

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 2002

OR

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

For the transition period from _____ to _____

Commission file number 0-32501

MacroPore Biosurgery, Inc.

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

Delaware

(State or other jurisdiction of incorporation or organization)

33-0827593

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

6740 Top Gun Street, San Diego, California

(Address of principal executive offices)

92121

(Zip code)

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

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

As of October 31, 2002, there were 13,032,479 shares of MacroPore Biosurgery, Inc. common stock outstanding.

MACROPORE BIOSURGERY, INC.

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PART I

FINANCIAL INFORMATION

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PART I FINANCIAL INFORMATION**Item 1. Financial Statements**

Independent Accountants' Review Report

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

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

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

The financial statements of the Company as of and for the year ended December 31, 2001 were audited by other accountants whose report dated February 15, 2002, expressed an unqualified opinion on those consolidated financial statements. Such financial statements were not audited by us and, accordingly, we do not express an opinion or any form of assurance on the information set forth in the accompanying condensed balance sheet as of December 31, 2001. Additionally, the condensed statements of operations and comprehensive income (loss) for the three and nine month periods ended September 30, 2001, and the related condensed statement of cash flows for the nine month period ended September 30, 2001 were not reviewed or audited by us and accordingly, we do not express an opinion or any form of assurance on them.

/s/ KPMG LLP

San Diego, California
November 1, 2002

MACROPORE BIOSURGERY, INC.**CONDENSED BALANCE SHEETS**

| | As of September 30, 2002 | As of December 31, 2001 |
|--|-----------------------------|----------------------------|
| | (Unaudited) | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 4,302,000 | \$ 2,700,000 |
| Short-term investments, available-for-sale | 17,432,000 | 31,251,000 |
| Accounts receivable, net of allowance for bad debts of \$50,000 and \$35,000, respectively | 1,527,000 | 463,000 |
| Inventories | 900,000 | 1,685,000 |
| Receivable from the sale of assets, related party | 9,000,000 | — |
| Note receivable, related party | 1,000,000 | — |
| Other current assets | 847,000 | 851,000 |

| | | | | |
|--|----|--------------|----|--------------|
| Total current assets | | 35,008,000 | | 36,950,000 |
| Property and equipment, net | | 3,664,000 | | 5,171,000 |
| Long-term notes receivable, related party | | 494,000 | | — |
| Other assets | | 1,088,000 | | 1,022,000 |
| | | | | |
| Total assets | \$ | 40,254,000 | \$ | 43,143,000 |
| Liabilities and Stockholders' Equity | | | | |
| Current liabilities: | | | | |
| Accounts payable and accrued expenses | \$ | 1,658,000 | \$ | 1,155,000 |
| Current portion of capital lease obligations | | 70,000 | | 121,000 |
| Current portion of long-term obligations | | 978,000 | | 555,000 |
| | | | | |
| Total current liabilities | | 2,706,000 | | 1,831,000 |
| Deferred revenue from license agreement, related party | | 675,000 | | 900,000 |
| Deferred gain on sale of assets, related party | | 8,247,000 | | — |
| Capital lease obligations, less current portion | | 46,000 | | 135,000 |
| Long-term obligations, less current portion | | 1,004,000 | | 1,791,000 |
| | | | | |
| Total liabilities | | 12,678,000 | | 4,657,000 |
| Stockholders' equity: | | | | |
| Preferred stock; \$0.001 par value; 5,000,000 authorized; -0- shares issued and outstanding in 2002 and 2001 | | — | | — |
| Common stock; \$0.001 par value; 95,000,000 shares authorized; 15,192,471 and 15,106,623 issued and outstanding in 2002 and 2001, respectively | | 15,000 | | 15,000 |
| Additional paid-in capital | | 68,652,000 | | 68,402,000 |
| Unearned compensation | | (1,314,000) | | (2,105,000) |
| Accumulated deficit | | (34,602,000) | | (27,099,000) |
| Treasury stock, at cost; 1,569,973 and 356,120 shares in 2002 and 2001, respectively | | (5,361,000) | | (1,077,000) |
| Accumulated other comprehensive income | | 186,000 | | 350,000 |
| | | | | |
| Total stockholders' equity | | 27,576,000 | | 38,486,000 |
| | | | | |
| Total liabilities and stockholders' equity | \$ | 40,254,000 | \$ | 43,143,000 |

See notes to condensed financial statements

MACROPORE BIOSURGERY, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(Unaudited)

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|--|---|--------------|--|--------------|
| | 2002 | 2001 | 2002 | 2001 |
| Revenues: | | | | |
| Sales to related party | \$ 3,073,000 | \$ 1,381,000 | \$ 6,870,000 | \$ 4,134,000 |
| Sales to third parties | 229,000 | 19,000 | 249,000 | 63,000 |
| | | | | |
| | 3,302,000 | 1,400,000 | 7,119,000 | 4,197,000 |
| Cost of revenues: | | | | |
| Cost of revenues including stock based compensation of \$4,000 and -0- for the three months ended September 30, 2002 and 2001, respectively; \$11,000 and \$10,000 for the nine months ended September 30, 2002 and 2001, respectively | 951,000 | 653,000 | 2,482,000 | 1,578,000 |
| Inventory provision | 1,395,000 | — | 1,395,000 | 1,228,000 |
| | | | | |
| Gross profit | 956,000 | 747,000 | 3,242,000 | 1,391,000 |

| | | | | |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
| Operating expenses: | | | | |
| Research and development, net of stock based compensation of \$25,000 and \$29,000 for the three months ended September 30, 2002 and 2001, respectively; \$185,000 and \$89,000 for the nine months ended September 30, 2002 and 2001, respectively | 1,271,000 | 1,345,000 | 4,144,000 | 4,041,000 |
| Sales and marketing, net of stock based compensation of \$33,000 and \$121,000 for the three months ended September 30, 2002 and 2001, respectively; \$100,000 and \$131,000 for the nine months ended September 30, 2002 and 2001, respectively | 1,082,000 | 1,412,000 | 2,779,000 | 3,791,000 |
| General and administrative, net of stock based compensation of \$215,000 and \$185,000 for the three months ended September 30, 2002 and 2001, respectively; \$732,000 and \$623,000 for the nine months ended September 30, 2002 and 2001, respectively | 899,000 | 858,000 | 2,867,000 | 2,762,000 |
| Stock based compensation (excluding cost of revenues stock based compensation) | 273,000 | 335,000 | 1,017,000 | 843,000 |
| Equipment impairment charge | 370,000 | — | 370,000 | — |
| Total operating expenses | 3,895,000 | 3,950,000 | 11,177,000 | 11,437,000 |
| Other income (expenses): | | | | |
| Interest income | 207,000 | 511,000 | 844,000 | 1,850,000 |
| Interest and other expenses | (158,000) | (20,000) | (223,000) | (55,000) |
| Equity loss in investment | (76,000) | (24,000) | (189,000) | (41,000) |
| Net loss | (2,966,000) | (2,736,000) | (7,503,000) | (8,292,000) |
| Other comprehensive income (loss): | | | | |
| Unrealized holding gains arising during period | 8,000 | 192,000 | 186,000 | 451,000 |
| Comprehensive loss | \$ (2,958,000) | \$ (2,544,000) | \$ (7,317,000) | \$ (7,841,000) |
| Basic and diluted net loss per share | \$ (0.21) | \$ (0.18) | \$ (0.51) | \$ (0.55) |
| Shares used in calculating basic and diluted net loss per share | 14,164,389 | 14,964,926 | 14,600,611 | 14,964,926 |

