SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2003

OR

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

For the transition period from to

Commission file number 0-32501

MacroPore Biosurgery, Inc.

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

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

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

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

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

As of October 17, 2003, there were 14,745,599 shares of MacroPore Biosurgery, Inc. common stock outstanding.

MACROPORE BIOSURGERY, INC.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Independent Accountants' Review Report

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

We have reviewed the accompanying consolidated condensed balance sheet of MacroPore Biosurgery, Inc. and subsidiaries as of September 30, 2003, and the related consolidated condensed statements of operations and comprehensive income (loss) for the three and nine months ended September 30, 2003 and 2002, and the consolidated condensed statements of cash flows for the nine months ended September 30, 2003 and 2002. These condensed consolidated financial statements are the responsibility of the Company's management.

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

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

We have previously audited, in accordance with auditing standards generally accepted in the United States of America, the consolidated balance sheet of MacroPore Biosurgery, Inc. and subsidiaries as of December 31, 2002, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated March 7, 2003, 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, 2002, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ KPMG LLP

San Diego, California
October 24, 2003

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	September 30, 2003 (Unaudited)	December 31, 2002
Assets		
Current assets:		
Cash and cash equivalents	$ 2,349,000	$ 5,108,000
Short-term investments, available-for-sale	14,540,000	19,875,000
Accounts receivable, net of allowance for doubtful accounts of $62,000 and $50,000 in 2003 and 2002, respectively	2,823,000	1,238,000
Inventories	987,000	1,150,000
Other current assets	654,000	843,000
Total current assets	21,353,000	28,214,000
Property and equipment, net	3,680,000	3,626,000
Other assets	133,000	562,000
Goodwill and intangibles, net	7,086,000	6,917,000
Total assets	$ 32,252,000	$ 39,319,000
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable and accrued expenses	$ 3,645,000	$ 2,521,000
Current portion of long-term obligations	566,000	410,000
Total current liabilities	4,211,000	2,931,000
Deferred gain on sale of assets, related party	8,243,000	9,623,000
Long-term obligations, less current portion	829,000	770,000
Total liabilities	13,283,000	13,324,000
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2003 and 2002	—	—
Common stock, $0.001 par value; 95,000,000 shares authorized; 16,777,581 and 16,646,664 shares issued and 14,745,599 and 14,527,681 shares outstanding in 2003 and 2002, respectively	17,000	17,000
Additional paid-in capital	74,793,000	74,730,000
Unearned compensation	(216,000)	(1,057,000)
Accumulated deficit	(48,240,000)	(40,102,000)
Treasury stock, at cost	(7,448,000)	(7,752,000)
Accumulated other comprehensive income	63,000	159,000
Total stockholders' equity	18,969,000	25,995,000
Total liabilities and stockholders' equity	$ 32,252,000	$ 39,319,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues:				
Revenues from related party	$ 4,230,000	$ 3,073,000	$ 8,421,000	$ 6,870,000
Revenues from third parties	265,000	229,000	906,000	249,000
	4,495,000	3,302,000	9,327,000	7,119,000
Cost of revenues:				
Cost of revenues (including stock based compensation expense of $3,000 and $4,000 for the three months ended September 30, 2003 and 2002, respectively; $9,000 and $11,000 for the nine months ended September 30, 2003 and 2002, respectively)	1,438,000	951,000	2,864,000	2,482,000
Inventory provision	—	1,395,000	—	1,395,000
Gross profit	3,057,000	956,000	6,463,000	3,242,000
Operating expenses:				
Research and development, excluding stock based compensation expense of $19,000 and $25,000 for the three months ended September 30, 2003 and 2002, respectively; $58,000 and $185,000 for the nine months ended September 30, 2003 and 2002, respectively	2,552,000	1,271,000	6,810,000	4,144,000
Sales and marketing, excluding stock based compensation expense of $17,000 and $33,000 for the three months ended September 30, 2003 and 2002, respectively; $53,000 and $100,000 for the nine months ended September 30, 2003 and 2002, respectively	1,055,000	1,082,000	3,354,000	2,779,000
General and administrative, excluding stock based compensation expense of $411,000 and $215,000 for the three months ended September 30, 2003 and 2002, respectively; $761,000 and $732,000 for the nine months ended September 30, 2003 and 2002, respectively	1,426,000	899,000	3,425,000	2,867,000
Stock based compensation (excluding cost of revenues stock based compensation)	447,000	273,000	872,000	1,017,000
Restructuring charge	458,000	—	458,000	—
Equipment impairment charge	—	370,000	—	370,000
Total operating expenses	5,938,000	3,895,000	14,919,000	11,177,000
Other income (expense):				
Interest income	88,000	207,000	335,000	844,000

Interest and other (expenses) income, net	(6,000)	(158,000)	(17,000)	(223,000)
Equity loss in investment	—	(76,000)	—	(189,000)
Net loss	(2,799,000)	(2,966,000)	(8,138,000)	(7,503,000)
Other comprehensive income (loss) - unrealized holding (loss) gain	(44,000)	8,000	(96,000)	(164,000)
Comprehensive loss	$ (2,843,000)	$ (2,958,000)	$ (8,234,000)	$ (7,667,000)
Basic and diluted net loss per share	$ (0.19)	$ (0.21)	$ (0.56)	$ (0.53)
Shares used in calculating basic and diluted net loss per share	14,605,273	13,808,269	14,557,167	14,244,491

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

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

	Nine Months Ended September 30,	
	2003	2002
Cash flows from operating activities:		
Net loss	$ (8,138,000)	$ (7,503,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,215,000	1,122,000
Loss on disposal of assets	—	87,000
Equipment impairment charge	—	370,000
Inventory provision	—	1,395,000
Warranty charge	243,000	—
Restructuring charge	458,000	—
Amortization of gain on sale of assets, related party	(1,342,000)	—
Stock based compensation	881,000	1,028,000
Interest income, related party	—	(16,000)
Equity loss in investment	—	189,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(1,585,000)	(1,064,000)
Inventories	163,000	(610,000)
Other current assets	189,000	4,000
Other assets	125,000	73,000
Accounts payable and accrued expenses	900,000	290,000
Deferred revenue from license agreement, related party	—	(225,000)
Net cash used in operating activities	(6,891,000)	(4,860,000)
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	38,029,000	43,680,000
Purchases of short-term investments	(32,790,000)	(30,025,000)
Purchases of property and equipment	(1,013,000)	(875,000)
Notes receivable, related party	—	(1,000,000)
Long-term notes receivable, related party	—	(478,000)
Deferred costs on sale of assets	—	(65,000)
Cost of sale of assets, related party	(38,000)	—
Acquisition costs	(644,000)	—
Proceeds from the sale of impaired assets	46,000	—
Net cash provided by investing activities	3,590,000	11,237,000
Cash flows from financing activities:		
Principal payments on capital leases	—	(140,000)
Principal payments on long-term obligations	(275,000)	(364,000)
Proceeds from long-term obligations	490,000	—
Proceeds from the exercise of employee stock options	33,000	13,000
Purchase of treasury stock	(248,000)	(4,284,000)
Proceeds from sale of treasury stock	542,000	—
Net cash provided by (used in) financing activities	542,000	(4,775,000)
Net (decrease) increase in cash	(2,759,000)	1,602,000
Cash and cash equivalents at beginning of period	5,108,000	2,700,000

Cash and cash equivalents at end of period	$ 2,349,000	$ 4,302,000
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 88,000	$ 182,000
Taxes	12,000	800
Supplemental schedule of non-cash investing activities:		
Increase in cost of acquisition (note 10)	$ 319,000	—
Note receivable, related party		9,000,000
Deferred gain on sale of assets, related party		(8,247,000)
Sale of assets to related party, net		(475,000)
Costs relating to sale of assets		(213,000)
Deferred costs on sale of assets		$ 65,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

MACROPORE BIOSURGERY, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2003
(UNAUDITED)

1. Basis of Presentation

The accompanying unaudited consolidated condensed financial statements as of and for the three and nine months ended September 30, 2003 and 2002 have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for audited financial statements. The consolidated condensed balance sheet at December 31, 2002 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of MacroPore Biosurgery, Inc. ("MacroPore" or the "Company") have been included. Operating results for the three and nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. For further information, refer to the consolidated financial statements for the year ended December 31, 2002 and footnotes thereto which were included in the Company's Annual Report on Form 10-K, dated March 28, 2003.

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 consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. The Company's significant estimates and accounting policies are revenue recognition, allowance for doubtful accounts, inventory provision, warranty provision and valuation of deferred income taxes.

3. Stock Based Compensation

The Company has adopted the disclosure-only provisions of Financial Accounting Standard Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock Based Compensation." Accordingly, the Company accounts for its stock based compensation plan under the provisions of Accounting Principles Board (APB) opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations under which compensation cost is measured by the excess, if any, of the fair market value of the Company's common stock at the date of grant over the exercise price of the option (intrinsic value method). Compensation cost is amortized using the straight-line method over the related vesting periods. Unearned stock based compensation costs for awards that are forfeited are reversed against compensation expense in the period of forfeiture. Stock based awards issued to non-employees are accounted for using a fair value method and are remeasured to estimated fair value at each period end until the earlier of the date that performance by the counterparty is complete or the awards are fully vested.

As required by SFAS No. 123, the Company has determined the pro forma information as if the Company had accounted for stock options under the fair value method prescribed by SFAS No. 123. The Company used the Black-Scholes option pricing model to determine fair value using the following weighted average assumptions: risk free interest rates ranging from 2.84% to 6.7%,

dividend yield of zero, expected market price volatility factor of 60% to 100% and a weighted average expected life of the options ranging from four to eight years. Had compensation cost for stock options been determined consistent with SFAS No. 123, the Company's net loss and related per share amounts on a pro forma basis would be as follows:

	For the Three Months Ended September30,		For the Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss:				
As reported	$ (2,799,000)	$ (2,966,000)	$ (8,138,000)	$ (7,503,000)
Add: Stock based employee	450,000	299,000	881,000	919,000

compensation expense included in reporting net loss, net of related tax effects				
Deduct: Total stock based employee compensation expense determined under fair value method for all awards, net of related tax effects	(986,000)	(937,000)	(3,490,000)	(3,355,000)
Pro forma	$ (3,335,000)	$ (3,604,000)	$ (10,747,000)	$ (9,939,000)
Loss per common share:				
As reported	$ (0.19)	$ (0.21)	$ (0.56)	$ (0.53)
Pro forma	(0.23)	$ (0.26)	$ (0.74)	$ (0.70)

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

4. Short-Term Investments

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

Management reviews the carrying values of its investments and writes down such investments to estimated fair value by a charge to operations when such review results in management’s determination that an investment’s impairment is considered to be other than temporary. The cost of securities sold is based on the specific identification method.

5. Inventories

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

6. Long-Lived Assets

The Company assesses potential impairments to its long-lived assets when there is a change in circumstances that indicate carrying values of assets may not be recovered. An impairment loss is recognized when the undiscounted cash flows expected to be generated by an asset are less than its carrying amount. Any required impairment loss would be measured as the amount by which the asset’s carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

7. Revenue Recognition

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

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

The Company recognizes revenue from the collection and storage of stem cell rich adipose tissue. In its StemBank product line, the Company recognizes revenue when (i) the collection procedure is performed, (ii) the adipose tissue is received by the Company, (iii) fees from the procedure are fixed and determinable and (iv) payment is probable. The Company uses the residual method to recognize revenue when a procedure includes elements to be delivered at a future date if evidence of the fair value of all undelivered elements exists. If evidence of the fair value of the undelivered elements does not exist, revenue is deferred on all elements and recognized when all elements are delivered.

The Company recognizes revenue from stem cell storage services as the services are performed.

The Company earns revenue for performing services under development agreements. Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, the amount of the milestone payments appears reasonably commensurate with the effort expended and collection of the payment is reasonably assured. Service income earned under development agreements is classified under revenues in the Company’s statements of operations. The costs associated with development agreements are recorded as research and development expense.

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

In September 2002, the Company entered into various agreements with Medtronic, Inc. and a related subsidiary for the sale of the Company's craniomaxillofacial implants product line. The net proceeds received in the agreements were recorded as a deferred gain on sale of assets, related party, until

such a time as the technology and know how transfer is completed pursuant to the contract terms. Upon successfully completing its requirements under these provisions of the contract, the Company will recognize the net gain on the sale in the statements of operations. Additionally, the Company will recognize a component of the deferred gain related to the sale of the craniomaxillofacial product to Medtronic under the Company's backup supply arrangement, which provides for sales of the craniomaxillofacial product to Medtronic at cost. Discounts from previously agreed prices have been recorded within revenues from related party and as a reduction to the deferred gain on sale of assets, related party.

The majority of the Company's revenues are from Medtronic, Inc., 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 and classified as revenues from related party.

