
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 March 31, 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 April 19, 2004, there were 13,917,834 shares of MacroPore Biosurgery, Inc. common stock outstanding.

MACROPORE BIOSURGERY, INC.

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PART I

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Independent Accountants' Review Report

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 March 31, 2004, and the related consolidated condensed statements of operations and comprehensive income (loss) and consolidated condensed statements of cash flows for the three months ended March 31, 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 American Institute of Certified Public Accountants. 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 generally accepted in the United States of America, 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 accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with auditing standards generally accepted in the United States of America, 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
April 30, 2004

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	<u>As of March 31, 2004</u> (Unaudited)	<u>As of December 31, 2003</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,371,000	\$ 2,820,000
Short-term investments, available-for-sale	11,762,000	11,448,000
Accounts receivable, net of allowance for doubtful accounts of \$52,000 and \$62,000 in 2004 and 2003, respectively	1,001,000	1,291,000
Inventories	856,000	831,000
Other current assets	551,000	526,000
Total current assets	17,541,000	16,916,000
Property and equipment, net	3,765,000	3,822,000
Other assets	293,000	332,000
Intangibles, net	2,324,000	2,392,000
Goodwill	4,627,000	4,627,000

Total assets	\$ 28,550,000	\$ 28,089,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,475,000	\$ 3,767,000
Current portion of long-term obligations	847,000	717,000
Total current liabilities	3,322,000	4,484,000
Deferred gain on sale of assets, related party	7,388,000	7,539,000
Long-term obligations, less current portion	1,445,000	1,157,000
Total liabilities	12,155,000	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; 16,787,018 and 16,777,644 shares issued and 13,917,834 and 14,195,062 shares outstanding in 2004 and 2003, respectively	17,000	17,000
Additional paid-in capital	74,709,000	74,698,000
Unearned compensation	(48,000)	(109,000)
Accumulated deficit	(47,895,000)	(49,385,000)
Treasury stock, at cost	(10,405,000)	(9,362,000)
Treasury stock receivable	—	(976,000)
Accumulated other comprehensive income	17,000	26,000
Total stockholders' equity	16,395,000	14,909,000
Total liabilities and stockholders' equity	\$ 28,550,000	\$ 28,089,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	<u>For the Three Months Ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
Revenues:		
Sales to related party	\$ 1,921,000	\$ 1,606,000
Sales to third parties	341,000	323,000
Research grant	90,000	—
	2,352,000	1,929,000
Cost of revenues:		
Cost of revenues (including stock based compensation expense of \$2,000 and \$3,000 for the three months ended March 31, 2004 and 2003, respectively)	877,000	639,000
Inventory provision	242,000	—
Gross profit	1,233,000	1,290,000
Operating expenses:		
Research and development, excluding stock based compensation expense of -0- and \$19,000 for the three months ended March 31, 2004 and 2003, respectively	2,507,000	2,151,000
Sales and marketing, excluding stock based compensation expense of \$11,000 and \$18,000 for the three months ended March 31, 2004 and 2003, respectively	958,000	1,295,000
General and administrative, excluding stock based compensation expense of \$35,000 and \$176,000 for the three months ended March 31, 2004 and 2003, respectively	1,226,000	1,048,000
Stock based compensation (excluding cost of revenues stock based compensation)	46,000	213,000
Total operating expenses	4,737,000	4,707,000
Other income (expense):		
Gain on the sale of assets, related party	5,000,000	—
Interest income	55,000	142,000
Interest and other expenses, net	(61,000)	(5,000)
Net income (loss)	1,490,000	(3,280,000)
Other comprehensive loss - unrealized holding loss	(9,000)	(41,000)

Comprehensive income (loss)	\$	1,481,000	\$	(3,321,000)
Net income (loss) per common share:				
Basic	\$	0.11	\$	(0.23)
Diluted	\$	0.10	\$	(0.23)
Weighted average common shares:				
Basic		13,943,269		14,524,608
Diluted		14,734,455		14,524,608

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	<u>Three Months Ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
Cash flows from operating activities:		
Net income (loss)	\$ 1,490,000	\$ (3,280,000)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	434,000	406,000
Inventory provision	242,000	—
Gain on sale of assets, related party	(5,000,000)	—
Amortization of gain on sale of assets, related party	(151,000)	(380,000)
Stock based compensation	48,000	216,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	290,000	(229,000)
Inventories	(267,000)	2,000
Other current assets	(25,000)	159,000
Other assets	39,000	3,000
Accounts payable and accrued expenses	(305,000)	(705,000)
Net cash used in operating activities	<u>(3,205,000)</u>	<u>(3,808,000)</u>
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	15,159,000	13,841,000
Purchases of short-term investments	(15,482,000)	(11,968,000)
Proceeds from sale of assets, related party	5,000,000	—
Purchases of property and equipment	(309,000)	(287,000)
Cost of sale of assets, related party	—	(27,000)
Acquisition costs	(11,000)	(46,000)
Net cash provided by investing activities	<u>4,357,000</u>	<u>1,513,000</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	(176,000)	(72,000)
Proceeds from long-term obligations	594,000	—
Proceeds from the exercise of employee stock options	24,000	9,000
Purchase of treasury stock	(1,043,000)	(207,000)
Net cash used in financing activities	<u>(601,000)</u>	<u>(270,000)</u>
Net increase (decrease) in cash	551,000	(2,565,000)
Cash and cash equivalents at beginning of period	2,820,000	5,108,000
Cash and cash equivalents at end of period	<u>\$ 3,371,000</u>	<u>\$ 2,543,000</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 39,000	\$ 31,000
Taxes	9,000	10,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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MACROPORE BIOSURGERY, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
March 31, 2004
(UNAUDITED)

1. Basis of Presentation

The accompanying unaudited consolidated condensed financial statements as of and for the three months ended March 31, 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 months ended March 31, 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. SFAS No. 123, "Accounting for Stock-Based Compensation," established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting described above, and has adopted the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure."

