

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2005

OR

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

For the transition period from _____ to _____

Commission file number 0-32501

MACROPORE BIOSURGERY, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE

(State or Other Jurisdiction
of Incorporation or Organization)

33-0827593

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

6740 TOP GUN STREET, SAN DIEGO, CALIFORNIA

(Address of principal executive offices)

92121

(Zip Code)

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

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

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

As of April 30, 2005, there were 14,032,184 shares of the registrant's common stock outstanding.

MACROPORE BIOSURGERY, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Report of Independent Registered Public Accounting Firm

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

We have reviewed the accompanying consolidated condensed balance sheet of MacroPore Biosurgery, Inc. and subsidiaries as of March 31, 2005, and the related consolidated condensed statements of operations and comprehensive income (loss), and cash flows for the three month periods ended March 31, 2005 and 2004. These consolidated condensed financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with the standards of 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 the 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 of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of MacroPore Biosurgery, Inc. and subsidiaries as of December 31, 2004, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated March 11, 2005, 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, 2004 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, 2004 and for the year then ended, discloses that the Company derives a substantial portion of its revenues from a related party. Our auditor's report on those financial statements dated March 11, 2005, includes an explanatory paragraph referring to the matter in note 1 of those financial statements.

/s/ KPMG LLP

San Diego, California
May 6, 2005

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	As of March 31, 2005 (Unaudited)	As of December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	\$ 864,000	\$ 2,840,000
Short-term investments, available-for-sale	7,301,000	10,579,000
Accounts receivable, net of allowance for doubtful accounts of \$17,000 and \$8,000 in 2005 and 2004, respectively	1,660,000	863,000
Inventories	533,000	379,000
Other current assets	734,000	984,000
Total current assets	11,092,000	15,645,000
Property and equipment, net	2,917,000	3,080,000
Other assets	300,000	236,000
Intangibles, net	2,055,000	2,122,000
Goodwill	4,387,000	4,387,000
Total assets	\$ 20,751,000	\$ 25,470,000

Liabilities and Stockholders' Equity

Current liabilities:

Accounts payable and accrued expenses	\$ 2,379,000	\$ 2,329,000
Current portion of long-term obligations	856,000	938,000
Total current liabilities	3,235,000	3,267,000
Deferred gain on sale of assets	5,650,000	5,650,000
Deferred license fee revenue	1,500,000	1,500,000
Deferred development revenue	1,083,000	1,092,000
Long-term obligations, less current portion	976,000	1,128,000
Total liabilities	12,444,000	12,637,000

Stockholders' equity:

Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2005 and 2004	—	—
Common stock, \$0.001 par value; 95,000,000 shares authorized; 16,827,518 and 16,820,018 shares issued and 13,954,684 and 13,947,184 shares outstanding in 2005 and 2004, respectively	17,000	17,000
Additional paid-in capital	74,738,000	74,737,000
Accumulated deficit	(56,002,000)	(51,475,000)
Treasury stock, at cost	(10,414,000)	(10,414,000)
Accumulated other comprehensive loss	(32,000)	(32,000)
Total stockholders' equity	8,307,000	12,833,000
Total liabilities and stockholders' equity	\$ 20,751,000	\$ 25,470,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	For the Three Months Ended	
	March 31,	
	2005	2004
Revenues:		
Sales to related party	\$ 1,755,000	\$ 1,921,000
Sales to third parties	2,000	341,000
Research grants	23,000	90,000
Development	9,000	—
	<u>1,789,000</u>	<u>2,352,000</u>
Cost of revenues:		
Cost of revenues (including stock based compensation expense of \$0 and \$2,000 for the three months ended March 31, 2005 and 2004, respectively)	745,000	877,000
Inventory provision	—	242,000
	<u>745,000</u>	<u>1,119,000</u>
Gross profit	1,044,000	1,233,000
Operating expenses:		
Research and development	3,273,000	2,507,000
Sales and marketing, excluding stock based compensation expense of \$0 and \$11,000 for the three months ended March 31, 2005 and 2004, respectively	391,000	958,000
General and administrative, excluding stock based compensation expense of \$0 and \$35,000 for the three months ended March 31, 2005 and 2004, respectively	1,909,000	1,226,000
Stock based compensation (excluding cost of revenues stock based compensation)	—	46,000
	<u>5,573,000</u>	<u>4,737,000</u>
Operating loss	(4,529,000)	(3,504,000)
Other income (expense):		
Gain on the sale of assets, related party	—	5,000,000
Interest income	55,000	55,000
Interest expense	(40,000)	(39,000)
Other expense, net	(13,000)	(22,000)
	<u>2,000</u>	<u>4,994,000</u>
Total other income	2,000	4,994,000

Net income (loss)	(4,527,000)	1,490,000
Other comprehensive income (loss): unrealized holding income (loss)	—	(9,000)
Comprehensive income (loss)	<u>\$ (4,527,000)</u>	<u>\$ 1,481,000</u>
Net income (loss) per common share:		
Basic	\$ (0.32)	\$ 0.11
Diluted	\$ (0.32)	\$ 0.10
Weighted average common shares:		
Basic	13,954,347	13,943,269
Diluted	13,954,347	14,734,455

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	<u>For the Three Months Ended March 31,</u>	
	<u>2005</u>	<u>2004</u>
Cash flows from operating activities:		
Net income (loss)	\$ (4,527,000)	\$ 1,490,000
Adjustments to reconcile income (loss) to net cash used in operating activities:		
Depreciation and amortization	426,000	434,000
Inventory provision	—	242,000
Increase in allowance for doubtful accounts	9,000	—
Amortization of gain on sale of assets, related party	—	(151,000)
Gain on sale of assets, related party	—	(5,000,000)
Stock based compensation	—	48,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(806,000)	290,000
Inventories	(154,000)	(267,000)
Other current assets	250,000	(25,000)
Other assets	(64,000)	39,000
Accounts payable and accrued expenses	50,000	(305,000)
Deferred development revenue	(9,000)	—
Net cash used in operating activities	<u>(4,825,000)</u>	<u>(3,205,000)</u>
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	7,564,000	15,159,000
Purchases of short-term investments	(4,286,000)	(15,482,000)
Proceeds from sale of assets, related party	—	5,000,000
Purchases of property and equipment	(196,000)	(309,000)
Acquisition costs	—	(11,000)
Net cash provided by investing activities	<u>3,082,000</u>	<u>4,357,000</u>
Cash flows from financing activities:		
Principal payments on long-term obligations	(234,000)	(176,000)
Proceeds from long-term obligations	—	594,000
Proceeds from the exercise of employee stock options	1,000	24,000
Purchase of treasury stock	—	(1,043,000)
Net cash used in financing activities	<u>(233,000)</u>	<u>(601,000)</u>
Net (decrease) increase in cash and cash equivalents	(1,976,000)	551,000
Cash and cash equivalents at beginning of period	2,840,000	2,820,000
Cash and cash equivalents at end of period	<u>\$ 864,000</u>	<u>\$ 3,371,000</u>
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	\$ 42,000	\$ 39,000
Taxes	7,000	9,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

MACROPORE BIOSURGERY, INC.,
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
MARCH 31, 2005
(UNAUDITED)

1. Basis of Presentation

The accompanying unaudited consolidated condensed financial statements as of March 31, 2005 and for the three months ended March 31, 2005 and 2004 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 annual financial statements. The consolidated condensed balance sheet at December 31, 2004 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of MacroPore Biosurgery, Inc. ("MacroPore" or the "Company") have been included. Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, refer to the consolidated financial statements for the year ended December 31, 2004 and footnotes thereto which were included in the Company's Annual Report on Form 10-K, dated March 31, 2005.

2. Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. Estimates and assumptions are reviewed periodically, and the effects of revisions are reflected in the consolidated financial statements in the periods they are determined to be necessary.

The Company's most significant estimates and critical accounting policies involve revenue recognition, determining the warranty provision, evaluating for goodwill impairment, and the accounting for product line dispositions.

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 employee stock option plans. Under the intrinsic value method, compensation expense is recognized only if the current market price of the underlying stock exceeds the exercise price as of the measurement date (typically the date of grant). Any resulting expense 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 permitted 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 income (loss) and net income (loss) per common share have been estimated using a grant date fair value model (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 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 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 Company estimated the weighted average estimated fair values of stock options granted for the three months ended March 31, 2005 and 2004 at \$2.28 and \$2.36 per share, respectively, on the date of grant. Fair value under SFAS No. 123 is determined

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using the Black-Scholes option-pricing model with the following assumptions:

	For the Three Months Ended March 31,	
	2005	2004
Expected term	6 years	7 years
Interest rate	3.97%	3.31 - 3.65%
Volatility	81.4%	89.3%
Dividends	—	—

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

For the Three Months Ended March 31,	
2005	2004

Net income (loss):			
As reported	\$	(4,527,000)	\$ 1,490,000
Add: Stock based employee compensation expense included in reported net income (loss), net of related tax effects		—	48,000
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects		(728,000)	(598,000)
Pro forma	\$	<u>(5,255,000)</u>	\$ <u>940,000</u>
Basic income (loss) per common share:			
As reported	\$	(0.32)	\$ 0.11
Pro forma	\$	(0.38)	\$ 0.07
Diluted income (loss) per common share:			
As reported	\$	(0.32)	\$ 0.10
Pro forma	\$	(0.38)	\$ 0.06

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

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("FAS 123R"). As amended by Securities and Exchange Commission Release No. 33-8568, "Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*", FAS 123R is effective for annual periods beginning after June 15, 2005 (January 1, 2006 for the Company).

FAS 123R will require all share-based payment transactions, including those with employees, to be measured at fair value. Moreover, the fair value of share-based payment awards (including employee stock option grants) will be recognized as expense in the statements of operations over the requisite service period of each award. FAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications.

The adoption of FAS 123R will have a material effect on the Company's results of operations. Based on pro forma amounts for historical periods presented earlier in this note, the Company's net loss will increase (or its net income would be reduced) each quarterly period once FAS 123R has been adopted.