8. Warranty

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

The following summarizes the Company's warranty reserve at September 30, 2003 and 2002:

	Balance at January 1	Additions (charges to expenses)	Claims	Balance at September 30
2003:				
Warranty reserve	$ —	$ 243,000	$ —	$ 243,000
2002:				
Warranty reserve	$ —	$ —	$ —	$ —

9. Earnings (Loss) Per Share

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

The Company has excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the three and nine months ended September 30, 2003 and 2002 as their inclusion would be antidilutive. The number of potentially dilutive common shares excluded from the calculations of diluted loss per share was 4,932,502 and 4,904,728 for the three and nine months ended September 30, 2003, respectively, and 3,976,212 and 3,955,883 for the three and nine months ended September 30, 2002, respectively.

10. Loss on Unused Office Space

In conjunction with the acquisition of StemSource, Inc. in 2002, the Company was left with significant unused office space associated with a non-cancelable 45 month operating lease commitment. The initial determination and computation of the initial provision for loss were

performed in accordance with EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination".

As of December 31, 2002, the Company had met the criteria of EITF 95-3 with regards to formulating a plan to exit an activity. Additionally, the cost represented an amount to be incurred by the combined company under a contractual obligation of the acquired company that existed prior to the consummation date and continued after the plan was scheduled to be completed with no economic benefit to the combined company.

As such, the initial provision for loss totaling $210,000 was recorded as a liability at the date of acquisition.

The initial provision for loss on unused office space recorded in 2002 was determined based upon management's analysis, review and assessment as of December 31, 2002, of the expected realization of projected sublease income associated with the expected excess facility capacity, compared to the aggregate scheduled lease payments through the remainder of the lease terms. Also, the Company consulted a national real estate consulting firm to evaluate the current market conditions regarding sublease rates, available commercial real estate capacity in the relevant market and other factors that would be necessary to assess the loss. These factors were used as the basis in estimating the sublease income in order to determine the net loss from unused office space.

During the second quarter of 2003, the estimated timeframe for when the Company would be able to exit the lease was changed. The Company again consulted a national real estate consulting firm to assess the expected range of probable sublease rates giving consideration to the current market for commercial real estate, remaining lease term, property location, and other relevant factors. Based on the expected sublease rates, remaining lease term and the estimated "sublease period", management concluded an additional provision of $361,000 was required in the second quarter of 2003. This additional provision was recorded as an increase to goodwill.

During the third quarter of 2003, the Company negotiated a settlement of the remaining lease payments with the lessor. Based on the settlement, management reduced the provision by $42,000 in the third quarter of 2003. This reduction was recorded as a decrease to goodwill.

At September 30, 2003 there was no accrual for loss on unused office space relating to lease assumed in the StemSource acquisition.

11. Long-term Debt

In September 2003 the Company entered into an Amended Master Security Agreement to provide financing for equipment purchases. In connection with the agreement, the Company issued two promissory notes to its lender under the agreement in an aggregate principal amount of approximately $490,000. These notes bear interest at 8.6% per annum with principal and interest due in monthly payments of approximately $6,000 and $8,000, respectively and mature over 48 and 36 month periods, respectively and are secured by equipment with a cost of $490,000.

Principal payments on the promissory notes are as follows:

For the years ended December 31,		
2003	$	21,000
2004	$	132,000
2005	$	144,000
2006	$	140,000
2007	$	53,000

12. Stockholders' Rights Plan

On May 28, 2003, the Board declared a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of Common Stock, par value $0.001 per share (the "Common Stock"), of the Company. The dividend is payable to the stockholders of record on June 10, 2003 (the "Record Date") with respect to shares of Common Stock issued thereafter until the Distribution Date (as defined below) and, in certain circumstances, with respect to shares of Common Stock issued after the Distribution Date. Except as set forth below, each Right, when it becomes exercisable, entitles the registered holder to purchase from the Company one one-thousandth (1/1000th) of a share of Series RP Preferred Stock of the Company, $0.001 par value per share (the "Preferred Stock"), at a price of $25.00 per one one-thousandth (1/1000th) of a share of Preferred Stock (the "Purchase Price"), subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement") between the Company and Computershare Trust Company, Inc., as Rights Agent, dated as of May 29, 2003.

Initially, the Rights will be attached to certificates representing shares of Common Stock then outstanding, and no separate certificates representing the Rights ("Right Certificates") will be distributed. The Rights will separate from the Common Stock upon the earlier to occur of (i) a person or group of affiliated or associated persons having acquired, without the prior approval of the Board, beneficial ownership of 15% or more of the outstanding shares of Common Stock or (ii) 10 days, or such later date as the Board may determine, following the commencement of or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in a person or group of affiliated or associated persons becoming an Acquiring Person (as defined below) except in certain circumstances (the "Distribution Date"). A person or group whose acquisitions of shares of Common Stock cause a Distribution Date pursuant to clause (i) above is an "Acquiring Person," with certain exceptions as set forth in the Rights Agreement.

The Rights are not exercisable until the Distribution Date and will expire at the close of business on May 29, 2013, unless earlier redeemed by the Company. For a summary of the terms of the Rights Agreement, refer to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.

13. Restructuring Event

In September 2003, the Company closed an administrative office in Königstein, Germany in an effort to reduce costs and consolidate operations in the U.S.A. The Company believes that the closure will save approximately $300,000 per annum, in rent, salaries and other expenses beginning in the fourth quarter of 2003.

In connection with the facility closure, the Company involuntarily terminated three employees. The employee terminations and the employee relocation all occurred on or before September 30, 2003. The Company incurred a liability of approximately $262,000 related to the severance benefits, of

which $259,000 was accrued at the end of the third quarter of 2003. All severance benefits for these involuntarily terminated employees are expected to be paid in cash in the fourth quarter of 2003.

The Königstein, Germany office is rented under an operating lease. As of September 30, 2003, the Company had ceased using the office space, but continued to remain liable for monthly rent payments of approximately $12,500 per month under a lease agreement that expires in February 2006 (the "Lease Agreement"). The Company currently subleases a small portion of the office space, but intends to exercise contractual provisions that allow the Company to terminate these subleases with 90 days notice. Thereafter, the Company will seek to sublease the entire facility for the remaining term of the Lease Agreement. However, due to the unique nature of the office building and the depressed rental market in and around Frankfurt, Germany, the Company expects that a sublease of the entire facility (if one is successfully negotiated) will yield only approximately 65% of the Company's monthly rental obligation. Accordingly, the Company may consider negotiating a settlement of the remaining lease payments with the lessor if it is unable to enter into a suitable sublease arrangement.

The following outlines the restructuring activity recorded to the liability account during the third quarter of 2003:

	Opening Balance	Charged to Expense*	Costs Paid	Adjustments to Liability	Ending Balance

One-time termination benefits	$ —	$ 262,000	$ (3,000)	$ —	$ 259,000
Lease termination	—	196,000	—	—	196,000
	$ —	$ 458,000	$ (3,000)	$ —	$ 455,000

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

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

The restructuring liabilities recorded as of September 30, 2003 do not include accrued brokerage commissions, if any, associated with finding new sublease tenants. Such commissions will be recognized when incurred and are expected to be de minimis.

14. Composition of Certain Financial Statement Captions

Inventories

	September 30, 2003 (Unaudited)	December 31. 2002
Raw materials	$ 412,000	$ 602,000
Finished goods	575,000	548,000
	$ 987,000	$ 1,150,000

Property and Equipment, net

	September 30, 2003 (Unaudited)	December 31. 2002
Office and computer equipment	$ 2,061,000	$ 1,874,000
Manufacturing and development equipment	3,403,000	2,721,000
Leasehold improvements	1,749,000	1,551,000
	7,213,000	6,146,000
Less accumulated depreciation and amortization	(3,533,000)	(2,520,000)
	$ 3,680,000	$ 3,626,000

Other Assets

	September 30, 2003 (Unaudited)	December 31. 2002
Deposits	$ 71,000	$ 400,000
Assets held for sale	62,000	162,000
	$ 133,000	$ 562,000

Goodwill and Intangibles, net

	September 30, 2003 (Unaudited)	December 31. 2002
Intangibles (net of accumulated amortization of $236,000 and $34,000 in 2003 and 2002, respectively)	$ 2,459,000	$ 2,661,000
Goodwill	4,627,000	4,256,000
	$ 7,086,000	$ 6,917,000

Accounts Payable and Accrued Expenses

	September 30, 2003 (Unaudited)	December 31. 2002
Accounts payable	$ 733,000	$ 599,000

Accrued bonus	517,000	397,000
Accrued vacation	440,000	325,000
Accrued restructuring reserve	455,000	—
Accrued warranty reserve	243,000	—
Accrued expenses – other	1,257,000	1,200,000
	$ 3,645,000	$ 2,521,000

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

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 in "Risk Factors" described in Item 3 of this Form 10-Q under the heading "Quantitative and Qualitative Disclosures About Market Risk." We encourage you to read those descriptions carefully. We caution investors 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 another 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

We were initially formed as a California general partnership in July 1996, and incorporated in the State of Delaware in May 1997. Our two platform technologies include biomaterials (bioresorbable implants) and biologics (regenerative medicine). Within our biomaterials platform we design, develop, manufacture and market bioresorbable polymer implants for use in the reconstruction, repair and regeneration of hard tissue (bone) and soft tissue throughout the body. Additionally, we design, develop, and manufacture related instruments and accessories used in connection with our implants. Our bioresorbable implants are used in spine, orthopedic, neurosurgical, and other musculoskeletal reconstructive surgical applications, while our bioresorbable thin films are used for soft tissue applications.

In September 2002 we sold our craniomaxillofacial "CMF" (skull and face) bone fixation implant and accessory product line to a subsidiary of Medtronic, Inc. ("Medtronic"). We will continue to be a backup supplier for the acquired products during a transition period, which we expect to be completed in the fourth quarter of 2003 or the first quarter of 2004.

In November 2002, we acquired StemSource, Inc. ("StemSource"), a California company specializing in stem cell bioengineering, research and technology. This has allowed us to begin developing our biologics platform technology of regenerative (stem cell) therapies using adult stem cells derived from a patient's own adipose (fat) tissue. In addition, this acquisition provides us technology in the field of stem cell preservation and banking, offering the opportunity for people worldwide to bank their stem cells for later personal use.

Our bioresorbable implants are made from a polylactide copolymer composed of lactic acid similar to that which occurs naturally in the human body. The polymer implant maintains its strength during the healing process, while slowly breaking down in the body through hydrolysis. The polymer fragments into single lactic acid molecules, and the lactic acid molecules are then metabolized by the liver into carbon dioxide and water, and released from the body through the lungs.

We have received regulatory clearance to market and sell some of our bioresorbable implant products in the United States, Canada, Europe and other countries.

In January 2000, we entered into a Development and Supply Agreement with Medtronic to co-develop bioresorbable implants for use in spinal fixation, stabilization and fusion applications and supply any such new implants to Medtronic as the distributor. Also, in connection with the sale to a subsidiary of Medtronic in September 2002 of substantially all of our assets related to the CMF product line, we granted the Medtronic subsidiary a perpetual exclusive license to certain intangible assets to be used in the CMF surgical field, along with use of our bioresorbable implants for repair of the bone harvest site in the iliac crest. We retained all other rights to use the intangible assets in other parts of the body. In another agreement with Medtronic on the same day as this sale, we extended the term of our existing co-development and supply agreement for spinal implants to 2012, and obtained a waiver of Medtronic's right of first offer to market our bioresorbable thin films in certain fields.

We are continuing development of new products and materials useful for the repair and regeneration of bone. We are currently engaged in a clinical marketing study related to our faster-resorbing polymer (FRP) which may be particularly useful in treating pediatric patients due to their rapid rate of bone growth, and we are developing additional products for use in spinal fusion procedures (in Europe), long-bone repair, healing of nonunion fractures and cyst or tumor removal site repair, among other things. These future products may require further development and regulatory clearance or approval, potentially including clinical trials, prior to marketing and commercial use.

Building on our initial biomaterials platform technology, we have developed the SurgiWrap™ and CardioWrap™ families of bioresorbable thin film. These products are constructed from the same polylactide copolymer as our other implants. Our bioresorbable thin films have present and potential clinical applications across multiple surgical specialties in which the primary intended market includes the control of postsurgical adhesions in cardiothoracic, general, spinal and obstetric surgeries. We have not yet obtained clearance to market these products in the United States ("U.S.") for postsurgical adhesion indications, although we have received clearance for postsurgical adhesion indications in Europe and in other countries. In addition to its soft tissue reinforcement properties, extensive preclinical research has demonstrated that our bioresorbable film also acts as a barrier, controlling the formation of fibrous bands which cause adhesions.

In 2001 we received our first regulatory clearances from the FDA to market our SurgiWrap™ bioresorbable film for reinforcement of soft tissues throughout the body and as a bridging material where indicated. Some of the uses include, but are not limited to, repair of fascial defects including vaginal prolapse repair, colon and rectal prolapse repair, and reconstruction of the pelvic floor. In June 2002, we hired a direct sales force in the U.S. to sell SurgiWrap™ film. The sales team covers some of the major metropolitan areas in the U.S. market. In the third quarter of 2003 we received expanded FDA clearance to market SurgiWrap™ film to minimize the attachment of soft tissue to the device in case of direct contact with the viscera (organs of the body).