See notes to condensed financial statements

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

| | Nine Months Ended September 30, | |
|--|--|----------------|
| | 2002 | 2001 |
| Cash flows from operating activities: | | |
| Net loss | \$ (7,503,000) | \$ (8,292,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,122,000 | 838,000 |
| Loss on disposal of assets | 87,000 | — |
| Equipment impairment charge | 370,000 | — |
| Inventory provision | 1,395,000 | 1,228,000 |
| Stock based compensation | 1,028,000 | 853,000 |
| Interest income, related party | (16,000) | — |
| Equity loss in investment | 189,000 | 41,000 |
| Increases (decreases) in cash caused by changes in operating assets and liabilities: | | |
| Accounts receivable | (1,064,000) | (184,000) |
| Inventories | (610,000) | (1,369,000) |
| Other current assets | 4,000 | (131,000) |
| Other assets | 73,000 | 120,000 |
| Accounts payable and accrued expenses | 290,000 | 38,000 |
| Deferred revenue from license agreement, related party | (225,000) | (225,000) |

Net cash used in operating activities

(4,860,000)

(7,083,000)

Cash flows from investing activities:

| | | |
|---|--------------|--------------|
| Proceeds from the sale and maturity of short-term investments | 43,680,000 | 78,763,000 |
| Purchases of short-term investments | (30,025,000) | (72,538,000) |
| Purchases of property and equipment | (875,000) | (2,480,000) |
| Note receivable, related party | (1,000,000) | — |
| Long-term notes receivable, related party | (478,000) | — |
| Deferred costs on sale of assets | (65,000) | — |
| Equity investment | — | (1,000,000) |

Net cash provided by investing activities

11,237,000

2,745,000

Cash flows from financing activities:

| | | |
|---|-------------|-----------|
| Principal payments on capital leases | (140,000) | (88,000) |
| Principal payments on long-term obligations | (364,000) | — |
| Proceeds from sale of common stock | 13,000 | 121,000 |
| Purchase of treasury stock | (4,284,000) | (384,000) |

Net cash used in financing activities

(4,775,000)

(351,000)

Net increase (decrease) in cash

1,602,000

(4,689,000)

Cash and cash equivalents at beginning of period

2,700,000

7,476,000

Cash and cash equivalents at end of period

\$ 4,302,000

\$ 2,787,000

Supplemental disclosure of cash flows information:

Cash paid during period for:

| | | |
|----------|------------|-----------|
| Interest | \$ 182,000 | \$ 39,000 |
| Taxes | 800 | 800 |

Supplemental schedule of non-cash investing activities:

| | | |
|--|-------------|------|
| Note receivable, related party | 9,000,000 | — |
| Deferred gain on sale of assets, related party | (8,247,000) | — |
| Sale of assets to related party, net | (475,000) | — |
| Costs relating to sale of assets | (213,000) | — |
| Deferred costs on sale of assets | \$ 65,000 | \$ — |

See notes to condensed financial statements

MACROPORE BIOSURGERY, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

SEPTEMBER 30, 2002

(Unaudited)

1. Basis of presentation

The accompanying unaudited condensed financial statements for the three and nine months ended September 30, 2002 and 2001 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 condensed balance sheet at December 31, 2001 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of MacroPore Biosurgery, Inc. ("MacroPore" or the "Company") have been included. Operating results for the three and nine months ended September 30, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002. For further information, refer to the financial statements for the year ended December 31, 2001 and footnotes thereto which were included in the Company's report on Form 10-K, dated March 22, 2002.

2. Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

3. Short-Term Investments

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

4. 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.

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During the three months ended September 30, 2002, the Company recorded an inventory provision of approximately \$1,395,000 for excess and obsolete inventory resulting from the sale of the Company's assets relating to its craniomaxillofacial (skull and face) bone fixation implant and accessory product line to a subsidiary of Medtronic, a shareholder of the Company, on September 30, 2002. This provision includes inventory held on-hand as of September 30, 2002 and reflects reduction in expected future utilization of remaining inventory for the craniomaxillofacial bone fixation implant and accessory product line after consideration of the Company's requirement to be a backup supplier of the acquired product line during a brief transition period.

During the three months ended June 30, 2001, the Company recorded an inventory provision of approximately \$1,228,000 for excess and obsolete inventory related to the Company's craniomaxillofacial bone fixation implant and accessory product line. The provision for excess and obsolete inventory was due to an anticipated reduction in expected future revenues of these products. This provision includes inventory held on-hand as of December 31, 2001.

5. Long-Lived Assets

The Company assesses potential impairments to its long-lived assets when there is a change in circumstances that indicate carrying values of assets may not be recovered. An impairment loss is recognized when the undiscounted cash flows expected to be generated by an asset 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.

During the three months ended September 30, 2002, the Company recorded an equipment impairment charge of \$370,000 related to production assets which were used for the craniomaxillofacial bone fixation implant and accessory product line which were not included in the Medtronic sale. The impairment charge represents the excess of such assets' cost over the estimated net proceeds the Company estimates it will receive from the sale of these assets. The remaining carrying amount of the assets totaling \$328,000 has been reclassified as held for sale and is included within Other Assets in the accompanying balance sheet as of September 30, 2002.

6. Revenue Recognition

The Company sells its products to distributors and hospitals. 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 sales to hospitals is recognized upon delivery of the product.

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

Substantially all of the Company's 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.

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7. Stock Based Compensation

In February 2002 the Company issued 50,000 fully vested stock options to non-employees for consulting services rendered. The fair value of the grants was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions: expected dividend yield of 0.0%, risk-free interest rate ranging from 3.87% to 4.03%, volatility of 108.0% and expected life of 4 years. As a result, the Company recorded stock based compensation expense of \$109,000 in the three months ended March 31, 2002.

In March 2002 an officer of the Company retired and upon retirement, the Company accelerated vesting and modified the exercise period of certain stock options. These options were remeasured using the fair market value of the Company's common stock at the date of modification over the exercise price or previously remeasured price of the stock options. The remeasurement resulted in additional \$58,000 of stock based compensation expense and amortization of \$34,000 of unearned compensation cost in the three months ended March 31, 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. No common share equivalents were included for the periods presented as their effect would be anti-dilutive.

The Company has excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders for the three and nine months ended September 30, 2002 and 2001 as their inclusion would be antidilutive. The number of potential common shares excluded from the calculations of diluted loss per share was 4,054,667 and 3,867,686 for the three and nine months ended September 30, 2002 and 3,806,835 and 3,488,035 for the three and nine months ended September 30, 2001.