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, its 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 as accumulated other comprehensive income (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 or interest expense. The amortized cost basis of securities sold is based on the specific identification method and all realized gains and losses are recorded as a component within other income (expense).

The Company reviews the carrying values of its investments and writes down such investments to estimated fair value by a charge to the statements of operations when the severity and duration of a decline in the value of an investment is considered to be other than temporary. The cost of securities sold or purchased is recorded on the settlement date.

At March 31, 2005, the excess of historical cost over the fair value of the Company's short-term investments 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 provisions for any stock deemed as excess or obsolete.

During the first quarter of 2004, the Company recorded a provision of approximately \$242,000 for excess inventory. Such excess 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 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 recoverable. Such long-lived assets are deemed to be impaired when the undiscounted future cash flows expected to be generated by the asset (or asset group) are less than the asset's 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 first quarter of 2005 and 2004, the Company had no impairment losses.

7. Revenue Recognition

Product Sales

The Company sells its products to distributors and, prior to the sale of its Thin Film product line in May 2004, also sold products directly to hospitals. The Company has agreements with its distributors wherein title and risk of loss pass upon shipment of the products to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order. Before the sale of the Thin Film product line in May 2004, revenue from sales to hospitals was recognized upon delivery of the product.

On occasion, the Company offers extended payment terms to customers. The Company does not recognize revenues under these arrangements until the payment becomes due or is received, if that occurs earlier. Moreover, 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 sales to related party in the statements of operations.

Any upfront payments received from license/distribution agreements are recognized as revenues ratably over the period in which the customer benefits from the license/ distribution agreement. Any recognized amounts are reported as sales to related party or sales to third parties depending upon the counterparty to the transaction.

In September 2002, the Company entered into various agreements with Medtronic and a subsidiary of Medtronic for the sale of the Company's CMF product line. The net proceeds received were recorded as deferred gain on sale of assets, related party. As part of the sale agreement, the Company agreed to act as a back-up supplier to Medtronic until Medtronic could integrate the acquired CMF assets into its manufacturing operations. The back-up supply agreement required that the Company sell CMF products ordered by Medtronic at the Company's manufacturing cost. The Company recognized as revenue in the first quarter of 2004, a portion of the deferred gain upon the sale of CMF products to Medtronic under the Company's back-up supply arrangement. The amount of the deferred gain recognized is equal to the excess of the fair value of products sold, based on historical selling prices of similar products, over the Company's manufacturing cost. The residual portion of the deferred gain on

sale of assets was fully recognized in the third quarter of 2004.

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 following performance criteria for that milestone have been met:

- Substantive effort was required to achieve the milestone,
- The amount of the milestone payments appears reasonably commensurate with the effort expended, and
- Collection (or retention) 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), plus any allowable grant fees for which the Company is entitled to funding from the NIH; or,
- The outputs generated to date versus the total outputs expected to be achieved under the research arrangement.

Revenue earned under development agreements is classified as research grant or development revenues in the Company's statements of operations, depending on the nature of the arrangement. The costs associated with development agreements are recorded as research and development expense.

In the three months ended March 31, 2005 and 2004, the Company recognized NIH grant revenue of \$23,000 and \$90,000, respectively, and incurred qualifying costs of \$22,000 and \$99,000. In the first quarter of 2005, the Company recognized development revenue of \$9,000 and incurred costs of \$10,000. There were no comparable development revenues or costs in 2004.

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 program.

The following summarizes the Company's warranty reserve at March 31, 2005 and 2004:

	As of January 1,	Additions- charges to expenses	Claims	As of March 31,
2005:				
Warranty reserve	\$ 102,000	\$ 12,000	\$ —	\$ 114,000
2004:				
Warranty reserve	\$ 267,000	\$ 28,000	\$ (63,000)	\$ 232,000

In August 2003, as part of its 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. In the three months ended March 31, 2004, the Company incurred claims of \$63,000 related to the replacement of this product.

9. Income Taxes

There was no provision or benefit for income taxes recorded due to the Company’s accumulated net loss position and the recognition of a full valuation allowance against deferred tax assets. There were also no components of current or deferred federal or state income tax provisions recorded for the periods presented.

10. 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,

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the number of additional common share equivalents that would have been outstanding if potential common shares had been issued using the treasury stock method. No common share equivalents were included for the first quarter of 2005, as their effect would be anti-dilutive.

The number of potential common shares excluded from the calculations of diluted income (loss) per share for the first quarter of 2005 and 2004 was 4,892,243 and 2,575,816, respectively. These potential common shares were related entirely to outstanding but unexercised option awards and warrants.

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

	<u>Three months ended March 31,</u>	
	<u>2005</u>	<u>2004</u>
Weighted average shares, basic	13,954,347	13,943,269
Dilutive effect of stock options and warrants	—	791,186
Weighted average shares, diluted	<u>13,954,347</u>	<u>14,734,455</u>

11. Long-term Debt

As of March 31, 2005 the future contractual principal payments, for the remainder of 2005 and subsequent years, on all of the Company’s promissory notes are as follows:

2005	\$ 702,000
2006	615,000
2007	427,000
2008	88,000
Total	<u>\$ 1,832,000</u>

12. Composition of Certain Financial Statement Captions

Inventories

	<u>March 31,</u> <u>2005</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2004</u>
Raw materials	\$ 213,000	\$ 189,000
Finished goods	320,000	190,000
	<u>\$ 533,000</u>	<u>\$ 379,000</u>

Other Current Assets

	<u>March 31,</u> <u>2005</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2004</u>
Prepaid expenses	\$ 589,000	\$ 809,000
Accrued interest receivable	92,000	121,000
Other receivables	53,000	54,000
	<u>\$ 734,000</u>	<u>\$ 984,000</u>

Property and Equipment, net

	<u>March 31,</u> <u>2005</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2004</u>

Manufacturing and development equipment	\$ 4,042,000	\$ 3,928,000
Office and computer equipment	2,258,000	2,186,000
Leasehold improvements	1,973,000	1,963,000
	8,273,000	8,077,000
Less accumulated depreciation and amortization	(5,356,000)	(4,997,000)
	<u>\$ 2,917,000</u>	<u>\$ 3,080,000</u>

Intangibles, net

	March 31, 2005 (Unaudited)	December 31, 2004
Intangibles	\$ 2,695,000	\$ 2,695,000
Less accumulated amortization	(640,000)	(573,000)
	<u>\$ 2,055,000</u>	<u>\$ 2,122,000</u>

The amortization expense of intangibles for the three months ended March 31, 2005 and 2004 was \$67,000 and \$68,000, respectively.

Estimated amortization of intangibles for the balance of 2005 and the years ended:

2005	\$ 203,000
2006	270,000
2007	270,000
2008	270,000
2009	270,000
Thereafter	772,000
	<u>\$ 2,055,000</u>

Accounts Payable and Accrued Expenses

	March 31, 2005 (Unaudited)	December 31, 2004
Accounts payable	\$ 938,000	\$ 481,000
Accrued bonus	222,000	472,000
Accrued vacation	625,000	579,000
Accrued expenses	480,000	695,000
Warranty reserve (note 8)	114,000	102,000
	<u>\$ 2,379,000</u>	<u>\$ 2,329,000</u>

13. Gain on Sale of Assets, Related Party

In January 2004, the Company received a \$5,000,000 milestone payment from Medtronic relating to the 2002 disposition of the Company's CMF product line. As part of the disposition arrangement, the Company had 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.

14. Sale of 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.

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 – and continues to report – the net proceed as deferred gain on sale of assets in the accompanying balance sheets.

The deferred gain on sale of assets will be recognized to gain on sale of assets in the statement of operations when the Company completes all remaining performance obligations under the Thin Film sale agreement. Specifically, the Company will continue to defer recognition of the 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.

Subject to the resolution of certain allegations set forth by MAST (discussed later in this note), the Company anticipates that it should be able to complete all of its remaining performance obligations, and recognize the deferred gain on sale of assets in the statement of

operations during 2005. The relevant allegations pertain to technology transfer.

Under the disposal agreement, the Company is also entitled to the following additional consideration, which has not been recognized in the financial statements covered by this report:

- \$200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) for a hernia wrap product (thin film combined product), 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 (“CEO”), provided the CEO 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 CEO on or before January 31, 2005 (four months prior to the Settlement Date). Moreover, in the event that MAST does not hire a CEO 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 Company currently believes that MAST hired a CEO in late 2004 and thus is obligated to pay the \$2,000,000 obligation in 2005. However, MAST has objected to the Company’s interpretation of the agreement and maintains that the individual hired does not qualify as the CEO under its terms, and also has asserted a right to offset based on various alleged wrongs. The Company intends to vigorously defend against any legal proceedings initiated by MAST and enforce any payments due to the Company.

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

- If MAST exercises its option on or before May 31, 2005, the purchase price will be \$3,000,000.
- 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. The Company has determined that the value of this purchase right is de minimis as of the end of the current reporting period based on a fair value analysis performed by a third party.

15. Thin Film Japan Distribution Agreement

In the third quarter of 2004, the Company entered into a Distribution Agreement with Senko Medical Trading Co. (“Senko”). Under this agreement, the Company granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan.

At the inception of this arrangement, the Company received a \$1.5 million license fee was recorded as deferred license fee revenue in the accompanying balance sheet. No portion of this license fee has been recognized in the statements of operations during any periods covered by these financial statements. The Company will recognize the deferred license fee as revenue systematically over the term of the Distribution Agreement once “Commercialization” has been achieved. In simplest terms, Commercialization occurs when one or more Thin Film product registrations are completed with the Japanese Ministry of Health, Labour and Welfare (“MHLW”). The Distribution Agreement contains certain provisions that could require the Company to return a portion of the upfront license fee. For instance, if it is determined in good faith by the Company and Senko that Commercialization of the Thin Film product is unobtainable, then 50% of the \$1,500,000 license fee will be returned to Senko. Also, if the Company terminates the Distribution Agreement at any time within the initial three years post-Commercialization, for any reason except for material breach by Senko, then a pro-rata share of the license fee will be returned to Senko. In no event will the Company recognize deferred license fee in the income statement if this would cause the remaining deferred income balance to fall below the amount that the Company potentially would have to refund to Senko.

