

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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

MacroPore, Inc

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report.)

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 July 23, 2002, there were 13,931,406 shares of MacroPore Biosurgery's common stock outstanding.

MACROPORE BIOSURGERY, INC.

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## PART I FINANCIAL INFORMATION

## Item 1. Financial Statements

## Independent Accountants' Review Report

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

We have reviewed the accompanying condensed balance sheet of MacroPore BioSurgery, Inc. (the Company) as of June 30, 2002, the related condensed statements of operations and comprehensive income (loss) for the three and six month periods ended June 30, 2002, and the related statement of cash flows for the six-month period ended June 30, 2002. These consolidated 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 six month periods ended June 30, 2001, and the related condensed statement of cash flows for the six-month period ended June 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  
August 2, 2002

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

	As of June 30, 2002	As of December 31, 2001
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,449,000	\$ 2,700,000
Short-term investments, available for sale	21,528,000	31,251,000
Accounts receivable, related party, net of allowance for bad debts of \$35,000	1,775,000	463,000
Inventories	2,162,000	1,685,000
Other current assets	570,000	851,000
	<hr/>	<hr/>
Total current assets	29,484,000	36,950,000

Property and equipment, net	5,209,000	5,171,000
Long-term notes receivable, related party	487,000	—
Other assets	852,000	1,022,000
Total assets	\$ 36,032,000	\$ 43,143,000
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,207,000	\$ 1,155,000
Current portion of capital lease obligations	117,000	121,000
Current portion of long-term obligations	577,000	555,000
Total current liabilities	1,901,000	1,831,000
Deferred revenue, related party	750,000	900,000
Capital lease obligations, less current portion	81,000	135,000
Long-term obligations, less current portion	1,544,000	1,791,000
Total liabilities	4,276,000	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; 15,182,138 and 15,106,623 issued and outstanding in 2002 and 2001, respectively	15,000	15,000
Additional paid-in capital	68,625,000	68,402,000
Unearned compensation	(1,566,000)	(2,105,000)
Accumulated deficit	(31,636,000)	(27,099,000)
Treasury stock, at cost; 1,193,065 and 356,120 shares in 2002 and 2001, respectively	(3,860,000)	(1,077,000)
Accumulated other comprehensive income	178,000	350,000
Total stockholders' equity	31,756,000	38,486,000
Total liabilities and stockholders' equity	\$ 36,032,000	\$ 43,143,000

See notes to condensed financial statements

**MACROPORE BIOSURGERY, INC.**  
**CONDENSED STATEMENTS OF OPERATION AND COMPREHENSIVE INCOME (LOSS)**  
**(Unaudited)**

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2002	2001	2002	2001
<b>Revenues:</b>				
Sales to related party	\$ 2,700,000	\$ 754,000	\$ 3,797,000	\$ 2,753,000
Sales to distributors and end-users	7,000	14,000	20,000	44,000
	2,707,000	768,000	3,817,000	2,797,000
<b>Cost of revenues:</b>				
Cost of revenues including stock based compensation expense of \$3,000 and \$5,000 for the three month periods ended June 30, 2002 and 2001, respectively; \$7,000 and \$10,000 for the six month periods ended June 30, 2002 and 2001, respectively	981,000	255,000	1,531,000	925,000
Inventory provision	—	1,228,000	—	1,228,000
	1,726,000	(715,000)	2,286,000	644,000
Gross profit (loss)				
<b>Operating expenses:</b>				
Research and development, excluding stock based compensation expense of \$25,000 and \$30,000 for the three month periods ended June 30, 2002 and 2001, respectively; \$160,000 and \$60,000 for the six month periods ended June 30, 2002 and 2001, respectively	1,388,000	1,512,000	2,873,000	2,696,000

Sales and marketing, excluding stock based compensation expense of \$34,000 and \$62,000 for the three month periods ended June 30, 2002 and 2001, respectively; \$67,000 and \$10,000 for the six month periods ended June 30, 2002 and 2001, respectively	1,026,000	1,367,000	1,697,000	2,379,000
General and administrative, excluding stock based compensation expense of \$216,000 and \$278,000 for the three month periods ended June 30, 2002 and 2001, respectively; \$517,000 and \$438,000 for the six month periods ended June 30, 2002 and 2001, respectively	855,000	977,000	1,968,000	1,904,000
Stock based compensation (excluding cost of revenues stock based compensation)	275,000	370,000	744,000	508,000
<b>Total operating expenses</b>	<b>3,544,000</b>	<b>4,226,000</b>	<b>7,282,000</b>	<b>7,487,000</b>
<b>Other income (expenses):</b>				
Interest income	263,000	622,000	637,000	1,340,000
Interest and other expense, net	9,000	(6,000)	(65,000)	(36,000)
Equity loss in investment	(57,000)	(17,000)	(113,000)	(17,000)
<b>Net loss</b>	<b>(1,603,000)</b>	<b>(4,342,000)</b>	<b>(4,537,000)</b>	<b>(5,556,000)</b>
<b>Other comprehensive income (loss):</b>				
Unrealized holding gains arising during period	129,000	106,000	178,000	259,000
<b>Comprehensive loss</b>	<b>\$ (1,474,000)</b>	<b>\$ (4,236,000)</b>	<b>\$ (4,359,000)</b>	<b>\$ (5,297,000)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.11)</b>	<b>\$ (0.29)</b>	<b>\$ (0.31)</b>	<b>\$ (0.37)</b>
Shares used in calculating basic and diluted net loss per share	14,651,945	14,947,403	14,822,336	14,947,403

See notes to condensed financial statements

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

	Six Months Ended June 30,	
	2002	2001
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,537,000)	\$ (5,556,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	723,000	515,000
Inventory provision	—	1,228,000
Stock based compensation	751,000	518,000
Interest income, related party	(9,000)	—
Equity loss in investment	113,000	17,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable, related party	(1,312,000)	76,000
Inventories	(477,000)	(1,275,000)
Other current assets	281,000	(146,000)
Other assets	57,000	91,000
Accounts payable and accrued expenses	52,000	62,000
Deferred revenue, related party	(150,000)	(150,000)
<b>Net cash used in operating activities</b>	<b>(4,508,000)</b>	<b>(4,620,000)</b>
<b>Cash flows from investing activities:</b>		
Proceeds from the sale and maturity of short-term investments	33,972,000	58,351,000
Purchases of short-term investments	(24,421,000)	(55,369,000)
Purchases of property and equipment	(761,000)	(2,145,000)
Long-term notes receivable, related party	(478,000)	—
Equity investment	—	(1,000,000)

Net cash provided by (used in) investing activities	8,312,000	(163,000)
<b>Cash flows from financing activities:</b>		
Principal payments on capital leases	(58,000)	(57,000)
Principal payments on long-term obligations	(225,000)	—
Proceeds from sale of Common Stock	11,000	109,000
Purchase of treasury stock	(2,783,000)	(20,000)
Net cash (used in) provided by financing activities	(3,055,000)	32,000
Net increase (decrease) in cash	749,000	(4,751,000)
Cash and cash equivalents at beginning of period	2,700,000	7,476,000
Cash and cash equivalents at end of period	\$ 3,449,000	\$ 2,725,000
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid during period for:		
Interest	\$ 122,000	\$ 27,000
Taxes	800	800
<b>Supplemental schedule of non-cash operating, investing, and financing activities:</b>		
Non-cash stock based compensation	\$ 751,000	\$ 581,000

See notes to condensed financial statements

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**MACROPORE BIOSURGERY, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**JUNE 30, 2002**  
**(Unaudited)**

**1. Basis of presentation**

The accompanying unaudited condensed financial statements for the three and six months ended June 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 six months ended June 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 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.