9. Composition of Certain Financial Statement Captions

Inventories

| | September 30, 2002 | December 31, 2001 |
|----------------|-----------------------|----------------------|
| | (Unaudited) | |
| Raw materials | \$ 576,000 | \$ 959,000 |
| Finished goods | 324,000 | 726,000 |
| | <u>\$ 900,000</u> | <u>\$ 1,685,000</u> |

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Other Assets

| | September 30, 2002 | December 31, 2001 |
|--------------------------|-----------------------|----------------------|
| | (Unaudited) | |
| Investment in StemSource | \$ 707,000 | \$ 896,000 |
| Assets held for sale | 328,000 | — |
| Deposits | 53,000 | 126,000 |
| | <u>\$ 1,088,000</u> | <u>\$ 1,022,000</u> |

Accounts Payable and Accrued Expenses

| | September 30, 2002 | December 31, 2001 |
|------------------|-----------------------|----------------------|
| | (Unaudited) | |
| Accounts payable | \$ 346,000 | \$ 294,000 |
| Accrued bonus | 295,000 | 398,000 |
| Accrued vacation | 290,000 | 244,000 |
| Accrued expenses | 727,000 | 219,000 |
| | <u>\$ 1,658,000</u> | <u>\$ 1,155,000</u> |

10. Notes Receivable, Related Party

On July 12, 2002, the Company loaned \$1,000,000 to StemSource, Inc. ("StemSource") in exchange for a convertible promissory note ("Note") and a warrant to purchase 100,000 shares of StemSource common stock. The Note has an annual interest rate of 8% and had a scheduled maturity date of October 31, 2002. The warrant expires on July 12, 2007. The outstanding principal balance and unpaid accrued interest on this Note may be converted, at the option of the Company, into shares of StemSource Series B Preferred Stock at the closing of StemSource's next Series B Preferred Stock financing transaction or series of financing transactions in which the aggregate gross proceeds to StemSource equal or exceed \$2,000,000. As of September 30, 2002, the Company had a 13.5% ownership interest in StemSource.

On October 31, 2002 the Note's maturity date was extended to December 31, 2002.

11. Long-Term Notes Receivable, Related Party

On February 26, 2002, the Company extended loans to two of its directors, who also serve as officers, in the aggregate amount of \$478,000, for the purchase of shares of the Company's common stock from another of the Company's stockholders. The loans carry an annual interest rate of 5.75%, subject to adjustment once a year on the anniversary of the issuance date of the loan based on prime plus one percent. The loans are secured by a pledge of all of the stock purchased with the proceeds of the loan, are full recourse and mature in February 2005.

12. Sale of Craniomaxillofacial Bone Fixation Implant and Accessory Product Line

In September 2002, the Company entered into an Asset Purchase Agreement ("the Agreement") to sell assets related to its craniomaxillofacial (skull and face) bone fixation implant and accessory product line

to Medtronic PS Medical, Inc. (a subsidiary of Medtronic, Inc.) for a total of up to \$16,000,000. In accordance with the terms of the Agreement the Company will receive consideration consisting of an initial payment of \$13,000,000 from Medtronic and additional payments totaling \$3,000,000 upon the successful transfer of technology and know how, including training, related to the manufacture of the craniomaxillofacial product line. The initial \$13,000,000 receivable from Medtronic under the Agreement is shown net of the \$4,000,000 payable to Medtronic associated with the Amended Development Agreement (see the paragraph below), as net receivable from the sale of assets, related party as of September 30, 2002 on the condensed balance sheet. The initial payment occurred in the fourth quarter of 2002 and the subsequent milestone payments are expected to occur in 2003. The Agreement also requires the Company not to market, in the craniomaxillofacial field, any products that compete with the acquired product line. However, the Company will continue to be a backup supplier of the acquired products to Medtronic at a price equal to the Company's cost of manufacture during the transition technology transfer period. The Agreement also allows the Company to receive up to \$5,000,000 if and when the Company completes successful clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement.

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

The Company is accounting for the net proceeds of the Agreements as a deferred gain on sale of assets, related party, until 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 gain on the sale in the statement of operations.

13. Subsequent Event

In October 2002, the Company entered into two agreements to acquire, for cash and common stock of the Company, the remaining outstanding shares of StemSource, Inc., a development-stage drug company engaged in adult stem-cell therapy research (StemSource). Prior to the acquisition, the Company owned 666,667 shares of StemSource's series A preferred stock, which represented a 13.5% ownership interest. In the first agreement, the Company purchased 2,717,500 common shares for \$1,861,488 in cash from certain individual shareholders of StemSource. The acquisition of these common shares increased the Company's ownership in StemSource to 38.2%. Secondly, the Company has signed a definitive agreement to acquire the remaining outstanding shares of StemSource's common and preferred stock in exchange for 1,456,720 shares of MacroPore common stock which is valued at approximately \$6,000,000. The acquisition will be accounted for as a purchase and is anticipated to close in the fourth quarter of 2002.

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 Exhibit 99.1 "Risk Factors." 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. 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, as well as related instruments and accessories used in connection with our implants. Our bioresorbable implants are used in craniomaxillofacial, neurosurgical and other musculoskeletal (spine and orthopedic) surgical applications. We have also developed a bioresorbable polymer thin film that we began marketing in June 2002 for use in a wide variety of soft tissue surgical applications. In October 2002 we closed the sale of our craniomaxillofacial (skull and face) bone fixation implant and accessory product line, although we will continue to be a backup supplier to the buyer during a brief transition period.

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. The lactic acid molecules are then metabolized by the liver into carbon dioxide and water, and released from the body through the lungs. We believe that our bone fixation implants are easier to use and are more efficacious than implants made from alternative materials, such as titanium or other metals.

We have received regulatory clearance or approval to market and sell some of our products in the United States, Canada, Europe and other countries. In January 2000, we entered into an exclusive worldwide Distribution Agreement with Medtronic, Inc. for the global marketing and distribution of some of our products for use in craniomaxillofacial applications. The Distribution Agreement also contemplates possible distribution by Medtronic of our products for use in other parts of the body. We also entered into a Development and Supply Agreement, in January 2000 with Medtronic, to co-develop bioresorbable implants for use in spinal fixation, stabilization and fusion applications and supply any such new implants to Medtronic as the distributor.

In September 2002, we entered into an Asset Purchase Agreement ("the Agreement") to sell assets related to our craniomaxillofacial (skull and face) bone fixation implant and accessory product line to Medtronic PS Medical, Inc. (a subsidiary of Medtronic, Inc.) for a total of up to \$16,000,000. In accordance with the terms of the Agreement we will receive consideration consisting of an initial payment of \$13,000,000 from Medtronic and additional payments totaling \$3,000,000 upon the successful transfer of technology and know how, including training, related to the manufacture of the

craniomaxillofacial product line. The initial \$13,000,000 receivable from Medtronic under the Agreement is shown net of the \$4,000,000 payable to Medtronic associated with the Amended Development Agreement (see the paragraph below), as net receivable from the sale of assets, related party as of September 30, 2002 on the condensed balance sheet. The initial payment occurred in the fourth quarter of 2002 and the subsequent milestone payments are expected to occur in 2003. The Agreement also requires us not to market, in the craniomaxillofacial field, any products that compete with the acquired product line. However, we will continue to be a backup supplier of the acquired products to Medtronic at a price equal to our cost of manufacture during the transition technology transfer period. The Agreement also allows us to receive up to \$5,000,000 if and when we successfully complete clinical evaluations for a new faster-resorbing polymer product, as defined in the Agreement.