Under SFAS No. 123, the weighted average fair value of stock options granted for the three months ended March 31, 2004 and 2003 was \$2.36 and \$3.64 respectively, on the date of grant. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	<u>For the Three Months Ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
Expected term	7 years	7 years
Interest rate	3.31 - 3.65%	3.34 - 3.60%
Volatility	89.3%	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:

	<u>For the Three Months Ended March 31,</u>	
	<u>2004</u>	<u>2003</u>
Net income (loss):		
As reported	\$ 1,490,000	\$ (3,280,000)
Add: Stock based employee compensation expense included in reported net income (loss), net of related tax effects	48,000	214,000
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(598,000)	(1,343,000)
Pro forma	<u>\$ 940,000</u>	<u>\$ (4,409,000)</u>
Basic income (loss) per common share:		
As reported	\$ 0.11	\$ (0.23)
Pro forma	\$ 0.07	\$ (0.30)
Diluted income (loss) per common share:		
As reported	\$ 0.10	\$ (0.23)
Pro forma	\$ 0.06	\$ (0.30)

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 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.

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

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

At March 31, 2004, the fair value of the Company's short-term investments that are below carrying cost is de minimis.

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 three months ended March 31, 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 backup 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 backup 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" (SFAS No. 144), the Company assesses certain of its long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recovered. An impairment occurs when the undiscounted cash flows expected to be generated by an asset 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.

At March 31, 2004, the Company has certain other assets held for sale. These assets include certain tangible assets related to the Company's bioresorbable thin film product line (note 13), as well as certain tangible assets associated with a foreign facility whose operations were terminated in September 2003 (note 11).

The carrying values of net assets held for sale included in other assets at March 31, 2004 are:

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Office and computer equipment	\$	121,000
Manufacturing and development equipment		91,000
Total	\$	<u>212,000</u>

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

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

7. Revenue Recognition

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

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

The Company recognizes revenue from the collection and storage of regenerative cell rich adipose tissue. In its cell banking service, the Company recognizes revenue when (i) the collection procedure is performed, (ii) the adipose tissue is received by the Company, (iii) fees from the procedure are fixed and determinable and (iv) payment is probable. In accordance with EITF 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.

The Company earns revenue for performing tasks under research agreements with both commercial enterprises and governmental agencies like the National Institutes of Health, or 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 appears 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,

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- 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 revenues in the Company's statements of operations. During the three months ended March 31, 2004, the Company recognized NIH grant revenue of \$90,000 and incurred qualifying costs of \$99,000. The qualifying costs were classified in the consolidated condensed statement of operations as research and development expenses. There were no comparable 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.

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

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 March 31, 2004 and 2003:

	Balance at January 1	Additions (charges to expenses)	Claims	Balance at March 31
2004:				
Warranty reserve	\$ 267,000	\$ 28,000	\$ (63,000)	\$ 232,000
2003:				
Warranty reserve	\$ —	\$ —	\$ —	\$ —

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9. Earnings (Loss) Per Share

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

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

Three months ended

	March 31,	
	2004	2003
Weighted average shares, basic	13,943,269	14,524,608
Dilutive effect of stock options	791,186	—
Weighted average shares, diluted	14,734,455	14,524,608

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 March 31,	
	2004	2003
Common stock options	2,575,816	4,977,645

10. Long-term Debt

In September 2003, the Company entered into an Amended Master Security Agreement to provide financing for equipment purchases. In 2004, in connection with this agreement, the Company issued one promissory note to the lender in an aggregate principal amount of approximately \$594,000 and it 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.

Principal payments on the promissory note are as follows:

For the years ended December 31,

2004	\$ 98,000
2005	158,000
2006	171,000
2007	130,000
2008	37,000
	<u>\$ 594,000</u>

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.

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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 is seeking to sublease the entire facility for the remaining term of the Lease Agreement. However, due to the unique nature of the office building and the depressed rental market in and around Frankfurt, Germany, the Company expects that a sublease of the entire facility (if one is successfully negotiated) will yield only approximately 65% of the Company's monthly rental obligation. Accordingly, the Company may consider negotiating a settlement of the remaining lease payments with the lessor if it is unable to enter into a suitable sublease arrangement.

The following outlines the restructuring activity recorded to the liability account during the three months ended March 31, 2004:

	Opening Balance	Charged to Expense	Costs Paid	Adjustments to Liability	Ending Balance
Lease termination	\$ 153,000	—	\$ (33,000)	—	\$ 120,000

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

The restructuring liabilities recorded as of March 31, 2004 do not include accrued brokerage commissions, if any, associated with finding new sublease tenants. Such commissions will be recognized when incurred and are not expected to be material.

12. Gain on sale of asset

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 disposal 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" in the accompanying consolidated condensed statement of operations.

13. Sale of Bioresorbable Thin Film Product Line

On December 13, 2003 the Company entered into an agreement with Medicis Ventures Management GmbH ("Medicis") to sell substantially all the assets of the Company's bioresorbable thin film product line. The transaction with Medicis was terminated in early May in favor of a new agreement with MAST Biosurgery AG ("MAST", a related party to Medicis), executed on May 7, 2004. The new agreement, which closed on May 13, 2004, provides for \$6,720,000 in cash at closing, a promissory note for \$280,000 payable on or before May 28, 2004, a secured installment payment of \$2,000,000 to be paid in the second quarter of 2005 and a \$200,000 milestone payment for a specified regulatory approval. Under certain circumstances, and at the election of MAST, the \$2,000,000 installment payment may be satisfied by the delivery of shares of MAST to the Company in lieu of cash

consideration. Under this agreement, the Company retains ownership of all rights to conduct the SurgiWrap business in the country of Japan, subject to an option of MAST to purchase these rights for three years at a minimum price of \$3,000,000, and a business development agreement

for Japan that may be triggered on MAST's exercise of the option. In addition, the Company would receive a nonexclusive, perpetual, worldwide, royalty-free license to the thin film technology for the regenerative-medicine field of use, and a worldwide exclusive, royalty-free license to thin-polymeric-film implants for spinal surgery. The Company has agreed to act as a back-up supplier of the thin film bioresorbable implant products for one year after the closing of the sale of the product line. As of March 31, 2004, the product line assets, which total \$212,000 were included in "assets held for sale."