As discussed in Note 14 above, the Company has granted MAST a Purchase Right to acquire the Company’s Thin Film-related interests and rights in Japan for \$3,000,000 or more, depending upon the fair market value upon exercise.

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

- Upon the Company notifying Senko of completion of the initial regulatory application to the MHLW for the Thin Film product, the Company is entitled to a nonrefundable payment of \$1,250,000. The Company notified Senko of the completion of the regulatory application in September 2004, received payment in October 2004, and recorded deferred development revenue of \$1,250,000. Of the amount deferred, the Company has recognized cumulative development revenues of

\$167,000, representing the fair value of the completed milestones relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the MHLW.

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

The Company has agreed to provide back-up supply of products to Senko subject to the terms of the Distribution Agreement in the event that (a) MAST exercises its Purchase Right (see Note 14) and (b) MAST materially fails to deliver product to Senko. In this circumstance, Senko would pay any amounts due for purchases of product, as well as payments in the nature of royalties, directly to the Company. The Company would be obliged to remit 5% of the gross margin to MAST on any products sold to Senko. The Company believes that it is unlikely in practice that this contingency will materialize. Accordingly, the Company estimates the fair value of this guarantee to be de minimis as of the end of the current reporting period.

16. Subsequent Event

In April 2005, the Company signed a definitive agreement to sell 1.1 million shares of common stock to an investor at \$10.00 per share. The transaction will be completed on or before May 31, 2005. As part of the agreement, the investor has been granted an option that expires December 31, 2006 to purchase an additional 2.2 million shares of common stock at \$10.00 per share. The investor has also been offered a seat on the Company's Board of Directors.

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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 primary focus is to discover and develop therapies for cardiovascular disease, spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery using regenerative cells from adipose tissue (human fat tissue). Adipose tissue is the richest and most accessible source for regenerative cells in the human body. This tissue contains adult stem cells, angiogenic cells (blood vessel forming) and other regeneration-promoting cells.

Our lead stem and regenerative cell therapy, currently in preclinical testing, targets cardiovascular disease, including myocardial infarction. Additionally, we have a pipeline of other preclinical investigational therapies that target multiple therapeutic areas. To facilitate the processing and delivery of adipose-derived regenerative cells, we are designing a proprietary point-of-care system, Celution™, to isolate and concentrate a patient's own regenerative cells in approximately one hour. Our goal is to commercialize systems that may be used across multiple therapeutic applications. Specifically, the commercialization model will comprise the sale of devices and related consumables.

Additionally, we have two bioresorbable surgical implant product lines. We manufacture the HYDROSORB™ family of FDA-cleared bioresorbable spine and orthopedic implants, which are distributed worldwide exclusively through Medtronic, Inc. ("Medtronic"). Moreover, although we disposed of most of our Thin Film product line in 2004, we retained the rights to manufacture and market such products in Japan. Accordingly, we are developing the Thin Film bioresorbable implants for Senko Medical Trading Co. ("Senko"), which has exclusive distribution rights to these products in Japan.

For the next several years we plan to fund the research and development of our regenerative cell technology through:

- Existing cash reserves;
- Potential future financings;
- Potential future grants;
- Profits, if any, from bioresorbable product sales;
- Cash flows related to recent product line divestitures and licensing agreements; and
- Potential regenerative cell technology partnerships.

During this time, we expect to:

- Complete the engineering and design of our point-of-care regenerative cell technology system and seek relevant regulatory clearances;
- Continue preclinical development of regenerative cell therapies for multiple therapeutic applications;
- Expand our intellectual property position related to our regenerative cell program;
- Advance regenerative cell technology programs into clinical development;
- Form at least one key regenerative cell related collaboration outside the area of cardiovascular disease; and
- Pursue available grant opportunities.

Our total revenues for the first quarter of 2005 were \$1,789,000 compared to \$2,352,000 for the same period in 2004. The decline in revenues is attributable to the absence of Craniomaxillofacial ("CMF") and Thin Film sales as a result of divesting these product lines to Medtronic and MAST Biosurgery AG ("MAST"), respectively. Of the total revenue for the first quarter of 2005, \$1,755,000 was attributable to HYDROSORB™ sales, compared to \$1,647,000 for the same period in 2004. HYDROSORB™ sales increased for the second consecutive quarter due predominantly to stocking orders for the radiographically identifiable Spine System products. The

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inventory build-up of HYDROSORB™ products during the first quarter of 2005 may not be indicative of any future ordering patterns or trends by Medtronic, as their marketing efforts have historically been below our expectations, which have resulted in slower than anticipated end-use market penetration.

Net loss for the quarter ended March 31, 2005 was \$4,527,000 compared to net income of \$1,490,000 for the same period in 2004, which included a one time, \$5,000,000 gain related to the sale of the CMF product line to Medtronic. Net loss in the first quarter of 2004 before the one time gain was \$3,510,000 as shown in the table below (1).

	For the Three Months Ended March 31,	
	2005	2004
Net income (loss) GAAP	\$ (4,527,000)	\$ 1,490,000
Less: Gain on the sale of asset, related party	—	(5,000,000)
Adjusted net loss	<u>\$ (4,527,000)</u>	<u>\$ (3,510,000)</u>

(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 one-time payment we received in the first quarter of 2004.

The increase in adjusted net loss during the first quarter of 2005 compared to the first quarter of 2004 is due in part to expenses related to research and development efforts for stem and regenerative cell therapies.

We ended the first quarter of 2005 with \$8,165,000 in cash, cash equivalents and short-term investments. We expect to increase our cash position by \$11,000,000 on or before May 31, 2005 through an equity placement agreement we entered into after the end of the quarter.

Equity Placement

After the end of the quarter, we signed a definitive agreement to raise \$11.0 million by selling 1.1 million shares of common stock to an investor at \$10.00 per share. The transaction will be completed on or before May 31, 2005. As part of the agreement, the investor has been granted an option that expires December 31, 2006 to purchase an additional 2.2 million shares of common stock at \$10.00 per share. The investor has also been offered a seat on our Board of Directors.

2005 Financial Projections

For the next several years, we expect to incur increasing losses as we invest into the research and development of our regenerative cell technology. Such losses will continue until the first regenerative cell technology products become commercialized.

In 2005, we expect bioresorbable technology-related revenues of \$6,000,000 to \$9,000,000. We are preparing for the commercialization of Thin Film products in Japan, which we anticipate to occur in 2005 or early 2006. Commercialization of the Thin Film product line may result in revenues related to stocking orders and royalty payments from Senko, provided MAST does not exercise its option for Thin Film-related interests and rights in Japan (see Disposition of Product Lines- Sale of Thin Film Product Line below for further details regarding this option). If MAST does exercise its option, they are required to make at least a \$3,000,000 payment to us and equally share with us their gross profits and royalties from Senko for a three-year period post-commercialization.

Further, we expect our overall research and development expenses in 2005 to be in the range of \$11,000,000 to \$13,000,000, as we continue preclinical studies and prepare to enter clinical studies in 2006 related to our regenerative cell technology. We expect our sales and marketing expenses to decline significantly this year as we will no longer incur expenses related to Thin Film independent sales representatives.

Disposition of Product Lines

Sale of Craniomaxillofacial Product Line

In September 2002, we entered into an Asset Purchase Agreement (the "Agreement") to sell assets related to our CMF implant and accessory product line to Medtronic for what resulted in total net consideration of \$15,500,000. In accordance with the terms of the Agreement, we received an initial payment of \$13,000,000 from Medtronic and a first milestone payment of \$1,000,000 in the fourth quarter of 2002. A final milestone payment of \$1,500,000 was received in 2004.

The Agreement requires us not to market in the craniomaxillofacial field, for five years, any products that compete with the acquired product line. Additionally, during the technology transfer transition period, we agreed to be a back-up supplier of CMF products to Medtronic at a price equal to our cost of manufacture.

The Agreement also allowed us to receive up to \$5,000,000 if and when we completed successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement. In January 2004, after we completed the successful clinical evaluations, we received a \$5,000,000 milestone payment from Medtronic and it was recognized as gain on sale of assets, related party, in the accompanying statements of operations.

In a separate, but simultaneous, 2002 transaction, we paid Medtronic \$4,000,000 in cash to amend an existing Development and Supply Agreement (the "Amended Development Agreement", and collectively with the Asset Purchase Agreement, the "Agreements") to remove a preexisting contractual right of first offer for distributorship by Medtronic of our bioresorbable thin film products for use in various types of soft tissue surgical applications. Medtronic will retain its right of first offer for distributorship of our other bioresorbable products in all fields, as well as to our bioresorbable thin film products for use in the spinal application field. In addition, the term of the Amended Development Agreement with Medtronic was extended to September 30, 2012.

We accounted for the net proceeds of the Agreements as deferred gain on sale of assets, related party. This gain was to be recognized only as certain events occurred. For instance, we recognized a portion of the deferred gain upon the sale of the CMF products to Medtronic under our back-up supply arrangement, which provided for sales of the CMF products to Medtronic at cost. The amount of the deferred gain recognized is equal to the excess of the fair value of products sold, based on historical selling prices of similar products, over the Company's manufacturing cost. The remainder of the deferred gain was recognized in the third quarter of 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

Sale of Thin Film 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 and one of its subsidiaries. We have received \$7,000,000 in cash and might receive the following additional contingent consideration:

- \$200,000, payable only upon receipt of 510(k) clearance from the U.S. Food and Drug Administration for a hernia wrap product (thin film combination), 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 had not hired 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. We believe that MAST hired a CEO in late 2004 and, thus, became obliged to pay the \$2,000,000 obligation in early 2005. However, MAST has objected to our interpretation of the agreement and maintains that the individual hired does not qualify as the CEO under its terms. Regardless, MAST's obligation is due to us no later than May 31, 2005, although MAST has now also asserted a right to offset based on various alleged wrongs. We intend to vigorously defend against any legal proceedings initiated by MAST and enforce any payments due to MacroPore.