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

We are accounting for the net proceeds of the Agreements as a deferred gain on sale of assets, related party, until the technology and know how transfer is completed pursuant to the terms of the Agreement. Upon successfully completing our requirements under these provisions of the Agreement, we will recognize the gain on the sale in the statement of operations.

In 2001, we had \$3,875,000 of revenues from the craniomaxillofacial product line. For the nine months ending September 30, 2002, the product line had \$2,302,000 of revenues. For the three months ending September 30, 2002, the product line had \$956,000 of revenues.

Medtronic continues to be a significant stockholder of the Company and our largest customer, as the distributor of our biosurgery products in the musculoskeletal field. Medtronic remains the primary distributor of our bioresorbable implant products for use in musculoskeletal applications under the Amended Development Agreement. The musculoskeletal products that fall under this agreement have 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.

In October 2002, we entered into two agreements to acquire, for cash and common stock of MacroPore, the remaining outstanding shares of StemSource, Inc., a development-stage drug company engaged in adult stem-cell therapy research. Before the acquisition, we owned 666,667 shares of StemSource's series A preferred stock, which represented a 13.5% ownership interest. In the first agreement, we purchased 2,717,500 common shares for \$1,861,488 in cash from certain individual shareholders of StemSource. The acquisition of these common shares increased our ownership in StemSource to 38.2%. Secondly, we signed a definitive agreement to acquire the remaining outstanding shares of StemSource's common and preferred stock in exchange for 1,456,720 shares of MacroPore common stock which is valued at approximately \$6,000,000. The acquisition will be accounted for as a purchase and is anticipated to close in the fourth quarter of 2002.

On July 12, 2002, we loaned \$1,000,000 to StemSource in exchange for a convertible promissory note ("Note") and a warrant to purchase 100,000 shares of StemSource's common stock. The Note has an annual interest rate of 8.0% and was originally scheduled to mature on October 31, 2002. The warrant expires on July 12, 2007. The Note may be converted, at our option, into shares of StemSource Series B Preferred Stock at the closing of StemSource's next Series B Preferred Stock financing

transaction or series of financing transactions in which the aggregate gross proceeds to StemSource equal or exceed \$2,000,000. On October 31, 2002 the Note's maturity date was extended to December 31, 2002.

In May 2001, we invested \$1,000,000 in cash in exchange for shares of Series A preferred stock of StemSource representing a 13.5% ownership interest.

We would intend to use the cash received from the sale of the craniomaxillofacial (skull and face) bone fixation implant and accessory product line to finance StemSource's operations. Our strategic vision is that StemSource would develop therapies that could be delivered via our surgical implant products.

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 2001 and 2002, we received regulatory clearance or marketing authorization for our products from various jurisdictions, for the following indications:

- the use of our MacroPore OS Spine bone graft containment system in spinal fusion procedures
- the use of our MacroPore ENT Reconstruction Film in ear, nose and throat applications for the prevention of postsurgical adhesions in the nasal cavity, guided tissue regeneration, nasal splinting and tympanic membrane repair
- the use of our OS Trauma system for the reconstruction of weak bony tissues in musculoskeletal procedures and the standalone reconstruction of iliac crest and rib anatomy
- the use of our MacroPore IB system as a cement restrictor in specified musculoskeletal applications
- the use of our MacroPore TS Surgi-Wrap™ product line in craniomaxillofacial applications
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the use of our MacroPore TS Surgi-Wrap™ film for wound support and soft tissue reinforcement throughout the entire human body

- the use of our MacroPore TS Surgi-Wrap™ products as an adhesion barrier for cardiothoracic, spinal, peritoneal and OB/GYN procedures in Europe
- the use of our MacroPore TS Surgi-Wrap™ products for hernia repair and soft tissue repair throughout the body in Europe
- the use of our MacroPore LP system in reconstructive surgery to correct pediatric skeletal birth defects and in cranial reconstruction
- the expanded use of some of our product lines, including MacroPore FX, MacroPore PS and MacroPore NS, for specified craniomaxillofacial procedures in the United States and Europe
- the use of our fixation products in craniomaxillofacial applications

We are also developing additional products for use in spinal fusion procedures, soft tissue repair, anti-adhesion 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 for the design of our high torque, bioresorbable StarBurst Screws, which are used in many of our products.

We incurred net losses of \$7,503,000 for the nine months ended September 30, 2002, \$11,207,000 for the year ended December 31, 2001 and \$8,645,000 for the year ended December 31, 2000. As of September 30, 2002, we had an accumulated deficit of \$34,602,000. 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 nine months ended September 30, 2002, revenues of \$6,487,000 or 91.1% came from sales of our bioresorbable implant products for use in musculoskeletal, craniomaxillofacial and soft tissue applications, revenues of \$257,000 or 3.6% came from sales of instruments and accessories used by surgeons to form, mold and manipulate our bioresorbable products during surgical procedures, and \$375,000 or 5.3% of our revenues came from a license agreement and a special project with Medtronic. Of the \$6,487,000, a total of \$2,302,000 or 35.5% came from craniomaxillofacial and other products that which were included in the September 2002 product line sale to Medtronic, and \$235,000 came from our recently introduced thin film products for soft tissue applications.

In 2001, revenues related to the product line sold in September 2002 were \$3,925,000 or 69.5% of our total revenue for that fiscal year. Because we saw more upside in the musculoskeletal and thin film product lines, as 2002 progressed, we decided to sell the craniomaxillofacial product line for a favorable cash price.

Results of Operations

Three months ended September 30, 2002 compared to three months ended September 30, 2001

Revenues. For the three months ended September 30, 2002, revenues were \$3,302,000 compared to \$1,400,000 for the three months ended September 30, 2001, an increase of \$1,902,000, or 135.9%. The increase in revenues in the three months ended September 30, 2002, was attributable to a \$1,784,000 increase in the sales of bioresorbable implant products and instrumentation for use in musculoskeletal applications, \$235,000 in bioresorbable thin film sales and a \$117,000 decrease in craniomaxillofacial product sales. The increase in musculoskeletal products revenue related to the increase in availability of the product from limited clinical evaluations to a full product release within the three months ended September 30, 2002. The increase in revenue of bioresorbable thin film product was attributable to the launch of the product during the three months ended September 30, 2002, with no comparable sales in the three months ended September 30, 2001. The craniomaxillofacial product decreased in the three months ended September 30, 2002 because of the decrease in replenishment product orders from Medtronic. Revenues attributable to Medtronic, which owns approximately 6.6% of our outstanding common stock, represented 93.1% of our revenues for the three months ended September 30, 2002, compared to 98.6% for the three months ended September 30, 2001. 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 September 30, 2002.

Cost of revenues. For the three months ended September 30, 2002, cost of revenues, excluding the inventory provision described below, was \$951,000 or 28.8% of revenues, compared to \$653,000 or 46.6% of revenues for the three months ended September 30, 2001. 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 sale of the craniomaxillofacial product line could hurt our margins until our other products' sales grow enough to replace the lost revenue.