14. Composition of Certain Financial Statement Captions

Inventories

	March 31, 2004 (Unaudited)	December 31, 2003
Raw materials	\$ 485,000	\$ 399,000
Finished goods	371,000	432,000
	<u>\$ 856,000</u>	<u>\$ 831,000</u>

Property and Equipment, net

	March 31, 2004 (Unaudited)	December 31, 2003
Office and computer equipment	\$ 1,956,000	\$ 1,922,000
Manufacturing and development equipment	3,930,000	3,685,000
Leasehold improvements	1,935,000	1,905,000
	7,821,000	7,512,000
Less accumulated depreciation and amortization	(4,056,000)	(3,690,000)
	<u>\$ 3,765,000</u>	<u>\$ 3,822,000</u>

Other Assets

	March 31, 2004 (Unaudited)	December 31, 2003
Deposits	\$ 81,000	\$ 120,000
Assets held for sale	212,000	212,000
	<u>\$ 293,000</u>	<u>\$ 332,000</u>

Intangibles, net

	March 31, 2004 (Unaudited)	December 31, 2003
Intangibles	\$ 2,695,000	\$ 2,695,000
Less accumulated amortization	(371,000)	(303,000)
	<u>\$ 2,324,000</u>	<u>\$ 2,392,000</u>

Accounts Payable and Accrued Expenses

	March 31, 2004 (Unaudited)	December 31, 2003
Accounts payable	\$ 672,000	\$ 520,000
Share repurchase payable	—	976,000
Accrued bonus	236,000	631,000
Accrued vacation	506,000	468,000
Warranty provision	232,000	267,000
Accrued restructuring costs	120,000	153,000
Accrued expenses	709,000	752,000

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 months ended March 31, 2004 should **not** be considered predictive of future results. This is because we recognized \$5,000,000 in other income during the quarter related to the successful completion of clinical research regarding Faster Resorbing Polymer. Such research was directly tied to the CMF product line we transferred to Medtronic in 2002. Accordingly, this transaction was of a non-recurring nature and we do not expect to generate similar income in future periods.

Overview

Our business is focused on the discovery, development and commercialization of regenerative medicine technologies. We have two technology platforms, bioresorbable technology and regenerative

cell technology. Our surgical implants, derived from our bioresorbable technology, represent one of the latest advancements in spine and orthopedic medicine. We manufacture surgical implants for spine and orthopedic application (to support hard tissues) and distribute them exclusively through Medtronic. Our regenerative cell technology is in the research and development stage. We are currently 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. 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.

In May 2004, we sold our product line of bioresorbable thin film surgical implants to MAST Biosurgery AG ("MAST"), a newly formed company. These products are designed as a barrier to separate soft tissues. We received an initial payment of \$6,720,000 in cash, a promissory note for \$280,000, payable on or before May 28, 2004 and will receive an additional \$2,000,000 (or stock in MAST) no later than the second quarter of 2005. We agreed to be a short-term backup supplier of products to MAST. In addition, we retained all thin film rights for the Japan market, an exclusive license to bioresorbable thin film for the spinal market and a perpetual nonexclusive license to bioresorbable thin film in connection with regenerative cell therapies. MAST has a three year option to acquire the Japan bioresorbable thin film market from us, for at least \$3,000,000, which option is conditionally subject to a business development agreement. We sold the product line in order to sharpen our focus on our main product areas, avoid the short-term negative cash flow required in building this business and raise cash.

Our strategy is to continue growing spine and orthopedic implant revenues and investing these revenues and other cash flow into the research and development of our regenerative cell technology. Thus, we expect negative returns and heavy cash expenditures for the remainder of 2004 and beyond. This is common in the life science industry, where innovative technologies and products often take substantial time to generate appreciable returns. Strategically, we believe our research and development investment will build a rich pipeline of products that target the high growth and demographically driven markets of orthopedics, spine and cardiovascular disorders. In addition, in some cases we intend to form strategic partnerships related to our regenerative cell technology platform to speed development and to better leverage the technology.

Total revenues for the first quarter of 2004 were \$2,352,000 compared to \$1,929,000 for the same period in 2003, an increase of 21.9%. Spine and orthopedics, which include the HYDROSORB™ family of products, accounted for \$1,647,000 in revenue, a 65.9% increase over the same period in 2003. Our bioresorbable thin films, which include SurgiWrap™, accounted for \$337,000 in revenue, a 5.6% increase over the same period in 2003. Our craniomaxillofacial "CMF" products accounted for \$274,000 in revenue that we generated under a back-up supply agreement established in September 2002 when we disposed of this product line to Medtronic. Revenues from a National Institutes of Health (NIH) grant, which we applied for and obtained in late 2003, totaled \$90,000.

The increase in revenues for the first quarter of 2004 compared to the first quarter of 2003 was primarily the result of increased surgeon demand for bioresorbable devices during the period and the pre-launch of a new product within the HYDROSORB™ product portfolio. Historically, the first quarter is our weakest of the year due in part to inventory stocking patterns by Medtronic. For this reason, the first quarter is not an accurate indicator of our projected results for the remainder of the year. We expect to realize an appreciable increase in revenues in 2004 over 2003. Future revenue growth from the spine and orthopedic products will depend largely on the following: (1) Medtronic increasing market penetration; (2) Physicians becoming more comfortable with bioresorbable materials and more aware of the products' advantages over metal and allograft; and (3) European acceptance of the use of bioresorbable materials in combination with Medtronic's bone growth protein INFUSE®. We expect that the growth of spine and

orthopedic product revenues and the back-up supply of bioresorbable thin films in 2004 will offset the loss of revenues that will not be realized as a result of product line divestitures, including bioresorbable thin film sales and sales of CMF product under a backup supply arrangement with Medtronic.

We experienced a decline of 14.5% in gross profit to 52.4% in the first quarter of 2004 compared to 66.9% during the same period in 2003. This was attributable to setting up an inventory provision for unsold and excess CMF inventory remaining after Medtronic notified us in April 2004 it had transferred manufacturing of CMF to their facilities and would no longer purchase CMF product under the backup supply agreement. Gross profit also declined due to increased labor costs associated with the manufacturing of the spine and orthopedic products. However, we believe that gross profit as a percentage of revenues will increase as we achieve economies of scale, since revenue growth should outpace the cost of manufacturing our products.

Net income for the first quarter of 2004 was \$1,490,000 after a one time, \$5,000,000 gain related to the completion of the clinical research regarding Faster Resorbing Polymers, a milestone of the 2002 CMF sale agreement with Medtronic. Adjusted net loss before the one time gain was \$3,510,000, compared to a net loss of \$3,321,000 for the same period in 2003 as outlined in the table below. The increase in net loss before the one time gain is attributable primarily to the \$242,000 inventory provision.

