SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 (Address of principal executive offices)	**92121** (Zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days: YES ☒ NO 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 April 23, 2003, there were 14,540,932 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 March 31, 2003, and the related consolidated condensed statements of operations and comprehensive income (loss), and the consolidated condensed statements of cash flows for the three months ended March 31, 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
April 25, 2003

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	As of March 31, 2003 (Unaudited)	As of December 31, 2002
Assets		
Current assets:		
Cash and cash equivalents	$ 2,543,000	$ 5,108,000
Short-term investments, available-for-sale	17,960,000	19,875,000
Accounts receivable, net of allowance for doubtful accounts of $65,000 and $50,000 in 2003 and 2002, respectively	1,467,000	1,238,000
Inventories	1,148,000	1,150,000
Other current assets	684,000	843,000
Total current assets	23,802,000	28,214,000
Property and equipment, net	3,575,000	3,626,000
Other assets	559,000	562,000
Goodwill and intangibles, net	6,896,000	6,917,000
Total assets	$ 34,832,000	$ 39,319,000
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,794,000	$ 2,502,000

Current portion of long-term obligations	417,000	410,000
Total current liabilities	2,211,000	2,912,000
Deferred gain on sale of assets, related party	9,216,000	9,623,000
Deferred revenue	22,000	19,000
Long-term obligations, less current portion	691,000	770,000
Total liabilities	12,140,000	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; 16,711,414 and 16,646,664 shares issued and outstanding in 2003 and 2002, respectively	17,000	17,000
Additional paid-in capital	74,744,000	74,730,000
Unearned compensation	(846,000)	(1,057,000)
Accumulated deficit	(43,382,000)	(40,102,000)
Treasury stock, at cost; 2,170,482 and 2,118,983 shares in 2003 and 2002, respectively	(7,959,000)	(7,752,000)
Accumulated other comprehensive income	118,000	159,000
Total stockholders' equity	22,692,000	25,995,000
Total liabilities and stockholders' equity	$ 34,832,000	$ 39,319,000

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

MACROPORE BIOSUGERY, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATION AND COMPREHENSIVE INCOME (LOSS) (UNAUDITED)

	For the Three Months Ended March 31,	
	2003	2002
Revenues:		
Sales to related party	$ 1,606,000	$ 1,097,000
Sales to third parties	323,000	13,000
	1,929,000	1,110,000
Cost of revenues:		
Cost of revenues (including stock based compensation expense of $3,000 and $4,000 for the three months ended March 31, 2003 and 2002, respectively)	639,000	550,000
Gross profit	1,290,000	560,000
Operating expenses:		
Research and development, excluding stock based compensation expense of $19,000 and $135,000 for the three months ended March 31, 2003 and 2002, respectively	2,151,000	1,485,000
Sales and marketing, excluding stock based compensation expense of $18,000 and $33,000 for the three months ended March 31, 2003 and 2002, respectively	1,295,000	671,000
General and administrative, excluding stock based compensation expense of $176,000 and $301,000 for the three months ended March 31, 2003 and 2002, respectively	1,048,000	1,113,000
Stock based compensation (excluding cost of revenues stock based compensation)	213,000	469,000
Total operating expenses	4,707,000	3,738,000
Other income (expense):		
Interest income	142,000	374,000
Interest and other expenses	(5,000)	(74,000)
Equity loss in investment	—	(56,000)
Net loss	(3,280,000)	(2,934,000)
Other comprehensive loss - unrealized holding loss	(41,000)	(301,000)
Comprehensive loss	$ (3,321,000)	$ (3,235,000)
Basic and diluted net loss per share	$ (0.23)	$ (0.20)
Shares used in calculating basic and diluted net loss per share	14,524,608	14,994,568

