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 June 30, 2004

OR

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

For the transition period from to

Commission file number 0-32501

MacroPore Biosurgery, Inc.

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

Delaware	**33-0827593**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6740 Top Gun Street, San Diego, California	**92121**
(Address of principal executive offices)	(Zip code)

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

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

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

As of July 23, 2004, there were 13,930,834 shares of MacroPore Biosurgery, Inc. common stock outstanding.

MACROPORE BIOSURGERY, INC.

INDEX

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Report of Independent Registered Public Accounting Firm

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

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

We conducted our reviews in accordance with standards established by the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards of the Public Company Accounting Oversight Board (United States), the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

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

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

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

/s/ KPMG LLP

San Diego, California
July 27, 2004

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	As of June 30, 2004 (Unaudited)	As of December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 2,093,000	$ 2,820,000
Short-term investments, available-for-sale	15,940,000	11,448,000
Accounts receivable, net of allowance for doubtful accounts of $32,000 and $62,000 in 2004 and 2003, respectively	1,457,000	1,291,000
Inventories	463,000	831,000
Other current assets	605,000	526,000
Total current assets	20,558,000	16,916,000

Property and equipment, net	3,554,000	3,822,000
Other assets	209,000	332,000
Intangibles, net	2,257,000	2,392,000
Goodwill	4,387,000	4,627,000
Total assets	$ 30,965,000	$ 28,089,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,427,000	$ 3,767,000
Current portion of long-term obligations	886,000	717,000
Total current liabilities	3,313,000	4,484,000
Deferred gain on sale of assets, related party	7,383,000	7,539,000
Deferred gain on sale of assets	6,266,000	—
Deferred income.	58,000	—
Long-term obligations, less current portion	1,328,000	1,157,000
Total liabilities	18,348,000	13,180,000
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2004 and 2003	—	—
Common stock, $0.001 par value; 95,000,000 shares authorized; 16,800,018 and 16,777,644 shares issued and 13,930,834 and 14,195,062 shares outstanding in 2004 and 2003, respectively	17,000	17,000
Additional paid-in capital	74,734,000	74,698,000
Unearned compensation	—	(109,000)
Accumulated deficit	(51,705,000)	(49,385,000)
Treasury stock, at cost	(10,405,000)	(9,362,000)
Treasury stock receivable	—	(976,000)
Accumulated other comprehensive income (loss)	(24,000)	26,000
Total stockholders' equity	12,617,000	14,909,000
Total liabilities and stockholders' equity	$ 30,965,000	$ 28,089,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
Revenues:				
Sales to related party	$ 894,000	$ 2,585,000	$ 2,815,000	$ 4,191,000
Sales to third parties	636,000	318,000	977,000	641,000
Research grant	10,000	—	100,000	—
	1,540,000	2,903,000	3,892,000	4,832,000
Cost of revenues:				
Cost of revenues (including stock based compensation expense of $1,000 and $3,000 for the three months ended June 30, 2004 and 2003; $3,000 and $6,000 for the six months ended June 30, 2004 and 2003, respectively)	314,000	787,000	1,191,000	1,426,000
Inventory provision	—	—	242,000	—
Gross profit	1,226,000	2,116,000	2,459,000	3,406,000
Operating expenses:				
Research and development, excluding stock based compensation expense of $32,000 and $20,000 for the three months ended June 30, 2004 and 2003, respectively; $32,000 and $39,000 for the six months ended June 30, 2004 and 2003, respectively	2,668,000	2,107,000	5,175,000	4,258,000
Sales and marketing, excluding stock based compensation expense of $11,000 and $18,000 for the three months ended June 30, 2004 and 2003, respectively; $22,000 and $36,000 for the six months ended June 30, 2004 and 2003, respectively	654,000	1,004,000	1,612,000	2,299,000
General and administrative, excluding stock based compensation	1,575,000	951,000	2,801,000	1,999,000

expense of $36,000 and $174,000 for the three months ended June 30, 2004 and 2003, respectively; $71,000 and $350,000 for the six months ended June 30, 2004 and 2003, respectively				
Stock based compensation (excluding cost of revenues stock based compensation)	79,000	212,000	125,000	425,000
Restructuring charge	70,000	—	70,000	—
Total operating expenses	5,046,000	4,274,000	9,783,000	8,981,000
Other income (expense):				
Gain on the sale of assets, related party	—	—	5,000,000	—
Interest income	57,000	105,000	112,000	247,000
Interest and other (expenses), net	(47,000)	(6,000)	(108,000)	(11,000)
Net loss	(3,810,000)	(2,059,000)	(2,320,000)	(5,339,000)
Other comprehensive loss: unrealized holding loss	(41,000)	(11,000)	(50,000)	(52,000)
Comprehensive loss	$ (3,851,000)	$ (2,070,000)	$ (2,370,000)	$ (5,391,000)
Basic and diluted net loss per share	$ (0.27)	$ (0.14)	$ (0.17)	$ (0.37)
Shares used in calculating basic and diluted net loss per share	13,920,186	14,540,734	13,933,111	14,532,716

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	Six Months Ended June 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	$ (2,320,000)	$ (5,339,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	866,000	822,000
Inventory provision	242,000	—
Bad debt provision (reduction)	(19,000)	—
Restructuring charge	70,000	—
Amortization of gain on sale of assets, related party	(156,000)	(788,000)
Amortization of gain on sale of assets	(189,000)	—
Gain on sale of assets, related party	(5,000,000)	—
Stock based compensation	119,000	431,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(147,000)	52,000
Inventories	(51,000)	96,000
Other current assets	(79,000)	268,000
Other assets	35,000	73,000
Accounts payable and accrued expenses	(413,000)	(574,000)
Deferred income	58,000	—
Net cash used in operating activities	(6,984,000)	(4,959,000)
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	30,006,000	29,106,000
Purchases of short-term investments	(34,548,000)	(25,892,000)
Proceeds from sale of assets, related party	5,000,000	—
Cost of sale of assets, related party	—	(37,000)
Proceeds from the sale of assets, net	6,960,000	—
Purchases of property and equipment	(463,000)	(531,000)
Acquisition costs	(21,000)	(344,000)
Proceeds from the sale of impaired assets	—	46,000
Net cash provided by investing activities	6,934,000	2,348,000
Cash flows from financing activities:		
Principal payments on long-term obligations	(382,000)	(173,000)
Proceeds from long-term obligations	722,000	—
Proceeds from the exercise of employee stock options	26,000	11,000
Purchase of treasury stock	(1,043,000)	(249,000)

Proceeds from sale of treasury stock	—	2,000
Net cash used in financing activities	(677,000)	(409,000)
Net decrease in cash	(727,000)	(3,020,000)
Cash and cash equivalents at beginning of period	2,820,000	5,108,000
Cash and cash equivalents at end of period	$ 2,093,000	$ 2,088,000
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 86,000	$ 63,000
Taxes	11,000	11,000
Supplemental schedule of non-cash investing activities		
Increase in cost of acquisition	$ —	$ (361,000)

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

1. Basis of Presentation

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

2. Use of Estimates

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

3. Stock Based Compensation

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

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

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

The weighted average estimated fair values of stock options granted during the three months and six months ended June 30, 2004 were $3.27 and $3.27 per share, respectively. The weighted average estimated fair values of stock options granted during the three and six months ended June 30, 2003 were $2.81 and $3.64 per share, respectively. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
Expected term	7 years	8 years	7 years	7 – 8 years
Interest rate	3.89 - 4.35%	2.84 – 3.47%	3.31% - 4.35%	2.84% - 3.60%
Volatility	87.0%	95.0%	87.0% - 89.3%	95.0% – 98.0%
Dividends	—	—	—	—

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss:				
As reported	$ (3,810,000)	$ (2,059,000)	$ (2,320,000)	$ (5,339,000)
Add: Stock based employee compensation expense included in reporting net loss, net of related tax effects	48,000	215,000	96,000	431,000
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(629,000)	(1,161,000)	(1,227,000)	(2,504,000)
Pro forma	$ (4,391,000)	$ (3,005,000)	$ (3,451,000)	$ (7,412,000)
Loss per common share:				
As reported	$ (0.27)	$ (0.14)	$ (0.17)	$ (0.37)
Pro forma	$ (0.32)	$ (0.21)	$ (0.25)	$ (0.51)

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

4. Short-Term Investments

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

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

Management reviews the carrying values of 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 is recorded on the settlement date.