Inventory provision. For the three months ended September 30, 2002, we recorded an inventory provision of \$1,395,000 or 42.2% of revenues, for which there was no comparable charge in the three months ending September 30, 2001. The inventory provision was a result of reduction in expected future revenues of our craniomaxillofacial bone fixation implants and accessories product line inventory due to the asset sale to Medtronic.

Gross profit. For the three months ended September 30, 2002, gross profit was \$956,000 or 29.0% of revenues, compared to \$747,000 or 53.4% of revenues for the three months ended September 30, 2001. Excluding the inventory provision, the gross profit would have been \$2,351,000 or 71.2% of revenues in the three months ended September 30, 2002. The increase in gross profit, excluding the inventory provision, as a percentage of revenues, was primarily 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 September 30, 2002, research and development expenses excluding related stock based compensation expenses were \$1,271,000, compared to \$1,345,000 for the three months ended September 30, 2001, a decrease of \$74,000, or 5.5%. Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and preclinical evaluations. The decrease in research and development expenses in the three months ended September 30, 2002 was primarily attributable to \$128,000 of lower product testing expenses, offset by higher personnel expenses of \$54,000 associated with the development of new product lines. Stock based compensation expense related to research and development was \$25,000 for the three months ended September 30, 2002, compared to \$29,000 for the three months ended September 30, 2001. 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 to increase for the remainder of the year ending December 31, 2002 as we expand our product development efforts and seek further regulatory approvals.

Sales and marketing expenses. For the three months ended September 30, 2002, sales and marketing expenses excluding related stock based compensation expenses were \$1,082,000, compared to \$1,412,000 for the three months ended September 30, 2001, a decrease of \$330,000, or 23.4%. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. The decrease in sales and marketing expenses in the three months ended September 30, 2002, were primarily attributable to a \$288,000 decrease in labor and associated expenses relating to our direct sales force labor mix, severance payments made to certain members of sales force terminated during the three months ended September 30, 2001 and other expense reductions of \$42,000 in promotional activities. Stock based compensation expense related to sales and marketing was \$33,000 for the three months ended September 30, 2002 and \$121,000 for the three months ended June 30, 2001. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses." We expect sales and marketing expenses to increase for the remainder of the year ending December 31, 2002 as we expand our sales and marketing efforts related to the introduction of new products.

General and administrative expenses. For the three months ended September 30, 2002, general and administrative expenses excluding related stock based compensation expenses were \$899,000, compared to \$858,000 for the three months ended September 30, 2001, an increase of \$41,000, or 4.8%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The increase in general and administrative expenses in the three months ended September 30, 2002 was primarily attributable to \$170,000 in higher professional fees, offset by \$129,000 of lower salary expense relating to our bonus expense and the salary of a

retired executive officer who retired in March of 2002. Stock based compensation related to general and administrative expenses was \$215,000 for the three months ended September 30, 2002, compared to \$185,000 for the three months ended September 30, 2001. For further information regarding 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, 2002.

Stock based compensation expenses. For the three months ended September 30, 2002, total non-cash stock based compensation expenses were \$273,000, compared to \$335,000 for the three months ended September 30, 2001, a decrease of \$62,000, or 18.5%. Stock based compensation results from options issued to employees and non-employees. 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 for the three months ended September 30, 2002 compared to the same period in 2001 is associated with compensation charges from accelerated vesting and modifications to compensatory stock options granted to employees and consultants in the prior year. The decrease of \$4,000 in research and development stock based compensation expense related to normal amortization of the unearned compensation over the vesting period. The decrease of \$88,000 in sales and marketing stock based compensation expense resulted from the rehiring on May 1, 2001 of certain members of our sales force who had been previously terminated, but continued to hold stock options that were allowed to continue vesting during the termination period. In addition, on September 17, 2001 we terminated certain members of our sales force and modified the vesting and exercise period of their options. These options were remeasured as of the rehire date and modification date, respectively, and additional compensation expense was recorded in the three months ended September 30, 2001. The increase of \$30,000 in general and administrative stock based compensation expense was attributable to the decrease in the fair market value of certain stock options to a consultant being recorded in the three months ended September 30, 2001.

Equipment impairment charge. In the three months ended September 30, 2002, we had an equipment impairment charge of \$370,000, for which there was no comparable charge in the three months ended September 30, 2001. The impairment charge represents the excess cost of the equipment over the net proceeds we estimate we will receive from sale of the assets, which were previously utilized in the manufacturing of craniomaxillofacial bone fixation implant and accessory product line, but not included in the Medtronic sale.

Interest income. For the three months ended September 30, 2002, interest income was \$207,000, compared to \$511,000 for the three months ended September 30, 2001, a decrease of \$304,000, or 59.5%. The decrease in interest income resulted primarily from lower interest rates and also from a decrease in the funds we had available for investments.

Interest and other expenses. For the three months ended September 30, 2002, interest and other expenses were \$158,000, compared to \$20,000 for the three months ended September 30, 2001, an increase of \$138,000. The increase in interest and other expense related to \$54,000 of additional interest expense on our long-term debt obligations because loan balances were greater than in the prior comparable period, and \$84,000 relating to a loss recorded on disposal of assets.

Equity loss in investment. For the three months ended September 30, 2002, our equity loss in investment was \$76,000, compared to \$24,000 for the three months ended September 30, 2001. Both figures relate entirely to our minority interest in StemSource, which we purchased in May 2001. Under the equity method of accounting, we recognize a pro rata share of StemSource operating losses.

Revenues. For the nine months ended September 30, 2002, revenues were \$7,119,000 compared to \$4,197,000 for the nine months ended September 30, 2001, an increase of \$2,922,000, or 69.6%. The increase in revenues in the nine months ended September 30, 2002, was attributable to a \$3,634,000 increase in the sales of bioresorbable implant products for use in musculoskeletal applications, \$289,000 in sales of bioresorbable thin film, and a \$1,001,000 decrease in the sales of craniomaxillofacial products. The increase in revenue of musculoskeletal products in the nine months ended September 30, 2002 related to the increase in availability of the product from limited clinical evaluations to a full product release. The increase in revenue of the bioresorbable thin film was attributable to the launch of surgical film during the three months ended September 30, 2002, with no comparable sales revenue in the nine months ended September 30, 2001. The revenue from craniomaxillofacial products decreased in the nine months ended September 30, 2002 because of the decrease in replenishment product orders from Medtronic. Revenues attributable to Medtronic represented 96.5% of our revenues for the nine months ended September 30, 2002, compared to 98.5% for the nine months ended September 30, 2001. The decrease in the revenue percentage attributable to Medtronic relates to the distribution of bioresorbable thin film products being sold by our own direct sales force and other third party distributors in the three months ended September 30, 2002.

Cost of revenues. Excluding the inventory provisions described below, for the nine months ended September 30, 2002, cost of revenues was \$2,482,000 or 34.9% of revenues, compared to \$1,578,000 or 37.6% of revenues for the nine months ended September 30, 2001. Cost of revenues includes material, manufacturing labor and overhead costs. The decrease in cost as a percentage of revenues was primarily attributable our ability to absorb more of our fixed manufacturing overhead costs. The sale of the craniomaxillofacial product line could hurt our margins until our other products' sales grow enough to replace the lost revenue.