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

MACROPORE BIOSURGERY, INC.
CONSOLIDATED CONDENSED STATEMENT OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31, 2003	2002
Cash flows from operating activities:		
Net loss	$ (3,280,000)	$ (2,934,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	406,000	353,000
Amortization of gain on sale of assets, related party	(380,000)	—
Stock based compensation	216,000	473,000
Interest income, related party	—	(2,000)
Equity loss in investment	—	56,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(229,000)	181,000
Inventories	2,000	(257,000)
Other current assets	159,000	59,000
Other assets	3,000	57,000
Accounts payable and accrued expenses	(708,000)	59,000
Deferred revenue	3,000	—
Deferred revenue from license agreement, related party	—	(75,000)
Net cash used in operating activities	(3,808,000)	(2,030,000)
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	13,841,000	21,291,000
Purchases of short-term investments	(11,968,000)	(16,949,000)
Purchases of property and equipment	(287,000)	(373,000)
Long-term notes receivable, related party	—	(478,000)
Cost of sale of assets, related party	(27,000)	—
Acquisition costs	(46,000)	—
Net cash provided by investing activities	1,513,000	3,491,000
Cash flows from financing activities:		
Principal payments on capital leases	—	(29,000)
Principal payments on long-term obligations	(72,000)	(88,000)
Proceeds from sale of common stock	9,000	—
Purchase of treasury stock	(207,000)	(476,000)
Net cash used in financing activities	(270,000)	(593,000)
Net (decrease) increase in cash	(2,565,000)	868,000
Cash and cash equivalents at beginning of period	5,108,000	2,700,000
Cash and cash equivalents at end of period	$ 2,543,000	$ 3,568,000
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 31,000	$ 63,000
Taxes	10,000	800

SEE NOTES TO UNAUDITED CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

MACROPORE BIOSURGERY, INC.
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
MARCH 31, 2003
(Unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated condensed financial statements for the three months ended March 31, 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 months ended March 31, 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 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 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 3.3% to 5.14%,

dividend yield of zero, expected market price volatility factor of 98% to 100% and a weighted average expected life of the options ranging from four to seven 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 March 31,	
	2003	2002
Net loss:		
As reported	$ (3,280,000)	$ (2,934,000)
Add: Stock based employee compensation expense included in reported net loss, net of related tax effects	214,000	356,000
Deduct: Total stock based employee compensation expense determined under fair value method for all awards, net of related tax effects	(1,343,000)	(1,349,000)
Pro forma	$ (4,409,000)	$ (3,927,000)
Loss per common share:		
As reported	$ (.23)	$ (.20)
Pro forma	(.30)	(.26)

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

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 and Goodwill

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 is 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. The Company warrants that its 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.

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 the collection procedure is performed and the adipose tissue is received by the Company; fees from the procedure are fixed and determinable, and 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. Income earned under development agreements are 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. 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. The net proceeds received in the Agreements was 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 terms of the Agreement. Upon successfully completing its requirements under these provisions of the Agreement, the Company will recognize the net gain on the sale in the statement of operations. Additionally, the Company will recognize a component of the deferred related to the sale of 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 as revenues and as a reduction to the deferred gain.

A 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.

8. 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 months ended March 31, 2003 and 2002 as their inclusion would be antidilutive. The number of potential common shares excluded from the calculations of diluted loss per share was 4,977,645 and 4,117,057 for the three months ended March 31, 2003 and 2002, respectively.

9. Composition of Certain Financial Statement Captions

Inventories

	March 31, 2003 (Unaudited)	December 31. 2002
Raw materials	$ 442,000	$ 602,000
Finished goods	706,000	548,000

	$ 1,148,000	$ 1,150,000

Property and Equipment, net

	March 31, 2003 (Unaudited)	December 31. 2002
Office and computer equipment	$ 1,947,000	$ 1,874,000
Manufacturing and development equipment	2,883,000	2,721,000
Leasehold improvements	1,604,000	1,551,000
	6,434,000	6,146,000
Less accumulated depreciation and amortization	(2,859,000)	(2,520,000)
	$ 3,575,000	$ 3,626,000

Other Assets

	March 31, 2003 (Unaudited)	December 31. 2002
Deposits	$ 399,000	$ 400,000
Assets held for sale	160,000	162,000
	$ 559,000	$ 562,000

Goodwill and Intangibles, net

	March 31, 2003 (Unaudited)	December 31. 2002
Intangibles (net of accumulated amortization of $101,000 and $34,000 in 2003 and 2002, respectively)	$ 2,594,000	$ 2,661,000
Goodwill	4,302,000	4,256,000
	$ 6,896,000	$ 6,917,000

Accounts Payable and Accrued Expenses

	March 31, 2003 (Unaudited)	December 31. 2002
Accounts payable	$ 431,000	$ 599,000
Accrued bonus	—	397,000
Accrued vacation	408,000	325,000
Accrued expenses	955,000	1,181,000
	$ 1,794,000	$ 2,502,000

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 2003.