In 2002 we received the CE Mark (marketing clearance in Europe) to market our SurgiWrap™ bioresorbable film for the prevention of postsurgical adhesions in cardiothoracic, general, spinal and gynecological & obstetric ("OB/GYN") surgeries. In Canada, Thailand, Korea, Mexico, Peru, Singapore, Malaysia and Australia we have received clearance to market our surgical film for the prevention of adhesions in the heart, spine, peritoneal cavity (including bowels and organs) and OB/GYN surgeries. To date we have established distribution agreements with a network of 29 independent international distributors to sell our bioresorbable surgical film throughout Europe, South America, the Middle East and the Far East.

Through the acquisition of StemSource in November 2002, we are moving to advance stem cell research that may lead to therapies which promote the healing or regeneration of the patient's own tissues with the patient's own stem cells. We believe adult stem cells, harvested from the patient's fat tissue

through a liposuction procedure, have the ability to offer replacement cells to treat life-altering or life-threatening disorders. StemSource's approach has significant advantages over many other stem cell technologies. StemSource developed devices and techniques to harvest adult stem cells from fat, and demonstrated the ability of adipose (fat)-derived stem cells to differentiate into a variety of tissues *in vitro*.

A stem cell is an unspecialized cell that can become many of the two-hundred-plus tissues that make up the body. Of the two types of stem cells, adult (found in various tissues after birth), and embryonic (fetal tissue), our efforts are exclusively directed toward adult stem cell autologous transplantation (separation of the stem cells from a person's fat and delivering them back to the same person where needed).

The acquisition of StemSource has also provided us a California state-licensed tissue bank facility for the preservation of extracted stem cells. Typically arranged through a patient's physician, stem cell banking is the process by which adult stem cells, taken from a liposuction or other procedure, are stored (cryopreserved) in a liquid nitrogen freezer at -320°F (-196°C) exclusively for the particular patient who banked them. The banked stem cells, frozen in suspended animation, can be preserved for the life of the individual.

We are required to obtain from the Food and Drug Administration regulatory clearance of our medical device products that we market in the United States. In addition, we must obtain marketing authorization for our products that we market in Europe, Canada, Mexico and certain other non-U.S. jurisdictions. During 2002 and 2003, we received additional regulatory clearance or marketing authorization for our products from various jurisdictions, for the following indications:

- the use of our SurgiWrap™ surgical barrier film to cover orbital implants used in enucleation (eye removal) surgery and to protect the surrounding orbital tissue from the surface of the implant (U.S.);

- the use of our HYDROSORB™ TELAMON™ device to maintain the relative position of bone graft material and to promote fusion in the lumbar spine (in Europe – HYDROSORB™ is a trademark of Medtronic, Inc.);

- the use of our bioresorbable adhesion barrier film to prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane to include the following anatomical regions: pericardium, epicardium, and retrosternal (Canada, Thailand, Korea, Australia);

- the use of our bioresorbable adhesion barrier film (in Europe) as a temporary physical barrier to separate opposing tissues and prevent the in growth of scar tissues and the formation or reformation of adhesions immediately adjacent to the barrier film; aid in reoperation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the barrier film; prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane to include the following anatomical regions:

    a) Pericardium, epicardium, and retrosternal;

    b) Peritoneum, peritoneal cavity, bowels, cecum, organs;

    c) Dura, spinal dura, peridural, epidural; and

    d) OB/GYN (e.g. female pelvic, reproductive organs, ovaries, uterus, uterine tubes, etc.);

- the use of our orthopedic graft containment products (OS Trauma) to support weak bony tissue in orthopedic reconstruction procedures including iliac crest and rib reconstructions;

- the use of SurgiWrap™ to reinforce soft tissues and minimize tissue attachment in case of direct contact with the viscera (organs of the body);

- the use of CardioWrap™ for a pericardium replacement device in patients that may require re-operation within six months; and

- the use of our orthopedic graft containment product to support weak bony tissue in orthopedic reconstruction procedures including iliac crest and rib reconstruction (in Europe).

We are also developing additional products for use in spinal fusion procedures, soft tissue repair, adhesion control products and long-bone repair, among other things. These future products may require further development and regulatory clearance or approval, potentially including clinical trials, prior to marketing and commercial use.

We continue to seek patent protection for our new products as evidenced by our recent receipt of a U.S. patent (No. 6,531,146) for our family of bioresorbable thin films (SurgiWrap™/CardioWrap™) for the control of postsurgical adhesions, as well as a new patent in Australia (No. 752357) for our macro-porous mesh.

For the nine months ended September 30, 2003 and 2002, revenues related to the craniomaxillofacial product line sold to Medtronic in September 2002 were $1,973,000 and $2,228,000, respectively. The 2003 revenues related to our back up supply arrangement included in revenue for the nine months ended September 30, 2003 was $1,342,000 from amortization of the deferred gain on sale of assets, related party. For the three months ended September 30, 2003 and 2002, revenues related to the craniomaxillofacial product line were $747,000 and $931,000, respectively. Included in revenue for the three months ended September 30, 2003 was $554,000 from amortization of the deferred gain on sale of assets, related party. We continue to be a backup supplier to Medtronic for the acquired products during a transition period, which we expect to be completed in the fourth quarter of 2003 or the first quarter of 2004. The amortization of deferred gain on the sale of assets, related party, relates to the recognition of revenue under the backup supplier agreement with Medtronic which provides for sales of CMF products at cost. Discounts from the previously agreed price have been recorded as revenue and a reduction to the deferred gain on sale of assets, related party.

Medtronic continues to be a significant stockholder of MacroPore and our largest customer in its capacity as the primary distributor of our bioresorbable implant products for use in musculoskeletal applications. We sell these products to Medtronic at fixed selling prices which are subject to adjustment upon biannual reviews. Therefore, our revenues, operating results and cash flow will be affected by fluctuations in the cost of sales, sales volumes and operating expenses.

We incurred net losses of $8,138,000 for the nine months ended September 30, 2003, and net losses of $13,003,000 and $11,207,000 for the years ended December 31, 2002 and 2001, respectively. As of September 30, 2003, we had an accumulated deficit of $48,240,000. These net losses resulted to a large extent from expenses associated with developing bioresorbable implant designs, performing preclinical studies, preparing submissions to the FDA and foreign regulatory agencies, expanding marketing and distribution channels, further developing our manufacturing capabilities, securing intellectual property rights and trademarks and supporting our status as a public company. We expect to expend substantial

additional financial resources to expand marketing, training and customer support needed to generate and support higher sales, obtain additional regulatory clearances and to develop new products, especially in the area of regenerative medicine.

For the nine months ended September 30, 2003, our $9,327,000 in revenue was comprised of $9,094,000 or 97.5% from sales of our bioresorbable implant products for use in musculoskeletal, soft tissue applications, and craniomaxillofacial. Craniomaxillofacial products were included in the September 2002 product line sale to Medtronic. The $9,094,000 in revenue from bioresorbable implant products was comprised of $6,437,000 or 70.8% of musculoskeletal sales, $1,759,000 or 19.3% of craniomaxillofacial revenue and $898,000 or 9.9% of bioresorbable thin film products for soft tissue applications. The $233,000 in revenue not related to bioresorbable implants was comprised of $224,000 from sales of instruments and accessories used by surgeons to form, mold and manipulate our bioresorbable products during surgical procedures and $9,000 from our stem cell storage services.

Results of Operations

Three months ended September 30, 2003 compared to three months ended September 30, 2002

Revenues. For the three months ended September 30, 2003, revenues were $4,495,000 compared to $3,302,000 for the three months ended September 30, 2002, an increase of $1,193,000 or 36.1%. The revenue for the three months ended September 30, 2003 was comprised of $3,483,000 in musculoskeletal applications, $262,000 in bioresorbable thin film products, $747,000 in craniomaxillofacial products of which $554,000 related to the amortization of gain on sale of assets, related party and $3,000 in stem cell storage services. The revenue for the three months ended September 30, 2002 was comprised of $2,086,000 in musculoskeletal applications, $210,000 in bioresorbable thin film products, $931,000 in craniomaxillofacial products and $75,000 that related to craniomaxillofacial product license fees. The $1,397,000 increase in musculoskeletal products revenue in the three months ended September 30, 2003 related to increased acceptance of our musculoskeletal products and our distributor placing a stocking order of an enhanced device in the three months ended September 30, 2003. The $52,000 increase in bioresorbable thin film product revenue in the three months ended September 30, 2003 was facilitated by the reorganization of our sales consultants to focus on certain regions to facilitate further market acceptance and sales of bioresorbable thin film products. The $184,000 decrease in craniomaxillofacial products and the $75,000 decrease in license fee revenue in the three months ended September 30, 2003 related to Medtronic continuing to transition the manufacturing of craniomaxillofacial products to their own facilities. We expect craniomaxillofacial product sales to continue to decrease throughout 2003 and cease shortly thereafter. Revenues attributable to Medtronic, which owns approximately 6.8% of our outstanding common stock, represented 94.1% of our revenues for the three months ended September 30, 2003, compared to 93.1% for the three months ended September 30, 2002. The increase in the revenue percentage attributable to Medtronic relates to the increase in sales of musculoskeletal products not offset by the distribution of our bioresorbable thin film products by our own direct sales force and other third party distributors in the three months ended September 30, 2003.

Cost of revenues. For the three months ended September 30, 2003, cost of revenues was $1,438,000 or 32.0% of revenues compared to $951,000 or 28.8% of revenues for the three months ended September 30, 2002. Cost of revenues includes material, manufacturing labor and overhead costs. Included in the cost of revenues for the three months ended September 30, 2003, with no comparable charges in the three months ended September 30, 2002, was a warranty charge of $243,000 which related to a warranty claim on certain products sold to Medtronic. In August, as part of our ongoing product monitoring process, we determined that some of the product sold to Medtronic did not meet certain performance expectations, based on criteria previously communicated by us to Medtronic. Based on this, we agreed to a “no charge” replacement of the affected inventory in the possession of Medtronic. The replacement product will be

provided under the warranty provision in our Development and Supply Agreement. We also wrote-off $111,000 in inventory that was related to this warranty claim in the three months ended September 30, 2003. The increase of 3.2% in cost as a percentage of revenues in the three months ended September 30, 2003 was primarily attributable to our warranty charge and write off of inventory, which was partially offset by increased sales revenue that allowed us to absorb more of our manufacturing labor and overhead costs. In subsequent quarters, we will continue to provide for a warranty provision based on our historical warranty claims. Therefore, we expect cost of revenues as a percentage of sales to slightly increase in the future. The continued reduction of revenues as a result of the sale of the craniomaxillofacial product line in September 2002 could negatively impact our margins unless our other products' sales grow enough to replace the lost revenue.

Inventory provision. For the three months ended September 30, 2002, we recorded an inventory provision of $1,395,000, for which there was no comparable charge in the three months ending September 30, 2003. The inventory provision was a result of reduction in expected future revenues of our craniomaxillofacial bone fixation implants and accessories product line inventory due to the asset sale to Medtronic.

Research and development expenses. For the three months ended September 30, 2003, research and development expenses, excluding related stock based compensation expenses were $2,552,000, compared to $1,271,000 for the three months ended September 30, 2002, an increase of $1,281,000 or 100.8%. 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 $1,281,000 increase in research and development expenses in the three months ended September 30, 2003, as compared to the three months ended September 30, 2002, was primarily attributable to our expenditures in the biologic (stem cell) platform technology. We expended $1,261,000 in the development of our biologic platform technology in the three months ended September 30, 2003 by employing 16 researchers, engineers and support staff, in addition to incurring other significant expenses related to regulatory, consulting, and facilities to develop this technology. There were no comparable expenses in the three months ended September 30, 2002. We incurred $1,291,000 of expense on our biomaterial platform technology relating to the development of musculoskeletal products and faster-resorbing polymer products in the three months ended September 30, 2003, as compared to $1,271,000 in the three months ended September 30, 2002. The $20,000 increase in spending during the three months ended September 30, 2003, as compared to the three months ended September 30, 2002, was attributable to continuing development of our biomaterials product line and employing a researcher in Europe which was partially offset by the discontinuing of research into the craniomaxillofacial product line which was sold to Medtronic. In addition, stock based compensation related to research and development was $19,000 for the three months ended September 30, 2003 and $25,000 for the three months ended September 30, 2002. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect research and development spending for the year ended December 31, 2003 to increase by approximately $3,500,000 as compared to the year ended December 31, 2002 as we continue to support the research and development of therapies based on adult stem cells which we acquired with the purchase of StemSource. We also plan to continue to fund product development efforts and seek further regulatory approvals for our current bioresorbable product lines related to musculoskeletal and thin film.