At June 30, 2004, the fair value of the Company’s short-term investments that are below carrying cost is immaterial.

5. Inventories

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

During the 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 back-up supplier for the craniomaxillofacial “CMF” product line. The Company sold the assets related to this product line to an affiliate of Medtronic, a shareholder of the Company, on September 30, 2002. In April of 2004, Medtronic indicated that it would no longer purchase CMF inventory from the Company under the back-up supply arrangement, leading to the determination that the remaining CMF inventory on hand would not be recoverable.

6. Long-Lived Assets

In accordance with SFAS No. 144 “Accounting for Impairment or Disposal of Long-Lived Assets,” the Company assesses certain of its long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recovered. An impairment occurs when the undiscounted cash flows expected to be generated by an asset are less

than its then carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. During the six months ended June 30, 2004 and 2003, the Company had no impairment losses.

7. Revenue Recognition

Product Sales

The Company sells its products to distributors, and before the sale of Thin Film product line in May 2004, also sold products to hospitals. Before the sale of the Thin Film product line in May, 2004, revenue from sales to hospitals was 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. On occasion, the Company offers extended payment terms to customers. The Company does not recognize revenues under these arrangements until the payment becomes due or, if earlier, is received.

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

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

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

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. The Company has recognized in 2002 and 2003, and during 2004, a portion of the deferred gain upon the sale of the CMF products to Medtronic under the Company's back-up supply arrangement, which 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 Medtronic acknowledges that the technology and know-how transfer has been completed pursuant to the contract terms, which we expect to occur in 2004.

In May 2004, the Company sold most, but not all, of its Thin Film product line. Refer to note 13.

Research

The Company earns revenue for performing tasks under research agreements with both commercial enterprises and

governmental agencies like the National Institutes of Health ("NIH"). Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, the amount of the milestone payments appear reasonably commensurate with the effort expended and collection of the payment is reasonably assured.

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

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

Revenue earned under development agreements is classified as research grant revenues in the Company's statements of operations. During the three and six months ended June 30, 2004, the Company recognized NIH grant revenue of $10,000 and $100,000 and incurred qualifying costs of $18,000 and $117,000, respectively. 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.

Other revenues

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

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

8. Warranty

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

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

	Balance at January 1	Additions (charges to expenses)	Claims	Balance at June 30
2004:				
Warranty reserve	$ 267,000	$ 36,000	$ (251,000)	$ 52,000
2003:				
Warranty reserve	$ —	$ —	$ —	$ —

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

9. Earnings (Loss) Per Share

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

The Company has excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the three and six months ended June 30, 2004 and 2003 as their inclusion would be antidilutive. The number of potentially dilutive common shares excluded from the calculations of diluted loss per share was 5,199,929 and 5,199,929 for the three and six months ended June 30, 2004, respectively, and 4,902,135 and 4,902,135 for the three and six months ended June 30, 2003, respectively.

10. Long-term Debt

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

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

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

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

For the years ended December 31,

2004	$ 452,000
2005	854,000
2006	523,000
2007	337,000
2008	48,000
	$ 2,214,000

The interest expense for the three and six months ended June 30, 2004 was $47,000 and $86,000, respectively.

11. Restructuring Event

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

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

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

2004. This additional provision was recorded as restructuring expense. The Company will continue to 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 six months ended June 30, 2004:

	December 31, 2003	Charged to Expense*	Costs Paid	Adjustments to Liability**	June 30, 2004
Lease termination	$ 153,000	$ 70,000	$ (67,000)	$ (5,000)	$ 151,000

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 June 30, 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.

* All amounts recorded as “Restructuring charge” in the accompanying statement of operations.

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

12. Gain on Sale of Assets, Related Party

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

13. Sale of Bioresorbable Thin Film Product Line

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

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

- $200,000, payable only upon receipt of 510K clearance from the U.S. Food and Drug Administration (“FDA”) for a hernia wrap product currently under development and subject to FDA clearance, and

- $2,000,000 on or before the earlier of (i) May 31, 2005, known as the “Settlement Date,” or (ii) 15 days after the date upon which MAST has hired a Chief Executive Officer, provided the Chief Executive Officer has held that position for at least four months and meets other requirements specified in the sale agreement. Note that clause (ii) effectively means that the Company will not receive payment of $2,000,000 before May 31, 2005 unless MAST has hired a Chief Executive Officer on or before January 31, 2005 (four months prior to the Settlement Date). Moreover, in the event that MAST does not hire a Chief Executive Officer on or before January 31, 2005, MAST may (at its sole option and subject to the requirements of the sale agreement) alternatively provide the Company with a 19% equity interest in the MAST business that is managing the Thin Film assets at May 31, 2005 in lieu of making the $2,000,000 payment.

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

	Carrying Value Prior to Disposition
Inventory (finished goods)	$ 177,000
Manufacturing and development equipment	212,000
Intellectual property rights	—
Goodwill	240,000
	$ 629,000

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

- For a period of up to one year after the closing date, provide up to 300 hours of training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line,

- For a period of up to one year after the closing date, act as a back-up supplier to MAST, and provide, in almost all cases, such product at the Company’s manufacturing cost, and

- For a period of up to one year after the closing date, supply or cause its suppliers to provide MAST with specified raw material at the Company's cost.

Because of these additional performance requirements, the Company did not initially recognize any gain on sale of the Thin Film assets in the accompanying statement of operations. Instead, the Company initially recorded approximately $6,455,000 as deferred gain on sale of assets in the accompanying balance sheet. The amount recorded as deferred gain on sale of assets does not include the two potential elements of contingent consideration described above, which will only be recognized when the contingencies are resolved.

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

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

In addition, the Company has been recognizing (and will continue to recognize) a portion of the deferred gain as revenues as and when the Company sells products to MAST under the back-up supply agreement. This is necessary to record revenues at fair value under EITF 00-21 (and gross margin) at the amount the Company would normally charge for selling the same product in an unencumbered transaction. During the second quarter of 2004, the Company recognized $189,000 in deferred gain as revenues.

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

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

(a) Spinal field, exclusive at least until 2012, and

(b) Field of regenerative medicine, non-exclusive on a perpetual basis

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

- If MAST exercises its option on or before May 31, 2005, the purchase price will be $3,000,000, although such amount may be reduced if MAST exercises its option within forty-five days of the Company entering into a business arrangement in Japan that involves the Company receiving an upfront, non-refundable license fee. On July 16, 2004, MacroPore did enter into a business arrangement in Japan with Senko Medical Trading Co., and received an upfront license fee of $1,500,000 (see note 15 below).

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

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

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

14. Composition of Certain Financial Statement Captions

Inventories

	June 30, 2004 (Unaudited)	December 31, 2003
Raw materials	$ 255,000	$ 399,000
Finished goods	208,000	432,000

	$ 463,000	$ 831,000

Property and Equipment, net

	June 30, 2004 (Unaudited)	December 31, 2003
Office and computer equipment	$ 2,057,000	$ 1,922,000
Manufacturing and development equipment	3,977,000	3,685,000
Leasehold improvements	1,941,000	1,905,000
	7,975,000	7,512,000
Less accumulated depreciation and amortization	(4,421,000)	(3,690,000)
	$ 3,554,000	$ 3,822,000

Other Current Assets

	June 30, 2004 (Unaudited)	December 31, 2003
Prepaid	$ 422,000	$ 316,000
Other receivables.	73,000	146,000
Accrued interest receivable	110,000	64,000
	$ 605,000	$ 526,000

Accounts Payable and Accrued Expenses

	June 30, 2004 (Unaudited)	December 31, 2003
Accounts payable	$ 568,000	$ 520,000
Accrued bonus	456,000	631,000
Accrued vacation	515,000	468,000
Accrued expenses	685,000	752,000
Accrued restructuring expense	151,000	153,000
Warranty reserve	52,000	267,000
Share repurchase payable	—	976,000
	$ 2,427,000	$ 3,767,000

Intangibles, net

	June 30, 2004 (Unaudited)	December 31, 2003
Intangibles	$ 2,695,000	$ 2,695,000
Less accumulated amortization	(438,000)	(303,000)
	$ 2,257,000	$ 2,392,000

The amortization expense of intangibles for the three and six months ended June 30, 2004 was $67,000 and $135,000, respectively.