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 or approval 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 an exclusive worldwide Distribution Agreement with Medtronic for the global marketing and distribution of some of our products for use in CMF applications. We also entered into a Development and Supply Agreement with Medtronic, in January 2000, 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. In September 2002, we entered into an agreement to sell substantially all of the assets related to the CMF product line to a subsidiary of Medtronic. The sale included 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, we extended the term of our existing co-development and supply agreement for spinal implants to 2012, and obtained a waiver of the right of first offer to market our bioresorbable 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 study related to our new 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, 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 surgical 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 in the United States ("U.S.") for post surgical adhesion indications, although we have received clearance for post surgical 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. Additional U.S. clearance includes the prevention of postsurgical adhesions in specific ear, nose and throat ("ENT") procedures. In June 2002, we hired a direct sales force in the U.S. to sell SurgiWrap™ film as an adhesion control product for specified ENT procedures and for soft tissue support. The initial 16-person sales team covered all the major metropolitan areas in the U.S. market.

In 2002 we received the CE Mark (marketing clearance in Europe) to market our bioresorbable film (SurgiWrap™) for the prevention of postsurgical adhesions in cardiothoracic, general, spinal and gynecological & obstetric ("OB/GYN") surgeries. In Canada, Thailand, Korea 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 28 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, Inc. in November 2002, we are moving to advance stem cell therapies that 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,

separating 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

  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

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 three months ended March 31, 2003 and 2002, revenues related to the craniomaxillofacial product line sold to Medtronic in September 2002 were $612,000 and $670,000, respectively. Included in revenue for the three months ended March 31, 2003 was $380,000 related to the amortization of 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 2003.

Medtronic continues to be a significant stockholder of MacroPore and our largest customer, as the primary distributor of our bioresorbable implant products for use in musculoskeletal applications. Under the Amended Development Agreement, 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. Although the Amended Development Agreement provides that direct selling costs are borne by the distributor, our cash flow may be adversely affected if our fixed costs increase and we are unable to negotiate or otherwise obtain an increase in product pricing with Medtronic.

We incurred net losses of $3,280,000 for the three months ended March 31, 2003, $13,003,000 and $11,207,000 for the years ended December 31, 2002 and 2001, respectively. As of March 31, 2003, we had an accumulated deficit of $43,382,000. 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 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. This investment is likely to result in continued operating losses for the foreseeable future until operational efficiencies are reached.

For the three months ended March 31, 2003, our $1,929,000 in revenue was composed of $1,826,000 or 94.7% from sales of our bioresorbable implant products for use in musculoskeletal, craniomaxillofacial and soft tissue applications. The other $103,000 in revenue was composed of $99,000 or 96.1% from sales of instruments and accessories used by surgeons to form, mold and manipulate our bioresorbable products during surgical procedures and $4,000 or 3.9% from stem cell banking. The $1,826,000 in revenue from bioresorbable implant products was composed of $515,000 or 28.2% of craniomaxillofacial revenue which were included in the September 2002 product line sale to Medtronic, $991,000 or 54.3% of musculoskeletal sales and $320,000 or 17.5% from

our thin film products for soft tissue applications. Included in revenue for the three months ended March 31, 2003 was $380,000 related to the amortization of gain on sale of assets, related party.

Results of Operations

Three months ended March 31, 2003 compared to three months ended March 31, 2002

Revenues. For the three months ended March 31, 2003, revenues were $1,929,000 compared to $1,110,000 for the three months ended March 31, 2002, an increase of $819,000, or 73.8%. The increase in revenues in the three months ended March 31, 2003, was attributable to a $628,000 increase in the sales of bioresorbable implant products and instrumentation for use in musculoskeletal applications, $319,000 increase in bioresorbable thin film sales, and $4,000 in stem cell banking. The increases were moderated by a decrease of $57,000 and $75,000 in craniomaxillofacial products and license fees with Medtronic, respectively. The increase in musculoskeletal products revenue related to the increase in availability of the product from limited clinical evaluations to a full product release. The increase in revenue of bioresorbable thin film product was attributable to increased acceptance and use of the product line by end users and the build up of inventory by our international distributors for the three months ended March 31, 2003, with no comparable sales in the three months ended March 31, 2002. The craniomaxillofacial product revenue and license fees decreased in the three months ended March 31, 2003 as Medtronic continues to transition the manufacturing of craniomaxillofacial production to their own facilities. We expect craniomaxillofacial product sales to continue to decrease throughout 2003. Revenues attributable to Medtronic, which owns approximately 6.9% of our outstanding common stock, represented 83.2% of our revenues for the three months ended March 31, 2003, compared to 98.8% for the three months ended March 31, 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 three months ended March 31, 2003 and the sale of craniomaxillofacial product line to Medtronic in September 2002.