Sales and marketing expenses. For the three months ended September 30, 2003, sales and marketing expenses excluding related stock based compensation expenses were $1,055,000, compared to $1,082,000 for the three months ended September 30, 2002, a decrease of $27,000 or 2.5%. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. We use Medtronic for the distribution of our musculoskeletal product lines and we are focusing our sales and marketing efforts on our bioresorbable thin film product line domestically through

a dedicated sales force and internationally through independent distributors. The $27,000 decrease in sales and marketing expenses in the three months ended September 30, 2003, as compared to the three months ended September 30, 2002, was primarily attributable to the decision not to supplement Medtronic's marketing of our products which was offset by the expense of a sales and marketing team dedicated to selling our bioresorbable thin film product line. We incurred $757,000 of expense for sales and marketing to directly sell our bioresorbable thin film product line domestically in the three months ended September 30, 2003, as compared to $532,000 in the three months ended September 30, 2002. We employed five fewer sales consultants in the three months ended September 30, 2003, as compared to the three months ended September 30, 2002, due to the reorganization of our sales consultants to focus on specific regions in the US domestic market where there is greater market acceptance of our bioresorbable thin film products. We incurred $245,000 of expense in international sales and marketing of bioresorbable thin film during the three months ended September 30, 2003, as compared to $122,000 for the three months ended September 30, 2002. The $123,000 increase in such spending during the three months ended September 30, 2003, as compared to the three months ended September 30, 2002, was attributable to the salary and travel expenses relating to developing international distributors and a sales office in Japan for the bioresorbable thin film product line. We incurred $53,000 of expense in general product and corporate marketing expenditures in the three months ended September 30, 2003, as compared to $428,000 for the three months ended September 30, 2002. The $375,000 decrease was a result of our decision not to continue to supplement Medtronic's marketing of the musculoskeletal and craniomaxillofacial product lines. In addition, stock based compensation related to sales and marketing was $17,000 for the three months ended September 30, 2003 and $33,000 for the three months ended September 30, 2002. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses". We do not expect to make significant marketing expenditures related to our biologic platform technology until our research and development efforts result in commercially viable products. We expect sales and marketing expenses to increase approximately $700,000 in 2003 as compared to 2002 as we continue our promotional efforts related to the bioresorbable thin film product line with a dedicated sales force.

General and administrative expenses. For the three months ended September 30, 2003, general and administrative expenses excluding related stock based compensation expenses were $1,426,000, compared to $899,000 for the three months ended September 30, 2002, an increase of $527,000 or 58.6%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The $527,000 increase in general and administrative expenses for the three months ended September 30, 2003 was primarily attributable to a bonus expense of $200,000, amortization of intangibles of $67,000 and the balance related to increases in domestic salaries, legal, and other general corporate expenditures. In addition, stock based compensation related to general and administrative expenses was $411,000 for the three months ended September 30, 2003, compared to $215,000 for the three months ended September 30, 2002. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect general and administrative expenses to increase approximately $700,000 in 2003 as compared to 2002.

Stock based compensation expenses. For the three months ended September 30, 2003, total non-cash stock based compensation expenses classified in operating expenses were $447,000, compared to $273,000 for the three months ended September 30, 2002, an increase of $174,000 or 63.7%. Stock based compensation results from options issued to employees, directors and non-employees. The stock based compensation relating to employees and directors represents 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 relating to non-employees represents the fair value of the underlying common stock on the initial date of grant, then marked to market over the vesting period until

meeting the performance commitment. Unearned stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. The overall increase in stock based compensation expense was related to the modification of certain options granted to Chief Financial Officer under his September 2003 separation agreement which was partially offset by a decrease related to the normal amortization of the stock based compensation expense over the remaining vesting periods. There was no stock based compensation expense relating to non-employees for the three months ended September 30, 2003.

Restructuring charge. In the three months ended September 30, 2003, we recorded a restructuring charge of $458,000, for which there was no comparable charge in the three months ended September 30, 2002. In an effort to reduce costs and consolidate operations in the United States, we closed our administrative office in Königstein, Germany in September 2003. In connection with the facility closure, we incurred restructuring charges of $262,000 relating to involuntarily terminating 3 employees including our Chief Financial Officer and $196,000 relating to a lease termination. We believe that the closure will save approximately $300,000 in rent, salaries and other expenses per annum, beginning in the fourth quarter of 2003.

Equipment impairment charge. In the three months ended September 30, 2002, we had an equipment impairment charge of $370,000, for which there was no comparable charge in the three months ended September 30, 2003. The impairment charge represents the excess cost of the equipment over the net proceeds we estimate we will receive from sale of the assets, which were previously utilized in the manufacturing of craniomaxillofacial bone fixation implant and accessory products, but not included in the Medtronic sale.

Interest income. For the three months ended September 30, 2003, interest income was $88,000, compared to $207,000 for the three months ended September 30, 2002, a decrease of $119,000 or 57.5%. The decrease in interest income resulted from lower interest rates and a decrease in funds we had available for investments.

Interest and other expenses. For the three months ended September 30, 2003, interest and other expenses were $6,000 compared to $158,000 for the three months ended September 30, 2002. The decrease was due to losses related to the disposal of equipment in the three months ended September 30, 2002, with no comparable expense in the three months ended September 30, 2003, and lower outstanding principal on our long-term debt obligations balances in the three months ended September 30, 2003.

Equity loss in investment. For the three months ended September 30, 2002, our equity loss in investment was $76,000, with no comparable loss in the three months ended September 30, 2003. The loss related entirely to our former 13.5% equity interest in StemSource, which we accounted for using the equity method. Under the equity method of accounting, we recognized a pro rata share of StemSource's operating losses. In November 2002 we acquired 100% of the outstanding stock of StemSource and now include 100% of StemSource in the results of operations.

Nine months ended September 30, 2003 compared to nine months ended September 30, 2002

Revenues. For the nine months ended September 30, 2003, revenues were $9,327,000 compared to $7,119,000 for the nine months ended September 30, 2002, an increase of $2,208,000 or 31.0%. The revenue for the nine months ended September 30, 2003 was comprised of $6,448,000 in musculoskeletal applications, $898,000 in bioresorbable thin film products, $1,973,000 in craniomaxillofacial products of which $1,342,000 relates to the amortization of gain on sale of assets, related party and $8,000 in stem cell storage services. The revenue for the nine months ended September 30, 2002 was comprised of $4,452,000 in musculoskeletal applications of which $150,000 related to an engineering project that

involved musculoskeletal products, $214,000 in bioresorbable thin film products, $2,228,000 in craniomaxillofacial products and $225,000 that related to craniomaxillofacial product license fees. Excluding the musculoskeletal engineering project of $150,000 in 2002, the $2,146,000 increase in musculoskeletal products revenue in the nine months ended September 30, 2003 resulted primarily from increased availability of our products due to a full product release and the introduction of an enhanced device. The $684,000 increase in bioresorbable thin film revenue in the nine months ended September 30, 2003 was attributable to increased market acceptance. The $255,000 decrease in craniomaxillofacial products and the $225,000 decrease in license fee revenue in the nine months ended September 30, 2003 related to Medtronic continuing to transition the manufacturing of craniomaxillofacial products to their own facilities. We expect craniomaxillofacial product sales to continue to decrease throughout 2003 and cease shortly thereafter. Revenues attributable to Medtronic represented 90.3% of our revenues for the nine months ended September 30, 2003, compared to 96.5% for the nine months ended September 30, 2002. The decrease in the revenue percentage attributable to Medtronic relates to the distribution of our bioresorbable thin film products by our own direct sales force and other third party distributors in the nine months ended September 30, 2003, and the sale of the craniomaxillofacial product line to Medtronic in September 2002.

Cost of revenues. For the nine months ended September 30, 2003, cost of revenues was $2,864,000 or 30.7% of revenues, compared to $2,482,000 or 34.9% of revenues for the nine months ended September 30, 2002. Cost of revenues includes material, manufacturing labor and overhead costs. Included in the cost of revenue for the nine months ended September 30, 2003 with no comparable charges in the nine months ended September 30, 2002, was a warranty charge of $243,000 related to a warranty claim on certain products sold to Medtronic. In August 2003, as part of our ongoing product monitoring process, we determined that some of the products sold to Medtronic did not meet certain performance expectations, based on criteria previously communicated by us to Medtronic. Based on this, we agreed to a "no charge" replacement of the affected inventory in the possession of Medtronic. The replacement product will be provided under the warranty provision in our Development and Supply Agreement. We also wrote-off $111,000 in inventory that was related to this warranty claim in the nine months ended September 30, 2003. The decrease of 4.2% in cost as a percentage of revenues in the nine months ended September 30, 2003 was primarily attributable to increased sales revenue that allowed us to absorb more of our manufacturing labor and overhead costs. In subsequent quarters, we will continue to provide for a warranty provision based on our historical warranty claims; therefore, we expect cost of revenues as a percentage of sales to slightly increase in the future. The continued reduction of revenues as a result of the sale of the craniomaxillofacial product line in September 2002 could negatively impact our margins unless our other products' sales grow large enough to replace the lost revenue.

Inventory provision. For the nine months ended September 30, 2002, we recorded an inventory provision of $1,395,000, for which there was no comparable charge in the nine months ending September 30, 2003. The inventory provision for the nine months ended September 30, 2002, was a result of a

reduction in expected future revenues of our craniomaxillofacial bone fixation implants and accessories product line inventory due to the asset sale to Medtronic.

Research and development expenses. For the nine months ended September 30, 2003, research and development expenses excluding related stock based compensation expenses were $6,810,000, compared to $4,144,000 for the nine months ended September 30, 2002, an increase of $2,666,000 or 64.3%. 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 $2,666,000 increase in research and development expenses in the nine months ended September 30, 2003, as compared to the nine months ended September 30, 2002, was primarily attributable to our expenditures in the biologic (stem cell) platform technology. We expended $3,163,000 in the development of our biologic platform technology in the nine months ended September 30, 2003 by

employing 16 researchers, engineers and support staff, in addition to, incurring other significant expenses related to regulatory, consulting, and facilities to develop this technology. There were no comparable expenses in the nine months ended September 30, 2002. We incurred $3,647,000 of expense in our biomaterial platform technology development of musculoskeletal products and faster-resorbing polymer products in the nine months ended September 30, 2003, as compared to $4,144,000 in the nine months ended September 30, 2002. The $497,000 decrease in spending during the nine months ended September 30, 2003, as compared to the nine months ended September 30, 2002, was attributable to the successful development of our bioresorbable thin film product line and the discontinuance of development of the craniomaxillofacial product line which was sold to Medtronic. In addition, stock based compensation related to research and development was $58,000 for the nine months ended September 30, 2003, and $185,000 for the nine months ended September 30, 2002. For further information regarding stock based compensation, you should read the discussion under the section entitled “Stock based compensation expenses.”

Sales and marketing expenses. For the nine months ended September 30, 2003, sales and marketing expenses excluding related stock based compensation expenses were $3,354,000, compared to $2,779,000 for the nine months ended September 30, 2002, an increase of $575,000 or 20.7%. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. We use Medtronic for the distribution of our musculoskeletal product lines; therefore, we are focusing our sales and marketing efforts on our bioresorbable thin film product line domestically through a dedicated sales force and internationally through independent distributors. The $575,000 increase in sales and marketing expenses in the nine months ended September 30, 2003, as compared to the nine months ended September 30, 2002, was primarily attributable to the expense of a sales and marketing team dedicated to selling our bioresorbable thin film product line which was offset by the decision not to supplement Medtronic’s marketing of our products. We incurred $2,387,000 of expense for sales and marketing to sell directly our bioresorbable thin film product line domestically in the nine months ended September 30, 2003, as compared to $908,000 in expense in nine months ended September 30, 2002. The $1,479,000 increase spending in the nine months ended September 30, 2003 primarily related to the salary costs of our sales and marketing team being employed for the full nine months as compared to the nine months ended September 30, 2002 where they were hired in the last three months of the period. We employed five fewer sales consultants in the nine months ended September 30, 2003, as compared to the nine months ended September 30, 2002, due to the reorganization of our sales consultants to focus on specific regions in the US domestic market where there is greater market acceptance of our bioresorbable thin film products. We incurred $718,000 of expense in international sales and marketing of bioresorbable thin film during the nine months ended September 30, 2003, as compared to $335,000 in the nine months ended September 30, 2002. The $383,000 increase in such spending during the nine months ended September 30, 2003, as compared to the nine months ended September 30, 2002, was attributable to salary and travel expenses relating to developing international distributors and a sales office in Japan for the bioresorbable thin film product line. We incurred $249,000 of expense in general product and corporate marketing expenditures in the nine months ended September 30, 2003, as compared to $1,536,000 in the nine months ended September 30, 2002. The $1,287,000 decrease in such spending during the nine months ended September 30, 2003 was a result of our decision not to continue to supplement Medtronic’s marketing of the musculoskeletal and craniomaxillofacial product lines. In addition, stock based compensation related to sales and marketing was $53,000 for the nine months ended September 30, 2003 and $100,000 for the nine months ended September 30, 2002. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, you should read the discussion under the section entitled “Stock based compensation expenses”.