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

2004	$ 134,000
2005	269,000
2006	269,000
2007	269,000
2008	269,000
Thereafter	1,047,000
	$ 2,257,000

Deferred Income

During the second quarter, in addition to other shipments of Thin Film products to MAST, the Company sold MAST approximately 13,000 units of Thin Film product. The product was supplied in accordance with the terms of the back-up supply arrangement contained in the MAST Asset Purchase Agreement (see note 13), except that the Company provided MAST extended payment terms.

In regards to this specific shipment, the Company decided to grant MAST payment terms that are longer than those given to the Company's other customers. Consistent with the Company's accounting policy (see note 7), the Company has not recognized the revenues and gross margin associated with this product sale during the second quarter of 2004. Instead, the Company has recorded deferred income in the amount of $58,000 (representing the inherent gross margin before any drawdown from deferred gain on sale of assets). Such revenue and gross profit will be recognized in the statement of operations when payment from MAST becomes due or, if earlier, is received.

15. Subsequent Event

On July 16, 2004, the Company entered into an exclusive Distribution Agreement with Senko Medical Trading Co. ("Senko"). Under this agreement, the Company granted Senko exclusive distribution rights to sell and distribute certain Thin Film products in Japan.

The term of the Distribution Agreement with Senko commences upon "Commercialization." In simplest terms, Commercialization occurs when one or more thin film product registrations are completed with the Japanese Ministry of

Health, Labor and Welfare ("MHLW"). Following Commercialization, the Distribution Agreement has duration of five years and is renewable for an additional five years thereafter at the mutual consent of both the Company and Senko.

At the inception of this arrangement, the Company received a $1,500,000 license fee. This license fee will be classified as deferred income on the balance sheet and recognized as revenues systematically over the terms of the distribution agreement. The Distribution Agreement contains certain provisions that could require the Company to return a portion of the upfront license fee. That is, if it is determined in good faith by the Company and Senko that Commercialization of the thin film product is unobtainable, then 50% of the $1,500,000 license fee will be returned to Senko. Also, if the Company terminates the Distribution Agreement at any time within the initial three (3) years post Commercialization, for any reason except for material breach by Senko, then a pro-rata share of the license fee will be returned to Senko.

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

- Upon the Company notifying Senko of completion of the initial regulatory application of the thin film product to MHLW, the Company is entitled to a nonrefundable payment of $1,250,000.

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

The Distribution Agreement also provides for the Company to supply certain products to Senko at fixed prices over the life of the agreement once the Company has received approval to market these products in Japan. In addition to the product price, Senko will also be obligated to pay the Company an amount in a royalty equal to 5% of the gross sales value of any products Senko sells to its customers.

The Distribution Agreement is assignable to MAST if and when MAST elects to exercise its Purchase Right (see note 13). To protect Senko from MAST's potential non-performance following the assignment of the Distribution Agreement, the Company has provided Senko with certain guarantees.

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.

Overview

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

- *Regenerative cell technology:* 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.

- *Bioresorbable 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 applications (to support bone) and distribute the spine and orthopedic bioresorbable implants exclusively through Medtronic, Inc. ("Medtronic"). We also are preparing to distribute thin film bioresorbable implants in Japan through Senko Medical Trading Co. Ltd.

Our strategy is to continue the support of growth in spine and orthopedic implant revenues and invest in the research and development of our regenerative cell technology. Strategically, we believe our research and development investment will build a pipeline of cell technology products that target the high growth and demographically driven markets such as cardiovascular disease, and spine and orthopedic disorders. In some cases we intend to form strategic partnerships related to our regenerative cell technology platform to speed development and to better leverage this technology.

Key corporate developments that we expect will occur in the second half include the receipt of the milestone payments outlined in the discussions below and the release of data from two pre-clinical, regenerative cell technology studies that examined the application of adipose-derived regenerative cells for myocardial infarction (heart attack). We will release the results of our large animal study in September, 2004, at the Transcather Cardiovascular Therapeutics meeting and expect to release the results of our small animal study in the fourth quarter.

After the close of the second quarter of 2004, we were advised that we would be awarded up to $850,000 of additional funding to continue with the second phase of our National Institutes of Health (NIH) Small Business Innovation Research (SBIR) grant to study of the potential role of adipose-derived regenerative cells in treating heart attack subject to availability of NIH funds and satisfactory progress. We expect to receive the funding under this grant during 2004 and 2005.

In May 2004, we sold the non-Japanese commercialization rights to our bioresorbable thin film surgical implant product line to MAST Biosurgery AG ("MAST") and a subsidiary of MAST. We received $7,000,000 in cash, and disposed of assets with a carrying value of $629,000. We also are entitled to receive an additional $2,000,000 in cash or a 19% interest in MAST on or before May 31, 2005. We did not immediately recognize the gain on the sale of these thin film assets in the income statement because there are additional services we must perform under the disposal arrangement. We expect to provide these services through the second quarter of 2005.

In July 2004, we granted Senko Medical Trading Co. ("Senko") exclusive sales and distribution rights to the thin film product line in Japan. In return for these rights, we received from Senko an upfront $1,500,000 license fee, and will collect an additional $1,250,000 upon submission of a regulatory application to the Japanese Ministry of Health, Labour and Welfare ("MHLW"), and $250,000 upon product approval by the MHLW. Assuming we receive product approval from the MHLW, Senko further has agreed to purchase a minimum quantity of thin film product from us, as well as pay us amounts in royalties on Senko's gross revenues for a three-year period following initiation of commercialization of the products in Japan. The initiation of commercialization is expected to take a minimum of 18 months or longer. In the event that both parties mutually agree that commercialization cannot be achieved, we would be required to return 50% of the upfront license fee to Senko.

MAST holds an option to acquire our rights in the thin film product line for the Japanese market, including our distribution agreement with Senko. If MAST should exercise the option, they would have to pay us up to $3,000,000. Moreover, we would be entitled to a 50% share in MAST's gross profits and royalties from Senko for a three-year period following initiation of commercialization of the products in Japan. Even if MAST exercises its option, we will continue to hold an exclusive worldwide license for bioresorbable thin films for the spinal market and a perpetual nonexclusive worldwide license to bioresorbable thin films in connection with regenerative cell technology.

Total revenues for the three months ended June 30, 2004 were $1,540,000 compared to $2,903,000 for the same period in 2003, a decrease of 47.0%. Total revenues for the six months ended June 30, 2004 were $3,892,000 compared to $4,832,000 for the same period in 2003, a decrease of 19.5%. The decrease in revenues for the three and six months ended June 30, 2004 was primarily the result of Medtronic's stocking patterns in spine and orthopedic products and the full implementation of CMF production in 2004 by Medtronic. Medtronic still remains our largest customer, accounting for 72.3% of our revenues in the six months ended June 30, 2004. In the third and fourth quarters of 2003, Medtronic placed initial stocking orders for our newly developed HYDROSORB™ products. In hindsight, these orders supplied Medtronic with sufficient inventories through at least the first half of 2004. Our sales of HYDROSORB™ spine and orthopedic implants to Medtronic in the second quarter of 2004 were significantly below our expectations. Based on information available at this time, we are not able to reliably project HYDROSORB™ product revenues and as a result, on July 19, 2004, we retracted our previously stated revenue guidance for 2004, and will provide an update only if sufficient information should become available.