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**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.

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 craniofacial skeleton implant and instrument products. 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 June 30, 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. The Company has not incurred any such loss.

## 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, a shareholder of the Company, under its distribution agreement dated January 5, 2000.

## 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%, expected 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 \$34,000 of unearned compensation

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cost, being accelerated and charged to stock based compensation expense 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. Weighted average shares exclude shares of unvested common stock subject to repurchase by the Company. 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 six months ended June 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 4,117,057 and 4,054,667 for the three and six months ended June 30, 2002 and 3,479,778 and 3,781,835 for the three and six months ended June 30, 2001.

## 9. Reclassification

Certain amounts reported in the Company's Statement of Operations and Comprehensive Income for the three and six months ended June 30, 2001 have been reclassified to conform to the presentation for the three and six months ended June 30, 2002.

## 10. Composition of Certain Financial Statement Captions

### Inventories

	June 30, 2002	December 31, 2001
	(Unaudited)	
Raw materials	\$ 998,000	\$ 959,000
Finished goods	1,164,000	726,000
	<u>\$ 2,162,000</u>	<u>\$ 1,685,000</u>

## Accounts Payable and Accrued Expenses

	June 30, 2002	December 31, 2001
	(Unaudited)	
Accounts payable	\$ 296,000	\$ 294,000
Accrued bonus	237,000	398,000
Accrued vacation	277,000	244,000
Accrued expenses	397,000	219,000
	<u>\$ 1,207,000</u>	<u>\$ 1,155,000</u>

### 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. Subsequent Event

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 matures on October 31, 2002. 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 two million dollars. As of June 30, 2002, the Company had a 13.4% ownership interest in StemSource.

## 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 develop, manufacture and market bioresorbable surgical implants to aid in the reconstruction, repair and regeneration of bone and the healing of soft tissues throughout the body, as well as related instruments and accessories used in connection with our implants. Our bioresorbable implants are used in craniomaxillofacial, neurological, orthopedic and reconstructive surgery. We have also developed a bioresorbable surgical film that we began marketing in June 2002 for use in a wide variety of soft tissue surgical applications.

Our bioresorbable products are made from a copolymer composed of a lactic acid similar to that which occurs naturally in the human body. The lactic acid copolymer maintains its strength during the healing process, while slowly breaking down in the body through hydrolysis into lactic acid molecules and ultimately metabolizing into carbon dioxide and water, which are then released from the body through the lungs and the kidneys. We believe that our products are easier to use and more cost-effective than products 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. We entered into an exclusive worldwide agreement with Medtronic, Inc. in January 2000, for the global marketing and distribution of some of our products for use in the craniofacial skeleton. The agreement also contemplates possible distribution by Medtronic of our products for use in other parts of the body. We also entered into an agreement to co-develop bioresorbable implants for use in spinal fixation, stabilization and fusion applications with Medtronic and supply any such new implants to Medtronic as the distributor.

We are required to obtain from the Food and Drug Administration regulatory clearance of our 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

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- 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 LP system in reconstructive surgery to correct pediatric skeletal birth defects and in cranial reconstruction
  - the use of our MacroPore IB system as a cement restrictor in specified musculoskeletal applications
  - 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
  - the use of our MacroPore TS Surgi-Wrap™ product line in craniomaxillofacial applications
  - 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

We are also developing additional products for use in spinal fusion procedures, soft tissue repair, anti-adhesion products, neurosurgery plating, 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 \$4,537,000 for the six months ended June 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 June 30, 2002, we had an accumulated deficit of \$31,636,000. 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 six months ended June 30, 2002, revenues of \$3,350,000 or 87.8% came from sales of our bioresorbable implant products for use in musculoskeletal and craniomaxillofacial applications, revenues of \$167,000 or 4.4% came from sales of instruments and accessories used by surgeons to form, mold and manipulate our bioresorbable products during surgical procedures, and \$300,000 or 7.8% of our revenues came from a license agreement and a special project with Medtronic. The musculoskeletal and craniomaxillofacial revenues for the six months ended June 30, 2002 were \$2,217,000 and \$1,133,000, respectively.

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## Results of Operations

### *Three months ended June 30, 2002 compared to three months ended June 30, 2001*

**Revenues.** For the three months ended June 30, 2002, revenues were \$2,707,000 compared to \$768,000 for the three months ended June 30, 2001, an increase of \$1,939,000, or 252.5%. The increase in revenues in the three months ended June 30, 2002 was attributable to a \$1,977,000 increase in sales of bioresorbable implant products for use in musculoskeletal applications of which \$1,544,000 related to an initial inventory purchase. The revenue increase was partially offset by a \$38,000 decrease in craniomaxillofacial revenues. Revenues attributable to Medtronic, which owns approximately 6.6% of our outstanding common stock, represented 99.7% of our revenues for the three months ended June 30, 2002, compared to 98.2% for the three months ended June 30, 2001.

**Cost of revenues.** For the three months ended June 30, 2002, cost of revenues was \$981,000 or 36.2% of revenues, compared to \$255,000 or 33.2% of revenues for the three months ended June 30, 2001. Cost of revenues includes material, manufacturing labor and overhead costs. The increase in cost as a percentage of revenues was primarily attributable to increased labor cost and our inability to absorb some of our fixed manufacturing overhead costs due to excess capacity.

**Inventory provision.** For the three months ended June 30, 2001, the Company recorded an inventory provision of \$1,228,000 or 159.9% of revenues, for which there was no comparable charge in the three months ending June 30, 2002. The inventory provision was a result of identified excess and obsolete craniofacial skeleton implant and instrument products inventory.



*Gross profit (loss).* For the three months ended June 30, 2002, gross profit was \$1,726,000 or 63.8% of revenues, compared to \$(715,000) or (93.1)% of revenues for the three months ended June 30, 2001. Excluding the inventory provision, the gross profit would have been \$513,000 or 66.8% of revenues in the three months ended June 30, 2001. The decrease in gross profit, excluding the inventory provision, as a percentage of revenues was primarily attributable to increased labor cost and the inability to absorb fixed manufacturing overhead costs, as discussed above.