General and administrative expenses. For the nine months ended September 30, 2003, general and administrative expenses excluding related stock based compensation expenses were $3,425,000, compared to $2,867,000 for the nine months ended September 30, 2002, an increase of $558,000 or

19.5%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The $558,000 increase in general and administrative expenses for the nine months ended September 30, 2003 was primarily attributable to the amortization of intangibles, legal, bonuses and other general corporate expenditures. In addition, stock based compensation related to general and administrative expenses was $761,000 for the nine months ended September 30, 2003, compared to $732,000 for the nine months ended September 30, 2002. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, you should read the discussion under the section entitled “Stock based compensation expenses.”

Stock based compensation expenses. For the nine months ended September 30, 2003, total non-cash stock based compensation expenses classified in operating expenses were $872,000, compared to $1,017,000 for the nine months ended September 30, 2002, a decrease of $145,000 or 14.3%. Stock based compensation results from options issued to employees, directors and non-employees. The stock based compensation relating to employees and directors represents 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 relating to non-employees represents the fair value of the underlying common stock on the initial date of grant, then marked to market over the vesting period until meeting the performance commitment. Unearned stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. The overall decrease in stock based compensation expense for the nine months ended September 30, 2003, as compared to nine months ended September 30, 2002, was related to the normal amortization of the stock based compensation expenses over the remaining vesting period and the modification of certain options granted to consultants and officers of the Company. The decrease of $127,000 in research and development stock based compensation expense was primarily due to issuing 50,000 fully vested stock options to non-employees for consulting services rendered in the nine months ended September 30, 2002 with no comparable expenses in the nine months ended September 30, 2003. The decrease of $47,000 in sales and marketing stock based compensation expense in the nine months ended September 30, 2003 was related to the normal amortization of the stock based compensation over the remaining vesting period. The increase of $29,000 in general and administrative stock based compensation expense in the nine months ended September 30, 2003 was primarily due to additional expenses of $234,000 incurred in the modification of certain options granted to the Chief Financial Officer in his September 2003 separation agreement, which was partially offset by $92,000 in

expense from modifying certain stock options held by our former president and $113,000 in expense related to the normal amortization of the stock based compensation expense over the remaining vesting period in the nine months ended September 30, 2002. There was no stock based compensation expense relating to non-employees for the nine months ended September 30, 2003.

Restructuring charge. In the nine months ended September 30, 2003, we recorded a restructuring charge of $458,000, for which there was no comparable charge in the nine months ended September 30, 2002. In an effort to reduce costs and consolidate operations in the United States, we closed our administrative office in Königstein, Germany in September 2003. In connection with the facility closure, we incurred restructuring charges of $262,000 relating to involuntarily terminating 3 employees including our Chief Financial Officer and $196,000 relating to a lease termination.

Equipment impairment charge. In the nine months ended September 30, 2002, we had an equipment impairment charge of $370,000, for which there was no comparable charge in the nine months ended September 30, 2003. The impairment charge represents the excess cost of the equipment over the net proceeds we estimate we will receive from sale of the assets, which were previously utilized in the manufacturing of craniomaxillofacial bone fixation implant and accessory products, but not included in the Medtronic sale.

Interest income. For the nine months ended September 30, 2003, interest income was $335,000, compared to $844,000 for the nine months ended September 30, 2002, a decrease of $509,000, or 60.3%. The decrease in interest income resulted from lower interest rates and a decrease in funds we had available for investments.

Interest and other expenses. For the nine months ended September 30, 2003, interest and other expenses were $17,000, compared to $223,000 for the nine months ended September 30, 2002. The decrease was due to losses related the disposal of equipment in the nine months ended September 30, 2002, with no comparable expense in the three months ended September 30, 2003, and lower outstanding principal balance in the nine months ending September 30, 2003.

Equity loss in investment. For the nine months ended September 30, 2002, our equity loss in investment was $189,000, with no comparable loss in the nine months ended September 30, 2003. The loss related entirely to our former 13.5% equity interest in StemSource, which we accounted for using the equity method. Under the equity method of accounting, we recognized a pro rata share of StemSource's operating losses. In November 2002 we acquired 100% of the outstanding stock of StemSource and now include 100% of StemSource in the results of operations.

Gain on Asset Sale to Medtronic

We have not yet recognized the full gain on the September 2002 asset sale to Medtronic, and will not do so until we successfully transfer to Medtronic the technology and know how, including training, related to the manufacture of the craniomaxillofacial product line, which we expect to occur in the fourth quarter of 2003 or the first quarter of 2004. However, we have recognized approximately $1,342,000 of the gain as revenue related to the sale of CMF product to Medtronic under our backup supply arrangement, which provides for sales of CMF products to Medtronic at cost. Discounts from the previously agreed price have been recorded as a reduction to the deferred gain. We have recorded $8,243,000 of unamortized "Deferred gain on sale of assets, related party" on our balance sheet at September 30, 2003.

Liquidity and Capital Resources

As of September 30, 2003, we had cash and cash equivalents, and short-term investments, available-for-sale, of $16,889,000 and working capital of $17,142,000. Since inception, we have financed our operations primarily through sales of stock and from the September 2002 product line sale to Medtronic. Our sales of preferred stock in 1999, 1998 and 1997 yielded net proceeds of $14,679,000. On August 8, 2000, we completed our initial public offering in Germany and listed our common stock for trading on the Frankfurt Stock Exchange in Frankfurt, Germany, at which time the outstanding shares of our preferred stock were converted into 6,831,398 shares of common stock. We received net proceeds of $43,244,000 from the sale of 3,500,000 shares of our common stock in our initial public offering. A portion of those net proceeds have been used for research and development, to expand our manufacturing operations, to promote our brand and to pursue regulatory approvals for our products. In addition, some of the proceeds have been used for working capital and general corporate purposes. We have invested some of the proceeds from the offering in short-term investments, pending other uses of the proceeds in our business.

Our capital requirements depend on numerous factors, including market acceptance of our products and regulatory approvals, the resources we devote to developing and supporting our products and other factors. We expect to devote substantial capital resources to continue our research and development efforts, to expand our support and product development activities and for other general corporate activities. We believe that our current cash and cash equivalents, short-term investments, available for

sale, and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through September 30, 2004. Due to the acquisition of StemSource, we will also have to commit substantial cash resources to fund StemSource's development activities which are estimated at approximately $4,000,000 in 2003 and more thereafter. Our strategic concept is to use the cash from the Medtronic asset sale to enable us to undertake the StemSource opportunity without depriving our remaining bioresorbable product lines of capital resources which would otherwise have been available to them. Nonetheless, until we begin to generate sufficient revenues from our bioresorbable products operations to cover our operating costs, we may need to seek additional sources of financing in the future. We cannot give assurance that we will generate sufficient revenues to cover our bioresorbable products operating costs or that we will be able to obtain additional financing on terms satisfactory to us, if at all.

Net cash used in operating activities was $6,891,000 and $4,860,000 for the nine months ended September 30, 2003 and 2002, respectively. For each period, net cash used in operating activities resulted primarily from net losses and working capital requirements. Net losses for each period resulted to a large extent from expenses associated with the development of our bioresorbable designs, preclinical studies, preparation of submissions to the FDA and foreign regulatory agencies, the establishment of marketing and distribution channels, and the improvement of our manufacturing capabilities. In the nine months ended September 30, 2003, net cash used in operating activities primarily resulted from (i) our net loss of $8,138,000, (ii) an increase in accounts receivable of $1,585,000 related to the increase in sales to Medtronic near the end of the period and (iii) $1,342,000 of non-cash amortization of gain on the sale of

assets to a related party that related to products acquired by Medtronic under a back-up supplier agreement at discounts from previously agreed prices. The cash used in these operating activities was offset by an increase in accounts payable and accrued expenses of $1,358,000 that related to the accrual of the restructuring charges, bonuses, and accrued studies and non-cash charges for depreciation and amortization of $1,215,000, and stock based compensation of $881,000. In the nine months ended September 30, 2002, net cash used in operating activities primarily related to our net loss of $7,503,000, increases in accounts receivable of $1,064,000 and inventory of $610,000, offset by non-cash charges of $1,122,000 of depreciation and amortization, inventory provision of $1,395,000 and $1,028,000 for stock based compensation. Our working capital requirements fluctuate with changes in our operating activities that include such items as sales and manufacturing costs, which affect the levels of accounts receivable, inventories and current liabilities. We expect to use less cash in operating activities as our product lines become more profitable.

Net cash provided by investing activities was $3,590,000 and $11,237,000 for the nine months ended September 30, 2003 and 2002, respectively. Net cash provided by investing activities for the nine months ended September 30, 2003 consisted of net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e. we cashed in short-term investments to fund our operating activities). In the nine months ended September 30, 2003 we purchased $1,013,000 in property and equipment primarily to support biomaterial manufacturing and research and development of the biologics platform technology and paid $644,000 of costs associated with the acquisition of StemSource related to professional services and the settlement of the remaining lease payments related to a lease assumed in the StemSource acquisition. Net cash provided by investing activities for the nine months ended September 30, 2002 consisted of net proceeds from the purchase and sale of short-term investments, which was offset by capital expenditures and loans (which have been repaid) to our corporate officers and a short term loan to StemSource. We expect to continue to have cash provided by investing activities as we sell our short-term investments to provide cash for our operating activities and property and equipment purchases.

Net cash provided by financing activities was $542,000 for the nine months ended September 30, 2003, which resulted primarily from (i) proceeds from the sale of 150,500 shares of our common stock held in treasury at a price of $3.60 per share and (ii) $490,000 from the issuance of two promissory notes

under an Amended Master Security Agreement to finance our equipment purchases. These amounts were offset by our purchase of 63,499 shares of our common stock on the open market at an average price of $3.90 per share and $275,000 for payments of long term obligations. Net cash used in financing activities for the nine months ended September 30, 2002 was primarily related to $4,284,000 for the repurchase of 1,213,853 shares of our common stock at an average price of $3.53, $364,000 for payments toward long term obligations and $140,000 for principal payments on capital lease obligations. On April 9, 2002, September 17, 2002 and August 11, 2003 the Board of Directors amended the April 3, 2001 authorization to purchase treasury stock and authorized the repurchase of up to 3,000,000 shares of the Company's common stock in the open market, from time to time until August 10, 2004, subject to the Company's assessment of market conditions and buying opportunities, and at a purchase price per share not to exceed €15.00, based on the exchange rate in effect on August 11, 2003.

In October 2000, we issued $2,433,000 of equipment financing promissory notes that mature in October 2005 at an interest rate of 9.3%. In 2002 we prepaid $621,000 relating to a 48 month promissory note and the lender changed the terms of this promissory note to bear interest at 8.8% per annum with principal and interest due in monthly payments of approximately $34,000, maturing over 35 months and secured by equipment with a cost of $1,442,000.

In September 2003 we entered into an Amended Master Security Agreement to provide financing for equipment purchases of $1,500,000 through September 2004. In connection with this agreement, we issued two promissory notes to our lender for a total of approximately $490,000. These notes bear an interest rate of 8.6% per annum with principal and interest due in monthly payments of approximately $6,000 and $8,000, respectively and mature over 48 and 36 month periods, respectively and are secured by equipment with a cost of $490,000.

As of September 30, 2003, we had property and equipment of $7,213,000, less accumulated depreciation of $3,533,000, to support our clinical, research, development, manufacturing and administrative activities. Our capital expenditures were $1,013,000 and $875,000 for the nine months ended September 30, 2003 and 2002, respectively. We expect capital expenditures for the next twelve months to be approximately $1,100,000 as we acquire additional equipment and expand our facilities to support our biologics platform technology. We intend to pay for future capital expenditures with available working capital or financing under our Amended Master Security Agreement.

The following summarizes our contractual obligations and other commitments at September 30, 2003, and the effect such obligations could have on our liquidity and cash flow in future periods:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 – 3 years**	**3 – 5 years**	**More than 5 years**
Long-Term Debt Obligations	1,395,000	566,000	765,000	64,000	—
Operating Lease Obligations	3,616,000	884,000	2,361,000	371,000	—
Total	5,011,000	1,450,000	3,126,000	435,000	—

Critical Accounting Policies and Significant Estimates

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

estimates, we will make adjustments to our financial statements as we become aware of the necessity for an adjustment.

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

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

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

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

We earn revenue for performing services under development agreements. Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when (i) the performance criteria for that milestone have been met if substantive effort is required to achieve the milestone, (ii) the amount of the milestone payments appears reasonably commensurate with the effort expended and (iii) collection of the payment is reasonably assured. Income earned under development agreements is classified under revenues in our statement of operations. The costs associated with development agreements are recorded as research and development expense.