Cost of revenues. For the three months ended March 31, 2003, cost of revenues was $639,000 or 33.1% of revenues, compared to $550,000 or 49.5% of revenues for the three months ended March 31, 2002. Cost of revenues includes material, manufacturing labor and overhead costs. The decrease in cost as a percentage of revenues was primarily attributable to increased sales revenue that allowed us to absorb more of our fixed manufacturing labor and overhead costs. The continued reduction of revenues as a result of the sale of the craniomaxillofacial product line in September 2002 could negatively impact our margins until our other products' sales grow enough to replace the lost revenue.

Gross profit. For the three months ended March 31, 2003, gross profit was $1,290,000 or 66.9% of revenues, compared to $560,000 or 50.5% of revenues for the three months ended March 31, 2002. The increase in gross profit as a percentage of revenues was attributable to increased revenue and the ability to absorb more fixed manufacturing labor and overhead costs, as discussed above.

Research and development expenses. For the three months ended March 31, 2003, research and development expenses excluding related stock based compensation expenses were $2,151,000, compared to $1,485,000 for the three months ended March 31, 2002, an increase of $666,000 or 44.8%. 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 clinical studies. The $666,000 increase in research and development expenses in the three months ended March 31, 2003 as compared to the three months ended March 31, 2002 was primarily attributable to our expenditures in the biologic (stem cell) platform technology and the continued development of our biomaterial platform technology. We expensed $836,000 in the development of our biologic platform technology in the three months ended March 31, 2003 by hiring or reassigning 14 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 March 31, 2002. We spent $1,120,000 in our biomaterial platform technology relating to the development of musculoskeletal

products and faster-resorbing polymer products in the three months ended March 31, 2003. This was an additional $250,000 in spending in the three months ended March 31, 2003 as compared to the three months ended March 31, 2002, which resulted from the hiring of additional staff and various pre-clinical studies for potential biomaterial products**.** We spent $195,000 developing our thin film and craniomaxillofacial product lines in the three months ending March 31, 2003 as compared to $615,000 in the three months ended March 31, 2002. The $420,000 decrease was attributable to the successful development of our thin film product line and the discontinuance of development of the craniomaxillofacial product line sold to Medtronic. In addition, stock based compensation related to research and development was $19,000 for the three months ended March 31, 2003 and $135,000 for the three months ended March 31, 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 $3,000,000 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 we acquired with the purchase of StemSource. We also plan to continue to fund the 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 March 31, 2003, sales and marketing expenses excluding related stock based compensation expenses were $1,295,000, compared to $671,000 for the three months ended March 31, 2002, an increase of $624,000 or 93.0%. 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 thin film product line domestically through a dedicated sales force and internationally through independent distributors. The $624,000 increase in sales and marketing expenses in the three months ended March 31, 2003 as compared to the three months ended March 31, 2002 was primarily attributable to the expense of a dedicated domestic sales and marketing team to sell our thin film product line in the United States and expenses associated with international sales and marketing as we began to develop an international market for the thin film product line. We spent $901,000 for sales and marketing to support 21 individuals to sell directly our thin film product line domestically in the three months ended March 31, 2003, with no comparable expense in three months ended March 31, 2002. We spent $293,000 in international sales and marketing of thin film, an increase of $207,000 in expenses during the three months ended March 31, 2003 as compared to the three months ended March 31, 2002. The main contributor to this increase related to setting up a sales office in Japan. We spent $101,000 in general product and corporate marketing expenditures in the three months ended March 31, 2003 or $484,000 less than the three months ended March 31, 2002 which was a result of our decision not to continue to supplement our distributor's marketing of our musculoskeletal and craniomaxillofacial product lines. In addition, stock based compensation related to sales and marketing was $18,000 for the three months ended March 31, 2003 and $33,000 for the three months ended March 31, 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 $1,000,000 in 2003 as compared to 2002 as we continue our promotional efforts related to the thin film product line with a dedicated sales force.