*Research and development expenses.* For the three months ended June 30, 2002, research and development expenses excluding related stock based compensation expenses were \$1,388,000, compared to \$1,512,000 for the three months ended June 30, 2001, a decrease of \$124,000, or 8.2%. Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and clinical trials. The decrease in research and development expenses in the three months ended June 30, 2002 was primarily attributable to lower personnel costs of \$122,000, which was associated with the completion of research relating to new product lines in the fourth quarter of 2001. In addition, stock based compensation expense related to research and development was \$25,000 for the three months ended June 30, 2002, compared to \$30,000 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 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 June 30, 2002, sales and marketing expenses excluding related stock based compensation expenses were \$1,026,000, compared to \$1,367,000 for the three months ended June 30, 2001, a decrease of \$341,000, or 24.9%. 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 June 30, 2002 was primarily attributable to a \$221,000 decrease in labor and associated costs relating to our sales force and other cost reductions of \$120,000 related to tradeshow expenses, promotional activities and materials expenses for the promotion of product lines. In addition, stock based compensation expense

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related to sales and marketing was \$34,000 for the three months ended June 30, 2002 and \$62,000 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 bioresorbable products.

*General and administrative expenses.* For the three months ended June 30, 2002, general and administrative expenses excluding related stock based compensation expenses were \$855,000, compared to \$977,000 for the three months ended June 30, 2001, a decrease of \$122,000, or 12.5%. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The decrease in general and administrative expenses in the three months ended June 30, 2002 of \$122,000 was primarily attributable to lower labor, accounting and legal expenses. In addition, stock based compensation related to general and administrative expenses was \$216,000 for the three months ended June 30, 2002, compared to \$278,000 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 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 June 30, 2002, non-cash stock based compensation expenses were \$275,000, compared to \$370,000 for the three months ended June 30, 2001, a decrease of \$95,000, or 25.7%. 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 is related to 2001 accelerated vesting and modification to compensatory stock options granted to employees and consultants. The decrease of \$5,000 in research and development stock based compensation expense related to normal amortization of the unearned compensation over the vesting period. The decrease of \$28,000 in sales and marketing stock based compensation expense resulted from the rehiring of certain members of our sales force during the three months ended June 30, 2001. These employees held stock options that continued to vest during the termination period and these options were remeasured as of the rehire date and additional compensation expense was recorded in the three months ended June 30, 2001. The decrease of \$62,000 in general and administrative stock based compensation expense was primarily due to additional expenses recorded in the three months ended June 30, 2001 as a result of accelerating vesting of certain stock options to a consultant.

*Interest income.* For the three months ended June 30, 2002, interest income was \$263,000, compared to \$622,000 for the three months ended June 30, 2001, a decrease of \$359,000, or 57.7%. The decrease in interest income resulted from lower interest rates and a decrease in the funds we had available for investments.

*Interest and other (expenses).* For the three months ended June 30, 2002, interest and other expenses were \$9,000, compared to \$(6,000) for the three months ended June 30, 2001. The decrease in interest and other (expense) related to the additional interest expense on our long-term debt obligations being offset by foreign currency gains.

*Equity loss in investment.* For the three months ended June 30, 2002, our equity loss in investment was \$57,000, compared to \$17,000 for the three months ended June 30, 2001. We account for our investment in StemSource, Inc., which we purchased in May 2001, under the equity method of accounting.

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### **Six months ended June 30, 2002 compared to six months ended June 30, 2001**

*Revenues.* For the six months ended June 30, 2002, revenues were \$3,817,000 compared to \$2,797,000 for the six months ended June 30, 2001, an increase of \$1,020,000, or 36.5%. The increase in revenues in the six months ended June 30, 2002 was attributable to a \$1,945,000 increase in sales of bioresorbable implant products for use in musculoskeletal applications of which \$1,544,000 related to an initial inventory purchase. The revenue increase was partially offset by a \$925,000 decrease in craniomaxillofacial revenues which related of a decrease in replenishment product orders from Medtronic. Revenues attributable to Medtronic represented 99.5% of our revenues for the six months ended June 30, 2002, compared to 98.4% for the six months ended June 30, 2001.

*Cost of revenues.* For the six months ended June 30, 2002, cost of revenues was \$1,531,000 or 40.1% of revenues, compared to \$925,000 or 33.1% of revenues for the six months ended June 30, 2001. Cost of revenues includes material, manufacturing labor and overhead costs. The increase in cost as a percentage of revenues was primarily attributable to increased labor cost and our inability to absorb some of our fixed manufacturing overhead costs due to excess capacity.

*Inventory provision.* For the six months ended June 30, 2001, the Company recorded an inventory provision of \$1,228,000 or 43.9% of revenues, for which there was no comparable charge in the six months ending June 30, 2002. The inventory provision was a result of identified excess and obsolete craniofacial skeleton implant and instrument products inventory.

*Gross profit (loss).* For the six months ended June 30, 2002, gross profit was \$2,286,000 or 59.9% of revenues, compared to \$644,000 or 23.0% of revenues for the six months ended June 30, 2001. Excluding the inventory provision, the gross profit would have been \$1,872,000 or 66.9% of revenues for the six months ended June 30, 2001. The decrease in gross profit, excluding the inventory provision, as a percentage of revenues was attributable to increased labor cost and the inability to absorb fixed manufacturing overhead costs, as discussed above.

*Research and development expenses.* For the six months ended June 30, 2002, research and development expenses excluding related stock based compensation expenses were \$2,873,000, compared to \$2,696,000 for the six months ended June 30, 2001, an increase of \$177,000, or 6.6%. Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies and clinical trials. The increase in research and development expenses in the six months ended June 30, 2002 was primarily attributable to non-personnel costs of \$177,000 associated with our research into the development of new product lines. In addition, stock based compensation expense related to research and development was \$160,000 for the six months ended June 30, 2002, compared to \$60,000 for the six 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."

*Sales and marketing expenses.* For the six months ended June 30, 2002, sales and marketing expenses excluding related stock based compensation expenses were \$1,697,000, compared to \$2,379,000 for the six months ended June 30, 2001, a decrease of \$682,000, or 28.7%. 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 six months ended June 30, 2002 was primarily attributable to a \$357,000 decrease in labor and associated costs relating to our sales force and other cost reductions of \$325,000 related to tradeshow expenses, promotional activities and materials expenses for the promotion of product lines. In addition, stock based compensation expense related to sales and marketing was \$67,000 for the six months ended June 30, 2002 and \$10,000 for the six 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."

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*General and administrative expenses.* For the six months ended June 30, 2002, general and administrative expenses excluding related stock based compensation expenses were \$1,968,000, compared to \$1,904,000 for the six months ended June 30, 2001, an increase \$64,000, or 3.4%. 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 six months ended June 30, 2002 was primarily attributable to a retirement package we extended to our former president and partially offset by a reduction in professional and general corporate expenditures. In addition, stock based compensation related to general and administrative expenses was \$517,000 for the six months ended June 30, 2002, compared to \$438,000 for the six 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."