Inventory provision. For the nine months ended September 30, 2002, we recorded an inventory provision of \$1,395,000 or 19.6% of revenues. For the nine months ended September 30, 2001, we recorded an inventory provision of \$1,228,000 or 29.3% of revenues. The inventory provision for the nine months ended September 30, 2002, was a result of a reduction in expected future revenues of our craniomaxillofacial bone fixation implants and accessories product line inventory due to the asset sale to Medtronic. The inventory provision for the nine months ended September 30, 2001 was a result of identified excess and obsolete craniomaxillofacial bone fixation implant and accessories inventory due to lower than anticipated replenishment orders from Medtronic.

Gross profit. For the nine months ended September 30, 2002, gross profit was \$3,242,000 or 45.5% of revenues, compared to \$1,391,000 or 33.1% of revenues for the nine months ended September 30, 2001. Excluding the inventory provisions, the gross profit would have been \$4,637,000 or 65.1% of revenues for the nine months ended September 30, 2002, compared to \$2,619,000 or 62.4% of revenues for the nine months ended September 30, 2001. The increase in gross profit, excluding the inventory provisions, as a percentage of revenues was attributable to increased revenue and the ability to absorb fixed manufacturing overhead costs, as discussed above.

Research and development expenses. For the nine months ended September 30, 2002, research and development expenses excluding related stock based compensation expenses were \$4,144,000, compared to \$4,041,000 for the nine months ended September 30, 2001, an increase of \$103,000, or 2.5%. Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and preclinical evaluations. The increase in research and development expenses in the nine months ended September 30, 2002 was primarily attributable to an increase of \$103,000 of non-personnel expenses associated with the development of new product lines. Stock based compensation expense related to research and development was \$185,000 for the nine months ended September 30, 2002, compared to

\$89,000 for the nine months ended September 30, 2001. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

Sales and marketing expenses. For the nine months ended September 30, 2002, sales and marketing expenses excluding related stock based compensation expenses were \$2,779,000, compared to \$3,791,000 for the nine months ended September 30, 2001, a decrease of \$1,012,000, or 26.7%. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. The decrease in sales and marketing expenses in the nine months ended September 30, 2002 was primarily attributable to a \$645,000 decrease in labor and associated expenses relating our sales force labor mix, severance payments made to certain members of sales force terminated during the three months ended September 30, 2001 and other expense reductions of \$367,000 in promotional activities. Stock based compensation expense related to sales and marketing was \$100,000 for the nine months ended September 30, 2002 and \$131,000 for the nine months ended September 30, 2001. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

General and administrative expenses. For the nine months ended September 30, 2002, general and administrative expenses excluding related stock based compensation expenses were \$2,867,000, compared to \$2,762,000 for the nine months ended September 30, 2001, an increase \$105,000, or 3.8%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The increase in general and administrative expenses in the nine months ended September 30, 2002, was primarily attributable to a retirement package we extended to our former president and an increase in the overall professional and general corporate expenditures. Stock based compensation related to general and administrative expenses was \$732,000 for the nine months ended September 30, 2002, compared to \$623,000 for the nine months ended September 30, 2001. For further information regarding stock based compensation, you should read the discussion under the section entitled "Stock based compensation expenses."

Stock based compensation expenses. For the nine months ended September 30, 2002, total non-cash stock based compensation expenses were \$1,017,000, compared to \$843,000 for the nine months ended September 30, 2001, an increase of \$174,000, or 20.6%. Stock based compensation results from options issued to employees and non-employees. Unearned stock based compensation is amortized over the remaining vesting periods of the options, which generally vest over a four year period from the date of grant. The overall increase in stock based compensation expense was related to the 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 nine months ended September 30, 2002. The increase of \$96,000 in research and development stock based compensation expense was primarily due to issuing 50,000 fully vested stock options to non-employees for consulting services rendered in the nine months ended September 30, 2002. The decrease of \$31,000 in sales and marketing stock based compensation expense was due primarily to a reduction in accrued compensation costs recorded in the nine months ended September 30, 2001 as a result of the forfeiture and cancellation of certain stock options that had been granted to members of our sales force upon the termination of their employment. The increase of \$109,000 in general and administrative stock based compensation expense was primarily due to additional expense recorded in the nine months ended September 30, 2002 as a result of accelerating vesting and modifying the exercise period of certain stock options held by our former president.

Equipment impairment charge. In the nine months ended September 30, 2002, we had an equipment impairment charge of \$370,000, for which there was no comparable charge in the nine months ending September 30, 2001. The impairment charge represents the excess cost of the equipment over the net proceeds we estimate we will receive from sale of the assets, which were previously utilized

in the manufacturing of craniomaxillofacial implant and accessory product line, but not included in the Medtronic sale.

Interest income. For the nine months ended September 30, 2002, interest income was \$844,000, compared to \$1,850,000 for the nine months ended September 30, 2001, a decrease of \$1,006,000, or 54.4%. The decrease in interest income resulted from primarily lower interest rates and also from a decrease in the funds we had available for investments.

Interest and other expenses. For the nine months ended September 30, 2002, interest and other expenses were \$223,000, compared to \$55,000 for the nine months ended September 30, 2001, an increase of \$168,000. The increase in interest and other expense related to \$81,000 of additional interest expense on our long-term debt obligations because loan balances were greater than in the prior comparable period and \$87,000 relating to a loss recorded on disposal of assets.

Equity loss in investment. For the nine months ended September 30, 2002, our equity loss in investment was \$189,000, compared to \$41,000 for the nine months ended September 30, 2001. Both figures relate entirely to our minority interest in StemSource, which we purchased in May 2001. Under the equity method of accounting, we recognize a pro rata share of StemSource's operating losses.

Gain on Asset Sale to Medtronic

We have not yet recognized any 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. Until then, we are including \$8,247,000 of "Deferred gain on sale of assets, related party" on our balance sheet.

Liquidity and Capital Resources

As of September 30, 2002, we had cash and cash equivalents, and short-term investments, available-for-sale, of \$21,734,000 and working capital of \$32,302,000. Since inception, we have financed our operations primarily through sales of stock and equipment financing. Our sales of preferred stock in 1997, 1998 and 1999 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 *Neuer Markt* segment of 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 has 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 available for sale investments, pending other uses of the proceeds in our business.

In early October 2002 we received net cash proceeds of \$9,000,000 from our transaction with Medtronic. We could receive additional cash later upon the satisfaction of contingencies.