General and administrative expenses. For the three months ended March 31, 2003, general and administrative expenses excluding related stock based compensation expenses were $1,048,000, compared to $1,113,000 for the three months ended March 31, 2002, a decrease of $65,000 or 5.8%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The $65,000 decrease in general and administrative expenses for the three months ended March 31, 2003 was primarily attributable to a

$113,000 decrease that related to domestic salaries, legal and other general expenditures that was offset by a $48,000 increase in international salaries, legal, and other general expenditures. In addition, stock based compensation related to general and administrative expenses was $176,000 for the three months ended March 31, 2003, compared to $301,000 for the three months ended March 31, 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 in absolute dollars to remain at current levels for the remainder of the year ending December 31, 2003.

Stock based compensation expenses. For the three months ended March 31, 2003, total non-cash stock based compensation expenses classified in operating expenses were $213,000, compared to $469,000 for the three months ended March 31, 2002, a decrease of $256,000, or 54.6%. 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 date of grant. 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 was related to the acceleration of vesting and other modifications to compensatory stock options granted to our former president and stock options granted to consultants for services rendered in the three months ended March 31, 2002. The decrease of $116,000 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 three months ended March 31, 2002. The decrease of $15,000 in sales and marketing stock based compensation expense was due primarily to a reduction in accrued compensation costs in the last year of vesting. The decrease of $125,000 in general and administrative stock based compensation expense was primarily due to additional expenses recorded in the three months ended March 31, 2002 as a result of accelerating vesting and modifying the exercise period of certain stock options held by our former president.

Interest income. For the three months ended March 31, 2003, interest income was $142,000, compared to $374,000 for the three months ended March 31, 2002, a decrease of $232,000, or 62.0%. The decrease in interest income resulted from lower interest rates and from a decrease in the funds we had available for investments.

Interest and other expenses. For the three months ended March 31, 2003, interest and other expenses were $5,000, compared to $74,000 for the three months ended March 31, 2002, a decrease of $69,000 or 93.2%. The decrease in interest and other expense related to a $31,000 decrease in interest expense on our long-term debt obligations, a $27,000 foreign currency gain and other income of $11,000.

Equity loss in investment. For the three months ended March 31, 2002, our equity loss in investment was $56,000, with no comparable loss in the three months ended March 31, 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 the technology and know how, including training, related to the

manufacture of the craniomaxillofacial product line, which we expect to occur in 2003. However, we have recognized approximately $646,000 related to the sale of CMF product to Medtronic under our backup supply arrangement, which provides for sales of the CMF product to Medtronic at cost. Discounts from previously agreed price have been recorded as a reduction to the deferred gain. We are including $9,216,000 of "Deferred gain on sale of assets, related party" on our balance sheet.

Liquidity and Capital Resources

As of March 31, 2003, we had cash and cash equivalents, and short-term investments, available-for-sale, of $20,503,000 and working capital of $21,591,000. 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 March 31,

2004. Due to the acquisition of StemSource, we will also have to commit substantial cash resources to fund StemSource's development activities in 2003, which is estimated at approximately $4,000,000. Our strategic concept is to use the cash from the Medtronic asset sale to enable us to undertake the StemSource opportunity without affecting 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 $3,808,000 and $2,030,000 for the three months ended March 31, 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 three months ended March 31, 2003, net cash used in operating activities primarily related to our net loss of $3,280,000, and the following events: a decrease in accounts payable and accrued expenses of $708,000 related to bonuses and outstanding raw materials invoices, non-cash gain on the sale of assets to a related party of $380,000 that related to products acquired by Medtronic under a back-up supplier agreement at discounts from previously agreed prices, and an increase in accounts receivable of $229,000 related to Medtronic. The cash used in these operating activities was offset by non-cash charges for depreciation and amortization of $406,000 and stock based compensation of $216,000, and other current assets of $159,000 primarily related to the collection of a non-trade receivable. In the three months ended

March 31, 2002, net cash used in operating activities primarily related to our net loss of $2,934,000 and an increase in inventory of $257,000, offset by non-cash charges of $473,000 for stock based compensation and $353,000 of depreciation and amortization. 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 and will offset the associated costs.