*Stock based compensation expenses.* For the six months ended June 30, 2002, total non-cash stock based compensation expenses were \$744,000, compared to \$508,000 for the six months ended June 30, 2001, an increase of \$236,000, or 46.5%. 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 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 six months ended June 30, 2002. The increase of \$100,000 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 six months ended June 30, 2002. The increase of \$57,000 in sales and marketing stock based compensation expense was due primarily to a reduction in accrued compensation costs recorded in the six months ended June 30, 2001 as a result of the forfeiture and cancellation of some stock options that had been granted to members of our sales force upon the termination of their employment. The increase of \$79,000 in general and administrative stock based compensation expense was primarily due to additional expense recorded in the six months ended June 30, 2002 as a result of accelerating vesting and modifying the exercise period of certain stock options held by our former president.

*Interest income.* For the six months ended June 30, 2002, interest income was \$637,000, compared to \$1,340,000 for the six months ended June 30, 2001, a decrease of \$703,000, or 52.5%. The decrease in interest income resulted from lower interest rates and a decrease in the funds we had available for investments.

*Interest and other expenses.* For the six months ended June 30, 2002, interest and other expenses were \$65,000, compared to \$36,000 for the six months ended June 30, 2001. The increase in interest and other expense related to the additional interest expense on our long-term obligations.

*Equity loss in investment.* For the six months ended June 30, 2002, our equity loss in investment was \$113,000, compared to \$17,000 for the six months ended June 30, 2001. We account for our investment in StemSource, Inc., which we purchased in May 2001, under the equity method of accounting.

## **Liquidity and Capital Resources**

As of June 30, 2002, we had cash and cash equivalents, and short-term investments, available-for-sale, of \$24,977,000 and working capital of \$27,583,000. 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.

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, unless we begin to generate sufficient revenues from our operations to cover our operating costs, we may need to seek additional sources of financing in the future. We cannot assure you that we will generate sufficient revenues to cover our 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 \$4,508,000 for the six months ended June 30, 2002, compared to \$4,620,000 for the six months ended June 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 six months ended June 30, 2002, net cash used in operating activities primarily related to our net loss of \$4,537,000 and an increase in accounts receivable and inventory, offset by non-cash charges for stock based compensation, and depreciation and amortization. In the six months ended June 30, 2001, net cash used in operating activities resulted primarily from our net loss of \$5,556,000 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 \$8,312,000 for the six months ended June 30, 2002, compared to \$163,000 used in investing activities for the six months ended June 30, 2001. Net cash provided by investing activities for the six months ended June 30, 2002, consisted of net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments, plus capital expenditures and our \$478,000 loan to two executive to enable them to buy outstanding Company stock which we classified as long-term notes receivable, related party. Net cash used in investing activities for the six months ended June 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 an equity investment in StemSource.

Net cash used in financing activities was \$3,055,000 for the six months ended June 30, 2002, compared to \$32,000 provided by financing activities for the six months ended June 30, 2001. Net cash used in financing activities for the six months ended June 30, 2002, was primarily related to our repurchase of 836,945 shares of our common stock on the open market, and principal payments on capital lease and our long-term note obligations. Net cash provided by financing activities for the six months ended June 30, 2001, was primarily attributable to the sale of common stock upon the exercise of stock options which was offset by the principal payments on capital leases.

Our revenues, operating results and cash flow are affected by product pricing, fixed cost of sales and fluctuations in variable cost of sales, sales volumes and operating expenses. In January 2000, we

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entered into an exclusive distribution agreement with Medtronic for the marketing, distribution and sale of our bioresorbable products for use in the craniofacial skeleton. We also entered into an agreement to co-develop bioresorbable implants for use in spinal fixation, stabilization and fusion applications with Medtronic and supply any such new implants to Medtronic as the distributor. Under the terms of these agreements, we sell our products to Medtronic at fixed prices that are subject to adjustment upon biannual reviews of Medtronic's sales price to its customers. Although the distribution agreement provides that direct selling costs are borne by the distributor, our cash flow may be adversely affected if our fixed costs increase and we are unable to negotiate or otherwise obtain an increase in product pricing with Medtronic.

We 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 \$13,000. 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 \$62,000. We have an additional \$1,400,000 of credit, at an interest rate of 9.3%, available to us through September 2002 under an equipment financing master security agreement.

As of June 30, 2002, we had property and equipment of \$7,875,000, less accumulated depreciation of \$2,666,000 to support our clinical, research, development, manufacturing and administrative activities. Our capital expenditures were \$761,000 for the six months ended June 30, 2002 and \$2,145,000 for the six months ended June 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. We intend to pay for future capital expenditures with available working capital and by using credit available under our equipment financing master security agreement.

In May 2001, we invested \$1,000,000 in cash in exchange for shares of Series A preferred stock of StemSource Inc., representing a 13.4% ownership interest. StemSource was formed in January 2001 to engage in biomedical research. Under our investor rights agreement with StemSource, we have the right to appoint a representative as a member of StemSource's board of directors. We are not obligated to provide StemSource with any additional funding. On July 12, 2002, we loaned \$1,000,000 to StemSource, Inc. in exchange for a convertible promissory note and a warrant to purchase 100,000 shares of StemSource, Inc. common stock. The convertible promissory note has an annual interest rate of 8% and matures on October 31, 2002. The convertible promissory 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 two million dollars. From time to time, we may enter into collaborative arrangements with, and acquire ownership interest in, other companies for the purpose of engaging in joint research and development activities.

### **Unearned Compensation**

We record unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair market value of our common stock on the date of grant. Unearned compensation is amortized to stock based compensation expense and reflected as such in the Statement of Operations and Comprehensive Income. Unearned compensation recorded through June 30, 2002 was \$6,669,000 with an accumulated amortization, net of

charges reversed during the period for the forfeiture of unvested awards, of \$5,103,000. The remaining \$1,566,000 as of June 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 \$504,000 for the period July 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 subsequently forfeited.

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### 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.

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 Statement No. 145, Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. Statement 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. Statement 145 is effective for fiscal years beginning after May 15, 2002, with early adoption of the provisions related to the rescission of Statement No. 4 encouraged. The Company does not expect this standard to have a material effect on the financial statements.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS No. 146"). SFAS No. 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including

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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. Given that SFAS No. 146 was issued in June 2002 and is not yet effective, the impact on the Company's financial position or results of operations from adopting SFAS No. 146 has not been determined.

### 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 considered 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 99.5% of our revenues in the six months ended June 30, 2002 and 100% of our accounts receivable at June 30, 2002 and 2001. We believe that our allowance for doubtful accounts as of June 30, 2002 with respect to Medtronic's account, even though small, is sufficient, given Medtronic's 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 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 inventory 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.

*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 like 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.

### **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 \$21,528,000 as of June 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 June 30, 2002, for example, and assuming an average investment duration of ten months, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. We believe that we currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows.

#### **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 six months ended June 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.