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 investment balances and revenue to be derived from the sale of our products will be sufficient to fund our operations at least through December 31, 2003. However, if we acquire StemSource as planned, we will also have to commit very substantial cash resources to fund StemSource's development activities. Our strategic concept was to use the cash from the Medtronic asset sale to enable us to undertake the StemSource opportunity

without starving our remaining bioresorbable product lines of capital which would otherwise have been available to them. Nonetheless, unless 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 assure 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 \$4,860,000 for the nine months ended September 30, 2002, compared to \$7,083,000 used in operating activities for the nine months ended September 30, 2001. For each period, net cash used in operating activities resulted primarily from net losses and working capital requirements. Net losses for each period resulted to a large extent from expenses associated with the development of our bioresorbable designs, preclinical studies, preparation of submissions to the FDA and foreign regulatory agencies, the establishment of marketing and distribution channels, and the improvement of our manufacturing capabilities. In the nine months ended September 30, 2002, net cash used in operating activities primarily related to our net loss of \$7,503,000 and an increase in accounts receivable and inventory, offset by non-cash charges for depreciation and amortization, stock based compensation, and the inventory provision. In the nine months ended September 30, 2001, net cash used in operating activities resulted primarily from our net loss of \$8,292,000 and an increase in inventory, offset by non-cash charges for depreciation and amortization, stock based compensation, and the inventory provision. 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.

Net cash provided by investing activities was \$11,237,000 for the nine months ended September 30, 2002, compared to \$2,745,000 provided by investing activities for the nine months ended September 30, 2001. Net cash provided by investing activities for the nine months ended September 30, 2002, 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 operations and our stock buy backs), plus capital expenditures and our loan to two executives to enable them to buy our outstanding stock which we classified as long-term notes receivable, related party and a short-term loan to StemSource. Net cash provided by investing activities for the nine months ended September 30, 2001, consisted of net proceeds from the sale of short-term investments, which was offset by the purchase of short-term investments, capital expenditures and the initial equity investment in StemSource.

Net cash used in financing activities was \$4,775,000 for the nine months ended September 30, 2002, compared to \$351,000 used in by financing activities for the nine months ended September 30, 2001. Net cash used in financing activities for the nine months ended September 30, 2002, was primarily related to our

repurchase of 1,213,853 shares of our common stock on the open market at an average price of \$3.53 per share, and principal payments on capital lease and our long-term note obligations. Net cash used in financing activities for the nine months ended September 30, 2001, was primarily attributable to the purchase of 143,561 shares of our common stock on the open market at an average price of \$2.67 per share and principal payments on capital leases, partially offset by \$121,000 from the sale of common stock upon the exercise of stock options.

We have equipment lease obligations that mature at various dates through 2004 with interest rates ranging from 12.4% to 23.7%. The total monthly payments under our equipment lease obligations are \$6,000. In October 2000, we obtained \$2,433,000 of equipment financing that matures in October 2005 at an interest rate of 9.3%. Our total monthly payments under the equipment financing arrangement are \$54,000.

As of September 30, 2002, we had property and equipment of \$5,888,000, less accumulated depreciation of \$2,224,000 to support our clinical, research, development, manufacturing and

administrative activities. The net carrying cost of the property and equipment sold to Medtronic in the September 2002 asset sale was \$476,000. Our capital expenditures were \$875,000 for the nine months ended September 30, 2002 and \$2,480,000 for the nine months ended September 30, 2001. We expect capital expenditures for the next twelve months to be approximately \$1,000,000 as we acquire additional equipment and expand our facilities (This is exclusive of any capital expenditures at StemSource.). We intend to pay for future capital expenditures with available working capital.

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:

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 a deterioration in the economic financial strength of the customer and the general business environment. Medtronic is our single largest customer, directly accounting for 96.5% of our revenues in the nine months ended September 30, 2002 and 90.1% of our accounts receivable at September 30, 2002. We believe that our allowance for doubtful accounts as of September 30, 2002 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.

Warranty reserves. We estimate our potential warranty reserve based on historical claims by our customers. The likelihood of a material change in our estimated warranty reserve depends on a significant change in actual product failures and increased customer claims from those incurred historically.

Valuation of deferred income taxes. 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 taken a 100% valuation allowance against our deferred tax assets, which consist mostly of net operating loss carryforwards. 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.

Principles of consolidation. We determine whether the equity method of consolidation is appropriate to account for our investments based on our ability to exercise control through decision-making, our ability to exercise significant influence over management of the company in which we have invested and our equity ownership interest in that company. If our ability to exercise significant influence or our decision-making abilities change materially from our evaluation, or our ownership interest in an investment increases or decreases, our operating results could be impacted, either positively or negatively.

Unearned Compensation

We record unearned compensation for options granted to employees equal to the excess of the fair market value of our common stock on the date of grant over the exercise price of options granted. 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 September 30, 2002 was \$6,669,000 with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of \$5,355,000. The remaining \$1,314,000 as of September 30, 2002 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 stock base compensation related to unearned compensation of \$252,000 for the period October 1, 2002 to December 31, 2002, \$848,000 in 2003 and \$214,000 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 forfeited.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2001, we had federal net operating loss carryforwards of \$17,916,000 and state net operating loss carryforwards of \$3,011,000, which may be available to offset future taxable income for tax purposes. The federal net operating loss carryforwards will begin to expire in 2012, if unused. The state net operating loss carryforwards will begin to expire in 2005, if unused. A portion of the net operating losses are limited in their annual utilization. As of December 31, 2001, we also had research tax credit carryforwards of \$345,000 for federal tax purposes and \$339,000 for state tax purposes. The federal and state research tax credit carryforwards will begin to expire in 2012, if unused. In addition, as of December 31 2001, we had state manufacturer's credit carryforwards of \$252,000, which will begin to expire in 2007, if unused. For financial reporting purposes, we have provided a full valuation against our deferred tax assets due to uncertainties regarding their realization.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001 and no longer permits the use of the pooling-of-interests method. SFAS No. 142 requires that amortization of goodwill cease and the carrying value of goodwill be evaluated for impairment at least annually using a fair value test. Identifiable intangible assets will continue to be amortized over their useful lives and reviewed at least annually for impairment using a method appropriate to the nature of the intangible asset. We adopted SFAS No. 141 on July 1, 2001 and SFAS No. 142 on January 1, 2002. The adoption of SFAS No. 141 and SFAS No. 142 did not have a material impact on our financial position or results of operations.

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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. We do not expect our adoption of SFAS No. 143 to have a material impact on our financial position or results of operations.

Also in August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. We adopted SFAS 144 on January 1, 2002. The adoption of SFAS No. 144 did not have a material impact on our financial position or 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 145 updates, clarifies and simplifies existing accounting pronouncements including: 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 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 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. We do not expect this standard to have a material effect on our financial statements.

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 impact on our financial position or results of operations from adopting SFAS No. 146 has not been determined.

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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 \$17,432,000 as of September 30, 2002, 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 September 30, 2002, for example, and assuming an average investment duration of nine 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 on the Euro or other currencies. Based on our cash balances and

revenues derived from markets other than the United States for the nine months ended September 30, 2002, a hypothetical 10% adverse change in the Euro against the U.S. dollar would not result in a material foreign 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 in operations or cash flows.

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

Item 4. Controls and Procedures

(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

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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 13,000 square feet is laboratory space, 6,000 square feet is office space and 8,000 square feet is manufacturing space. Our lease has a five-year term, expiring in 2003.

We also lease:

- a 14,000 square foot research and development facility located at 6749 Top Gun Street, San Diego, California for a five-year term, expiring in 2006
- 5,800 square feet of office space in Frankfurt, Germany for use in marketing and administration for a five-year term, expiring in 2006

We pay an aggregate of approximately \$45,000 in rent per month for our properties located in the United States and approximately €10,000 for our property in Germany.