For the three months ended:	March 31, 2004	March 31, 2003
Net income (loss) GAAP:	\$ 1,490,000	\$ (3,280,000)
Less: Gain on the sale of asset, related party	(5,000,000)	—
Adjusted net income (loss) (1)	<u>\$ (3,510,000)</u>	<u>\$ (3,280,000)</u>

(1) We believe adjusted net income (loss) is a useful measure by which investors can evaluate and compare our operating performance on a comparable basis, unaffected by the large one-time payment we received in the first quarter of 2004

We ended the first quarter of 2004 with \$15,133,000 in cash and cash equivalents and short term investments. Based on our anticipated research and development expenses and other operating expenses, we believe that our current cash and cash equivalents, short term investments, equipment financing arrangements, product line dispositions and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through March 31, 2005. In May 2004 we sold our bioresorbable thin film product line (while retaining rights to Japan and certain other fields) and received an initial cash payment of \$6,720,000 and a promissory note for \$280,000. Additionally, we expect to receive in 2004 a \$1,000,000 to \$2,000,000 payment from Medtronic for the completion of the transfer of know-how related to the sale of CMF.

For the full year 2004, we have established the following financial and corporate goals that we believe will be important for building shareholder value and advancing our research and development programs toward commercialization:

- Receive \$1,000,000 to \$2,000,000 milestone payment from Medtronic related to the transfer of know-how in connection to the sale of CMF
- Enter into a commercialization agreement for SurgiWrap™ for the territory of Japan
- Receive award of \$750,000 for Phase II of the NIH grant
- Announce pre-clinical study results using adipose-derived regenerative cell technology for cardiac therapy

Results of Operations

Revenues

The following table summarizes the components of our revenues for the three months ended March 31, 2004 and 2003:

For the three months ended:	March 31, 2004	March 31, 2003	Difference	%
Spine and orthopedics products	\$ 1,647,000	\$ 993,000	\$ 654,000	65.9%
Thin film products	337,000	319,000	18,000	5.6%
Craniomaxillofacial (CMF) products:				
Product sales	123,000	233,000	(110,000)	(47.2)%
Amortization of gain on sale	151,000	380,000	(229,000)	(60.3)%
Total craniomaxillofacial	274,000	613,000	(339,000)	(55.3)%
Research grant (NIH)	90,000	—	90,000	—
Regenerative cell storage services	4,000	4,000	—	—
Total	<u>\$ 2,352,000</u>	<u>\$ 1,929,000</u>	<u>\$ 423,000</u>	<u>21.9%</u>
% of revenues attributable to Medtronic	81.7%	83.3%	(1.6)%	

- The \$654,000 or 65.9% increase in spine and orthopedics product revenue in 2004 as compared with 2003 resulted primarily from an increased surgeon demand for bioresorbable devices during the period and the pre-launch of a new product within the Hydrosorb™ product portfolio.
- The \$18,000 or 5.6% increase in bioresorbable thin film product revenue in 2004 as compared to 2003 reflected the constraining effects on the business of our announced December 2003 agreement to sell the business to Medicis Ventures Management GmbH, a related party of MAST, as we continue the implementation of our independent sales representative distribution model.
- The \$339,000 or 55.3% decrease in CMF product sales in 2004 as compared to 2003 related to Medtronic transitioning the manufacturing of CMF products to their own facilities. We do not expect any material CMF product revenue in the future as Medtronic intends to no longer purchase CMF product under the backup supply arrangement.
- The \$90,000 in research grant revenue in 2004 relates to an agreement with the National Institutes of Health (“NIH”). Under this arrangement, the NIH will reimburse us for up to \$100,000 in “qualifying expenditures” related to Phase I research on Adipose Derived Cell Therapy for Myocardial Infarction. To receive funds under the grant arrangement, we must: (i) demonstrate that we have 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

The U.S. government obtains significant rights over any commercial products or intellectual property that we developed, in whole or in part, using funds provided under the NIH grant. In particular, the U.S. government receives a “nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced for or on behalf of the United States” for any technologies developed as a result of the grant. Nevertheless, we retain all underlying intellectual property rights, including patents, to the developed technology and we plan to market any commercially viable products resulting from the research efforts.

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.

- There was no change in revenue in 2004 as compared to 2003 in regenerative cell storage services and revenue is expected to remain flat and insignificant throughout the remainder of 2004.
- Revenues attributable to Medtronic, which owns approximately 7.2% of our outstanding common stock, represented 81.7% of our revenues in 2004 as compared to 83.3% in 2003. The decrease in the revenue percentage attributable to Medtronic primary relates to us receiving research revenue and the decrease of CMF revenues in 2004.

The future: In 2004 and beyond, we expect that the spine and orthopedic product revenues will grow to offset the loss of revenues that will not be realized as a result of product line divestitures. Our 2004 revenue from spine and orthopedic products, though, will depend largely on Medtronic’s (our sole distributor of spine and orthopedic products) ability to maintain and/or increase its market share in the bioresorbable spine and orthopedic arena. Because our products are sold to Medtronic at fixed selling prices that are subject to adjustment biannually (which are based on Medtronic’s selling prices to its customers), our revenue from this product line is dependent upon increased market adoption of our technology and Medtronic’s pricing strategies.

We expect the percentage of revenues attributable to Medtronic to increase now that we have completed the sale of the non-Japan bioresorbable thin film product line to MAST, as (non-Medtronic) sales of bioresorbable thin film products becomes a lower percentage of our overall sales revenue.

Under our arrangement with the NIH, if we are successful with Phase I of the research on Adipose Derived Cell Therapy for Myocardial Infarction as defined by the grant agreement, we will become eligible to receive up to \$750,000 in additional grants from the NIH for Phase II research. We believe we will be successful with Phase I and the Phase II grant of \$750,000 will be awarded to us in 2004.

Cost of revenues

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

<u>For the three months ended:</u>	<u>March 31, 2004</u>	<u>March 31, 2003</u>	<u>Difference</u>	<u>%</u>
Cost of revenues:				
Cost of revenues	\$ 877,000	\$ 639,000	\$ 238,000	37.2%
% of revenue	37.3%	33.1%	4.2%	
Inventory provision	242,000	—	242,000	—
% of revenue	10.3%	—	10.3%	
Total	\$ 1,119,000	\$ 639,000	\$ 480,000	75.1%
Cost of revenue as % of revenues	47.6%	33.1%	14.5%	

- The 4.2% increase in cost of revenue as a percentage of revenue in 2004 as compared to 2003 primarily related to an increase in labor costs associated with the manufacturing of spine and orthopedic product line.