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

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

Allowance for doubtful accounts. We provide a reserve against our receivables for estimated losses that may result from our customers' inability to pay. These reserves are based on known uncollectible accounts, aged receivables, historical losses and our estimate of our customers' credit-worthiness. Should a customer's account become past due, we generally place a hold on the account and discontinue further shipments to that customer, minimizing further risk of loss. The likelihood of our recognition of a material loss on an uncollectible account mainly depends on deterioration in the economic financial strength of the customer and the general business environment. Medtronic is our single largest customer, directly accounting for 90.3% and 96.5% of our revenues in the nine months ended September 30, 2003 and 2002, respectively. We believe that our allowance for doubtful accounts as of September 30, 2003 with respect to Medtronic's account is sufficient, given Medtronic's collection history and overall

financial strength.

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

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

Warranty. We provided an estimated warranty provision at the time products are sold to our customers. Estimates are principally based on the past history of warranty claims and applied to all items sold where little or no claims experience may exist. In addition, the number and magnitude of warranty claims expected to be approved, and policies related to additional actions, are taken into consideration. Our estimate of warranty obligations is reevaluated on a quarterly basis.

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

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

Unearned Compensation

We record unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair market value of our common stock on the date of grant. Unearned compensation is amortized to stock based compensation expense and reflected as such in the Statements of Operations and Comprehensive Income (Loss). Unearned compensation recorded through September 30, 2003 was $6,663,000, with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of $6,447,000. The remaining $216,000 as of September 30, 2003 will be amortized using the straight-line method over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. We expect to record amortization expense for unearned compensation of $107,000 for the period October 1, 2003 to December 31, 2003, and $109,000 in 2004. The amount of unearned compensation expense recorded in future periods may decrease if unvested options for which unearned compensation has been recorded are subsequently forfeited.

Recent Accounting Pronouncements

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure – An Amendment of FASB Statement No. 123 (SFAS 148)." This Statement provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and requires prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We have elected not to adopt the recognition and measurement provisions of SFAS No. 123 and continue to account for our stock-based employee compensation plan under APB Opinion No. 25 and related interpretations. We have adopted the interim disclosure provisions required by SFAS 148 for our March 31, 2003 Form 10-Q.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities". FIN 46 clarifies the application of Accounting Research Bulletin No. 51 - Consolidated Financial Statements to those entities defined as "Variable Interest Entities" (more commonly referred to as special purpose entities) in which equity investors do not have the characteristics of a "controlling financial interest" or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to all Variable Interest Entities created after January 31, 2003, and by the beginning of the first interim or annual reporting period commencing after December 15, 2003 for Variable Interest Entities created prior to February 1, 2003. The adoption of FIN 46 did not have a material effect on our consolidated financial position or consolidated results of operations as we currently do not have any variable interest entities falling within the scope of FIN 46.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS 133. In particular, SFAS No. 149 clarifies under what circumstances a contract within an initial net investment meets the characteristic of a derivative and when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is generally effective for contracts entered into or modified after June 30, 2003. The adoption of SFAS No. 149 did not have a material effect on our consolidated financial position or consolidated results of operations as we currently do not have any derivative instruments and hedging activities falling within the scope of SFAS No. 149.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material effect on our consolidated financial position or consolidated results of operations.

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 $14,540,000 as of September 30, 2003, consist primarily of investments in debt instruments of financial institutions, corporations with strong credit ratings and United States government obligations. These securities are subject to interest rate risk inasmuch as their fair value will fall if market interest rates increase; however, due to the nature of the securities we believe this risk is not dramatic. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at September 30, 2003, for example, and assuming average investment duration of eight months, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. We believe that we 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. Although we transact business in various foreign countries, settlement amounts are usually based on the U.S. dollar. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not engaged in any hedging activity in the Euro or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the nine months ended September 30, 2003, a hypothetical 10% adverse change in the Euro against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

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

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

Risk Factors

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

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

We commenced operations in May 1997 and therefore our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced fields such as the medical device field. Due to our

limited operating history, comparisons of our year-to-year operating results are not necessarily meaningful and the results for any periods should not be relied upon as an indication for future performance. Since our limited operating history makes the prediction of future results difficult or impossible, our recent revenue growth should not be taken as an indication of any future growth or of a sustainable level of revenue.

Moreover, our operating results can vary substantially from analyst expectations and from previous periodic results for many reasons, including the timing of product introductions and distributor purchase orders. Also, the sale of our craniomaxillofacial bone fixation implant and accessory product line in 2002, which had represented a large portion of our revenues, will distort quarterly and annual earning comparisons through 2003 and 2004. Earnings surprises can have a disproportionate effect on the stock prices of emerging companies such as ours. Also, our stock price is likely to be disproportionately affected by changes which generally affect the economy, the stock market or the medical device industry.

We have never been profitable

We have incurred net losses in each year since we started doing business, including net losses of $8,138,000 for the nine months ended September 30, 2003. These losses have resulted primarily from expenses associated with our research and development activities, including extensive *in vitro* testing and numerous preclinical studies and general and administrative expenses. We anticipate that our recurring operating expenses will increase for the next several years, as our research and development expenses may increase in order to develop and market new products and fund additional preclinical research and possibly clinical trials. We expect to achieve profitability (on a non-operating basis) for 2003 if we complete the know-how transfer milestone under our 2002 sale of the craniomaxillofacial product line to Medtronic in 2003. This would enable us to recognize $8,243,000 of non-operating gain as of September 30, 2003 in 2003. We expect to continue to incur operational losses at least through the end of 2003 and the amount of future net losses and time necessary to reach operational profitability are somewhat uncertain. Even if our bone fixation and bioresorbable thin film medical device product lines achieve operational profitability, development-stage losses related to our development of stem cell regenerative technology could keep us in a loss position on a consolidated basis for several years.

We are adopting a high-risk strategy

In the second half of 2002 we sold our craniomaxillofacial bone fixation implant and accessories product line to Medtronic and acquired StemSource, which is a development-stage adult stem cell company. Our craniomaxillofacial product line produced relatively stable revenues and (we believe) had slower-growth prospects, compared to our retained musculoskeletal bone fixation implant and accessories product line and our bioresorbable thin film product line for soft-tissue repair and regeneration which we believe have a higher risk/reward profile. By focusing on these less-mature and more volatile product areas, we accept more risk. In addition, we intend to use the cash we received from the sale of the craniomaxillofacial product line to finance the business acquired from StemSource and its development-stage cash needs. This is a high-risk strategy because there can be no assurance that our StemSource technology will ever be developed into commercially viable products (scientific 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 use our medical device products to deliver stem cells where needed in the body (strategic risk), or that our cash resources will be adequate to develop the StemSource technology until it becomes profitable (if ever) while still serving the cash needs of our medical device product lines (financial risk). Instead of using the cash received from selling that product line to reinvest in our core business, we are using it in one of the riskiest industries in the entire economy. This fundamentally changes our risk/reward profile and may make our stock an unsuitable investment for some investors.

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

We are in the early stage of commercialization with many of our products although we have derived revenue from sales of certain products to our distributors, particularly Medtronic, Inc. We believe that our long-term viability and growth will depend in large part on receiving additional regulatory clearances or approvals and expanding our sales and marketing efforts for our existing products and new products that may result from our research and development activities. We are presently pursuing product opportunities in musculoskeletal bone fixation and soft tissue repair and regeneration throughout the body that will require extensive additional capital investment, research, development, clinical testing and regulatory clearances or approvals prior to commercialization. There can be no assurance that our product development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all. Most of our stem cell related products and /or services are years away.

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

We rely on Medtronic to distribute our products

We have limited experience in sales, marketing and distribution. Therefore, our strategy for sales and marketing of our resorbable products has included entering into agreements with other companies to market many of our current and certain future products incorporating our technology. We have derived the

vast majority of our 2003 and 2002 revenues from the sale of products to our distribution partner Medtronic. Although we have engaged a direct sales force to market our SurgiWrap™ bioresorbable film product line in the United States and we have entered into independent international distribution agreements in foreign countries for our bioresorbable product lines, we cannot guarantee that this sales force or international distributors will adequately penetrate the markets to generate significant revenues to offset our reliance on Medtronic.

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

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

Medtronic owns approximately 6.8% of our outstanding common stock, which may limit our ability

to negotiate commercial arrangements optimally with Medtronic.

Medtronic is not constrained in its ability to distribute or develop products competitive to ours; it is free to pursue existing or alternative technologies in preference to our technology in the spine.

There can be no assurance that our interests will continue to coincide with those of Medtronic or that Medtronic will not develop independently or with third parties products which could compete with ours or that disagreement over rights or technology or other proprietary interests will not occur. To the extent that we choose not to or are unable to enter into future agreements, we would experience increased capital requirements to undertake the marketing or sale of some of our current and future products. There can be no assurance that we will be able to effectively market or sell our current or future products independently in the absence of such agreements. The loss of the marketing services provided by Medtronic, or the loss of revenues generated by Medtronic could have a substantial negative effect on the results of our operations and financial condition.

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

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

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

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

We have limited manufacturing experience

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

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

We have to maintain quality assurance certification and manufacturing approvals

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

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

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

We currently purchase the high molecular weight, medical grade, lactic acid copolymer used in manufacturing most of our products, from a single qualified source. Although we have a contract with B.I. Chemicals, Inc., which guarantees continuation of supply through August 15, 2004, we cannot guarantee that they will elect to continue the contract beyond that date, or that they will not elect to discontinue the manufacture of the material. They have agreed that if they discontinue manufacturing they will either find a replacement supplier, or provide us with the necessary technology to self-manufacture the material, either of which could mean a substantial increase in material costs. Also, despite this agreement they might fail to do these things for us. Under the terms of the contract, B.I. Chemicals, Inc. may choose to raise their prices upon nine months prior notice which may also result in a substantially increased material cost. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates. Lack of adequate commercial quantities or inability to develop alternative sources meeting regulatory requirements at similar prices and terms within a reasonable time or any interruptions in supply in the future could have a significant negative effect on our ability to manufacture products, and, consequently, could have a material adverse effect on the results of our operations and financial condition.

We may not be able to protect our proprietary rights

Our success depends in part on whether we can obtain additional patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. We have several U.S. patents for the design of our bioresorbable plates and high torque screws and one for our SurgiWrap™ bioresorbable film, and we have filed applications for various additional U.S. patents, as well as certain corresponding patent applications outside the United States, relating to our technology. However, we

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

Our stem cell technology license agreement with the University of California Regents 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 stem cell technology and/or commercialize related products.

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. Patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

Litigation, which would result in substantial costs to us and diversion of effort on our part, may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights.

If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us.

Any such litigation or interference proceeding, regardless of outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties and require disputed rights to be licensed from third parties or require us to cease using certain technology.

In addition to patents, which as noted cannot protect the fundamentals of our technology and our 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 or trade secret protection, for any reason, third party claims against our patents, trade secrets or proprietary rights, or our involvement in disputes over our patents, trade secrets or proprietary rights, including involvement in litigation, could have a substantial negative effect on the results of our operations and financial condition.

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

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other

intellectual property rights to the same extent as United States laws. We currently have pending patent applications in the European Patent Office, Australia, Japan, Canada, China, Korea and Mexico and we have published other international patent applications.

We are subject to intensive US FDA regulation

As newly developed medical devices, our bioresorbable surgical implants must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments, prior to their sale. Our current and future bioresorbable surgical implants for humans are subject to 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 market, the manufacturer generally must obtain FDA clearance or approval through either the 510(k) premarket notification process or the lengthier premarket approval application ("PMA") process. It generally takes from three to 12 months from submission to obtain 510(k) premarket clearance although it may take longer. Approval of a PMA could take four or more years from the time the process is initiated. The 510(k) and PMA processes can be expensive, uncertain and lengthy, and there is no guarantee of ultimate clearance or approval. We expect that some of our future products under development will be subject to the lengthier PMA process. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA, and there can be no guarantee of ultimate clearance or approval. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications and criminal prosecution.

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

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

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

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

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

We may need to raise more cash in the future

If we do not increase our sales quickly enough or if we choose to invest additional cash in areas of promise, we may be required to seek additional capital to finance our operations in the future. As of September 30, 2003, we had $16,889,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. Our 2002 sale of the craniomaxillofacial product line to Medtronic has buttressed that cash position, but our acquisition of StemSource has and will continue to result in a substantial cash requirement for research and development. Other than our current equipment financing lines of credit, we currently have no commitments for any additional debt or equity financing, and there can be no guarantee that adequate funds for our operations from any additional debt or equity financing, our operating revenues, arrangements with distribution partners or from other sources will be available when needed or on terms attractive to us. The inability to obtain sufficient funds may require us to delay, scale back or eliminate some or all of our research or product development programs, manufacturing operations, clinical studies or regulatory activities or to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, and could have a substantial negative effect on the results of our operations and financial condition.