## **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**

We held our annual meeting of stockholders on May 28, 2002. Of the 14,593,973 shares of our common stock which could be voted at the annual meeting, 7,826,222 shares of our common stock were represented at the annual meeting in person or by proxy, which constituted a quorum. Voting results were as follows:

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

	For	Withheld
Marshall G. Cox	7,686,590	139,632
Christopher J. Calhoun	7,765,718	60,504
Michael Simpson	6,849,498	976,724
Ari Bisimis	7,715,879	110,343
David Rickey	7,761,665	64,557
Edmund Krix*	6,560,987	1,265,235

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

- b. Approval of an amendment to our Amended and Restated 1997 Stock Option and Stock Purchase Plan to increase the number of shares of common stock available for issuance there under to 7,000,000:

For	Against	Abstain	Broker Non-Votes
5,950,155	1,461,322	414,745	0

- c. Approval of an amendment to our certificate of incorporation to change our name to MacroPore Biosurgery, Inc.:

For	Against	Abstain	Broker Non-Votes
7,784,184	27,415	14,623	0

**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 June 30, 2002, we had 95 full-time employees, comprised of 24 employees in research and development, 27 employees in manufacturing, 17 employees in management and finance and administration, and 27 employees in marketing. As of June 30, 2001, we had 87 full-time employees, comprised of 27 employees in research and development, 23 employees in manufacturing, 17 employees in management and finance and administration

and 20 employees in 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
  - 3.1 Amended and Restated Certificate of Incorporation filed June 18, 2002
  - 10.1 Amended and Restated 1997 Stock Option and Stock Purchase Plan as amended
  - 15.1 Letter re unaudited interim financial information
  - 99.1 Risk Factors
  - 99.2 Certification under Section 906 of the Sarbanes-Oxley Act of 2002
- b. Reports on Form 8-K—Form 8-K filed on May 15, 2002 with respect to an event of May 15, 2002—press release announcing the Company's financial results for the three months ended March 31, 2002.
- c. Form 8-K filed on May 24, 2002 with respect to an event of May 20, 2002—the termination of the engagement of Arthur Andersen LLP as the Company's auditors.
- d. Form 8-K filed on June 18, 2002 with respect to an event of June 14, 2002—the appointment of KPMG LLP as the Company's auditors.

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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 August 12, 2002.

### MACROPORE BIOSURGERY, INC.

By: /s/ CHRISTOPHER J. CALHOUN

\_\_\_\_\_  
Christopher J. Calhoun  
*Vice-Chairman, Chief Executive Officer, President*

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## EXHIBIT INDEX

- 3.1 Amended and Restated Certificate of Incorporation filed June 18, 2002
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**AMENDED AND RESTATED  
CERTIFICATE OF INCORPORATION OF  
MACROPORE, INC.**

MACROPORE, INC. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware,

DOES HEREBY CERTIFY:

FIRST: That the original name of this corporation is MacroPore, Inc., the original Certificate of Incorporation (the "Original Certificate") was filed under the Corporation's current name, and that the date of filing the Original Certificate with the Secretary of State of the State of Delaware is May 16, 1997.

SECOND: That in accordance with Sections 228, 242 and 245 of the Delaware General Corporation Law, the Board of Directors and the holders of the outstanding capital stock of the Corporation adopted, approved and filed with the Secretary of State for the State of Delaware an Amended and Restated Certificate of Incorporation (the "First Amended Certificate") on September 30, 1997, that amended and restated the Original Certificate.

THIRD: That in accordance with Sections 228, 242 and 245 of the Delaware General Corporation Law, the Board of Directors and the holders of the outstanding capital stock of the Corporation adopted, approved and filed with the Secretary of State for the State of Delaware an Amended and Restated Certificate of Incorporation (the "Second Amended Certificate") on October 26, 1998, that amended and restated the First Amended Certificate.

FOURTH: That in accordance with Sections 228, 242 and 245 of the Delaware General Corporation Law, the Board of Directors and the holders of the outstanding capital stock of the Corporation adopted, approved and filed with the Secretary of State for the State of Delaware an Amended and Restated Certificate of Incorporation (the "Third Amended Certificate") on June 14, 1999, that amended and restated the Second Amended Certificate.

FIFTH: That in accordance with Sections 228, 242 and 245 of the Delaware General Corporation Law, the Board of Directors and the holders of the outstanding capital stock of the Corporation adopted, approved and filed with the Secretary of State for the State of Delaware an Amended and Restated Certificate of Incorporation (the "Fourth Amended Certificate") on November 15, 1999, that amended and restated the Third Amended Certificate.

SIXTH: That in accordance with Sections 228 and 242 of the Delaware General Corporation Law, the Board of Directors and the holders of the outstanding capital stock of the Corporation adopted, approved and filed with the Secretary of State for the State of Delaware a Certificate of Amendment to the Fourth Amended Certificate (the "Fifth Amended Certificate") on January 11, 2000 that amended the Fourth Amended Certificate.

SEVENTH: That in accordance with Sections 228, 242 and 245 of the Delaware General Corporation Law, the Board of Directors and the holders of the outstanding capital stock of the Corporation adopted, approved and filed with the Secretary of State for the State of Delaware an Amended and Restated Certificate of Incorporation (the "Sixth Amended Certificate") on August 4, 2000, that amended and restated the Fifth Amended Certificate.

EIGHT: That this Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate") amends and restates the Sixth Amended Certificate. This Amended and Restated Certificate was duly adopted by the directors and stockholders of the Company in accordance with the applicable provisions of Sections 242 and 245 of the Delaware General Corporation Law.

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NINTH: That the Amended and Restated Certificate is hereby amended and restated in its entirety to read as follows:

ARTICLE I

The name of the corporation is MacroPore Biosurgery, Inc. (the "Corporation").

ARTICLE II

The address of the registered office of the Corporation in the State of Delaware is:

CorpAmerica, Inc.  
30 Old Rudnick Lane  
Dover, DE  
County of Kent

The name of the Corporation's registered agent at said address is CorpAmerica, Inc.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware (the "Delaware General Corporation Law").

ARTICLE IV

A. This Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Corporation is authorized to issue is One Hundred Million (100,000,000) shares, Ninety Five Million (95,000,000) shares of which shall be Common Stock (the "Common Stock") and Five Million (5,000,000) shares of which shall be Preferred Stock (the "Preferred Stock"). The Common Stock and the Preferred Stock shall each have a par value of \$0.001 per share.

B. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares of Common Stock then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation.

C. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, within the limitations and restrictions stated in this Amended and Restated Certificate of Incorporation, to fix or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price or prices, the liquidation preferences of any wholly unissued series of Preferred Stock, and the number of shares constituting any such series and the designation thereof, or any of them; and to increase or decrease the number of shares of any series subsequent to the issue of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be so decreased, the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

#### ARTICLE V

The Board of Directors may from time to time make, amend, supplement or repeal the Bylaws; provided, however, that the stockholders may change or repeal any Bylaw adopted by the Board of Directors by the affirmative vote of the holders of a majority of the voting power of all of the then outstanding shares of the capital stock of the Corporation; and, provided further, that no amendment or supplement to the Bylaws adopted by the Board of Directors shall vary or conflict with any amendment or supplement thus adopted by the stockholders.

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#### ARTICLE VI

The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

#### ARTICLE VII

To the fullest extent permitted by the Delaware General Corporation Law, as the same exists or as may hereafter be amended, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director.