- The \$242,000 inventory provision in 2004 related to excess inventory. Such inventory was produced in consideration of our responsibility to be a backup 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 backup 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 would negatively impact our margins unless other sources of revenue grow large enough to compensate for the lost revenue. We believe, in fact, that revenue from the spine and orthopedic product line will increase sufficiently that the cost of revenue as a percentage of revenue will decrease due to achieving economies of scale whereby larger revenues absorb more of our fixed manufacturing labor and overhead costs.

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 preclinical studies. It excludes related stock based compensation expenses. The following table summarizes the components of our research and development expenses for the three months ended March 31, 2004 and 2003:

<u>For the three months ended:</u>	<u>March 31, 2004</u>	<u>March 31, 2003</u>	<u>Difference</u>	<u>%</u>
Regenerative cell technology	\$ 1,464,000	\$ 836,000	\$ 628,000	75.1%

Bioresorbable polymer implants	944,000	1,315,000	(371,000)	(28.2)%
Research grant (NIH)	99,000	—	99,000	—
Total	<u>\$ 2,507,000</u>	<u>\$ 2,151,000</u>	<u>\$ 356,000</u>	16.6%

- Development of our regenerative cell technology platform involves using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications. The \$628,000 or 75.1% increase in 2004 as compared to 2003 was a result of an investment in additional staffing of researchers, engineers and support staff from 15 to 25. In addition to these increased labor costs of \$372,000, we incurred an increase in pre-clinical studies, regulatory fees, consulting fees and facility expenses totaling \$256,000.
- Our bioresorbable polymer implants platform technology is used for the development of spine and orthopedic products. The decrease of \$371,000 or 28.2% in spending on this technology in 2004 as compared to 2003 was because we successfully developed our bioresorbable thin film product line and no longer performed development work on the CMF product line, as it was sold to Medtronic in 2002.
- We entered into an agreement with the NIH. Under this arrangement, the NIH will reimburse us for up to \$100,000 in “qualifying expenditures” related to Phase I research on Adipose Derived Cell Therapy for Myocardial Infarction. In 2004, we incurred \$99,000 of direct qualifying expenses as defined in the grant agreement between the NIH and us.

The future: We believe that our research and development expenditures associated with the regenerative cell technology platform using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications have provided us with significant progress in understanding the potential clinical applications. We anticipate in 2004 expenditures in this area of research to be \$7,800,000 to \$8,800,000 in order to continue to conduct pre-clinical studies on harvesting therapeutical useful

quantities of regenerative cells for cardiac tissue repair, bone regeneration, cosmetic and reconstruction surgery and wound healing. We do not expect to bring products with this technology to market and generate significant revenue in 2004.

We expect that our current research and development expenditures in the bioresorbable platform technology will remain consistent with past levels because of ongoing product development for biomaterial/polymer products and the support required for our pipeline of new and next generation of spine and orthopedic products.

We believe we will be successful with Phase I of the NIH research on Adipose Derived Cell Therapy for Myocardial Infarction and we will become eligible for Phase II of the NIH research grant. Therefore, we expect research expenses to be incurred related to this project in 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 was distributed domestically through a dedicated sales force, independent sales representatives and internationally through independent distributors. The following table summarizes the components of our sales and marketing expenses for the three months ended March 31, 2004 and 2003:

<u>For the three months ended:</u>	<u>March 31, 2004</u>	<u>March 31, 2003</u>	<u>Difference</u>	<u>%</u>
General corporate marketing	\$ 125,000	\$ 100,000	\$ 25,000	25.0%
Domestic sales and marketing	560,000	902,000	(342,000)	(37.9)%
International sales and marketing	273,000	293,000	(20,000)	(6.8)%
Total	<u>\$ 958,000</u>	<u>\$ 1,295,000</u>	<u>\$ 337,000</u>	(26.0)%

- General corporate marketing expenditures relate to expenditures for maintaining our corporate image and reputation within the research and surgical communities. The increase of \$25,000 or 25% in 2004 as compared to 2003 was due to an educational program and materials created to inform end users of our biomaterial products.
- Domestic sales and marketing relates to costs associated with managing our domestic bioresorbable thin film product distribution which includes independent sales representatives and our domestic thin film sales consultants and marketing staff. The decrease of \$342,000 or 37.9% in spending in domestic sales and marketing expenditures in 2004 as compared to 2003 was due to our efforts at controlling costs as we reduced the marketing staff from 3 to 1 and the number of our bioresorbable thin film sales consultants from 19 to 8. Our remaining sales consultants focused on specific regions in the US domestic market where there is greater market acceptance of our bioresorbable thin film products. In addition, we changed our distribution model and began using licensed independent sales representatives paid on commission that allowed us to increase the availability of our product without increasing our salary costs.
- International marketing relates to costs associated with developing international bioresorbable thin film distributors and supporting a bioresorbable thin film sales office in Japan and the United Kingdom. The decrease of \$20,000 in spending in international sales and marketing expenditures in 2004 as compared to 2003 was due to a reduction in general expenses in the United Kingdom due to one year of experience in working with international distributors for thin film.

The future: We project that corporate marketing expenditures will slightly increase in 2004 due to the creation of a biomaterials education support department. We project our other sales and marketing expenses to decline significantly now that we have sold our non-Japan thin film business.

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 months ended March 31, 2004 and 2003:

For the three months ended:	March 31, 2004	March 31, 2003	Difference	%
General and administrative expenses	\$ 1,226,000	\$ 1,048,000	\$ 178,000	17.0%

- The \$178,000 increase in general and administrative expenses in 2004 as compared to 2003 was a result of a combination of increases in salary, legal, consulting and professional services and overall general corporate expenditures.

The future: We expect general and administrative expenses to trend at its current level for the balance of the year.

Stock based compensation expenses

Stock based compensation expenses includes 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 months ended March 31, 2004 and 2003:

For the three months ended:	March 31, 2004	March 31, 2003	Difference	%
Research and development related	\$ —	\$ 19,000	\$ (19,000)	—
Sales and marketing related	11,000	18,000	(7,000)	(38.9)%
General and administrative related	35,000	176,000	(141,000)	(80.1)%
Total	\$ 46,000	\$ 213,000	\$ (167,000)	(78.4)%

- The \$167,000 decrease in stock based compensation expense in 2004 as compared to 2003 was related to the normal amortization of the stock based compensation expenses over the remaining vesting period. There was no stock based compensation expense relating to non-employees for the three months ended March 31, 2004.