Net cash provided by investing activities was $1,513,000 and $3,491,000 for the three months ended March 31, 2003 and 2002, respectively. Net cash provided by investing activities for the three months ended March 31, 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 and our financing activities). We purchased $287,000 in property and equipment primarily to support biomaterial manufacturing and research and development of the biologics platform technology. We used $46,000 for cost related to the acquisition of StemSource. Net cash provided by investing activities for the three months ended March 31, 2002 consisted of net proceeds from the purchase and sale of short-term investments, which was offset by capital expenditures and loans to our corporate officers. 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 used in financing activities was $270,000 and $593,000 for the three months ended March 31, 2003 and 2002, respectively. Net cash used in financing activities for the year ended March 31, 2003 was primarily related to our repurchase of 51,499 shares of our common stock for $207,000 on the open market at an average price of $4.02 per share and payments toward long term obligations of $72,000. We do not expect to purchase any more treasury shares in the current year. Net cash used by financing activities for the three months ended March 31, 2002 was primarily related to the repurchase of 156,530 shares of our common stock at an average price of $3.04 and payments toward capital leases and long term obligations.

In October 2000, we obtained $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.

As of March 31, 2003, we had property and equipment of $6,434,000, less accumulated depreciation of $2,859,000 to support our clinical, research, development, manufacturing and administrative activities. Our capital expenditures were $287,000 and $373,000 for the three months ended March 31, 2003 and 2002, respectively. We expect capital expenditures for the next twelve months to be approximately $500,000 as we acquire additional equipment and expand our facilities that include capital expenditures for our biologics platform technology. We intend to pay for future capital expenditures with available working capital.

The following summarizes our contractual obligations and other commitments at March 31, 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	1,108,000	417,000	691,000	—	—
Operating Lease Obligations	4,494,000	1,004,000	2,807,000	683,000	—
Total	5,602,000	1,421,000	3,498,000	683,000	—

Critical Accounting Policies

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 from our estimates, we will make adjustments to our financial statements as we become aware of the necessity for an adjustment. Specifically, we make estimates in the following areas:

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 the collection procedure is performed and the adipose tissue is received by MacroPore; fees from the procedure are fixed and determinable, and 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 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. Income earned under development agreements are 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 its Distribution Agreement dated January 5, 2000 and amended December 22, 2000 and October 8, 2002, as well as its Development and Supply Agreement 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 83.2% and 98.8% of our revenues in the three months ended March 31, 2003 and 2002, respectively. We believe that our allowance for doubtful accounts as of March 31, 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 potential 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.

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 Statement of Operations and Comprehensive Income (Loss). Unearned compensation recorded through March 31, 2003 was $6,665,000 with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of $5,819,000. The remaining $846,000 as of March 31, 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 $633,000 for the period April 1, 2003 to December 31, 2003 and $213,000 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 August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to all entities and to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal operation of long-lived assets, except for some lessee obligations. SFAS No. 143 is effective for financial statements issued for fiscal years beginning after June 15, 2002. The adoption of SFAS No. 143 did not have a material impact on our consolidated financial position or consolidated results of operations.

In April 2002, the FASB issued SFAS No. 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS No. 145 updates, clarifies and simplifies existing accounting pronouncements including (i) rescinding Statement No. 4, which required all gains and losses from extinguishment of debt to be aggregated and, if material, classified as an extraordinary item, net of related income tax effect, and (ii) amending Statement No. 13 to require that certain lease modifications that have economic effects similar to sale-leaseback transactions be accounted for in the same manner as sale-leaseback transactions. SFAS No. 145 is effective for fiscal years beginning after May 15, 2002, with early adoption of the provisions related to the rescission of Statement No. 4 encouraged. The adoption of SFAS No. 145 did not have a material impact on our consolidated financial position or consolidated results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS No. 146 did not have a material impact on our consolidated financial position or consolidated results of operations.

In December 2002, the FASB issued FASB Interpretation No. 45 (FIN 45). FIN 45 provides guidance on how companies should record and disclose "guarantees." The primary principle of FIN 45 is that guarantees must be recorded as a liability, regardless of the probability of occurrence. The amount of the liability to be accrued depends on the likelihood of the liability to occur. The liability recognition provisions of FIN 45 shall be applied on a prospective basis to guarantees issued or modified after December 31, 2002. Additionally, FIN 45 requires certain disclosures about guarantees in our December 31, 2002 consolidated financial statements. The adoption of FIN 45 did not have a material impact on our consolidated financial position or consolidated results of operations as we currently do not have any guarantees falling within the scope of this standard.