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 \$6,450,000 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.

We do not expect to complete our performance obligations until later in 2005 and, accordingly, will not recognize the majority of the deferred gain until that time. The recognition of the gain will also be dependent upon the resolution of certain MAST allegations regarding technology transfer.

In 2004 we recognized \$772,000 of the deferred gain as revenues related to the sale of Thin Film products to MAST under the back-up supply agreement at cost. No deferred gain was recognized as revenue in the first quarter of 2005 because there were no shipments of product to MAST. The recognition of the deferred gain was necessary in 2004 in order to state revenues at fair value of products sold, based on historical selling prices of similar products, over the Company's manufacturing cost.

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

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

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

- If MAST exercises its option on or before May 31, 2005, the purchase price will be \$3,000,000.
- After May 31, 2005 but before May 31, 2007, the exercise price of the Purchase Right will be 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 protection of intellectual property rights in the country of Japan. Moreover, under certain circumstances MAST must share certain milestone payments and gross profits with us, if MAST exercises the Purchase Right and Thin Film products are marketed in Japan.

Thin Film Japan Distribution Agreement

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

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

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

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

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

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

We will also be entitled to earn additional payments from Senko based on achieving defined milestones. We will recognize such payments as revenues when the performance criteria for a milestone have been met, presuming that achievement of the milestone involves substantive effort and the fees received are commensurate with the level of effort expended. On September 28, 2004, we notified Senko of completion of the initial regulatory application to the MHLW for the Thin Film product. As a result, we became entitled to a nonrefundable payment of \$1,250,000, which we received in October 2004 and recorded as deferred development revenue. Of the amount deferred, we recognized \$167,000 (totaling \$9,000 and \$158,000 in 2005 and 2004, respectively) as development revenues. The amount recognized as development revenues represents the relative fair value of the completed milestone as compared with the fair value of all milestones expected to be necessary to achieve regulatory approval by the MHLW.

Results of Operations

Revenues

The following table summarizes the components of our revenues for the three months ended March 31, 2005 and 2004:

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	For the three months ended March 31,			
	2005	2004	\$ Difference	% Difference
Spine and orthopedic products	\$ 1,755,000	\$ 1,647,000	\$ 108,000	6.5%
Thin film products	—	337,000	(337,000)	—
Craniomaxillofacial (CMF) products:				
Product sales	—	123,000	(123,000)	—
Amortization of gain on sale	—	151,000	(151,000)	—
Total craniomaxillofacial	—	274,000	(274,000)	—
Research grant (NIH)	23,000	90,000	(67,000)	(74.4)
Development (Senko)	9,000	—	9,000	—
Regenerative cell storage services	2,000	4,000	(2,000)	(50.0)
Total	\$ 1,789,000	\$ 2,352,000	\$ (563,000)	(23.9)%
% attributable to Medtronic	98.1%	81.7%		

- Spine and orthopedic revenues represent sales of bioresorbable implants used in spine and orthopedic surgical procedures. These revenues were dominated by stocking orders during the first quarter of 2005 for the pre-launch of our radiographically identifiable Spine System products, which received FDA clearance in August of 2004. This product represents the latest design enhancement to our family of HYDROSORB™ products. Its unique feature is the integration of small markers of radiographically visible resorbable material within the product. These patent pending markers enable the surgeon to preserve the benefit of fusion visualization, while simultaneously tracking the exact position of the implant during the intraoperative and postoperative periods. Because the markers are fabricated from a resorbable material, they do not pose the issues that permanent markers could pose after the implant resorbs.

Surgeon demand for bioresorbable devices as well as the pre-launch of a new product within the HYDROSORB™ products portfolio contributed to spine and orthopedic revenues during the three months ended March 31, 2004.

Refer to “The future” discussion below for our expectations regarding the outlook for spine and orthopedic revenues. Note that Medtronic owns approximately 7.2% of our outstanding common stock at March 31, 2005.

- Thin Film product revenues in 2004 represent sales of SurgiWrap™ bioresorbable Thin Film used to support and reinforce soft tissues and to minimize tissue attachment to the device in case of contact with the viscera (organs of the body). We sold most, but not all, of our intellectual property rights and tangible assets related to our Thin Film product line to MAST in the second quarter of 2004. We are obliged by contract to sell these products to MAST at our manufacturing costs. However, as MAST begins to assume the manufacturing process, we expect domestic revenue from Thin Film products to decline and end in 2005. No revenues from the Thin Film product line were recognized during the first quarter of 2005.
- The CMF product revenues represent sales of the CMF product line used for trauma and reconstructive procedures in the midface and craniofacial skeleton (the head and skull). We sold this product line to Medtronic in 2002. As with the Thin Film products, we sold CMF products at cost in 2004 under a contractual back-up supply agreement with Medtronic. A portion of the deferred gain related to sale of assets was recognized in order to reflect the fair value of products sold, based on historical selling prices of similar products, over our manufacturing cost. During the third quarter of 2004, we completed all remaining performance obligations related to the 2002 sale of the CMF product line to Medtronic. Therefore, we did not earn any CMF product revenues during the first quarter of 2005 and do not expect to recognize revenue on this product line in the future.
- The research grant revenue relates to our agreement with the National Institutes of Health (“NIH”). Under this arrangement, the NIH reimburses us for “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. To receive funds under the grant arrangement, we are 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.

During the three months ended March 31, 2005 and 2004, we incurred \$22,000 and \$99,000, respectively, in qualifying expenditures. We also earned \$1,000 in allowable grant fees in 2005, for a total of \$23,000 in reimbursements. We have recorded revenues for the same amount. Although we had incurred \$99,000 in costs during the three months ended March 31, 2004, we recorded revenues of \$90,000, consistent with our policy to recognize revenues under the NIH grant arrangement as the lesser of (i) qualifying costs incurred (and not previously recognized), plus our allowable grant fees 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.

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

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- Upon notifying Senko of completion of the initial regulatory application to the MHLW for the Thin Film product, we were entitled to a nonrefundable payment of \$1,250,000. We so notified Senko on September 28, 2004, received payment in October of 2004, and recorded deferred development revenue. Of the amount deferred, we have recognized development revenues of \$9,000 during the three months ended March 31, 2005, representing the relative fair value of the completed milestones completed this quarter as compared with the fair value of all milestones expected to be necessary to achieve regulatory approval by the MHLW;
- Upon the achievement of commercialization of the Thin Film product line in Japan, we are entitled to a nonrefundable payment of \$250,000. As of March 31, 2005, commercialization had not occurred; however, commercialization is expected later in 2005 or early 2006.

The future: We sell our spine and orthopedic products exclusively to Medtronic at fixed selling prices that are subject to adjustment biannually (based on Medtronic's selling prices to its customers). Our revenue from this product line is dependent upon the market's adoption of our technology, which is largely dependent upon Medtronic's marketing efforts and pricing strategies. To increase our revenues from spine and orthopedic products, we depend largely on Medtronic's ability and commitment to build and expand HYDROSORB™ market share. We currently expect market demand and revenues for our HYDROSORB™ products to increase during the remainder of 2005, particularly as Medtronic and its customers employ our radiographically identifiable Spine System products. We have, however, been disappointed in the past by Medtronic's level of effort in marketing our HYDROSORB™ products, and if their level of effort does not improve our sales will suffer.

We are entitled to receive up to \$850,000 in additional grants related to Adipose-Derived Cell Therapy for Myocardial Infarction as defined by the NIH grant agreement for Phase II research. To date, we have received and recognized \$251,000 of such funding. We expect to incur "qualifying expenses" in 2005 and 2006 of \$599,000. Subject to availability of NIH funds and satisfactory progress toward meeting the goals and objectives of our grant application, we expect to recognize any remaining grant revenues during 2005 and 2006.

We will continue to recognize revenue from the milestone payment from Senko, based on the fair value of the milestones completed relative to the total efforts expected to be necessary to obtain regulatory clearance with the MHLW. Obtaining regulatory clearance with the MHLW for initial commercialization is expected in 2005 or early 2006. Accordingly, we expect to recognize approximately \$1,333,000 in revenues associated with this milestone arrangement throughout 2005 and the early part of 2006.

To the extent that sales of our spine and orthopedic products to Medtronic (and to Medtronic's customers) increase, 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.

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 months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	2005	2004	\$ and % Difference	% Difference
Cost of revenues:				
Cost of revenues	\$ 745,000	\$ 877,000	\$ (132,000)	(15.1)%
% of revenue	41.6%	37.3%	4.3%	11.5
Inventory provision	—	242,000	(242,000)	—
% of revenue	—%	10.3%	—%	—
Total	\$ 745,000	\$ 1,119,000	\$ (374,000)	(33.4)%
% of revenues	41.6%	47.6%		

- The cost of revenues, as a percent of revenues (excluding inventory provision amounts), increased 11.5% in the three months ended March 31, 2005 as compared to the same period in 2004. The percentage increase in 2005 from 2004 was due to the decrease in sales volume and the insufficient production of inventory to absorb fixed manufacturing and labor expense. Excess manufacturing capacity expensed in the three months ended March 31, 2005 was \$102,000 as compared to \$106,000 in the same period in 2004.
- The \$242,000 inventory provision during the three months ended March 31, 2004 with no comparable charges in 2005 related to excess inventory. Such inventory was produced in consideration of our responsibility to be a back-up supplier for the 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

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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 as well as the May 2004 sale of our non-Japan bioresorbable Thin Film product line will deprive us of economies of scale and will negatively impact our margins unless other sources of revenue grow large enough to compensate for the lost revenue.