Net loss for the three months ended June 30, 2004 was $3,810,000 compared to a net loss of $2,059,000 for the same period in 2003. Net loss for the six months ended June 30, 2004 was $2,320,000, after the $5,000,000 gain related to the completion of the clinical research regarding Faster Resorbing Polymers. Adjusted net loss before the gain was $7,320,000 compared to a net loss of $5,339,000 for the same period in 2003 as outlined in the table below.

For the six months ended:	June 30, 2004	June 30, 2003
Net loss GAAP:	$ (2,320,000)	$ (5,339,000)
Less: Gain on the sale of asset, related party	(5,000,000)	—
Adjusted net loss (1)	$ (7,320,000)	$ (5,339,000)

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

The increase in the adjusted net loss for the three and six months ended June 30, 2004 is attributable primarily to a decrease in HYDROSORB™ revenues, an increase in research and development expenses related to our regenerative cell technology program, and an increase in general and administrative expenses, compared to the same period in 2003.

We ended the second quarter of 2004 with $18,033,000 in cash and cash equivalents and short term investments, which includes the $7,000,000 payment from MAST. We have since received $1,500,000 from Senko, and have been awarded a grant of up to $850,000 to continue with the second phase of our NIH SBIR study of the potential role of adipose-derived regenerative cells in treating heart attack. We expect to receive the funding under this grant during 2004 and 2005. Additionally, in 2004 we expect to receive a $1,250,000 milestone from Senko for submitting a thin film regulatory application with the MHLW and a $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. 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, and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through June 30, 2005.

Disposition of Product Line

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

- $200,000, payable only upon receipt of 510K clearance from the U.S. Food and Drug Administration for a hernia wrap product, and

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

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

Because of these and other additional performance requirements, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately $6,455,000 as deferred gain on sale in the balance sheet. The amount recorded as deferred gain on sale does not include the potential contingent consideration described above, which will only be added to the deferred gain on sale when the contingencies are resolved. However, we have recognized the effect of the potential 19% interest that we will receive back in the thin film assets if certain events occur. Accordingly, we recorded 19% of the carrying value or $124,000 of the assets transferred as "retained interest in transferred assets." As of June 30, 2004, we classified this asset as a component of "other assets."

We do not expect to complete our performance obligations until the second quarter of 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. However, we recognized $189,000 of the deferred gain as revenues related to the sale of thin film products to MAST under the back-up supply agreement at cost. This is necessary to state revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction.

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

(a) Spinal field, exclusive until 2012, and

(b) Field of regenerative medicine, non-exclusive on a perpetual basis

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

- If MAST exercises its option on or before May 31, 2005, the purchase price will be $3,000,000, subject to reduction if we enter into a business arrangement in Japan and receive an upfront, non-refundable license fee less than 45 days before the option exercise. On July 16, 2004, we entered into a business arrangement in Japan with Senko Medical Trading Co., and received an upfront license fee of $1,500,000.

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

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

Results of Operations

Three months and six months ended June 30, 2004 compared to three months and six months ended June 30, 2003

Revenues

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
Spine and orthopedics products	$ 886,000	$ 1,972,000	$ (1,086,000)	(55.1)%	$ 2,533,000	$ 2,965,000	$ (432,000)	(14.5)%
Thin film products:								
Product sales (non-MAST related)	222,000	317,000	(95,000)	(30.0)%	559,000	636,000	(77,000)	(12.1)%
Product sales to MAST	223,000	—	223,000	—	223,000	—	223,000	—
Amortization of gain on sale (MAST)	189,000	—	189,000	—	189,000	—	189,000	—
Total thin film	634,000	317,000	317,000	100.0%	971,000	636,000	335,000	52.7%
Craniomaxillofacial (CMF) products:								
Product sales	3,000	205,000	(202,000)	(98.5)%	126,000	438,000	(313,000)	(71.2)%
Amortization of gain on sale	5,000	408,000	(403,000)	(98.8)%	156,000	788,000	(632,000)	(80.3)%
Total craniomaxillofacial	8,000	613,000	(605,000)	(98.7)%	282,000	1,226,000	(944,000)	(77.0)%
Research grant (NIH)	10,000	—	10,000	—	100,000	—	100,000	—
Regenerative cell storage services	2,000	1,000	1,000	100.0%	6,000	5,000	1,000	20.0%
Total	$ 1,540,000	$ 2,903,000	$ (1,363,000)	(47.0)%	$ 3,892,000	$ 4,832,000	$ (940,000)	(19.5)%
% attributable to Medtronic	58.1%	89.0%	(30.9)%		72.3%	86.7%	(14.4)%	

- Spine and orthopedic revenues represent sales of bioresorbable implants utilized in spine and orthopedic surgical procedures to maintain the relative position of bone graft material when used in conjunction with traditional rigid fixation. In the third and fourth quarters of 2003, Medtronic (our sole

distributor of spine and orthopedic products) placed initial stocking orders for our newly developed HYDROSORB™ products. We had anticipated that demand for these products from Medtronic's customers would draw down these inventories sufficiently to require Medtronic to buy substantial additional amounts in the second quarter of 2004. In fact, sales to Medtronic in the second quarter of 2004 were well below our expectations. This led us to conclude that our visibility of short-term customer demand was not reliable enough to support current or prior issued revenue projections, and on July 19, 2004 we withdrew our previously stated revenue guidance for 2004. We continue to believe that, in view of these products' clinical advantages over metal and allograft implants, the market for these products should improve and grow; but the timing and extent of this change is dependent on the efforts of Medtronic, and on factors such as physician inertia. In order for our strategy of generating cash flow from our biomaterials platform to finance research and development of our regenerative cell technology to succeed, it is important for the HYDROSORB™ products to succeed in the market.

- Thin film products revenue represents sales of SurgiWrap™ bioresorbable thin film used to support and reinforce soft tissues and to minimize tissue attachment to the device in case of contact with the viscera (organs of the body). Revenue increases in the 2004 periods primarily related to the disposition of the thin film product line to MAST. Specifically, $412,000 in Thin Film product sales to MAST relates to an initial stocking order under terms of the back-up supply agreement. Of this amount $189,000 relates to the amortization of deferred gain on sale which is necessary to state our revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction.

- The CMF products revenue represents sales of the CMF line of products used for trauma and reconstructive procedures in the midface and craniofacial skeleton (the head and skull). The decrease in CMF product revenue in the 2004 periods 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 back-up supply arrangement.

- The research grant revenue relates to an agreement with the National Institutes of Health ("NIH"). Under this arrangement, the NIH reimbursed us for $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 were required to: (i) demonstrate that we incurred "qualifying expenses," as defined in the grant agreement between the NIH and us, (ii) maintain a system of controls, whereby we can accurately track and report all expenditures related solely to research on Adipose-Derived Cell Therapy for Myocardial Infarction, and (iii) file appropriate forms and follow appropriate protocols established by the NIH. As of June 30, 2004, we had completed the Phase I of the research grant with the NIH and we have incurred the full amount of qualifying expenses under the research grant.

  The U.S. government obtains certain rights over any commercial products or intellectual property related to adipose-derived cell therapy for myocardial infarction developed using funds provided under the NIH grant. The U.S. government does not, however, obtain any rights to pre-grant or post-grant commercial products or intellectual property developed independent of NIH funds. 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 related to adipose-derived cell therapy for myocardial infarction 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.

- The decrease in revenue attributable to Medtronic, which owns approximately 7.2% of our outstanding common stock, in the 2004 periods as compared to the same periods in 2003, relates to an increase in thin film revenue from MAST and the decrease of spine and orthopedic and CMF revenues from Medtronic in 2004. The CMF product line was fully transitioned to Medtronic in 2004.

The future: We sell our spine and orthopedic products exclusively to Medtronic at fixed selling prices that are subject to adjustment biannually (which are based on Medtronic's selling prices to its customers) and our revenue from this product line is dependent upon the adoption of our technology and Medtronic's marketing and pricing strategies. To increase our revenues from spine and orthopedic products we depend largely on Medtronic's ability to advance the market share for bioresorbable materials for spine and orthopedic markets. Additionally, because our products -particularly HYDROSORB™- are relatively new to the market, and because our internal estimates of second quarter 2004 HYDROSORB™ sales were proven wrong, we have now concluded that we are currently unable to accurately forecast Medtronic's demand. Therefore, in July 2004, we retracted our previously stated revenue guidance for 2004 until more data becomes available.

