Inc. for the quarter ended September 30, 2004 as filed with the Securities and Exchange Commission on the date hereof, Christopher J. Calhoun, as Chief Executive Officer of MacroPore Biosurgery, Inc., and Mark E. Saad, as Chief Financial Officer of MacroPore Biosurgery, Inc., each hereby certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, respectively, that:

1. The Form 10-Q report of MacroPore Biosurgery, Inc. that this certification accompanies fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934.
2. The information contained in the Form 10-Q report of MacroPore Biosurgery, Inc. that this certification accompanies fairly presents, in all material respects, the financial condition and results of operations of MacroPore Biosurgery, Inc.

Dated: November 15, 2004

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

Dated: November 15, 2004

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