Research and development expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and preclinical studies. The following table summarizes the components of our research and development expenses for the three months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	<u>2005</u>	<u>2004</u>	<u>\$ Difference</u>	<u>% Difference</u>
Regenerative cell technology	\$ 2,540,000	\$ 1,464,000	\$ 1,076,000	73.5%
Bioresorbable polymer implants	674,000	944,000	(270,000)	(28.6)
Research grants (NIH)	22,000	99,000	(77,000)	(77.8)
Development milestone-Senko	37,000	—	37,000	—
Total	\$ 3,273,000	\$ 2,507,000	\$ 766,000	30.6%

- 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 increases in regenerative cell technology expenses from 2004 to 2005 resulted primarily from the hiring of additional researchers, engineers and support staff. We incurred an additional \$277,000 in labor-related expenses in the three months ended March 31, 2005, as compared with 2004. The remainder of the increases as compared with 2004 related to increases in legal, research supplies, consulting fees and facility expenses of \$799,000 in the three months ended March 31, 2005.
- 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 2005 as compared with 2004 was a result of a strategic decision to strongly focus our research and development efforts on our regenerative cell technology.
- In 2004, we entered into an agreement with the NIH to reimburse us for up to \$950,000 (Phase I \$100,000 and Phase II \$850,000) in “qualifying expenditures” related to research on Adipose-Derived Cell Therapy for Myocardial Infarction. In the three months ended March 31, 2005, we incurred \$22,000 of direct qualifying expenses relating to Phase II. In the three months ended March 31, 2004, we incurred \$99,000 of direct qualifying expenses relating to Phase I of the agreement.
- Under a Distribution Agreement with Senko we are responsible for the completion of the initial regulatory application to the MHLW and commercialization of the Thin Film product line in Japan. Commercialization occurs when one or more Thin Film product registrations are completed with the MHLW. During the three months ended March 31, 2005, we incurred \$37,000 of expenses related to this regulatory and registration process.

The future: We are developing a system to isolate autologous, homologous-use, regenerative cells. Simultaneously, we are generating scientific knowledge through internal research to support the clinical use of these cells and have made significant progress in understanding the potential clinical applications. Our most advanced stem and regenerative cell therapy currently in preclinical testing is for the repair of cardiovascular muscle tissue that is damaged after a heart attack. Our strategy is to continue to increase our research and development efforts in this field and we anticipate expenditures in this area of research to be approximately \$8,000,000 to \$10,000,000 in 2005. We are also researching therapies for spine and orthopedic conditions, gastrointestinal disorders and new approaches for aesthetic and reconstructive surgery. The expenditures will primarily relate to developing therapeutic applications and conducting preclinical studies on harvesting therapeutically useful quantities of regenerative cells for cardiac tissue repair, bone regeneration, cosmetic and reconstructive 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 sale of our CMF and Thin Film (non-Japan territory) product lines. However, we will continue to invest in product development for biomaterial/polymer products to develop our pipeline of new and next generation spine and orthopedic products.

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

project during the remainder of 2005 and 2006.

Sales and marketing expenses

Sales and marketing expenses include costs of marketing personnel, tradeshow, and promotional activities and materials. It excludes related stock based compensation expenses. Medtronic is responsible for the distribution, marketing and sales support of our spine and orthopedic devices. Our bioresorbable Thin Film product line (before the sale of the non-Japan Thin Film business to MAST in May 2004) was distributed domestically through a dedicated sales force, independent sales representatives and internationally through independent distributors. The following table summarizes the components of our sales and marketing expenses for the three months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	<u>2005</u>	<u>2004</u>	<u>\$ Difference</u>	<u>% Difference</u>
General corporate marketing	\$ 148,000	\$ 193,000	\$ (45,000)	(23.3)%
Domestic sales and marketing	—	560,000	(560,000)	—
International sales and marketing	243,000	205,000	38,000	18.5
Total	\$ 391,000	\$ 958,000	\$ (567,000)	(59.2)%

Note: Certain prior period amounts have been reclassified to conform to current period presentation.

- General corporate marketing expenditures relate to expenditures for maintaining our corporate image and reputation within the research and surgical communities. The decrease in 2005 as compared to 2004 was due to one-time costs incurred for an educational program we created in 2004 to inform end-users and distributors of the benefits and surgical applications for our biomaterials products. Additionally, in 2005 we allocated fewer personnel resources to general corporate marketing.
- Domestic sales and marketing relate to expenses associated with managing our domestic bioresorbable Thin Film product distribution, which included independent sales representatives and our domestic Thin Film sales consultants and marketing staff. The elimination of such expenses in 2005 as compared to 2004 was due to the transfer of our sales force and marketing staff to MAST upon the sale of the Thin Film product line to MAST in May 2004.
- International sales and marketing relate to costs associated with developing an international bioresorbable Thin Film distributor, supporting a bioresorbable Thin Film sales office in Japan and establishing relationships to support and promote our regenerative cell technology. The increased spending in 2005 as compared to 2004 relates to an increase in personnel resources currently dedicated to this marketing group.

The future: We project that corporate marketing as well as our international sales and marketing expenditures will remain reasonably stable for the balance of 2005.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. It excludes related stock based compensation expenses. The following table summarizes the general and administrative expenses for the three months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	2005	2004	\$ Difference	% Difference
General and administrative expenses	\$ 1,909,000	\$ 1,226,000	\$ 683,000	55.7%

- The primary reason for the increase in 2005 as compared to 2004 was the result of salary, administrative and professional service expenses rising due to the hiring and retaining of a qualified management team to implement and manage our strategic plan. Salary expenses increased approximately \$376,000 in 2005 as compared to 2004 and professional services and other general corporate expenditures rose approximately \$307,000 from the prior year.

The future: We expect general and administrative expenses to increase as we incur costs for professional services related to Sarbanes-Oxley compliance as well as a full year of salary costs for our new Chief Financial Officer. Also, we expect to incur additional legal expenses in connection with the University of Pittsburgh's recently filed lawsuit challenging inventorship of our licensor's U.S. patent relating to adult stem cells isolated from adipose tissue. We may also incur legal expenses if we cannot resolve our disagreements with MAST.

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 (in their capacity as board members) 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 initially is the fair value of the underlying common stock on the initial date of grant, but such amount is updated over the vesting period until the non-employee has met the performance commitment. Unearned employee stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four-year period from the date of grant. The following table summarizes the components of our stock based compensation expenses for the three months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	2005	2004	\$ Difference	% Difference
Sales and marketing related	\$ —	\$ 11,000	\$ (11,000)	—%
General and administrative related	—	35,000	(35,000)	—
Total	\$ —	\$ 46,000	\$ (46,000)	—%

- All unearned stock based compensation was fully expensed by the end of 2004.

The future: We may from time to time award stock based compensation to consultants, in lieu of, or in addition to, cash compensation. In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("FAS 123R"). As amended by Securities and Exchange Commission Release No. 33-8586, "Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment," FAS 123R is effective for annual periods beginning after June 15, 2005 (January 1, 2006 for us). Upon adoption, FAS 123R will require us to measure all share-based payment transactions, including those with employees, at fair value. Moreover, the fair value of share-based payment awards will be recognized as expense in the statements of operations over the requisite service period of each award. Employee stock options will, to the extent they vest after December 31, 2005, result in stock-based compensation expense charges beginning in 2006. FAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications. Even with our adoption of FAS 123R we plan to continue to grant options (which now will result in an expense) to our employees and as appropriate, to non-employee service providers.

Other income

The following is a table summarizing the gain on the sale of assets, related party for the three months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	2005	2004	\$ Difference	% Difference
Gain on sale of assets, related party	\$ —	\$ 5,000,000	\$ (5,000,000)	—%

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

The future. In 2005, we expect that we should be able to recognize the deferred gain on the sale of the Thin Film assets to MAST, which is not a related party, subject to the resolution of certain MAST allegations regarding technology transfer. This would result in a one-time gain of approximately \$5,650,000.

Financing items

The following table summarizes interest income, interest expense, and other expense for the three months ended March 31, 2005 and 2004:

	For the three months ended March 31,			
	2005	2004	\$ Difference	% Difference
Interest income	\$ 55,000	\$ 55,000	\$ —	—%
Interest expense	(40,000)	(39,000)	(1,000)	2.6
Other expense	(13,000)	(22,000)	9,000	(41.0)
Total	\$ 2,000	\$ (6,000)	\$ 8,000	133.3%

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- Interest income and interest expense remained consistent from 2004 to 2005.
- The changes in other expense in 2005 as compared to 2004 resulted primarily from changes in foreign currency exchange rates.

Deferred gain on sale of assets

At March 31, 2005, we have reflected \$5,650,000 of unamortized deferred gain on sale of assets on our balance sheet. This deferred gain related to the sale of our Thin Film product line to MAST in May 2004. Because of additional performance requirements required under the disposition arrangement, we did not initially recognize any gain on sale of the Thin Film assets in our statement of operations. Instead, we initially recorded approximately \$6,450,000 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, rights to intangible assets, and acting in the capacity of a back-up supplier to MAST for a period of one year. Under the back-up supply agreement, we have agreed to supply product ordered by MAST at our manufacturing cost.

We do not expect to complete our performance obligations until later in 2005 and, accordingly, would not be able to recognize the deferred gain until that time. The recognition of the gain will also be dependent upon the resolution of certain MAST allegations regarding technology transfer. 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 at fair value of products sold, based on historical selling prices of similar products, over the Company's manufacturing cost. No deferred gain on sale of assets was recognized as revenue during the three months ended March 31, 2005, as no products were sold to MAST under the backup supply agreement.

Deferred license fee revenue

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

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

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

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

We do not expect commercialization to be achieved until later in 2005 or early 2006.

Deferred development revenue

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

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

We notified Senko on September 28, 2004 regarding the completion of the initial regulatory application and recorded deferred development revenue of \$1,250,000. Of the amount deferred, we have recognized development revenues of \$167,000 (totaling \$9,000 and \$158,000 in 2005 and in the third and fourth quarter of 2004, respectively), representing the fair value of the completed milestone relative to the fair value of the total efforts expected to be necessary to achieve regulatory approval by the MHLW.