We expect revenue from thin film products to initially increase in the third quarter as we recognize approximately $1,188,000 in revenue from MAST initial stocking orders that were shipped in the second quarter of 2004 but accounted for as deferred income, in accordance with our revenue recognition policies. We deferred the recognition of this income because we extended the payment terms on certain shipments to MAST beyond our normal policy. After this initial stocking order, we expect revenue from the thin film product line to decline as MAST begins to assume the manufacturing process.

We expect the percentage of revenues attributable to Medtronic to increase as sales of thin film become a lower percentage of our overall sales revenue, although this may change when commercialization of the thin film products in Japan occurs and we begin thin film shipments to Senko.

We were successful with Phase I of the research on Adipose-Derived Cell Therapy for Myocardial Infarction as defined by the NIH grant agreement. Therefore, we became entitled to receive up to $850,000 in additional grants from the NIH for Phase II research for which we expect to incur "qualifying expenses" in 2004 and 2005 subject to availability of NIH funds and satisfactory progress.

Cost of revenues

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%

Cost of revenues:									
Cost of revenues	$ 314,000	$ 787,000	$ (473,000)	(60.1)%	$ 1,191,000	$ 1,426,000	$ (235,000)	(16.5)%	
% of revenue	20.4%	27.1%	(6.7)%		30.6%	29.5%	1.1%		
Inventory provision	—	—	—	—	242,000	—	242,000	—	
% of revenue	—	—	—	—	6.2%	—	—	—	
Total	$ 314,000	$ 787,000	$ (473,000)	(60.1)%	$ 1,433,000	$ 1,426,000	$ 7,000	0.5%	
Cost of revenue as% of revenues	20.4%	27.1%	(6.7)%		36.8%	29.5%	7.3%		

- The cost of revenues, as a percent of revenues, decreased 6.7% in the three months ended June 30, 2004, as compared to the same period in 2003. This decline was due primarily to thin film products shipped to MAST and recorded as deferred income absorbing a portion of raw materials, labor and overhead costs. Historically, the cost of revenue as a percentage of revenue has been higher for thin film products than the other product lines.

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

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

Research and development expenses

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
Regenerative cell technology	$ 1,795,000	$ 1,066,000	$ 729,000	68.4%	$ 3,259,000	$ 1,902,000	$ 1,357,000	71.3%
Bioresorbable polymer implants	819,000	1,041,000	(222,000)	(21.3)%	1,763,000	2,356,000	(593,000)	(25.2)%
Research grants (NIH)	54,000	—	54,000	—	153,000	—	153,000	—
Total	$ 2,668,000	$ 2,107,000	$ 561,000	26.6%	$ 5,175,000	$ 4,258,000	$ 917,000	21.5%

- Regenerative cell technology expenses relate to the development of a technology platform that involves using adipose (fat) tissue as a source for autologous regenerative cells for therapeutic applications. The increase in regenerative cell technology expense as compared with the same periods in 2003 was a result of hiring 16 additional researchers, engineers and support staff in 2004 and incurring an additional $346,000 and $718,000 in labor related expenses in the three and six months ended June 30, 2004, respectively, as compared with the same periods in 2003. The remainder of the increase related to increases in legal, research supplies, consulting fees and facility expenses of $383,000 and $639,000 in the three and six month ended June 30, 2004, respectively, as compared to the same periods in 2003.

- Bioresorbable polymer surgical implants platform technology is used for development of spine and orthopedic products. The decrease in research and development costs associated with bioresorbable polymer implants in the 2004 periods as compared with the same periods in 2003 was a result of the successful completion of our bioresorbable thin film product line in late 2003.

- In 2004, we entered into an agreements with the NIH to reimburse us for up to $850,000 (Phase I $100,000 and Phase II $750,000) in “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. Phase II of the reimbursement was subsequently increased by the NIH to $850,000 (subject to availability of funds and satisfactory progress) bringing the total reimbursement amount to $950,000. For the six months ended June 30, 2004, we incurred a total of $117,000 of direct qualifying expenses relating to Phase I and $36,000 of direct qualifying expenses related to Phase II, for a total cost relating to NIH grants of $153,000.

The future: We are developing a system to isolate autologous, homologous-use, regenerative cells. Simultaneously, we are generating scientific knowledge through internal research to support the clinical use of these cells and have made significant progress in understanding the potential clinical applications. Our most advanced research and development program is in the repair of cardiovascular tissues that are damaged after a heart attack. We are also researching applications

in bone repair, spinal disc regeneration, and cosmetic and reconstructive surgery. Our strategy is to continue to increase our research and development efforts in this field and we anticipate expenditures in this area of research to approximate $7,800,000 to $8,800,000 in 2004. The expenditures will primarily relate to conducting pre-clinical studies on harvesting therapeutically useful quantities of regenerative cells for cardiac tissue repair, bone regeneration, cosmetic and reconstruction surgery.

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

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

Sales and marketing expenses

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
General corporate marketing	$ 188,000	$ 96,000	$ 92,000	95.8%	$ 381,000	$ 196,000	$ 185,000	94.4%
Domestic sales and marketing	286,000	728,000	(442,000)	(60.7)%	846,000	1,630,000	(784,000)	(48.1)%
International sales and marketing	180,000	180,000	—	—%	385,000	473,000	(88,000)	(18.6)%
Total	$ 654,000	$ 1,004,000	$ (350,000)	(34.9)%	$ 1,612,000	$ 2,299,000	$ (687,000)	(29.8)%

- General corporate marketing expenditures relate to expenditures for maintaining our corporate image and reputation within the research and surgical communities. The increases in the 2004 periods as compared to the same periods in 2003 was due to an educational program which we voluntarily (and not as a result of any commitment to Medtronic) created in 2004 to inform end users and Medtronic's sale teams of the benefits and surgical applications for our biomaterials products.

- Domestic sales and marketing relates to costs associated with managing our domestic bioresorbable thin film product distribution, which included independent sales representatives and our domestic thin film sales consultants and marketing staff. The sharp decreases in 2004 as compared to the same periods in 2003 was due to our efforts at controlling costs as we reduced the marketing staff and the number of our bioresorbable thin film sales consultants before the transfer of our dedicated sales force and marketing staff in May 2004 to MAST. After the transfer, even those reduced expenses were eliminated. In addition, before the sale of the product line to MAST, 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. The level spending in the three months ended June 30, 2004 and the decrease of $88,000 in the six months ended June 30, 2004 as compared to the same periods in 2003 related to the closure of our United Kingdom sales office, offset by higher salary and bonus costs for our remaining international marketing and sales team.

The future: We project that corporate marketing as well as our international sales and marketing expenditures will remain stable for the balance of 2004. Our domestic sales and marketing expenditures will significantly decline as a result of the sale of our non-Japan thin film business to MAST.

General and administrative expenses

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
General and administrative expenses	$ 1,575,000	$ 951,000	$ 624,000	65.6%	$ 2,801,000	$ 1,999,000	$ 802,000	40.1%

- These increases were a result of salary costs rising $308,000 and $359,000 in the three and six month periods ended June 30, 2004, respectively, as compared to the same periods in 2003, as well as a one-time bonus of $216,000 paid to our former Chief Financial Officer in the second quarter associated with his work in arranging the MAST transaction. The remainder of the increase related to increase in professional services and other general overall corporate expenditures of $100,000 and $227,000, respectively, as compared to the same periods in 2003.

The future: We expect general and administrative expenses to increase as we begin to incur the salary costs for our new Chief Financial Officer and other professional services related to Sarbanes-Oxley compliance. The salary increases which resulted in higher expenses in the first half of 2004 will similarly affect comparisons in the second half of 2004.