The Corporation shall indemnify to the fullest extent permitted by law, any person made or threatened to be made a party to an action or proceeding, whether criminal, civil, administrative or investigative, by reason of the fact that he, his testator or intestate is or was a director, officer or employee of the Corporation or any predecessor of the Corporation, or serves or served at any other enterprise as a director, officer or employee at the request of the Corporation or any predecessor to the Corporation.

Neither any amendment or repeal of this Article VII, nor the adoption of any provision of this Corporation's Certificate of Incorporation inconsistent with this Article VII, shall eliminate or reduce the effect of this Article VII in respect of any matter occurring, or any action or proceeding arising, or that, but for this Article VII, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

#### ARTICLE VIII

The Corporation is to have perpetual existence.

#### ARTICLE IX

The number of directors which shall constitute the whole Board of Directors shall be fixed by the Board of Directors in the manner provided in the Bylaws.

#### ARTICLE X

Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept (subject to any statutory provisions) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors in the Bylaws of the Corporation.

IN WITNESS WHEREOF, the Corporation has caused this Amended and Restated Certificate of Incorporation to be signed by the President of the Corporation on June 12, 2002.

MACROPORE, INC.

By: /s/ CHRISTOPHER J. CALHOUN

Name: Christopher J. Calhoun  
Title: Vice Chairman, President and Chief Executive Officer

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[MACROPORE, INC. AMENDED AND RESTATED 1997 STOCK OPTION AND STOCK PURCHASE PLAN \(Effective as of January 24, 2002\)](#)

EXHIBIT 10.1

**MACROPORE, INC.**  
**AMENDED AND RESTATED**  
**1997 STOCK OPTION AND STOCK PURCHASE PLAN**  
**(Initially Adopted as of October 22, 1997)**  
**(Effective as of January 24, 2002)**

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**MACROPORE, INC.**  
**AMENDED AND RESTATED**  
**1997 STOCK OPTION AND STOCK PURCHASE PLAN**  
**(Effective as of January 24, 2002)**

**SECTION 1. PURPOSE.**

The purpose of the Plan is to offer selected employees, directors and consultants an opportunity to acquire a proprietary interest in the success of the Company, or to increase such interest, to encourage such selected persons to remain in the employ of the Company and to attract new employees with outstanding qualifications. The Plan provides for the direct award or sale of Shares and for the grant of Options to purchase Shares. Options granted under the Plan may include Nonstatutory Options as well as incentive stock options intended to qualify under section 422 of the Internal Revenue Code.

**SECTION 2. DEFINITIONS.**

(a) *"Board of Directors"* shall mean the Board of Directors of the Company, as constituted from time to time.

(b) *"Change in Control"* means the occurrence of any of the following events:

(i) the consummation of the acquisition of fifty-one percent (51%) or more of the outstanding Stock of the Company by one person or by two or more persons acting as a partnership, limited partnership, syndicate or other group pursuant to a tender offer validly made under any federal or state law (other than a tender offer by the Company);

(ii) the consummation of a merger, consolidation or other reorganization of the Company (other than a reincorporation of the Company), if after giving effect to such merger, consolidation or other reorganization of the Company, the stockholders of the Company immediately prior to such merger, consolidation or other reorganization do not represent a majority in interest of the holders of voting securities (on a fully diluted basis) with the ordinary voting power to elect directors of the surviving or resulting entity after such merger, consolidation or other reorganization;

(iii) the sale of all or substantially all of the assets of the Company to a third party who is not an affiliate (including a Parent or Subsidiary) of the Company;

(iv) the dissolution of the Company pursuant to action validly taken by the stockholders of the Company in accordance with applicable state law; or

(v) the occurrence of any other tender offer, merger, consolidation, sale, reorganization, dissolution or other such event or series of events, which in the opinion of a majority of the Board (as reflected in a written resolution of the Board) has resulted in a change of control of the Company.

(c) *"Code"* shall mean the Internal Revenue Code of 1986, as amended.

(d) *"Committee"* shall mean a committee consisting of members of the Board of Directors that is appointed by the Board of Directors. If no Committee has been appointed, the entire Board of Directors shall constitute the Committee. At such time as the officers and directors of the Company become reporting persons with respect to the Securities Exchange Act of 1934, the Committee shall have membership composition which enables the Plan to qualify under Rule 16b-3 with regard to the grant of Options or other rights to acquire Shares to persons who are subject to Section 16 of the Securities Exchange Act of 1934.

(e) *"Company"* shall mean Macropore, Inc., a Delaware corporation.

(f) *"Disability"* shall mean that an Optionee is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment.

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(g) *"Employee"* shall mean (i) any individual who is a common-law employee of the Company or of a Subsidiary, (ii) a member of the Board of Directors, or (iii) a consultant who performs services for the Company or a Subsidiary. Service as a member of the Board of Directors or as a consultant shall be considered employment for all purposes under the Plan except the second sentence of Section 4(a).

(h) *"Exercise Price"* shall mean the amount for which one Share may be purchased upon exercise of an Option, as specified by the Committee in the applicable Stock Option Agreement.

(i) *"Fair Market Value"* shall mean the fair market value of a Share, as determined by the Committee in good faith. Such determination shall be conclusive and binding on all persons.

(j) *"ISO"* shall mean an employee incentive stock option described in Code section 422(b).

(k) *"Nonstatutory Option"* shall mean an employee stock option that is not an ISO.

(l) *"Offeree"* shall mean an individual to whom the Committee has offered the right to acquire Shares (other than upon exercise of an Option).

(m) *"Option"* shall mean an ISO or Nonstatutory Option granted under the Plan and entitling the holder to purchase Shares.

(n) *"Optionee"* shall mean an individual who holds an Option.

(o) *"Plan"* shall mean this Macropore, Inc. 1997 Stock Option and Stock Purchase Plan.

(p) *"Purchase Price"* shall mean the consideration for which one Share may be acquired under the Plan (other than upon exercise of an Option), as specified by the Committee.

(q) *"Service"* shall mean service as an Employee.

(r) *"Share"* shall mean one share of Stock, as adjusted in accordance with Section 9 (if applicable).

(s) *"Stock"* shall mean the common stock of the Company.

(t) *"Stock Option Agreement"* shall mean the agreement between the Company and an Optionee which contains the terms, conditions and restrictions pertaining to his or her Option.

(u) *"Stock Purchase Agreement"* shall mean the agreement between the Company and an Offeree who acquires Shares under the Plan which contains the terms, conditions and restrictions pertaining to the acquisition of such Shares.

(v) *"Subsidiary"* shall mean any corporation, of which the Company and/or one or more other Subsidiaries own not less than 50 percent of the total combined voting power of all classes of outstanding stock of such corporation. A corporation that attains the status of a Subsidiary on a date after the adoption of the Plan shall be considered a Subsidiary commencing as of such date.

### SECTION 3. ADMINISTRATION.

(a) *Committee Membership.* The Plan shall be administered by the Committee, which shall consist of members of the Board of Directors. The members of the Committee shall be appointed by the Board of Directors.

(b) *Committee Procedures.* The Board of Directors shall designate one of the members of the Committee as chairperson. The Committee may hold meetings at such times and places as it shall determine. The acts of a majority of the Committee members present at meetings at which a quorum exists, or acts reduced to or approved in writing by all Committee members, shall be valid acts of the Committee.