The future. We anticipate expensing the remaining \$48,000 in unearned stock based compensation in the next quarter.

Other income

The following is a table summarizing the gain on the sale of assets, related party for the three months ended March 31, 2004 and 2003:

For the three months ended:	March 31, 2004	March 31, 2003	Difference	%
Gain on the sale of assets, related party	\$ 5,000,000	\$ —	\$ 5,000,000	—

- The \$5,000,000 gain on the sale of assets, related party in 2004 related to a \$5,000,000 milestone payment from Medtronic relating to the disposition of our CMF product line. Specifically, as part of the disposal arrangement, we agreed to complete clinical research regarding Faster Resorbable Polymer, an area that directly relates to the CMF product line we transferred to Medtronic. We became entitled to the \$5,000,000 payment after fulfilling the research requirements set out in the CMF sale agreement. We have no further performance obligations related to this aspect of the CMF sale agreement.

The future. The \$5,000,000 gain is a one-time event. We do not expect to recognize similar gains in future periods. However, we do anticipate recognizing the remaining deferred gain on sale of assets, amounting to approximately \$7,388,000 at March 31, 2004, plus the additional \$1,000,000 to \$2,000,000 to be received, as gain on sale of assets, related party, in 2004 because the know-how transfer and training under the sale agreement should be complete. That milestone is the last remaining one under the CMF sale agreement, and until it is finalized we can not recognize gain even on aspects of the transaction for which we have already received substantial cash proceeds.

Financing items

The following tables summarize interest income, and interest and other expenses for the three months ended March 31, 2004 and 2003:

For the three months ended:	March 31, 2004	March 31, 2003	Difference	%
Interest income	\$ 55,000	\$ 142,000	\$ (87,000)	(61.3)%

For the three months ended:	March 31, 2004	March 31, 2003	Difference	%
Interest and other expenses	\$ (61,000)	\$ (5,000)	\$ 56,000	1120.0%

- The \$87,000 decrease in interest income in 2004 as compared to 2003 resulted from a decrease in the funds we had available for investments and lower interest rates. We anticipate interest income to slightly increase as our cash position increases in the remainder of 2004.
- The \$56,000 increase in interest and other expenses in 2004 as compared to 2003 was primarily due to the foreign currency gains in 2003, which did not recur in 2004.

Gain on Asset Sale to Medtronic

At March 31, 2004, we have reflected \$7,388,000 of unamortized "Deferred gain on sale of assets, related party" on our balance sheet. This deferred gain related to our sale of our CMF product line to Medtronic in September 2002. We have not yet recognized the full gain on the sale and will not do so until

we successfully transfer pursuant to the contract terms to Medtronic the technology and know-how, including training, related to the manufacture of the CMF product line. We expect this to occur in 2004. However, to date we have recognized approximately \$2,464,000 of the gain as revenue related to the sale of CMF product line to Medtronic under our back-up supply arrangement, which provides for sales of CMF products to Medtronic at cost. Discounts from contractual sales prices in effect prior to the sale of

the CMF product line have been recorded as a reduction to the deferred gain. We also expect an additional \$1,000,000 to \$2,000,000 payment from Medtronic for satisfying the transfer of manufacturing know-how related to the CMF business sale in 2004. This payment will be recognized as additional "gain on sale of assets, related party" upon receipt.

Liquidity and Capital Resources

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

<u>For the three months ended:</u>	<u>March 31, 2004</u>	<u>March 31, 2003</u>
Net cash used in operating activities	\$ (3,205,000)	\$ (3,808,000)
Net cash provided by investing activities	4,357,000	1,513,000
Net cash used in financing activities	\$ (601,000)	\$ (270,000)

Operating Activities

Net cash used in operating activities in the first quarter of 2004 primarily resulted from our negative cash flow from operations.

Net cash used in operating activities in the first quarter of 2003 primarily resulted from our net loss and changes in working capital due to the payment of liabilities relating to bonuses and timing of product shipments.

Investing Activities

Net cash provided by investing activities in the first quarter of 2004 primarily resulted from the receipt of the non-recurring payment of \$5,000,000 for the completion of the CMF Faster Resorbable Polymer clinical research.

The net cash provided by investing activities in the first quarter of 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 first quarters of 2004 and 2003 we used cash to purchase \$309,000 and \$287,000, 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 first quarter of 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 24,000 shares of our common stock for \$67,000 on the open market at a price of \$2.79 per share, and
- the payment of \$176,000 on our long term obligations.

Net cash used in financing activities was offset by proceeds from an Amended Master Security Agreement we entered in September 2003 to provide financing for equipment purchases. In the first quarter of 2004, in connection with this agreement, we issued one promissory note in the principal amount of approximately \$594,000 and it 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.

The net cash used in financing activities in the first quarter of 2003 was primarily related to the repurchase of 51,499 shares of our common stock for \$207,000 on the open market at an average price of \$4.02 per share and payments toward long term obligations of \$72,000.

Short-Term and Long-Term Liquidity

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

	<u>March 31, 2004</u>	<u>December 31, 2003</u>	<u>Difference</u>	<u>%</u>
Cash and cash equivalents	\$ 3,371,000	\$ 2,820,000	\$ 551,000	19.5%
Short-term investments, available for sale	11,762,000	11,448,000	314,000	2.7%
Total cash and short-term investments, available for sale	<u>\$ 15,133,000</u>	<u>\$ 14,268,000</u>	<u>\$ 865,000</u>	<u>6.1%</u>
Current assets	\$ 17,541,000	\$ 16,916,000	\$ 625,000	3.7%
Current liabilities	3,322,000	4,484,000	(1,162,000)	(25.9)%
Working capital	<u>\$ 14,219,000</u>	<u>\$ 12,432,000</u>	<u>\$ 1,787,000</u>	<u>14.4%</u>

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 March 31, 2005. However, in order to provide greater financial flexibility and liquidity, we may need to raise additional capital from time to time.

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

- generating revenues,
- issuing our stock,
- selling, in September 2002, the CMF product line,
- completing clinical research regarding CMF Faster Resorbable Polymer, and
- obtaining long-term financing.