We depend on a few key officers

Our performance is substantially dependent on the performance of our executive officers and other key scientific staff, including Christopher J. Calhoun, our President and Chief Executive Officer and Marc Hedrick, MD, our Chief Scientific Officer and Medical Director, each of whom we rely upon for strategic business decisions and guidance. We do not currently have "key person" life insurance policies on any of our employees. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to

attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff or the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

We recently acquired StemSource and may undertake additional business acquisitions which will present risks associated with integrating new businesses

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

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

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

We may not have enough product liability insurance

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

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

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

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

In the United States, our stock is traded through the Pink Sheets, which results in an illiquid market. Investors trading in this market may be disadvantaged in comparison to investors trading in our stock in Europe. Our stock had been traded on the Neuer Markt segment of the Frankfurt Stock Exchange, but the Neuer Markt closed in 2002. 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.

We pay no dividends

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

Item 4. Controls and Procedures

(a) Evaluation of disclosure controls and procedures

Our chief executive officer and principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in Securities Exchange Act of 1934 Rules 13a-14 and 15d-14) as of a date (the "Evaluation Date") within 90 days before the filing date of this quarterly report, has concluded that as of the Evaluation Date, our disclosure controls and procedures are effective.

(b) Changes in internal controls

There were no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the Evaluation Date.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 2. Changes in Securities and Use of Proceeds

On September 19, 2003, we sold 150,000 shares of unregistered common stock to an individual at a price of $3.60 per share. We did not use an underwriter, and we relied on the Regulation S exemption from the Securities Act's registration requirement. We intend to use the proceeds from this sale for general working capital working purposes.

Item 3. Defaults Upon Senior Securities

None

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

We held our annual meeting of stockholders on October 23, 2003. Of the 14,585,599 shares of our common stock which could be voted at the annual meeting, 5,388,924 shares of our common stock were represented at the annual meeting in person or by proxy, which constituted a quorum. Voting results were as follows:

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

	For	Withheld
Ari Bizimis*	5,082,094	306,830
Christopher J. Calhoun	5,178,896	209,938
Marshall G. Cox	5,176,341	212,583
Marc H. Hedrick, MD	5,183,621	205,303
Ronald D. Henriksen	5,183,104	205,820
E. Carmack Holmes, MD	5,183,711	205,213
David M. Rickey	5,178,061	210,863

*Mr. Bizimis resigned as a Director a short time prior to the meeting of the shareholders and he has declined to serve the new term for which he was elected.

b. The proposal to ratify the selection of KPMG LLP as the Company's independent auditors for the fiscal year ending December 31, 2003, received the following votes:

For	Against	Abstain
5,155,581	7,108	226,235

Item 5. Other Information

Properties and Facilities

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

- 14,000 square feet, of which approximately 4,000 square feet is for research and development and 10,000 square feet is office space at 6749 Top Gun Street, San Diego, California for a five-year term expiring in 2006.
- 16,000 square feet for research and development activities located at 6749 Top Gun Street, San Diego, California for a five year term expiring 2007.
- 5,800 square feet, of office space located at Ömühlweg 33, Königstein, Germany for use in marketing and administration for a five-year term, expiring in 2006. We ceased business operations at this location, and it became excess in September 2003.

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

Staff

As of September 30, 2003, we had 91 full-time employees, comprised of 34 employees in research and development, 22 employees in manufacturing, 15 employees in management and finance and administration and 20 employees in sales and marketing. As of September 30, 2002, we had 89 full-time employees, comprised of 21 employees in research and development, 25 employees in manufacturing, 17 employees in management and finance and administration, and 26 employees in sales and marketing. From time to time, we also employ independent contractors to support our administrative organizations. Our employees are not represented by any collective bargaining unit and we have never experienced a work stoppage.

Item 6. Exhibits and Reports on Form 8-K

a. Exhibits

10.1	Amended Master Security Agreement between the Company and General Electric Corporation, September, 2003
10.2	Lease Termination Agreement for the Premises Located at 1125 Business Center Circle, Thousand Oaks, California, July, 2003
10.3*	Separation Agreement and General Release between the Company and Ari Bizimis, September, 2003
15.1	Letter re unaudited interim financial information
31.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002

b. Reports on Form 8-K

We furnished, on Form 8-K, Item 12, during this fiscal quarter, copies of announcements of historical financial results. Pursuant to SEC staff guidance, such furnished Form 8-K information need not be listed in this Item 6(b) of Form 10-Q.

*Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text (the "Mark"). This exhibit has been filed separately with the Secretary of the Commission without the Mark pursuant to our Application Requesting Confidential Treatment under Rule 406 under the Security Act of 1933.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in San Diego, California, on November 11, 2003.

MACROPORE BIOSURGERY, INC.

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

EXHIBIT INDEX

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AMENDMENT

THIS AMENDMENT is made as of the 8th day of September, 2003, between General Electric Capital Corporation ("Secured Party") and Macropore Biosurgery, Inc. ("Debtor") in connection with that certain Master Security Agreement, dated as of October 2, 2001 ("Agreement"). The terms of this Amendment are hereby incorporated into the Agreement as though fully set forth therein. Section references below refer to the section numbers of the Agreement. The Agreement is hereby amended as follows:

5. REPORTS.

Subsection (b) is hereby replaced with the following:

"(b) Debtor will deliver to Secured Party financial statements as follows. If Debtor is a privately held company, then Debtor agrees to provide monthly financial statements, certified by Debtor's president or chief financial officer including a balance sheet, statement of operations and cash flow statement within 30 days of each month end and its complete audited annual financial statements, certified by a recognized firm of certified public accountants, within 120 days of fiscal year end or at such time as Debtor's Board of Directors receives the audit. If Debtor is a publicly held company, then Debtor agrees to provide quarterly unaudited statements and annual audited statements, certified by a recognized firm of certified public accountants, within 10 days after the statements are provided to the Securities and Exchange Commission ("SEC") unless the reports are available on the SEC web site. All such statements are to be prepared using generally accepted accounting principles ("GAAP") and, if Debtor is a publicly held company, are to be in compliance with SEC requirements."

7. DEFAULT AND REMEDIES.

Subsection (a) is hereby amended with the following:

"(a) Debtor shall be in default under this Agreement and each of the other Debt Documents if:

(i) Debtor breaches its obligation to pay when due any installment or other amount due or coming due under any of the Debt Documents;

(ii) Debtor, without the prior written consent of Secured Party, attempts to or does sell, rent, lease, license, mortgage, grant a security interest in, or otherwise transfer or encumber (except for Permitted Liens) any of the Collateral;

(iii) Debtor breaches any of its insurance obligations under Section 4;

(iv) Debtor breaches any of its other obligations under any of the Debt Documents and fails to cure that breach within thirty (30) days after written notice from Secured Party;

(v) Any warranty, representation or statement made by Debtor in any of the Debt Documents or otherwise in connection with any of the Indebtedness shall be false or misleading in any material respect;

(vi) Any of the Collateral is subjected to attachment, execution, levy, seizure or confiscation in any legal proceeding or otherwise, or if any legal or administrative proceeding is commenced

against Debtor or any of the Collateral, which in the good faith judgment of Secured Party subjects any of the Collateral to a material risk of attachment, execution, levy, seizure or confiscation and no bond is posted or protective order obtained to negate such risk;

(vii) Debtor breaches or is in default under any other agreement between Debtor and Secured Party;

(viii) Debtor or any guarantor or other obligor for any of the Indebtedness (collectively "Guarantor") dissolves, terminates its existence, becomes insolvent or ceases to do business as a going concern;

(ix) If Debtor or any Guarantor is a natural person, Debtor or any such Guarantor dies or becomes incompetent;

(x) A receiver is appointed for all or of any part of the property of Debtor or any Guarantor, or Debtor or any Guarantor makes any assignment for the benefit of creditors;

(xi) Debtor or any Guarantor files a petition under any bankruptcy, insolvency or similar law, or any such petition is filed against Debtor or any Guarantor and is not dismissed within forty-five (45) days;

(xii) Debtor's improper filing of an amendment or termination statement relating to a filed financing statement describing the Collateral; or

(xiii) Debtor defaults under any other material obligation for (A) borrowed money, (B) the deferred purchase price of property or (C) payments due under any lease agreement. For purposes of the preceding sentence, "material obligation" shall mean any obligation to pay Five Hundred Thousand dollars or more during any twelve month period.

(xiv) At any time during the term of this Agreement Debtor sells more than 50% of its interest in the company to another corporation or business or all or substantially all of its assets without Secured Party's prior written consent.

TERMS USED, BUT NOT OTHERWISE DEFINED HEREIN SHALL HAVE THE MEANINGS GIVEN TO THEM IN THE AGREEMENT. EXCEPT AS EXPRESSLY AMENDED HEREBY, THE AGREEMENT SHALL REMAIN IN FULL FORCE AND EFFECT. IF THERE IS ANY CONFLICT BETWEEN THE PROVISIONS OF THE AGREEMENT AND THIS AMENDMENT, THEN THIS AMENDMENT SHALL CONTROL.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment simultaneously with the Agreement by signature of their respective authorized representative set forth below.

General Electric Capital Corporation		**Macropore Biosurgery, Inc.**	
By:	/s/ John Edel	By:	/s/ Charles E. Galetto
Name	: John Edel	Name:	Charles E. Galetto
Title:	Senior Vice-President	Title:	V.P. of Finance

EXHIBIT 10.2

LEASE TERMINATION AGREEMENT

For the Premises Located at
1125 Business Center Circle, Thousand Oaks, California

THIS LEASE TERMINATION AGREEMENT (this "Agreement") is dated and made effective as of July 31, 2003 (the "Effective Date"), by and between 975 Business Center, LLC, a Delaware limited liability company, 975 Courtyard, LLC, a Delaware limited liability company, 975 Santa Barbara, LLC, a Delaware limited liability company, as tenants-in-common (collectively, the "Lessor") and MacroPore Biosurgery, Inc., a Delaware corporation (the "Lessee") with regard to the following facts and intentions:

R E C I T A L S

A. On or about July, 2, 2001, Thousand Oaks Business Center Partnership, a California limited partnership, as the original lessor, and StemSource, Inc., a Delaware corporation, as the original lessee, entered into that certain Standard Industrial Lease, as amended, a copy of which is attached hereto as Exhibit A (the "Lease"), covering certain real property situated at 1125 Business Center Circle, Thousand Oaks, California 91330 (the "Premises").

B. Thousand Oaks Business Center Partnership has since transferred ownership of the Premises to the Lessor (*i.e.*, 975 Business Center, LLC, a Delaware limited liability company, 975 Courtyard, LLC, a Delaware limited liability company and 975 Santa Barbara, LLC, a Delaware limited liability company, as tenants-in-common).

C. In connection with that certain Assignment and Assumption of Lease dated October 31, 2002, and pursuant to the merger of StemSource, Inc. with and into MacroPore Biosurgery, Inc., ("MacroPore"), MacroPore has succeeded to the rights, responsibilities, obligations and duties of StemSource, Inc. as the lessor under the Lease.

D. The original term of the Lease expires July 24, 2006 (the "Original Termination Date").

E. The Lessee has vacated and surrendered the Premises as of June 30, 2003. The Lessor has accepted Lessee's surrender of the Premises effective as of July 31, 2003.

F. The parties desire to terminate the Lease effective as of July 31, 2003 on the terms and conditions as set forth in this Agreement.

A G R E E M E N T

In consideration of the mutual covenants contained herein, the sufficiency of which are hereby acknowledged, the parties agree as follows:

Termination of Lease. The parties agree to terminate the Lease effective as of July 31, 2003 (the "Effective Date", subject to fulfillment of the following conditions:

(a) Termination Payment of $240, 000. As consideration for entering this Agreement, Lessee shall pay Lessor, the sum of Two Hundred Forty Thousand Dollars ($240,000) (the "Termination Payment") (which along with the Security Deposit, shall be accepted by Lessor as complete accord and satisfaction for all amounts currently or later due under the Lease). Lessee shall deliver the Termination Payment to Lessor in *c/o* SIMA Management Corporation, 115 West Canon Perdido Street, Suite 200, Santa Barbara, California 93101 on or before 5:00 p.m. August 12, 2003 (the "Payment Date");

(b) Security Deposit Retained by Lessor. As additional consideration for entering this Agreement, Lessee hereby releases any and all claim, lien, right, or interest to the Security Deposit that Lessee (or StemSource, Inc.) may have in the Security Deposit (as described in the Lease), including any accrued interest, claim for offset, or otherwise. The Security Deposit, along with all accrued interest shall become the property of the Lessor; and

(c) Surrender of Possession of the Premises. Lessee shall surrender possession of the Premises, including any tenant improvements constructed by Lessee during Lessee's tenancy.

2. Representations and Warranties. Each party hereby represents to the other that: (a) such party has the sole legal power, right and authority to enter into this Agreement; (b) all requisite corporate action has been taken by such party in connection with entering into this Agreement; (c) no additional consent of any individual, officer, director, shareholder, partner, member, manager, trustee, trustor, beneficiary, creditor, investor, judicial or administrative body, governmental authority or other party shall be required for such party to consummate the transaction contemplated by this Agreement; and (d) Lessee is the sole owner of the Lessee's leasehold interest under the Lease, free of any liens, subleases, claims or encumbrances; and (e) the individuals executing this Agreement on behalf of such party have the legal power, right and actual authority to bind such party to the terms and conditions hereof.