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(c) *Committee Responsibilities.* Subject to the provisions of the Plan, the Committee shall have full authority and discretion to take the following actions:

(i) To interpret the Plan and to apply its provisions;

(ii) To adopt, amend or rescind rules, procedures and forms relating to the Plan;

(iii) To authorize any person to execute, on behalf of the Company, any instrument required to carry out the purposes of the Plan;

(iv) To determine when Shares are to be awarded or offered for sale and when Options are to be granted under the Plan;

(v) To select Offerees and Optionees;

(vi) To determine the number of Shares to be awarded or offered for sale or to be made subject to each Option;

(vii) To prescribe the terms and conditions of each award or sale of Shares, including (without limitation) the Purchase Price and vesting of the award, and to specify the provisions of the Stock Purchase Agreement relating to such award or sale;

(viii) To prescribe the terms and conditions of each Option, including (without limitation) the Exercise Price and vesting of the Option, to determine whether such Option is to be classified as an ISO or as a Nonstatutory Option, and to specify the provisions of the Stock Option Agreement relating to such Option;

(ix) To amend any outstanding Stock Purchase or Stock Option Agreement; provided, however, that the rights and obligations under any Stock Purchase or Stock Option Agreement shall not be materially altered or impaired adversely by any such amendment, except with the consent of the Optionee or Offeree;

(x) To determine the disposition of an Option or other right to acquire Shares in the event of an Optionee's or Offeree's divorce or dissolution of marriage;

(xi) To correct any defect, supply any omission, or reconcile any inconsistency in the Plan and any Stock Purchase or Stock Option Agreement; and

(xii) To take any other actions deemed necessary or advisable for the administration of the Plan.

All decisions, interpretations and other actions of the Committee shall be final and binding on all Offerees, Optionees, and all persons deriving their rights from an Offeree or Optionee. No member of the Committee shall be liable for any action that he or she has taken or has failed to take in good faith with respect to the Plan, any Option or any other right to acquire Shares under the Plan.

(d) *Financial Reports.* To the extent required by applicable law, and not less often than annually, the Company shall furnish to Optionees and Offerees Company summary financial information including a balance sheet regarding the Company's financial condition and results of operations, unless such Optionees or Offerees have duties with the Company that assure them access to equivalent information. Such financial statements need not be audited.

#### **SECTION 4. ELIGIBILITY.**

(a) *General Rule.* Only Employees shall be eligible for designation as Optionees or Offerees by the Committee. In addition, only individuals who are employed as common-law employees by the Company or a Subsidiary shall be eligible for the grant of ISOs.

(b) *Ten-Percent Shareholders.* An Employee who owns more than 10 percent of the total combined voting power of all classes of outstanding stock of the Company or any of its Subsidiaries shall not be eligible for designation as an Optionee or Offeree unless (i) the Exercise Price for an ISO

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(and, to the extent required by applicable law, the Exercise Price for a Nonstatutory Option and Purchase Price for a sale of Shares) is at least 110 percent of the Fair Market Value of a Share on the date of grant, and (ii) in the case of an ISO, such ISO by its terms is not exercisable after the expiration of five years from the date of grant.

(c) *Attribution Rules.* For purposes of Subsection (b) above, in determining stock ownership, an Employee shall be deemed to own the stock owned, directly or indirectly, by or for his brothers, sisters, spouse, ancestors and lineal descendants. Stock owned, directly or indirectly, by or for a corporation, partnership, estate or trust shall be deemed to be owned proportionately by or for its shareholders, partners or beneficiaries.

(d) *Outstanding Stock.* For purposes of Subsection (b) above, "outstanding stock" shall include all stock actually issued and outstanding immediately after the grant. "Outstanding stock" shall not include shares authorized for issuance under outstanding options held by the Employee or by any other person.

#### **SECTION 5. STOCK SUBJECT TO PLAN.**

(a) *Basic Limitation.* Shares offered under the Plan shall be authorized but unissued Shares, or issued Shares that have been reacquired by the Company. The aggregate number of Shares which may be issued under the Plan (upon exercise of Options or other rights to acquire Shares) shall not exceed seven million (7,000,000) Shares, subject to adjustment pursuant to Section 9. The number of Shares which are subject to Options or other rights to acquire Shares outstanding at any time under the Plan shall not exceed the number of Shares which then remain available for issuance under the Plan. During the term of the Plan, the Company shall at all times reserve and keep available sufficient Shares to satisfy the requirements of the Plan.

(b) *Additional Shares.* In the event that any outstanding Option or other right to acquire Shares for any reason expires or is cancelled or otherwise terminated, the Shares allocable to the unexercised portion of such Option or other right shall again be available for the purposes of the Plan.

#### **SECTION 6. TERMS AND CONDITIONS OF AWARDS OR SALES.**

(a) *Stock Purchase Agreement.* Each award or sale of Shares under the Plan (other than upon exercise of an Option) shall be evidenced by a Stock Purchase Agreement between the Offeree and the Company. Such award or sale shall be subject to all applicable terms and conditions of the Plan and may be subject to any other terms and conditions which are not inconsistent with the Plan and which the Committee deems appropriate for inclusion in a Stock Purchase Agreement. The provisions of the various Stock Purchase Agreements entered into under the Plan need not be identical.

(b) *Duration of Offers and Nontransferability of Rights.* Any right to acquire Shares under the Plan (other than an Option) shall automatically expire if not exercised by the Offeree within the number of days specified by the Committee and communicated to the Offeree by the Committee. Such right shall not be transferable and shall be exercisable only by the Offeree to whom such right was granted.

(c) *Purchase Price.* To the extent required by applicable law, the Purchase Price of Shares to be offered under the Plan shall not be less than eighty-five percent (85%) of the Fair Market Value of such Shares, except as otherwise provided in Section 4(b). Subject to the preceding sentence, the Purchase Price shall be determined by the Committee at its sole discretion. The Purchase Price shall be payable in a form described in Section 8.

(d) *Withholding Taxes.* As a condition to the purchase of Shares, the Offeree shall make such arrangements as the Committee may require for the satisfaction of any federal, state or local withholding tax obligations that may arise in connection with such purchase.

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(e) *Restrictions on Transfer of Shares.* No Shares awarded or sold under the Plan may be sold or otherwise transferred or disposed of by the Offeree during the one hundred eighty (180) day period following the effective date of a registration statement covering securities of the Company filed under the Securities Act of 1933. Subject to the preceding sentence, any Shares awarded or sold under the Plan shall be subject to such special conditions, rights of repurchase, rights of first refusal and other transfer restrictions as the Committee may determine. Such restrictions shall be set forth in the applicable Stock Purchase Agreement and shall apply in addition to any general restrictions that may apply to all holders of Shares. To the extent required by applicable law, any service-based vesting conditions shall not be less rapid than the schedule set forth in Section 7(e).