As a result of the non-recurring payment of \$5,000,000 for the completion of CMF clinical research and long-term financing of \$594,000, our liquidity metrics in March 31, 2004 appear superior to those as of December 31, 2003. We increased our cash and short-term investment position by \$865,000 or 6.1% and working capital by \$1,787,000 or 14.4% in comparison at December 31, 2003.

In the second quarter of 2004 we received \$6,720,000 in non-recurring cash proceeds related to the disposal of the non-Japan bioresorbable thin film product line. On or before May 28, 2004 we expect to

receive an additional \$280,000 in satisfaction of a promissory note from MAST. Later in 2004, we anticipate completing the requirements to successfully transfer, pursuant to the contract terms to Medtronic, the technology and know-how, including training, related to the manufacture of the CMF product line and receiving a payment between \$1,000,000 and \$2,000,000.

We believe that our borrowing requirements and debt repayments will continue to involve a relatively small amount of cash. To fund our 2004 expected capital expenditures of \$1,000,000 to \$1,300,000, we intend to borrow under our Amended Master Security Agreement, which has an available credit facility of \$1,500,000.

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, create and expand sales distribution channels, and assuage legal risks and challenges to our business model.

Our capital requirements will depend on numerous factors, including the resources we devote to developing and supporting our products, market acceptance of our developed products, regulatory approvals and other factors. We have positioned ourselves to expand our cash position through actively pursuing grants, licensing, co-development and marketing 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 on Medtronic's (our sole distributor of spine and orthopedics implants) efforts in the bioresorbable spine and orthopedics arena.

If we continue our research and development expenses at or beyond our current level, in our regenerative cell platform for an extended time, we may need to seek partnerships or additional sources of financing beyond our current projections in the future.

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

Contractual Obligations	Total	Payments due by period			
		Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Long-term debt obligations	\$ 2,292,000	\$ 847,000	\$ 1,436,000	\$ 9,000	\$ —
Operating lease obligations	3,100,000	892,000	2,135,000	73,000	—
Total	\$ 5,392,000	\$ 1,739,000	\$ 3,571,000	\$ 82,000	\$ —

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. We believe that our most critical accounting policies relate to the accounting for our revenues, allowance for doubtful accounts, inventory, warranties and income taxes.

Revenue Recognition

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

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

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

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

We earn revenue for performing services under development agreements 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 payments appears reasonably commensurate with the effort expended and (iii) collection of the payment is reasonably assured. Income earned under development agreements is classified under revenues in our statement of operations. The costs associated with development agreements are recorded as research and development expense. 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 from the NIH or (ii) the amount determined by comparing the outputs generated to date versus the total outputs expected to be achieved under the research arrangement.

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

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

Allowance for doubtful accounts

We provide a reserve against our receivables for estimated losses that may result from our customers' inability to pay. These reserves are based on known uncollectible accounts, aged receivables, historical losses and our estimate of our customers' credit-worthiness. Should a customer's account

become past due, we generally place a hold on the account and discontinue further shipments to that customer, minimizing further risk of loss. The likelihood of our recognition of a material loss on an uncollectible account mainly depends on deterioration in the economic financial strength of the customer and the general business environment. Medtronic is our single largest customer, directly accounting for 81.7% and 83.3% of our revenues in the three months ended March 31, 2004 and 2003, respectively.

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

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

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

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

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

In the third quarter of 2003, we determined that some of the products we sold did not meet certain customer expectations, based on criteria previously communicated to our customer. After detecting this matter, we elected to replace all lots of 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.

Accounting for income taxes

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

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

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). The remaining \$48,000 as of March 31, 2004 will be amortized using the straight-line method over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. We expect to record the remaining unearned compensation of \$48,000 in the second quarter of 2004. The amount of unearned compensation expense recorded may decrease if unvested options for which unearned compensation has been recorded are subsequently forfeited.

Recent Accounting Pronouncements

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

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 and in any other documents incorporated by reference into this report. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

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

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

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

Moreover, our operating results can vary substantially from analyst expectations and from previous periodic results for many reasons, including the timing of product introductions and distributor purchase orders. Also, the sale of our craniomaxillofacial "CMF" bone fixation implant and accessory product line, which had represented a large portion of our revenues, plus the 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 industry.

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 preclinical research and possibly clinical trials. We expect to continue to incur operational losses at least through the end of 2004, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Even though our bone fixation product line achieved profitability, development-stage losses related to our development of regenerative cell technology could keep us in a loss position on a consolidated basis for several years.

We are adopting a high-risk strategy

We intend to use the cash we received from the profits of the spine products and the proceeds of the sale of the CMF 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 use our medical device products to deliver regenerative cells where needed in the body (strategic risk), or that our cash resources will be adequate to develop the regenerative cell technology until it becomes profitable (if ever) while still serving the cash needs of our medical device product lines (financial risk). Instead of using the cash to reinvest in our core business, we are using it in one of the

riskiest industries in the economy. This fundamentally changes our risk/reward profile and may make our stock an unsuitable investment for some investors.

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

We are in 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, Inc. We believe that our long-term viability and growth will depend in large part on receiving additional regulatory clearances or approvals for our products and expanding our sales and marketing for our spine and orthopedics bone fixation implants and other new products that may result from our research and development activities. We are presently pursuing product opportunities in spine and orthopedics bone fixation and 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. Most of our cell related products and/or services are at least 3-5 years away.

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

We rely on Medtronic to distribute our products

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

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

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

Medtronic owns more than 7.2% 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 is not constrained in its ability to distribute or develop products competitive to ours, and it is free to pursue existing or alternative technologies in preference to our technology in the spine.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that Medtronic will not develop independently or with third parties products which could compete with ours or that disagreement over rights or technology or other proprietary interests will not occur. To the extent that we choose not to or are unable to enter into future agreements, we would experience increased capital requirements to undertake the marketing or sale of some of our current and future products. There can be no assurance that we will be able to effectively market or sell our current or future products

independently in the absence of such agreements. The loss of the marketing services provided by Medtronic, or the loss of revenues generated by Medtronic, could have a substantial negative effect on the results of our operations and financial condition.

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

We compete with many domestic and foreign companies in developing our technology and products, including medical device, pharmaceutical and biopharmaceutical companies. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than do we. There can be no assurance that our competitors will not succeed in developing alternative technologies and products that are more effective, easier to use or more economical than those which we have developed or are in the process of developing or that would render our technology and products obsolete and non-competitive in these fields. In general, we do not have the legal right to preclude other companies from making 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 us, any of which could have a substantial negative effect on our business. Finally, under the terms of our distribution agreements, Medtronic and our other partners may pursue parallel development of other technologies or products, which may result in a partner developing additional products that will compete with our products.