3. General Indemnity. Lessee shall indemnify, defend and hold Lessor harmless (with counsel reasonably acceptable to Lessor) from and against any and all claims, losses, liabilities and expenses, including attorneys' fees resulting from Lessee's negligent use or occupation of the Premises. Notwithstanding the foregoing, Lessor represents and warrants that Lessor (including any representatives of Lessor) are not as of the Effective Date, aware of any claim for indemnity against the Lessee.

4. Acceptance of Surrender of the Premises. Lessor accepts the surrender of the Premises by Lessee and acknowledges that the Premises are in good condition and repair, and that no further removal of any alterations is required.

5. Attorneys' Fees. If any action, lawsuit or proceeding relating to this Agreement, or any default thereunder, whether or not any action, lawsuit or proceeding is commenced, then the non-prevailing party shall reimburse the prevailing party for its attorneys' and expert witness' fees and costs and all fees, costs and expenses incurred in connection with such action, lawsuit or proceeding, including, without limitation, any post-judgment fees, costs or expenses incurred on any appeal, in collection of any judgment or in appearing in any bankruptcy proceeding. The prevailing party shall be determined under Civil Code Section 1717(b)(1) or any successor statute.

6. Successors. This Agreement shall be binding on and inure to the benefit of the parties and their respective successors, heirs and assigns.

7. Severability. If any one or more provisions contained in this Agreement is deemed invalid, illegal or unenforceable in any respect, such provision shall be enforced to the fullest extent permissible by law, and the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

8. Entire Agreement. This Agreement represents the entire agreement between the parties hereto and supersedes all prior negotiations, discussions, offers, understandings, representations and agreements (whether written or oral) with respect to the matters herein.

9. Further Assurances. Each of the parties shall deliver such further documents and instruments and shall take such other actions as may be reasonably required or appropriate to evidence or carry out the intent and purposes of this Agreement.

10. Amendment; Waiver. This Agreement may not be changed, waived, discharged or terminated, except by an instrument in writing signed by the party against whom enforcement of the change, waiver, discharge or termination is sought. No delay, failure or discontinuance in exercising any right, remedy, power or privilege hereunder shall affect or operate as a waiver of such right, remedy, power or privilege hereunder.

11. Governing Law. This Agreement was made in and is to be performed entirely within the State of California, and its interpretation, its construction and the remedies for its enforcement or breach are to be applied pursuant to, and in accordance with the laws of the State of California.

12. Counterparts. This Agreement may be executed by facsimile and any number of counterparts and shall constitute an agreement binding on all parties notwithstanding that all parties are not signatories to the original or the same counterpart provided that all parties are furnished a copy or copies thereof reflecting the signature of all parties.

13. Definitions. All capitalized terms not otherwise defined herein shall have the meaning set forth in the Lease.

14. Inconsistencies Between the Lease and this Agreement. If there is any conflict or inconsistency between the terms of the Lease and the terms of this Agreement, then the terms of this Agreement shall control.

15. Confidentiality. Lessor shall keep confidential and cause its agents, contractors, employees and representatives to keep confidential, and shall not divulge, disclose, communicate, use or misuse, any documents, instruments, financial statements or other information concerning the Premises, the Lease, this Agreement or any negotiations or discussions with respect thereto between the parties (the

"Confidential Information"). Notwithstanding the foregoing, Lessee shall be entitled to disclose and communicate the Confidential Information to its lenders, accountants, attorneys, and investors and to the extent required by law to federal, state and local authorities, provided that Lessee agrees to use reasonable efforts to notify such governmental authorities that each party considers such information confidential and to provide Lessor reasonable opportunity to legally stop such disclosure.

16. Brokers. The parties hereto represent and warrant to each other that neither party dealt with any broker or finder in connection with the consummation of this Agreement and each party agrees to protect, defend, indemnify, hold and save the other party harmless from and against any and all claims or liabilities for brokerage commissions or finder's fees arising out of either of their acts in connection with this Agreement**.**

17. Time is of the Essence. Time is of the essence of each and every term, condition, obligation and provision hereof. Lessee acknowledges it shall lose all rights if Lessor fails to act in strict accordance within the terms, conditions and time limits set forth herein.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the day and year first above written.

Lessee:

MacroPore Biosurgery, Inc.

a Delaware corporation

By: /s/ Christopher J. Calhoun
Name: Christopher J. Calhoun
Title: President & CEO

By: _____
Name: _____
Title: _____

Lessor:

975 Business Center, LLC
a Delaware limited liability company

By: /s/ James P. Knell
Name: James P. Knell
Title: _____

975 Courtyard, LLC
a Delaware limited liability company
By: /s/ James P. Knell
Name: James P. Knell
Title: _____

975 Santa Barbara, LLC, a Delaware limited liability company

Date: 8-8-03

By: /s/ James P. Knell
Name: James P. Knell
Title:

Date: 8-8-03

Attachments

Exhibit A – Lease

EXHIBIT 10.3

SEPARATION AGREEMENT AND GENERAL RELEASE

This Separation Agreement and General Release is made and entered into by and between MACROPORE BIOSURGERY, INC. ("MACROPORE") and ARI BIZIMIS.

WHEREAS, ARI BIZIMIS has been employed by MACROPORE as its Chief Financial Officer since April 1, 2000.

WHEREAS, ARI BIZIMIS has decided to resign from employment with MACROPORE (including all positions from any of its subsidiaries) where he served as Chief Financial Officer and Director, effective as of September 30, 2003.

WHEREAS, MACROPORE and ARI BIZIMIS do not believe that there are or will be any disputes between them or legal claims arising from ARI BIZIMIS'S employment relationship with MACROPORE, but nevertheless desire to ensure a completely amicable end to that relationship and to fully and finally settle any and all differences or claims that might otherwise arise out of ARI BIZIMIS'S resignation.

NOW, THEREFORE, in consideration of the mutual promises contained herein, it is agreed as follows:

1. **Resignation From Employment Relationship**. The employment relationship between MACROPORE and ARI BIZIMIS shall cease effective September 30, 2003 and the payment of any sums, pursuant to this Agreement, after September 30, 2003, shall not be considered to be wages. MACROPORE shall, however, withhold the ordinary and customary federal and state taxes and withholdings to such extent as required by law.

2. **Consideration**. In consideration of this Agreement and Release, MACROPORE agrees to pay ARI BIZIMIS a sum of Two Hundred Thousand Euro € 200,000. less standard tax and withholding requirements (if required under applicable law "Withholdings"). MACROPORE agrees that the outstanding stock option grants to ARI BIZIMIS shall be treated as described on Exhibit "1" (subject only to formal resolution of MACROPORE's Board of Directors) which is attached hereto and fully incorporated into this agreement**.** In addition, ARI BIZIMIS will be given title to his current MACROPORE personal computer, printer and fax machine.

3. **Contingent Additional Consideration.** MACROPORE agrees to pay ARI BIZIMIS a contingent bonus payment in the amount of *** of any *** Consideration (defined below) actually received by MACROPORE from *** , or any other legal entity that will act as *** pursuant to the *** described in the *** Agreement (the consummation of which is not yet complete or certain) between MACROPORE and ***. The "*** Consideration" refers to the cash consideration *** of $*** as currently identified in Section 2.3 of the *** Agreement, and does not relate to any other payments that might be made under the *** Agreement, or any related agreement. Any contingent bonus payments will be made within 30 days of (and shall be solely contingent upon and proportional to) MACROPORE's receipt of *** payments from ***. For purpose of clarification, the *** Agreement currently anticipates that the *** shall be paid in three installments, and pursuant to this Separation Agreement, ARI BIZIMIS would be entitled to

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

CONFIDENTIAL TREATMENT REQUESTED

a payment of *** of each *** installment (in U.S. Dollars and less any Withholdings required by law) within 30 days after that installment is actually received by MACROPORE.

4. **Confidentiality**. Each party agrees to keep the facts and terms of this Separation Agreement and General Release in strict confidence and refrain from making any negative or critical remarks about the other party. Except for litigation relating to the breach or enforcement of this agreement, this agreement shall not be admissible in any legal proceeding.

5. **References**. ARI BIZIMIS agrees that any requests for references will be directed to CHRISTOPHER J. CALHOUN. MACROPORE agrees that in response to such reference requests, that only positive references will be provided. MACROPORE will not be liable with respect to any requests for references that are directed to anyone other than CHRISTOPHER J. CALHOUN.

6. **Release of Claims**. In consideration of the payment of money (as specified in #2 and #3 above) by MACROPORE and all other promises contained herein, and as a material inducement to MACROPORE to enter this agreement, ARI BIZIMIS hereby irrevocably and unconditionally releases, acquits, and forever discharges MACROPORE and its assigns, agents, directors, officers, employees, representatives, attorneys, parent companies, divisions, subsidiaries, affiliates (and agents, directors, officers, employees, representatives, and attorneys of such parent companies, divisions, subsidiaries, and affiliates), and all persons acting by, through, under, or in concert with any of them (hereinafter 'the Releasees'), from any and all claims, demands, or liabilities whatsoever, whether known or unknown or suspected to exist by ARI BIZIMIS which ARI BIZIMIS ever had or may now have against the Releasees, or any of them, including, without limitation, any claims, demands, or liabilities (including attorneys' fees and costs actually incurred) in connection with ARI BIZIMIS' employment and resignation from such employment. This release expressly covers, but is not limited to, any claims that ARI BIZIMIS may raise or have raised under any state or federal law prohibiting discrimination in employment on the basis of age or on any other basis prohibited by law.

7. **California Civil Code Section 1542 Waiver**. ARI BIZIMIS expressly acknowledges and agrees that all rights under Section 1542 of the California Civil Code are expressly waived. That section provides:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR.

8. **Employer Property And Trade Secrets**. ARI BIZIMIS will return to MACROPORE all of the MACROPORE equipment not specified above currently in his possession.

ARI BIZIMIS further agrees never to disclose to any person or entity any confidential or proprietary information of or about MACROPORE, except upon the express authorization and consent of MACROPORE. MACROPORE agrees that ARI BIZIMIS may disclose such trade

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CONFIDENTIAL TREATMENT REQUESTED

secrets to *** that are reasonably necessary to aid in the consummation of the pending *** Agreement identified in paragraph #3 above.

9. **No Admission Of Wrongdoing**. This Agreement shall not in any way be construed as an admission by the released parties of any acts of wrongdoing whatsoever against ARI BIZIMIS or any other person.

10. **Entire Agreement**. This Agreement and Release sets forth the entire agreement between the parties hereto, and fully supersedes any and all prior agreements or understandings between the parties hereto pertaining to the subject matter hereof.

11. **Venue**. Any proceeding brought to enforce this agreement shall be brought in San Diego Co., CA.

12. **Construction.** If any provision herein shall be deemed void, invalid, unenforceable, or otherwise stricken, in whole or in part, this Agreement shall be deemed amended to delete or modify, as necessary, the offending provision or provisions and to alter the bounds thereof in order to render it valid and enforceable. The parties hereby agree to substitute a valid provision that will most closely approximate the economic/legal effect and intent or the invalid provision. The parties agree to execute any additional documents that may reasonably be necessary to effectuate the purposes of this agreement.

I HAVE READ AND CAREFULLY CONSIDERED THIS SEPARATION AGREEMENT AND GENERAL RELEASE, AND HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS ABOUT IT AND HAVE HAD MY QUESTIONS ANSWERED. FURTHER, MACROPORE HAS INDICATED THAT I AM FREE TO DISCUSS THIS AGREEMENT WITH MY FAMILY AND MY ATTORNEY PRIOR TO SIGNING. I AM SIGNING THIS AGREEMENT FREELY AND VOLUNTARILY.

Signed: /s/ Ari Bizimis Date: 9/30/03
ARI BIZIMIS

MACROPORE BIOSURGERY, INC.

Signed: /s/ Christopher J. Calhoun Date: 9/30/03
CHRISTOPHER J. CALHOUN

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

EXHIBIT 15.1

LETTER RE UNAUDITED INTERIM FINANCIAL INFORMATION

November 11, 2003

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

Re: Registration Statement No. 333-82074

With respect to the subject registration statement, we acknowledge our awareness of the use therein of our report dated October 24, 2003 related to our review of interim financial information.

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

/s/ KPMG LLP

San Diego, California

EXHIBIT 31.1

Certification of Principal Executive Officer and Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher J. Calhoun, certify that:

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

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:

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

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

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

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

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

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

Date: November 11, 2003
/s/ Christopher J. Calhoun
Christopher J. Calhoun,
Chief Executive Officer and Principal Financial Officer

EXHIBIT 32.1

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

CHRISTOPHER J. CALHOUN hereby certifies that:

1. He is the Chief Executive Officer and Principal Financial Officer of MacroPore Biosurgery, Inc.

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

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

Dated: November 11, 2003

By: /s/ Christopher J. Calhoun

Christopher J. Calhoun
Chief Executive Officer and Principal Financial Officer