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 June 15, 2003 for Variable Interest Entities created prior to February 1, 2003. We do not expect this interpretation to 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.

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 $17,960,000 as of March 31, 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. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at March 31, 2003, for example, and assuming average investment duration of ten 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 which 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 three months ended March 31, 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. 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 $3,280,000 for the three months ended March 31, 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, as well as. We anticipate that our recurring operating expenses will increase for the next several years, as our research and development expenses may increase in order to develop and market new products and fund additional preclinical research and possibly clinical trials. We expect to continue to incur losses through the end of 2003, and the amount of future net losses and time necessary to reach profitability are somewhat uncertain. Even if our bone fixation and thin film medical device product lines achieve 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 announced an agreement to acquire StemSource, which is a development-stage adult stem cell company. Our craniomaxillofacial product line was relatively stable and slower-growth,

compared to our retained musculoskeletal bone fixation implant and accessories product line and our thin film for soft-tissue repair and regeneration. 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 newly acquired 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 successfully to manage a company in a different business than we have operated in the past (operational risk), that we will be able to use our medical device products to deliver 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 for our SurgiWrap™ bioresorbable barrier film and other new products resulting 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 2002 and 2003 revenues from the sale of products to our distribution partner Medtronic Inc. (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 6.9% of our stock, which may limit our ability to negotiate commercial arrangements optimally with Medtronic.

Although Medtronic has exclusive distribution rights to our co-developed spinal implants, Medtronic is 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 do not have much manufacturing experience

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

pay us royalties on the sales. The resulting loss of payments from Medtronic for the purchase of these products would have a substantial negative effect on the results of our operations and financial condition.

We have to maintain quality assurance certification and manufacturing approvals

The manufacture of our 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 FDA regulation

As newly developed medical devices, our bioresorbable surgical implants must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments, prior to their sale. Our current and future bioresorbable surgical implants for humans are subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices and drugs. Included among these regulations are premarket clearance and premarket approval requirements, design control requirements, and QSRs. 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 March 31, 2003, we had $20,503,000 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 will 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, Ari Bizimis, our Chief Financial Officer and Marc Hedrick, MD, our Chief Scientific Officer and Medical Director. 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, Inc., as well as 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
- 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, Inc., 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

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 the 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 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 chief 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, have 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

None

Item 3. Defaults Upon Senior Securities

None

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

None

Item 5. Other Information

Properties and Facilities

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

- 14,000 square feet, of which approximately 4,000 square feet is for research and development and 10,000 square feet is office space at 6749 Top Gun Street, San Diego, California for a five-year term expiring in 2006.
- 16,000 square feet of additional research and technology facility 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.
- 15,000 square feet of which all is used for research and development, located at 1125 Business Center Circle, Thousand Oaks, California for a five-year term, expiring in 2006. This space will become excess in May of this year.

We pay an aggregate of approximately $66,000 in rent per month for our properties located in the United States and approximately €11,000 in rent per month for our property in Germany.

Staff

As of March 31, 2003, we had 103 full-time employees, comprised of 35 employees in research and development, 22 employees in manufacturing, 18 employees in management and finance and administration and 28 employees in sales and marketing. As of March 31, 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

15.1 Letter re unaudited interim financial information

99.1 Certifications 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

None

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in San Diego, California, on May 15, 2003.

MACROPORE BIOSURGERY, INC.

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

Certification of Principal Executive 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 quarterly 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 quarterly 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 quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

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

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 45 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003
/s/ Christopher J. Calhoun
Christopher J. Calhoun,
Chief Executive Officer

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

I, Ari E. Bizimis, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly 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 quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

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

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003
/s/ Ari E. Bizimis

Ari E. Bizimis,
Chief Financial Officer

EXHIBIT INDEX

15.1 Letter re unaudited interim financial information

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

EXHIBIT 15.1

LETTER RE UNAUDITED INTERIM FINANCIAL INFORMATION

May 15, 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 May 15, 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 99.1

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

CHRISTOPHER J. CALHOUN and ARI E. BIZIMIS hereby certify that:

1. They are the Chief Executive Officer and Chief Financial Officer, respectively, of MacroPore Biosurgery, Inc.

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

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

Dated: May 15, 2003

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

By: /s/ Ari E. Bizimis
Ari E. Bizimis
Chief Financial Officer