Staff

As of September 30, 2002, we had 89 full-time employees, comprised of 21 employees in research and development, 25 employees in manufacturing, 17 employees in management and finance and administration, and 26 employees in sales and marketing. As of September 30, 2001, we had 72 full-time employees, comprised of 24 employees in research and development, 17 employees in manufacturing, 16 employees in management and finance and administration and 15 employees in sales and marketing. From time to time, we also employ independent contractors to support our administrative organizations. Our employees are not represented by any collective bargaining unit and we have never experienced a work stoppage.

Item 6. Exhibits and Reports on Form 8-K

a. Exhibits

- 2.1* Asset Purchase Agreement, dated September 30, 2002, by and between MacroPore Biosurgery, Inc. and Medtronic PS Medical, Inc.
- 2.2* License Agreement, dated October 8, 2002 between MacroPore Biosurgery, Inc. and Medtronic PS Medical, Inc.
- 2.3* Amended and Restated Distribution Agreement, dated October 8, 2002, between MacroPore Biosurgery, Inc. and Medtronic, Inc.
- 2.4* Amendment No. 2 to Development and Supply Agreement, dated September 30, 2002, between MacroPore Biosurgery, Inc. and Medtronic, Inc.
- 15.1 Letter re unaudited interim financial information
- 99.1 Risk Factors
- 99.2 Certifications under Section 906 of the Sarbanes-Oxley Act of 2002

* Incorporated by reference to the same numbered Exhibit in our Form 8-K current report filed on October 23, 2002.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in San Diego, California, on November 14, 2002.

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, the principal executive officer of MacroPore Biosurgery, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of MacroPore Biosurgery, Inc.;
2. Based on my knowledge, this 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 officers 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.

The registrant's other certifying officers 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 function):

- (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: November 14, 2002

/s/ CHRISTOPHER J. CALHOUN

Christopher J. Calhoun,
Chief Executive Officer, President

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

I, Ari Bisimis, the principal executive officer of MacroPore Biosurgery, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of MacroPore Biosurgery, Inc.;
2. Based on my knowledge, this 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 officers 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 officers 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 function):
 - (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: November 14, 2002

/s/ ARI BISIMIS

Ari Bisimis,
Chief Financial Officer

| | |
|------|---|
| 2.1* | Asset Purchase Agreement, dated September 30, 2002, by and between MacroPore Biosurgery, Inc. and Medtronic PS Medical, Inc. |
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| 99.1 | Risk Factors |
| 99.2 | Certifications under Section 906 of the Sarbanes-Oxley Act of 2002 |

* Incorporated by reference to the same numbered Exhibit in our Form 8-K current report filed on October 23, 2002.

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EXHIBIT 15.1

LETTER RE UNAUDITED INTERIM FINANCIAL INFORMATION

November 6, 2002

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 November 1, 2002 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

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[EXHIBIT 15.1](#)

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 quarterly operating results can vary substantially from analyst expectations and from previous quarterly 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, 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 \$7,503,000 for the first nine months of 2002. These losses have resulted primarily from expenses associated with our research and development activities, including extensive in-vitro testing and numerous preclinical studies and general and administrative expenses. We anticipate that our recurring operating expenses will increase for the next several years, as our research and development expenses may increase in order to develop and market new products and fund additional preclinical research and possibly clinical trials. We expect to continue to incur losses through the end of this year, and the amount of future net losses and time necessary to reach profitability are somewhat uncertain. Even if our medical device product lines achieve profitability, development-stage losses at StemSource 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 drug 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 propose to acquire StemSource and use the cash we received from the craniomaxillofacial product line to finance its development-stage cash needs. This is a high-risk strategy because there can be no assurance that StemSource will ever develop a successful or salable drug (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 StemSource drugs where needed in the body (strategic risk), or that our cash resources will be adequate to carry

StemSource until it becomes profitable (if ever) while still serving the cash needs of our medical device product lines (financial risk). Instead of using the craniomaxillofacial product line to stabilize our future operations or using cash received from selling that product line to reinvest in our core business or preserve as safety cushion, 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 TS Surgi-Wrap™ bioresorbable 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. StemSource's products 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 2001 and 2002 revenues from the sale of products to our distribution partner Medtronic Inc. (Medtronic). We have recently launched a new direct sales force to market our Surgi-Wrap™ product line throughout 15 major markets in the United States and signed international distributor agreements in 11 countries. We cannot guarantee that this sales force and the international distributors will adequately penetrate the markets to generate significant revenues in the near future, if at all.

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.

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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 6.6% 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

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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 expand our manufacturing capacity to 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, 2003, 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 event of which could mean a substantial increase in material costs. Also, despite this agreement they might fail to do these things for us. Under the terms of the contract, B.I. Chemicals, Inc. may choose to raise their prices upon nine months prior notice which may also result in a substantially increased material cost. Although we believe that we would be able to obtain the material from at least one other source in the event of a failure of supply, there can be no assurance that we will be able to obtain adequate increased commercial quantities of the necessary high quality within a reasonable period of time or at commercially reasonable rates. Lack of adequate commercial quantities or inability to develop alternative sources meeting regulatory requirements at similar prices and terms within a reasonable time or any interruptions in supply in the future could have a significant negative effect on our ability to manufacture products, and, consequently, could have a material adverse effect on the results of our operations and financial condition.

We may not be able to protect our proprietary rights

Our success depends in part on whether we can obtain additional patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. We have several U.S. patents for the design of our bioresorbable plates and high torque screws and we have filed

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

Our 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 and Canada 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 (and drugs, if any) 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 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 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 one or more years from the date of submission of the application. 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.

We may become involved in drug development if we acquire StemSource. The FDA process for testing and approving new drugs is lengthy and extremely expensive.

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 the Company will be able to successfully commercialize its current or future products in any foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on the results of our operations and financial condition.

We may need to raise more cash in the future

If we do not increase our sales quickly enough or if we choose to invest additional cash in areas of promise, we may be required to seek additional capital to finance our operations in the future. As of September 30, 2002, we had \$21,734,000 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 if we acquire StemSource, its operations will result in a substantial cash burn. 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 Calhoun, our President and Chief Executive Officer, Ari Bisimis, our Chief Financial Officer and Bryan Cornwall, our Vice President of Research & Technology. 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 are in the process of completing a business acquisition which, as with additional acquisitions we may undertake in the future, will present risks associated with integrating that new business

We are in the process of acquiring the outstanding equity ownership of StemSource, Inc., a stem-cell therapy research company, and have begun the process of integrating this business. Mergers and acquisitions, especially in our industry, are inherently risky, and no assurance can be given that our

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current or future acquisitions will be successful and will not materially adversely affect our business, operating results, or financial condition. Our acquisition of StemSource, Inc., as well as any future acquisitions, involves numerous risks including, among others:

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

We plan to continue to review potential acquisition candidates in the ordinary course of our business. As with the acquisition of StemSource, 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 is changing

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, but the Neuer Markt is going to close. We believe we will be able to re-list our shares 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.

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QuickLinks

[EXHIBIT 99.1](#)