Liquidity and Capital Resources

Cash provided by (used in) operating, investing and financing activities for the three months ended March 31, 2005 and 2004, is summarized as follows:

	<u>For the three months ended March 31,</u>	
	<u>2005</u>	<u>2004</u>
Net cash used in operating activities	\$ (4,825,000)	\$ (3,205,000)
Net cash provided by investing activities	3,082,000	4,357,000
Net cash used in financing activities	(233,000)	(601,000)

Operating activities

Net cash used in operating activities during the three months ended March 31, 2005 resulted from our net loss of \$4,527,000 and changes in working capital due to the timing of product shipments (accounts receivable) and payment of liabilities.

Net cash used in operating activities in the three months ended March 31, 2004 primarily resulted from our negative cash flow from operations. Although we reported net income of \$1,490,000 for this period, this figure includes a one-time \$5,000,000 gain related to the sales of the CMF product line to Medtronic. Without this gain, our adjusted net loss for the period would have been \$3,510,000.

Our net losses (as adjusted) for both periods resulted largely from expenses related to our research and development efforts for stem and regenerative cell therapies.

Investing activities

Net cash provided by investing activities in the three months ended March 31, 2005 resulted primarily from the sale and maturity of our short-term investments, the proceeds from which were used to fund operating activities during the quarter.

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

Capital spending is essential to our product innovation initiatives and to maintaining our operational capabilities. Therefore, in the three months ended March 31, 2005 and 2004, we used cash to purchase \$196,000 and \$309,000, respectively, of property and equipment primarily 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 three months ended March 31, 2005 related mainly to the payment of \$234,000 on our long-term obligations.

The net cash used in financing activities in the three months ended March 31, 2004 related to:

- The repurchase of 286,602 shares of our common stock for \$1,043,000; and
- The payment of \$176,000 on our long term obligations.

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

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at March 31, 2005 and December 31, 2004:

	<u>March 31, 2005</u>	<u>December 31, 2004</u>	<u>\$ Difference</u>	<u>% Difference</u>
Cash and cash equivalents	\$ 864,000	\$ 2,840,000	\$ (1,976,000)	(69.6)%
Short-term investments, available for sale	7,301,000	10,579,000	(3,278,000)	(31.0)
Total cash and cash equivalents and short-term investments, available for sale	<u>\$ 8,165,000</u>	<u>\$ 13,419,000</u>	<u>\$ (5,254,000)</u>	<u>(39.2)</u>
Current assets	\$ 11,092,000	\$ 15,645,000	\$ (4,553,000)	(29.1)

Current liabilities	3,235,000	3,267,000	(32,000)	(1.0)
Working capital	<u>\$ 7,857,000</u>	<u>\$ 12,378,000</u>	<u>\$ (4,521,000)</u>	(36.5)%

We believe that existing funds, cash generated by operations, and existing and accessible sources of financing are adequate to satisfy our working capital, capital expenditures, debt service and other financial commitments at least through March 31, 2006. However, in order to provide greater financial flexibility and liquidity, and in view of the substantial cash needs of our regenerative cell business during its development stage, we will need to raise additional capital.

From inception to March 31, 2005, we have financed our operations primarily by:

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

The need to finance operating losses without the benefits of a non-recurring payment of \$5,000,000 for the completion of CMF clinical research as well as receipt of \$594,000 in long-term financing in 2004, has resulted in deterioration of our liquidity metrics in 2005 as compared to 2004. However, we expect to increase our cash position by \$11,000,000 on or before May 31, 2005 through an equity placement agreement we entered into in April 2005. This agreement covers the sale of 1.1 million shares of our common stock to an investor at \$10.00 per share. Also as part of the agreement, the investor has been granted an option that expires December 31, 2006 to purchase an additional 2.2 million shares of common stock at \$10.00 per share. We also offered the investor one seat on our board of directors.

We believe that our near-term borrowing requirements and debt repayments will continue to involve a relatively small amount of cash. To fund 2005 expected capital expenditures of \$500,000, we intend to use available working capital and if available, borrow under our Amended Master Security Agreement.

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

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

We expect to incur research and development expenses, well beyond our current level, in our regenerative cell platform for an extended time. This will occur whether or not our spine and orthopedics biomaterials business returns to profitability. We will continue to seek collaborations and new sources of financing, such as through additional sales of equity securities, in order to fund operations, satisfy financial obligations, and achieve our research and development objectives.

The following summarizes our contractual obligations and other commitments at March 31, 2005, and the effect such obligations could have on our liquidity and cash flow in future periods:

Contractual Obligations	Total	Payments due by period			
		Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Long-term debt obligations	\$ 1,832,000	\$ 856,000	\$ 976,000	\$ —	\$ —
Interest commitment on debt	199,000	97,000	102,000	—	—
Operating lease obligations	2,044,000	743,000	1,301,000	—	—
Research study obligations	291,000	291,000	—	—	—
Total	<u>\$ 4,366,000</u>	<u>\$ 1,987,000</u>	<u>\$ 2,379,000</u>	<u>\$ —</u>	<u>\$ —</u>

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 recognition and disclosure of contingent assets and liabilities.

While our estimates are based on assumptions we consider reasonable at the time they are 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

We derive our revenue from a number of different sources, including but not limited to:

- Product sales,
- Upfront payments from license or distribution agreements, and
- Fees for achieving certain defined milestones under development or commercialization arrangements.

Many of our revenue generating arrangements are relatively simple in nature, meaning that there is little judgment necessary with regard to the timing of when we recognize revenues or how such revenues are presented in the financial statements.

However, we have also entered into more complex arrangements, including but not limited to our contracts with the NIH and Senko. Moreover, some of our non-recurring transactions, such as our disposition of the majority of our Thin Film business to MAST or our sale of our CMF product line to Medtronic, contain elements that relate to our core revenue producing activities.

As a result, some of our most critical accounting judgments relate to the identification, timing, and presentation of revenue-related activities. These critical judgments are discussed further in the paragraphs that follow.

Multiple-elements

Some of our revenue generating arrangements contain a number of distinct revenue streams, known as “elements.” For example, our Distribution Agreement with Senko contains direct or indirect future revenue streams related to:

- A distribution license fee (which was paid at the outset of the arrangement),
- Milestone payments for achieving commercialization of the Thin Film product line in Japan,
- Training for representatives of Senko,
- Sales of Thin Film products to Senko, and
- Payments in the nature of royalties on future product sales made by Senko to its end customers.

Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables (“EITF 00-21”), governs whether each of the above elements in the arrangement should be accounted for individually, or whether the entire contract should be treated as a single unit of accounting.

EITF 00-21 indicates that individual elements may be separately accounted for only when:

- The delivered element has stand alone value to the customer,
- There is objective evidence of the fair value of the remaining undelivered elements, and
- If the arrangement contains a general right of return related to any products delivered, delivery of the remaining goods and services is probable and within the complete control of the seller.

In the case of the Senko Distribution Agreement, we determined that (a) the milestone payments for achieving commercialization and (b) the future sale of Thin Film products to Senko were “separable” elements. That is, each of these elements, upon delivery, will have stand alone value to Senko and there will be objective evidence of the fair value of any remaining undelivered elements at that time. The arrangement does not contain any general right of return, and so this point is not relevant to our analysis.

On the other hand, we concluded that (a) the upfront distribution license fee, (b) the revenues from training for representatives of Senko, and (c) the payments in the nature of royalties on future product sales are not separable elements under EITF 00-21.

In arriving at our conclusions, we had to consider whether our customer, Senko, would receive stand alone value from each

delivered element. We also, in some cases, had to look to third party evidence to support the fair value of certain undelivered elements – notably, training – since we as a company do not routinely deliver this service on a stand alone basis. Finally, we had to make assumptions about how the non-separable elements of the arrangement are earned, particularly the estimated period over which Senko will benefit from the arrangement (refer to the “Recognition” discussion below for further background).

Our conclusions, in effect, cause us to recognize certain revenues from the Senko Distribution Agreement sooner than if we had alternatively concluded that none of the elements in the arrangement were separable. Notably, we have recognized \$167,000 in cumulative development revenues from the Senko Distribution Agreement, mostly related to achieving certain milestones related to the commercialization of Thin Film products in Japan. Had our judgments regarding the separation of elements been different, we likely would have recognized as revenues an amount less than this.

Recognition

Besides determining whether to account separately for components of a multiple-element arrangement, we also use judgment in determining the appropriate accounting period in which to recognize revenues that we believe (a) have been earned and (b) are realizable. The following describes a small sampling of the recognition issues we have considered during the reporting period.

- Upfront License Fees
 - As part of the Senko Distribution Agreement, we received an upfront fee upon execution of the arrangement. We concluded that such fee was not earned at that time and, instead, reported the cash as deferred license fee revenue. We then had to consider over what period the

upfront fee should be recognized as revenue, especially considering that the fee was refundable under certain conditions. We ultimately concluded that the fee would be earned – and, thus recognized as revenues – beginning when regulatory approval was received to market Thin Film products in Japan. We further concluded that revenues would be reported on a straight-line basis over a five year period. We selected the straight-line method because we otherwise could not reliably estimate the manner in which Senko would benefit from the terms of the Distribution Agreement. The license fees will be recognized over a five year period as this corresponds to the initial term of the Distribution Agreement. We note that the Distribution Agreement is renewable for an additional five year period upon mutual consent of Senko and MacroPore. However, we believe that it is too soon to judge whether Senko will benefit from the upfront license fee payment for longer than the initial five year term; we will re-examine this assumption each reporting period and make any necessary adjustments on a prospective basis.