Stock based compensation expenses

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
Research and development related	$ 32,000	$ 20,000	$ 12,000	60.0%	$ 32,000	$ 39,000	$ (7,000)	(17.9)%
Sales and marketing related	11,000	18,000	(7,000)	(38.9)%	22,000	36,000	(14,000)	(38.9)%
General and administrative related	36,000	174,000	(138,000)	(79.3)%	71,000	350,000	(279,000)	(79.7)%
Total	$ 79,000	$ 212,000	$ (133,000)	(62.9)%	$ 125,000	$ 425,000	$ (300,000)	(70.6)%

- These decreases were primarily a result of the normal amortization of the stock based compensation expenses over the remaining vesting period. In the three months ended June 30, 2004, we charged $32,000 to research and development for options granted to a consultant. We determined the value of these options using the Black-Scholes option pricing model. There was no comparable charge in the same period in 2003. The options to the consultant were 100% vested and related to services fully rendered.

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

Restructuring charge

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
Restructuring charge	$ 70,000	$ —	$ 70,000	—%	$ 70,000	$ —	$ 70,000	—%

- In September 2003, we closed an administrative office in Königstein, Germany an effort to reduce costs and consolidate operation in the United States. The Königstein, Germany office is rented under a operating lease. Restructuring charges increased in 2004 as a result of a change in the estimated timeframe for when we would be able to sublease or exit the lease on the Königstein, Germany office space.

The future. At each subsequent reporting period we will evaluate our restructuring liability to ensure that the provisions are appropriate. Additional accruals may be necessary to reflect our inability to obtain previously estimated subleases.

Other income

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
Gain on the sale of assets, related party	$ —	$ —	$ —	—%	$ 5,000,000	$ —	$ 5,000,000	—%

- This first quarter 2004 gain related to a 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. We anticipate recognizing the remaining deferred gain on sale of the CMF assets, amounting to approximately $7,383,000 at June 30, 2004, plus an additional $1,000,000 to $2,000,000 yet to be received, as gain on sale of assets, related party, in 2004. We cannot recognize this deferred gain in income until Medtronic acknowledges that we have completed the transfer of know-how as defined in the sale agreement. We believe that any issues regarding whether we have completed the know-how transfer should be resolved by the end of this year. See the section “Deferred gain on sale of assets, related party” below for further information. We expect to be able to recognize most of the deferred gain on the sale of the thin film assets to MAST in 2005.

Financing items

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

	Three months ended:				Six months ended:			
	June 30, 2004	June 30, 2003	Difference	%	June 30, 2004	June 30, 2003	Difference	%
Interest income	$ 57,000	$ 105,000	$ (48,000)	(45.7)%	$ 112,000	$ 247,000	$ (135,000)	(54.7)%
Interest and other expenses	$ (47,000)	$ (6,000)	$ 41,000	683.3%	$ (108,000)	$ (11,000)	$ 97,000	881.8%

- Interest income decreased $48,000 in the three months ended June 30, 2004 and decreased $135,000 in the six months ended June 30, 2004 as compared to the same period in 2003 because of a decrease in the funds we had available for investment and lower interest rates.

- Interest and other expenses increased $41,000 in the three months ended June 30, 2004 and increased $97,000 in the six months ended June 30, 2004 as compared to the same periods in 2003. These increases resulted from foreign currency gains in 2003, which did not recur in 2004, and an increase in interest expense on our long-term obligations due to larger borrowings associated with the acquisition of new equipment in late 2003 and early 2004.

Deferred gain on sale of assets, related party

At June 30, 2004, we have reflected $7,383,000 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 it is undisputed that we have successfully transferred 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 $2,469,000 of the initial deferred 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 sales revenue and a reduction to the deferred gain. The remainder of the deferred gain will be recognized when Medtronic acknowledges that the technology and know-how transfer has been completed pursuant to the contract terms; which, as discussed below, is expected to occur in 2004.

Pursuant to the sale of the CMF product line to Medtronic in 2002, we were obliged to transfer certain “know-how”, including manufacturing processes, patents, and other intellectual property, to Medtronic. Know-how transfer is achieved when Medtronic reached specified manufacturing yields on a certain basket of CMF products. If such know-how transfer is achieved within one year of the installation of all necessary specified assets at Medtronic’s facility as defined in the CMF Asset Purchase Agreement dated September 30, 2002 (the “APA”), we would be entitled to a $2,000,000 milestone payment. If the know-how was transferred after the specified time frame, the amount of the milestone payment would be reduced to $1,000,000. It is our understanding that Medtronic refused to acknowledge know-how transfer due to certain factors. When these conditions are resolved, which should occur in the third quarter or early in the fourth quarter of this year, we believe Medtronic will acknowledge that know-how transfer is complete. Even after the know-how transfer is acknowledged by Medtronic, we anticipate that they will continue to contend that the payment should be reduced.

In the second quarter of 2004, we provided notice to Medtronic that the requisite know-how had been transferred, pursuant to the terms of, and within the framework specified by, the APA entitling us to the $2,000,000 payment. However, Medtronic has not remitted any payment to us to date. We have received notice from Medtronic that they do not intend to make any payment at this time, and that they believe that the full know-how payment should be reduced.

Upon receipt of the notice we initiated the dispute resolution mechanisms provided for in the APA, by filing a written notice of dispute with Medtronic. At this time, we are uncertain as to whether the $2,000,000 milestone payment will ultimately be reduced to $1,000,000. We believe, though, that we have complied in all respects with the provisions of the APA sufficiently within the contractual framework to entitle us to the $2,000,000 milestone payment. Accordingly, we will continue to pursue collection of this payment.

Deferred gain on sale of assets

At June 30, 2004, we have reflected $6,266,000 of unamortized "Deferred gain on sale of assets" on our balance sheet. This deferred gain related to our sale of our Thin Film product line to MAST in May 2004. Because of additional performance requirements, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately $6,455,000 as deferred gain on sale in the balance sheet. These performance requirements include training to MAST representatives in all aspects of the manufacturing process related to the transferred Thin Film product line, transfer of thin film tangible assets and rights to intangible assets and act in the capacity of a back-up supplier to MAST for a period of one year. Under the back-up supply agreement, we have agreed to supply product ordered by MAST at our manufacturing cost.

We do not expect to complete our performance obligations until at least the second quarter of 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. However, we have been recognizing a portion of the deferred gain as revenues as and when we sell products to MAST under the back-up supply agreement. This is necessary to state revenues and gross margin at the amount we would normally charge for selling the same product in an unencumbered transaction. During the second quarter of 2004, we recognized $189,000 in deferred gain as revenues.

Deferred income

In the second quarter of 2004, in addition to other shipments of Thin Film products to MAST, we sold approximately 13,000 units of Thin Film product to MAST. The product was supplied in accordance with the terms of the back-up supply arrangement contained in MAST Asset Purchase Agreement, except for extended payment terms.

In regards to this specific shipment, we decided to grant MAST extended payment terms, as compared with those given to our other customers. Consistent with our accounting policy, we did not recognize the revenues and gross margin associated with this product sale during the second quarter of 2004. Instead, we have recorded deferred income in the amount of $58,000 (representing the inherent gross margin before any draw down from deferred gain on sale of assets). We expect to recognize this deferred income, (plus an associated $641,000 of deferred gain on sale of assets), in the statement of operations in the third quarter of 2004, when payment from MAST becomes due or, if earlier, is received.

Liquidity and Capital Resources

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

For the six months ended:	June 30, 2004	June 30, 2003
Net cash used in operating activities	$ (6,984,000)	$ (4,959,000)
Net cash provided by investing activities	6,934,000	2,348,000
Net cash used in financing activities	$ (677,000)	$ (409,000)

Operating activities

Net cash used in operating activities in the six months ended 2004 and 2003 primarily resulted from our net loss, as adjusted for the $5,000,000 gain on sale of assets, related party and changes in working capital due to the payment of liabilities and timing of product shipments.

Investing activities

Net cash provided by investing activities in the six month ended 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 and $6,960,000 from the sale of our thin film product line (except for the territory of Japan) to MAST.