We also compete with manufacturers of traditional non-bioresorbable implants, such as titanium implants. Doctors have historically been slow to adopt new technologies such as ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires other very significant marketing expenditures or definitive product superiority.

We do not have much manufacturing experience

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

set forth under their agreement, Medtronic may itself then manufacture and sell such product and only pay us royalties on the sales. The resulting loss of payments from Medtronic for the purchase of these products would have a substantial negative effect on the results of our operations and financial condition.

We have to maintain quality assurance certification and manufacturing approvals

The manufacture of our 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 several U.S. patents for the design of our bioresorbable plates and high torque screws and we have filed applications for various additional U.S. patents, as well as certain corresponding patent applications outside the United States, relating to our technology. However, we believe we cannot patent the use of our lactic acid copolymer for surgical implants, nor are our particular implants generally patentable. There can be no

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

Our regenerative cell technology license agreement with the Regents of the University of California contains certain developmental milestones, which if not achieved could result in the loss of exclusivity or loss of the license rights. The loss of such rights could significantly impact our ability to continue the development of the regenerative cell technology and/or commercialize related products. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested.

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.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office 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. 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 European Patent Office, Australia, Japan, Canada, China, Korea, and Mexico and we have published other international patent applications.

We are subject to intensive FDA regulation

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

The regulatory process can be lengthy, expensive and uncertain. Before any new medical device may be introduced to the 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 products and we are constantly engaged in the process of obtaining additional clearances for new and existing products. There can be no guarantee that we will be able to

maintain our existing 510(k) clearances or that it will be able to obtain the necessary 510(k) clearances or PMA approvals to market and manufacture our other products in the United States for their intended use on a timely basis, if at all. The FDA approval process may be particularly problematic for our regenerative cell technology products in view of the novel nature of the technology. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a substantial negative effect on the results of our operations and financial condition.

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

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

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

We may need to raise more cash in the future

If we do not increase our sales quickly enough or if we choose to invest additional cash in areas of promise, we may be required to seek additional capital to finance our operations in the future. As of March 31, 2004, we had \$15,133,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. The acquisition of StemSource, Inc. (StemSource) has and will continue to result in a substantial requirement for research and development expenses. Other than our current equipment financing lines of credit, we currently have no commitments for any additional debt or equity financing, and there can be no guarantee that adequate funds for our operations from any additional debt or equity financing, our operating revenues, arrangements with distribution partners or from other sources will be available when needed or on terms attractive to us. The inability to obtain sufficient funds may require us to delay, scale back or eliminate some or all of our research or product development programs, manufacturing operations, clinical studies or regulatory activities or to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, and could have a substantial negative effect on the results of our operations and financial condition.

We depend on a few key officers

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

We may undertake business acquisitions which will present risks associated with integrating new businesses

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

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

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

We may not have enough product liability insurance

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

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

Our Amended and Restated Certificate of Incorporation and Bylaws contain certain provisions that could prevent or delay the acquisition of the Company by means of a tender offer, proxy contest or otherwise, or could discourage a third party from attempting to acquire control of us, even if such events would be beneficial to the interests of our stockholders. Such provisions may have the effect of delaying, deferring or preventing a change of control of us and consequently could adversely affect the market price

of our shares. Also, in 2003 we adopted a Stockholder Rights Plan, of the kind often referred to as a poison pill. The purpose of the Stockholder Rights Plan is to prevent coercive takeover tactics that may otherwise be utilized in takeover attempts. The existence of such a rights plan may also prevent or delay the change in control of the Company which could adversely affect the market price of our shares.

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

In the United States, our stock is traded through the Pink Sheets, which results in an illiquid market. Investors trading in this market may be disadvantaged in comparison to investors trading in our stock in Europe. Our stock had been traded on the Neuer Markt segment of the Frankfurt Stock Exchange, but the Neuer Markt closed in 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 \$11,762,000 as of March 31, 2004, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to market rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at March 31, 2004, for example, and assuming average investment duration of eight 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 transact business in various foreign countries, settlement amounts are usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro or other currencies. Based on our cash balances and revenues derived from markets

other than the United States for the three months ended March 31, 2004, a hypothetical 10% adverse change in the Euro against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

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

Item 4. Controls and Procedures

Christopher J. Calhoun, who is our chief executive 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)), has concluded that as of March 31, 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. The Company is not currently a party to any material legal proceeding.

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchase of Equity Securities

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
January 1 – 30, 2004	262,602(1)	\$ 3.72	N/A	N/A
February 1 – 29, 2004	24,000(2)	\$ 2.79	24,000	32,918
March 1 – 31, 2004	—	—	—	—
Total	<u>286,602</u>	<u>\$ 3.64</u>	<u>24,000</u>	<u>32,918</u>

(1) Repurchased from one stockholder pursuant to his exercise of a put option available to him under the 2002 merger agreement between the Company and StemSource Inc.

(2) 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 is August 10, 2004.

Item 3. Defaults Upon Senior Securities

None

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

None

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

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

Staff

As of March 31, 2004, we had 94 full-time employees, comprised of 42 employees in research and development, 22 employees in manufacturing, 16 employees in management and finance and administration and 14 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

15.1 Letter re unaudited interim financial information

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31.1 Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 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 furnished, on Form 8-K, Item 12, during this fiscal quarter, disclosure of announcements 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.

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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 May 17, 2004.

MACROPORE BIOSURGERY, INC.

By: /s/ Christopher J. Calhoun
Christopher J. Calhoun
Chief Executive Officer and Principal Financial Officer

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EXHIBIT INDEX

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Letter Re Unaudited Interim Financial Information

May 17, 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 April 30, 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 Principal Executive Officer and Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Christopher J. Calhoun, certify that:

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

Date: May 17, 2004

/s/ Christopher J. Calhoun

Christopher J. Calhoun,

Chief Executive Officer and Principal Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002**CHRISTOPHER J. CALHOUN hereby certifies that:**

1. He is the Chief Executive Officer and Principal Financial Officer of MacroPore Biosurgery, Inc.
2. The Form 10-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.
3. 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: May 17, 2004

By: /s/ Christopher J. Calhoun
Christopher J. Calhoun
*Chief Executive Officer and Principal
Financial Officer*