- Government Grants
 - We are eligible to receive grants from the NIH related to our research on adipose derived cell therapy to treat myocardial infarctions. There are no specific standards under U.S. GAAP that prescribe the recognition or classification of these grants in the income statement. Absent such guidance, we have established an accounting policy to recognize NIH grant revenues at the lesser of:
 - Qualifying costs incurred (and not previously recognized), plus any allowable grant fees, for which MacroPore is entitled to grant funding; or,
 - The amount determined by comparing the research outputs generated to date versus the total outputs that are expected to be achieved under the research arrangement.
 - Our accounting policy could theoretically defer revenue recognition beyond the period in which we have earned the rights to such fees. However, we selected this accounting policy to counteract the possibility of recognizing revenues from the NIH arrangement too early. For instance, if our policy permitted revenues to be recognized solely as qualifying costs were incurred, we could alter the amount of revenue recognized by incurring more or less cost in a given period, irrespective of whether these costs correlate to the research outputs generated. On the other hand, if revenue recognition were based on output measures alone, it would be possible to recognize revenue in excess of costs actually incurred; this is not appropriate since qualifying costs remain the basis of our funding under the NIH grant. The application of our accounting policy, nonetheless, involves significant judgment, particularly in estimating the percentage of outputs realized to date versus the total outputs expected to be achieved under the grant arrangement.
- Milestones
 - In certain of our non-governmental development arrangements, we receive payments upon the achievement of certain defined milestones. Our accounting policy is to recognize milestone payments as revenues when received if:

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- Substantive effort is required to achieve the milestone,
 - The amount of the milestone payments appear reasonably commensurate with the effort expended, and
 - Collection (or retention) of the payment is reasonably assured.
- Determining whether each of these criteria has been satisfied requires significant judgment. For example, our Distribution Agreement with Senko calls for payments to us when certain defined milestones are achieved. The first such milestone payment for \$1,250,000 became payable to us when we filed a commercialization application with the Japanese regulatory authorities. However, we determined that the payment received was not commensurate with the level of effort expended, particularly compared with other steps we believe are necessary to commercialize the Thin Film product line in Japan. Accordingly, we did not recognize the \$1,250,000 received as revenues, but instead recorded all but \$167,000 of this amount as deferred development revenue. The \$167,000 (totaling \$9,000 and \$158,000 in 2005 and 2004, respectively) was recognized as development revenues based on our estimates of the level of effort expended as compared with the total level of effort we expect to incur under the arrangement to successfully achieve regulatory approval of the Thin Film product line in Japan. These estimates were subject to judgment and there may be changes in estimates regarding the total level of effort as we continue to seek regulatory approval. Indeed, there can be no assurance that commercialization in Japan will ever be achieved.
- Back-up Supply Arrangements
 - We agreed to serve as a backup supplier of products in connection with our dispositions of both:
 - The CMF product line to Medtronic; and
 - Specific Thin Film assets to MAST.

Specifically, we agreed to supply CMF or Thin Film product to Medtronic and MAST, respectively, at our cost for a defined period of time. When we actually delivered products under the backup supply arrangements, however, we recognized revenues in the financial statements at the estimated selling price which we would receive in the marketplace. We used judgment, based on historical data and expectations about future market trends, in determining the estimated market selling price of products subject to the backup supply arrangements. The amount of the deferred gain recognized as revenue is equal to the excess of the fair value of products sold, based on historical selling prices of similar products, over the Company's manufacturing cost.

Presentation

We have presented amounts earned under our NIH research arrangement as research grant revenue. Simply, we believe that the activities underlying the NIH agreement constitute our ongoing major or central operations. Moreover, the government obtains rights under the arrangement, in the same manner (but perhaps not to the same extent) as a commercial customer that similarly contracts with MacroPore to perform research activities. For instance, the government and any authorized third parties may use our federally funded research and/or inventions without payment of royalties to us. We recognize that

others may conclude that the receipt of amounts under the NIH royalty arrangement should be presented as a reduction of any qualifying expenses incurred – that is, reported in the income statement on a net basis.

Warranty Provisions

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 our operating results. 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 prior to the third quarter of 2003.

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

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

Goodwill Impairment Testing

In late 2002, we purchased StemSource and recognized over \$4,600,000 in goodwill associated with the acquisition, of which \$4,387,000 remains on our balance sheet today. As required by Statement of Financial Accounting Standard No. 142, Goodwill and Other Intangible Assets (“SFAS 142”), we must test this goodwill at least annually for impairment. Moreover, this testing must be performed at a level of the organization known as the reporting unit. A reporting unit is at least the same level as a company’s operating segments, and sometimes even one level lower.

Specifically, the process for testing goodwill for impairment under SFAS 142 involves the following steps:

- Company assets and liabilities, including goodwill, are allocated to each reporting unit for purposes of completing the goodwill impairment test.
- The carrying value of each reporting unit – that is, the sum of all of the net assets allocated to the reporting unit – is then compared to its fair value.
- If the fair value of the reporting unit is lower than its carrying amount, goodwill may be impaired – additional testing is required.

When we completed our goodwill impairment testing in 2004, the fair values of our two reporting units each exceeded their respective carrying values. Accordingly, we determined that none of our reported goodwill was impaired.

The application of the goodwill impairment test involves a substantial amount of judgment. For instance, SFAS 142 requires that assets and liabilities be assigned to a reporting unit if both of the following criteria are met:

- The asset will be employed in or the liability relates to the operations of a reporting unit.
- The asset or liability will be considered in determining the fair value of the reporting unit.

This allocation process involves judgment. We developed mechanisms to assign company-wide assets like shared property and equipment, as well as company-wide obligations such as borrowings under our GE Loan Facility, to our two reporting units. In some cases, certain assets were not allocable to either reporting unit and were left unassigned.

The most complex and challenging asset to assign to each reporting unit was our acquired goodwill. As noted previously, all of our recorded goodwill relates to our acquisition of StemSource in 2002. All of the StemSource assets and liabilities still on hand at our 2004 testing date were allocated to our regenerative cell reporting unit. However, when we first acquired StemSource, we determined that a portion of the goodwill related to the bioresorbable reporting unit. The amount of goodwill allocated represented our best estimate of the synergies (notably future cost savings from shared research and development activities) that the bioresorbable reporting unit would obtain by virtue of the acquisition.

Finally, with the consultation and assistance of a third party, we estimated the fair value of our reporting units by using various estimation techniques. In particular, we estimated the fair value of our bioresorbable reporting unit based on an equal weighting of the market values of comparable enterprises and discounted projections of estimated future cash flows. Clearly, identifying comparable companies and estimating future cash flows as well as appropriate discount rates involves judgment. On the contrary, we estimated the fair value of our regenerative cell reporting unit solely using an income approach, as we believe there are no comparable enterprises on which to base a valuation. The assumptions underlying this valuation method involve a substantial amount of judgment, particularly since our regenerative cell business has yet to generate any revenues and does not have a commercially viable product.

Again, the manner in which we assigned assets, liabilities, and goodwill to our reporting units, as well as how we determined the fair value of such reporting units, involves significant uncertainties and estimates. The judgments employed may have an effect on whether a goodwill impairment loss is recognized. Notably, the carrying value of our regenerative cell reporting unit, including assigned goodwill, totaled \$7,100,000 as of the 2004 testing date. Furthermore, we estimated the fair value of this reporting unit to be \$12,600,000 as of this date, meaning that a subtle change in how certain assets and liabilities were allocated to our reporting units, or the manner in which we estimated fair value, could have resulted in a different conclusion as to whether some of our goodwill was impaired.

Dispositions

In 2002, we sold our CMF (skull and face) bone fixation implant and accessory product line to Medtronic.

Moreover, in 2004, we sold most of the assets and intellectual property rights in our (non-Japan) Thin Film business to MAST.

As is common in the life sciences industry, the sale agreements contained provisions beyond the simple transfer of net assets to the acquiring enterprises for a fixed price. Specifically, as part of the arrangement, we also agreed to perform the following services:

- Provide training to Medtronic or MAST personnel on production and other aspects of the CMF and Thin Film product lines, respectively.
- Provide a back-up supply of CMF product to Medtronic and Thin Film products to MAST, at cost, for a specified period of time,
- In the case of Medtronic, perform clinical evaluations for a new faster-resorbing polymer product.

Disposing assets and product lines is not one of our core ongoing or central activities. Accordingly, determining the appropriate accounting for these transactions involved some of our most difficult, subjective and complex judgments. In particular, we made assumptions around the appropriate manner and timing in which to recognize the gain on disposal for each transaction in the statement of operations. Moreover, we considered whether the dispositions should be reflected as discontinued operations in accordance with Statement of Financial Accounting Standard No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets."

For instance, upon the closing of the CMF sale agreement on September 30, 2002, we received net cash of \$9,000,000, and transferred assets to Medtronic with a net carrying value of \$476,000. The net difference of \$8,524,000 was recorded as part of a Deferred gain on sale of assets, related party on our balance sheet. We deferred recognition of the majority of this gain until Medtronic accepted the transferred net assets, which was demonstrated only when Medtronic had:

- Stopped relying on us to provide product under the back-up supply agreement,
- Integrated the acquired CMF manufacturing equipment into its operations, and
- Permitted us to deliver training to Medtronic personnel on production and other aspects of the CMF product line.

Until those events occurred, we did not believe that we have transferred all risk and rewards related to the CMF product line to Medtronic and, accordingly, recognition of the deferred gain in earnings would be inappropriate.

The risks and rewards of ownership related to the CMF product line ultimately passed to Medtronic in August 2004. The remainder of the deferred gain was recognized in the third quarter of 2004 when the technology and know-how transfer was completed pursuant to the contract terms.

Conversely, we have yet to recognize the majority of the deferred gain related to our disposition of certain Thin Film assets, which occurred in May 2004. Again, the Asset Purchase Agreement governing the Thin Film sale obligates us to perform certain actions for the benefit of the buyer – MAST – for a defined period of time, such as serving as a back-up supplier. As of March 31, 2005, we still have not performed all of our obligations under the arrangement and, thus, believe that recognition of the majority of the deferred gain is not appropriate at this time. We anticipate that we should be able to complete all of the remaining obligations under the Thin Film sale agreement during 2005, meaning that the remaining deferred gain of \$5,650,000 at March 31, 2005 should be recognized as gain in the statement of operations later in 2005. The recognition of the gain will also be dependent upon the resolution of certain MAST allegations regarding technology transfer.