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

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore, in the six months of 2004 and 2003 we used cash to purchase $463,000 and $531,000, 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 six months ended June 30, 2004 related to:

- The repurchase of 262,602 shares of our common stock for $976,000 from a former director and officer of StemSource at a price of $3.72 per share,
- The repurchase of 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 $382,000 on our long-term obligations.

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

The net cash used in financing activities in the six months ended June 30, 2003 was primarily related to the repurchase of 63,499 shares of our common stock for $249,000 on the open market at an average price of $3.92 per share and payments toward long-term obligations of $173,000.

Short-term and long-term liquidity

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

	June 30, 2004	December 31, 2003	Difference	%
Cash and cash equivalents	$ 2,093,000	$ 2,820,000	$ (727,000)	(25.8)%
Short-term investments, available for sale	15,940,000	11,448,000	4,492,000	39.2%
Total cash and cash equivalents and short-term investments, available for sale	$ 18,033,000	$ 14,268,000	$ 3,765,000	26.4%
Current assets	$ 20,558,000	$ 16,916,000	$ 3,642,000	21.5%
Current liabilities	3,313,000	4,484,000	(1,171,000)	(26.1)%
Working capital	$ 17,245,000	$ 12,432,000	$ 4,813,000	38.7%

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 June 30, 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 June 30, 2004, we have financed our operations primarily by:

- Generating revenues,
- Issuing our stock,
- Selling, in September 2002, the CMF product line,
- Earning a contractual milestone payment by completing clinical research regarding CMF Faster Resorbable Polymer

- Selling, in May 2004 the Thin Film product line (except for the territory of Japan), and
- Obtaining a modest amount of capital equipment long-term financing.

As a result of the non-recurring receipt of $5,000,000 for the completion of CMF clinical research, long-term financing of $722,000 and the sale of our non-Japan bioresorbable Thin Film product line for $7,000,000, our liquidity metrics as of June 30, 2004 appear superior to those as of December 31, 2003. We increased our cash and short-term investment position by $3,765,000 or 26.4% and working capital by $4,813,000 or 38.7% in comparison to December 31, 2003.

In July 2004, we granted Senko Medical Trading Co. (“Senko”) exclusive sales and distribution rights to the Thin Film product line in Japan. In return for these rights, we received from Senko an upfront $1,500,000 license fee, and will collect $1,250,000 upon submission of a regulatory application to the Japanese Ministry of Health, Labour and Welfare (“MHLW”), and $250,000 upon product approval by MHLW.

Later in 2004, we anticipate receiving the milestone payment (between $1,000,000 and $2,000,000) for 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. See the section “Deferred gain on sale of assets, related party” for further information.

We believe that our borrowing requirements and debt repayments will continue to involve a relatively small amount of cash. To fund the rest of 2004 expected capital expenditures of $500,000 to $800,000, we intend to borrow under our Amended Master Security Agreement, which has an available credit facility of approximately $788,000.

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 for the rest of 2004 and beyond 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 in large part on the success of 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 June 30, 2004, and the effect such obligations could have on our liquidity and cash flow in future periods:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1**	**1 – 3 years**	**3 – 5 years**	**More than**

		year			5 years
Long-term debt obligations	$ 2,214,000	$ 886,000	$ 1,328,000	$ —	$ —
Operating lease obligations	2,749,000	829,000	1,920,000	—	—
Total	$ 4,963,000	$ 1,715,000	$ 3,248,000	$ —	$ —

Critical Accounting Policies and Significant Estimates

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

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

Revenue recognition

Product sales

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

We warranty that our products are free from manufacturing defects at the time of shipment to our customers. We have recorded a reserve for the estimated costs that may incur under our warranty program.

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

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

Research

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

When we are reimbursed for costs incurred under grant arrangements with the NIH, we recognize revenues for the lesser of:

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

Income earned under development agreements is classified as research revenues in the statements of operations.

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

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.

Inventory

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

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

Warranty provision

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

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

In the past, our warranty provision was based primarily on actual history of warranty claims submitted by our customers. Prior to the third quarter of 2003, we had de minimis warranty claims despite recognizing approximately $27 million in cumulative sales of medical devices. Accordingly, we had no warranty reserves as of 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 assets. The likelihood of a material change in our expected realization of these assets depends on our generation of future taxable income, and secondarily on our ability to deduct tax loss carryforwards against future taxable income and the effectiveness of our tax planning strategies in the various tax jurisdictions that we operate in. At such time as it is determined that it is more likely than not that the deferred assets are realizable, the valuation allowance will be reduced.

Unearned Compensation

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

Risk Factors

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

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

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

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

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

We had tried to help set investor expectations as to our operating results by periodically announcing financial guidance. However, due to our disappointing revenues in the second quarter of 2004 and our conclusion that we did not have sufficient visibility on the timing and size of end customer demand for the HYDROSORB™ bioresorbable implants which we distribute through Medtronic, we withdrew our previously issued guidance on July 19, 2004 and will not be issuing further guidance until after visibility improves. Our inability to sustain and provide guidance will make us more subject to the stock-price effects of any future operating volatility.

We have never been profitable on an operational basis

We have incurred net losses in each year since we started doing business. These losses have resulted primarily from expenses associated with our research and development activities, and general and administrative expenses. We anticipate that our recurring operating expenses will increase for the next several years, as our research and development expenses may increase in order to develop and market new products and fund additional pre-clinical research and possibly clinical trials. We expect to continue to incur operational losses at least through the end of 2004, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Development-stage losses related to our development of regenerative cell technology 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 cash from the profits of the spine products and the Japan thin film products, and the proceeds of the sale of the CMF and non-Japan bioresorbable thin film product lines, to finance the regenerative cell technology and its development-stage cash needs. This is a high-risk strategy because there can be no assurance that our regenerative cell technology will ever be developed into commercially viable products (scientific risk), that we will be able to preclude other companies from depriving us of market share and profit margins by selling products based on our inventions (legal risk), that we will be able successfully to manage a company in a different business than we have operated in the past (operational risk), that we will be able to successfully use our bioresorbable products to deliver regenerative cells where needed in the body (strategic risk), or that our cash resources will be adequate to develop the regenerative cell technology until it becomes profitable (if ever) while still serving the cash needs of our 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.

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

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

We are in a relatively early stage of commercialization with many of our products although we have derived revenue from sales of certain products to our distributors, particularly Medtronic. We believe that our long-term viability and growth will depend in large part on receiving additional regulatory clearances or approvals for our products and expanding our sales and marketing for our spine and orthopedics 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 hard-tissue-fixation bioresorbable implant products to our distribution partner 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. Medtronic's sale of our products to end customers in the first half of 2004, and its rate of product orders placed with us, in the first half of 2004 disappointed our expectations.

Besides putting us in a position where we have to rely on a third party (Medtronic) to prioritize and execute the sale of our key products to the end customers, the intermediation of Medtronic deprives us of visibility into the actual, real-time demand for our product from the end customers. This lack of visibility can deprive us of the reliable data we need to make optimal operational and strategic decisions. In addition, this lack of visibility resulted in our second quarter 2004 financial performance falling short of our own and the market's expectations and compelled us to, on July 19, 2004, withdraw our previously announced financial guidance for the remainder of 2004.

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 we, any of which could have a substantial negative effect on our business. Finally, under the terms of our distribution agreements, Medtronic and our other partners may pursue parallel development of other technologies or products, which may result in a partner developing additional products that will compete with our products.

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

We 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 various U.S. patents for the design of our bioresorbable plates and high torque screws and devices and we have filed applications for numerous additional U.S. patents, as well as certain corresponding patent applications outside the United States, relating to our technology. However, we believe we cannot patent the use of our lactic acid copolymer for surgical implants, nor are many of our particular implants generally patentable. There can be no assurance that any of the pending patent applications will be approved, or that we will develop additional proprietary products that are patentable, or that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products or design around our patents.

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

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 Europe, Australia, Japan, Canada, China, Korea, and Singapore among others.

We are subject to intensive FDA regulation

As newly developed medical devices, our bioresorbable surgical implants, and our regenerative cell harvesting, isolation and delivery devices must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments, prior to their sale. Our current and future bioresorbable surgical implants for humans and our

regenerative cell harvesting, isolation and delivery devices are subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices and drugs. Included among these regulations are premarket clearance and premarket approval requirements, design control requirements, and the Quality System Regulations / Good Manufacturing Practices. Other statutory and regulatory requirements govern, among other things, establishment registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and postmarket reporting.

The regulatory process can be lengthy, expensive and uncertain. Before any new medical device may be introduced to the United States market, the manufacturer generally must obtain FDA clearance or approval through either the 510(k) premarket notification process or the lengthier premarket approval application “PMA” process. It generally takes from three to 12 months from submission to obtain 510(k) premarket clearance although it may take longer. Approval of a PMA could take four or more years from the time the process is initiated. The 510(k) and PMA processes can be expensive, uncertain and

lengthy, and there is no guarantee of ultimate clearance or approval. We expect that some of our future products under development will be subject to the lengthier PMA process. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA, and there can be no guarantee of ultimate clearance or approval. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications and criminal prosecution.

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

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

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

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

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

We 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 June 30, 2004, we had $18,033,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. Our regenerative cell business will continue to result in a substantial requirement for research and development expenses. 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 Chief Executive Officer, Marc Hedrick, MD, our President and John Fraser, PhD, our Vice President of Research and Technology. We rely upon them for strategic business decisions and guidance. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

We may 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 $15,940,000 as of June 30, 2004, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to (minor) market rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at June 30, 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 transacted business in various foreign countries before the May 2004 sale of our non-Japan thin film business to MAST, settlement were usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the three months ended June 30, 2004, a hypothetical 10% adverse change in the Euro or Yen against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

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

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

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

Item 4. Controls and Procedures

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

PART II OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company has been involved in routine litigation incidental to the conduct of its business. The Company is not currently a party to any material legal proceeding.

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

None

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

In June 2004 we promoted Marc Hedrick to President and hired Mark Saad as our Chief Financial Officer.

Properties and Facilities

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

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

- 16,000 square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five-year term expiring 2007.

- 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 June 30, 2004, we had 90 full-time employees, comprised of 44 employees in research and development, 21 employees in manufacturing, 19 employees in management and finance and administration and 6 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

2.1 Asset Purchase Agreement dated May 7, 2004 between MacroPore Biosurgery, Inc. and MAST Biosurgery AG (Incorporated by reference to Exhibit 2.1 of Form 8-K filed May 28, 2004.)

10.17 Mutual Consent to Termination of Asset Purchase Agreement dated May 7, 2004 from Medicis Ventures Management GmbH terminating the Asset Purchase Agreement dated as of December 13, 2003.

10.18 Offer Letter for the Position of Chief Financial Officer dated June 2, 2004 between MacroPore Biosurgery, Inc. and Mark Saad.

15.1 Letter re unaudited interim financial information

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

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

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

b. Reports on Form 8-K

We filed, on May 28, 2004 a Form 8-K to report the sale of substantially all the assets of our thin-polymeric-film soft-tissue-support/barrier bioabsorbable surgical implants (“thin film”) line of business, excluding assets and rights for such line of business in Japan (Items 2 and 7).

We also filed, on May 14, 2004, a Form 8-K to report the issuance of a press release announcing such thin film asset sale (Items 5 and 7).

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 August 16, 2004.

MACROPORE BIOSURGERY, INC.

Dated: August 16, 2004

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

Dated: August 16, 2004

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

EXHIBIT INDEX

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

EXHIBIT 10.17

Date: May 7, 2004

MUTUAL CONSENT TO TERMINATION
OF ASSET PURCHASE AGREEMENT

The Asset Purchase Agreement dated December 13, 2003 between MacroPore Biosurgery, Inc. and Medicis Ventures Management GmbH, which the parties hereby confirm has never been amended or modified (the "Agreement"), is hereby terminated by mutual consent under Section 10.1(c) thereof. The parties hereby agree that this termination is without liability of either party to the other, and each of the parties hereby forgives, releases and waives any and all rights and claims against the other arising under or in connection with the Agreement, to the extent such rights and claims arose upon or before such termination of the Agreement; provided, that the parties hereby confirm that Section 12.13 of the Agreement shall survive termination of the Agreement as expressly provided in Section 12.13.

MACROPORE BIOSURGERY, INC.

By: /s/ Charles E. Galetto
Name: Charles E. Galetto
Title: Sr. Vice President Finance

MEDICIS VENTURES MANAGEMENT GMBH

By: /s/ Kai Deusch
Name: Dr. Kai Deusch
Title: Managing Director (CEO)

EXHIBIT 10.18

OFFER LETTER FOR THE POSITION
OF CHIEF FINANCIAL OFFICER

June 02, 2004

Mr. Mark E. Saad
250 Mercer Street B1306
New York, NY 10012

We are pleased to offer you the position of Chief Financial Officer at a salary of $25,000 per month (equivalent to $300,000 per year if computed on an annual basis), payable semi-monthly. You will report to Christopher J. Calhoun, MacroPore's President and Chief Executive Officer. Your start date in your new position will be as soon as possible.

To assist in your relocation to San Diego, we are pleased to reimburse your reasonable costs of relocation up to a maximum of $125,000. (Please be advised that some of this reimbursement could be taxable income to you.)

You will receive MacroPore's benefit package for executive officers, including PPO medical insurance for you and your family, group life insurance, group and supplemental long-term disability insurance, and participation in our 401(k) plan and our Flexible Spending Account Plan. Your benefits will also include an auto allowance of $800 per month, and an annual reimbursement of $2,000 for your tax return preparation fees. Your paid time off per year will be four (4) weeks.

/s/ CJC	/s/ MES
CJC Initial	MES Initial

Upon your acceptance of this offer I will recommend to the MacroPore Board of Directors that you be granted an option to purchase 190,000 shares of the common stock of the Company at the fair market value of the Company's common stock on the date of grant. Vesting of the option grant will begin as of the date of grant, with 25% of the options vesting on the one-year anniversary of the date of grant, and 1/48th of the options vesting each month thereafter. The grant and its terms will be contingent upon the Board's approval. The options will be exercisable once they vest, subject to your remaining an employee of the Company, as described in the stock option agreement you will receive from the Company

You will have a target annual bonus of 25% of your base salary; prorated for the 2004 over the number of months you are an employee. This bonus is generally paid in January of each year and is based upon your achievement of mutually agreed-upon performance objectives and the Company's performance during the preceding year.

Employment with MacroPore is "at will" and may be terminated without cause by either party. This letter describes a written offer of employment and does not constitute a contract.

Mark, this letter describes an exciting opportunity to work together to continue to build a successful organization. We would be pleased to have you join our company.

Sincerely,

/s/ Christopher J. Calhoun
Christopher J. Calhoun
President and Chief Executive Officer

Acceptance:
I understand and accept the above offer

Signature:	/s/ Mark E. Saad	6-2-04
	Mark E. Saad	Date

EXHIBIT 15.1

Letter Re Unaudited Interim Financial Information

August 16, 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 July 27, 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

EXHIBIT 31.1

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

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

1. I have reviewed this quarterly report on Form 10-Q of MacroPore Biosurgery, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2004
/s/ Christopher J. Calhoun
Christopher J. Calhoun,
Chief Executive Officer

EXHIBIT 31.2

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

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

1. I have reviewed this quarterly report on Form 10-Q of MacroPore Biosurgery, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2004
/s/ Mark E. Saad
Mark E. Saad,
Chief Financial Officer

EXHIBIT 32.1

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

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

1. The Form 10-Q report of MacroPore Biosurgery, Inc. that this certification accompanies fully complies with the requirements of section 13(a) of the Securities Exchange Act of 1934.

2. The information contained in the Form 10-Q report of MacroPore Biosurgery, Inc. that this certification accompanies fairly presents, in all material respects, the financial condition and results of operations of MacroPore Biosurgery, Inc.

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

Dated: August 16, 2004

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

Dated: August 16, 2004