We have, however, recognized a portion of the deferred gains when we sell product to Medtronic and MAST under the respective back-up supply agreements. Refer to the "Revenue Recognition" section of this Critical Accounting Policies and Significant Estimates discussion for further details.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-based Payment" ("FAS 123R"). As amended by Securities and Exchange Commission Release No. 33-8568, "Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*", FAS 123R is effective for us on January 1, 2006 and will have a material effect on our results of operations. Upon adoption, FAS 123R will require us to measure all share-based payment transactions, including those with employees, at fair value (most notably, this includes employee stock option grants, even where the exercise price is equal to the grant date fair market value). Moreover, the fair value of share-based payment awards will be recognized as expense in the statements of operations over the requisite service period of each award. FAS 123R also changes the manner in which deferred taxes are recognized on share-based payment awards, as well as the accounting for award modifications.

Based on pro forma amounts for historical periods presented in note 3 of our consolidated financial statements, our net loss will

increase (or our net income will be reduced) each annual period as a result of adopting FAS 123R.

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 subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this quarterly report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

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

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

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

Moreover, our operating results can vary substantially from our previously published financial guidance (such as occurred 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 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) Thin Film surgical implants for separation of soft tissues, will distort quarterly and annual earning comparisons through 2004 and 2005. Earnings surprises can have a disproportionate effect on the stock prices of emerging companies such as ours. Also, our stock price is likely to be disproportionately affected by changes which generally affect the economy, the stock market or the medical device and biotechnology industries.

We had tried to influence our investors' expectations as to our 2004 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. We have since concluded that visibility regarding our bioresorbable implants has improved somewhat, and we have advised the markets that revenues for these products in 2005 are expected to be in the range of \$6,000,000 to \$9,000,000.

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, due to the continued need to develop and market new products and fund additional preclinical research and possibly clinical trials. We expect to continue to incur operational losses in our spine and orthopedics business at least through the end of 2005, and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Development-stage losses related to our development of regenerative cell technology are expected to keep us in a loss position on a consolidated basis for several years.

We are adopting a high-risk strategy.

We intend to use cash from any profits of the HYDROSORB™ products and the Japan Thin Film products, the proceeds of the sale of the (non-Japan) Thin Film product line, and cash raised from future financings or any other source 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 to successfully manage a company in a different business than we have operated in the past (operational risk), that we will be able to successfully deliver regenerative cells where needed in the body (scientific risk), or that our cash resources will be adequate to develop the regenerative cell technology until it becomes profitable (if ever) while still serving the cash needs of our biomaterials medical device product lines (financial risk). Instead of using the cash to reinvest in our biomaterials business, we are using it in one of the riskiest industries in the economy (strategic risk). This fundamentally changes our risk/reward profile and may make our stock an unsuitable investment for some investors.

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

Further legal risk arises from a lawsuit, filed by the University of Pittsburgh in the fourth quarter of 2004, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. We are the exclusive, worldwide licensee from the University of California under this patent, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. If the University of Pittsburgh wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, and our regenerative cell strategy could be materially adversely affected.

We rely on Medtronic to distribute a majority of our products

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

We remain significantly dependent on Medtronic to generate sales revenues for all of our spine and orthopedics bioresorbable products. The amount and timing of resources which may be devoted to the performance of Medtronic's contractual responsibilities are not within our control. There can be no guarantee that Medtronic will perform its obligations as expected or pay us any additional option or license fees. There is also no guarantee that it will 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 2004, and its rate of product orders placed with us in the same period, disappointed our expectations. 2004 results were exceptionally weak, and we are significantly disappointed with the marketing efforts of Medtronic for our products at this time.

Our dependence upon Medtronic to market and sell our bioresorbable products places us in a position where we cannot accurately predict the extent to which our products will be actively and effectively marketed, depriving us of some of the reliable data we need to make optimal operational and strategic decisions. The consequent lack of visibility resulted in our second quarter 2004 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. Our third and fourth quarter 2004 sales were worse than expected as well, further demonstrating the lack of control and visibility. We have since concluded that visibility regarding our bioresorbable implants has improved somewhat, and we have advised the markets that revenues for these products in 2005 are expected to be in the range of \$6,000,000 to \$9,000,000.

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

Medtronic owns 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, it also distributes other products that are competitive to ours. Medtronic might choose to develop and distribute existing or alternative technologies in preference to our technology in the spine or preferentially market competitive products that can achieve higher profit margins.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that disagreement over rights or technology or other proprietary interests will not occur. 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 we do. 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.

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These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory clearances or approvals, and manufacturing and marketing such products. It is possible that 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, 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 was lower in 2004 than we had expected.

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

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

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

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

We will need to raise more cash in the future

As of March 31, 2005, we had \$8,165,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. Our regenerative cell business will continue to result in a substantial requirement for research and development expenses for several years, during which it could bring in no significant revenues. 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 as well as our ability to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, thus having a substantial negative effect on the results of our operations and financial condition.

We have limited manufacturing experience

We have a limited manufacturing history and limited experience in manufacturing some of our products. In part, our future success is significantly dependent 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) Thin Film product line deprived us of some economies of scale in manufacturing. Current demand for spine and orthopedics products from Medtronic is so low that economies of scale are in some instances lacking in regard to that product line as well.

If we are unable to sufficiently meet Medtronic's requirements for certain products as set forth under its agreement, Medtronic itself may 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. The manufacture of those used 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 a potential 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 for our bioresorbable products

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, 2006, 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 the 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. There is also no assurance that any patents issued to us will provide us with competitive advantages, 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 commercialize related products. Also, our power as licensee to successfully use these rights to exclude competitors from the market is untested. In addition, further legal risk arises from a lawsuit, recently filed by the University of Pittsburgh, seeking a determination that its assignors, rather than the University of California's assignors, are the true inventors of U.S. Patent No. 6,777,231. We are the exclusive, worldwide

licensee from the University of California under this patent, which relates to adult stem cells isolated from adipose tissue that can differentiate into two or more of a variety of cell types. If the University of Pittsburgh wins the lawsuit, our license rights to this patent could be nullified or rendered non-exclusive with respect to any third party that might license rights from the University of Pittsburgh, and our regenerative cell strategy could be materially adversely affected.

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

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

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

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

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

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

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. We currently have pending patent applications in 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 are also 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 obtain the necessary 510(k) clearances or PMA approvals to market and manufacture our other products in the United States for their intended use on a timely basis, if at all. The FDA approval process may be particularly problematic for our regenerative cell technology products in view of

the novel nature of the technology. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a substantial negative effect on the results of our operations and financial condition.

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

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

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

We depend on a few key officers

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

We may not have enough product liability insurance

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

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

Our Amended and Restated Certificate of Incorporation and Bylaws contain certain provisions that could prevent or delay the

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

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

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

We pay no dividends

We currently do not intend 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 \$7,301,000 as of March 31, 2005, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to market rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at March 31, 2005, for example, and assuming average investment duration of seven months, the fair value of the portfolio would not decline by a material amount. We do

not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. While we do not always have the intent, we do currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows. Changes in interest rates would, of course, affect the interest income we earn on our cash balances after re-investment.

Foreign Currency Exchange Rate Exposure

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our cash balances in Europe and Japan. Although we transacted business in various foreign countries before the May 2004 sale of our non-Japan Thin Film business to MAST, settlements were usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the first quarter ended March 31, 2005, 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 expect such sales or royalties to begin later in 2005 or early 2006.

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, 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 March 31, 2005, our disclosure controls and procedures are effective.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company has been involved in routine litigation incidental to the conduct of its business. As of March 31, 2005, we were not a party to any material legal proceeding.

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

None

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

Property

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 additional square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five-year term expiring 2008.

We pay an aggregate of approximately \$60,000 in rent per month for our properties. The aggregate sublease amount is \$6,000 per month.

Staff

As of March 31, 2005, we had 121 full-time employees, comprised of 67 employees in research and development, 24 employees in manufacturing, 25 employees in management and finance and administration and 5 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

- 10.1 Salary and Bonuses for Named Executive Officers
- 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

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Pursuant to 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 Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in San Diego, California, on May 12, 2005.

MACROPORE BIOSURGERY, INC.

Dated: May 12, 2005

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

Dated: May 12, 2005

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

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MACROPORE BIOSURGERY, INC.

EXHIBIT INDEX

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Salary and Bonuses for Named Executive Officers

The following table includes all 2004 performance bonuses paid to our Named Executive Officers during first quarter of 2005, along with salaries established and paid to these officers in the first quarter of 2005:

Named Executive Officer	Annual Salary Established	Bonus Paid
Christopher J. Calhoun	\$ 363,397	\$ 79,900
Mark E. Saad	\$ 303,397	\$ 12,500
Marc H. Hedrick, MD	\$ 278,397	\$ 50,000
Sharon V. Schulzki	\$ 265,997	\$ 41,750
Charles E. Galetto	\$ 215,000	\$ 21,500
Bruce Reuter	\$ 200,000	\$ 18,300

Letter Re Unaudited Interim Financial Information

May 11, 2005

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

Re: Registration Statement No. 333-82074 and No. 333-122691

With respect to the subject registration statement, we acknowledge our awareness of the use therein of our report dated May 6, 2005 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 independent registered public accounting firm, or a report prepared or certified by an independent registered public accounting firm within the meaning of Sections 7 and 11 of the Act.

/s/ KPMG LLP

San Diego, California

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

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

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

Date: May 12, 2005

/s/ Christopher J. Calhoun

Christopher J. Calhoun,
Chief Executive Officer

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

I, Mark E. 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: May 12, 2005

/s/ Mark E. Saad

Mark E. Saad,
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350/ SECURITIES EXCHANGE ACT RULE 13a-14(b), 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 three months ended March 31, 2005 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, respectively, that:

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

Dated: May 12, 2005

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

Dated: May 12, 2005

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