#### **SECTION 7. TERMS AND CONDITIONS OF OPTIONS.**

(a) *Stock Option Agreement.* Each grant of an Option under the Plan shall be evidenced by a Stock Option Agreement between the Optionee and the Company. Such Option shall be subject to all applicable terms and conditions of the Plan and may be subject to any other terms and conditions which are not

inconsistent with the Plan and which the Committee deems appropriate for inclusion in a Stock Option Agreement. The provisions of the various Stock Option Agreements entered into under the Plan need not be identical.

(b) *Number of Shares.* Each Stock Option Agreement shall specify the number of Shares that are subject to the Option and shall provide for the adjustment of such number in accordance with Section 9. The Stock Option Agreement shall also specify whether the Option is an ISO or a Nonstatutory Option.

(c) *Exercise Price.* Each Stock Option Agreement shall specify the Exercise Price. The Exercise Price of an ISO shall not be less than one hundred percent (100%) of the Fair Market Value of a Share on the date of grant, except as otherwise provided in Section 4(b). The Exercise Price of a Nonstatutory Option shall not be less than eighty-five percent (85%) of the Fair Market Value of a Share on the date of grant, except as otherwise provided in Section 4(b). Subject to the preceding two sentences, the Exercise Price under any Option shall be determined by the Committee in its sole discretion. The Exercise Price shall be payable in a form described in Section 8.

(d) *Withholding Taxes.* As a condition to the exercise of an Option, the Optionee shall make such arrangements as the Committee may require for the satisfaction of any federal, state, local or foreign withholding tax obligations that may arise in connection with such exercise. The Optionee shall also make such arrangements as the Committee may require for the satisfaction of any federal, state, local or foreign withholding tax obligations that may arise in connection with the disposition of Shares acquired by exercising an Option.

(e) *Exercisability.* Each Stock Option Agreement shall specify the date when all or any installment of the Option is to become exercisable. To the extent required by applicable law, an Option shall become exercisable no less rapidly than the rate of twenty percent (20%) per year for each of the first five years from the date of grant. Subject to the preceding sentence, the vesting of any Option shall be determined by the Committee in its sole discretion.

(f) *Term.* Stock Option Agreement shall specify the term of the Option. The term shall not exceed ten (10) years from the date of grant, except as otherwise provided in Section 4(b). Subject to the preceding sentence, the Committee at its sole discretion shall determine when an Option is to expire.

(g) *Nontransferability.* No Option shall be transferable by the Optionee other than by will or by the laws of descent and distribution. An Option may be exercised during the lifetime of the Optionee only by him or by his guardian or legal representative. No Option or interest therein may be transferred, assigned, pledged or hypothecated by the Optionee during his lifetime, whether by operation of law or otherwise, or be made subject to execution, attachment or similar process.

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(h) *Exercise of Options on Termination of Service.* Each Stock Option Agreement shall set forth the extent to which the Optionee shall have the right to exercise the Option following termination of the Optionee's service with the Company and its Subsidiaries. Such provisions shall be determined in the sole discretion of the Committee, need not be uniform among all Options issued pursuant to the Plan, and may reflect distinctions based on the reasons for termination of employment. Notwithstanding the foregoing, to the extent required by applicable law, each Option shall provide that the Optionee shall have the right to exercise the vested portion of any Option held at termination for at least 30 days following termination of service with the Company for any reason, and that the Optionee shall have the right to exercise the Option for at least six months if the Optionee's service terminates due to death or Disability.

(i) *No Rights as a Shareholder.* An Optionee, or a transferee of an Optionee, shall have no rights as a shareholder with respect to any Shares covered by an Option until the date of the issuance of a stock certificate for such Shares.

(j) *Modification, Extension and Assumption of Options.* Within the limitations of the Plan, the Committee may modify, extend or assume outstanding Options or may accept the cancellation of outstanding Options (whether granted by the Company or another issuer) in return for the grant of new Options for the same or a different number of Shares and at the same or a different Exercise Price.

(k) *Restrictions on Transfer of Shares.* No Shares issued upon exercise of an Option may be sold or otherwise transferred or disposed of by the Optionee during the one hundred eighty (180) day period following the effective date of a registration statement covering securities of the Company filed under the Securities Act of 1933. Subject to the preceding sentence, any Shares issued upon exercise of an Option shall be subject to such rights of repurchase, rights of first refusal and other transfer restrictions as the Committee may determine. Such restrictions shall be set forth in the applicable Stock Option Agreement and shall apply in addition to any restrictions that may apply to holders of Shares generally.

## **SECTION 8. PAYMENT FOR SHARES.**

(a) *General Rule.* The entire Exercise Price of Shares issued under the Plan shall be payable in lawful money of the United States of America at the time when such Shares are purchased, except as provided in Subsections (b), (c) and (d) below.

(b) *Surrender of Stock.* To the extent that a Stock Option Agreement so provides, payment may be made all or in part with Shares which have already been owned by the Optionee or the Optionee's representative for any time period specified by the Committee and which are surrendered to the Company in good form for transfer. Such Shares shall be valued at their Fair Market Value on the date when the new Shares are purchased under the Plan.

(c) *Promissory Notes.* To the extent that a Stock Option Agreement so provides, payment may be made all or in part with a full recourse promissory note executed by the Optionee. The interest rate and other terms and conditions of such note shall be determined by the Committee. The Committee may require that the Optionee pledge his or her Shares to the Company for the purpose of securing the payment of such note. In no event shall the stock certificate(s) representing such Shares be released to the Optionee until such note is paid in full.

(d) *Cashless Exercise.* To the extent that a Stock Option Agreement so provides and a public market for the Shares exists, payment may be made all or in part by delivery (on a form prescribed by the Committee) of an irrevocable direction to a securities broker to sell Shares and to deliver all or part of the sale proceeds to the Company in payment of the aggregate Exercise Price.

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## **SECTION 9. ADJUSTMENT OF SHARES.**

(a) *General.* In the event of a subdivision of the outstanding Stock, a declaration of a dividend payable in Shares, a declaration of a dividend payable in a form other than Shares in an amount that has a material effect on the value of Shares, a combination or consolidation of the outstanding Stock into a lesser number of Shares, a recapitalization, a reclassification or a similar occurrence, the Committee shall make appropriate adjustments in one or more of (i) the



number of Shares available for future grants of Options or other rights to acquire Shares under Section 6, (ii) the number of Shares covered by each outstanding Option or other right to acquire Shares or (iii) the Exercise Price of each outstanding Option or the Purchase Price of each other right to acquire Shares,

(b) *Reorganizations.* In the event that the Company is a party to a merger or reorganization, outstanding Options or other rights to acquire Shares shall be subject to the agreement of merger or reorganization.

(c) *Reservation of Rights.* Except as provided in this Section 9, an Optionee or Offeree shall have no rights by reason of (i) any subdivision or consolidation of shares of stock of any class, (ii) the payment of any dividend, or (iii) any other increase or decrease in the number of shares of stock of any class. Any issue by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall not affect, and no adjustment by reason thereof shall be made with respect to, the number or Exercise Price of Shares subject to an Option, or the number or Purchase Price of shares subject to any other right to acquire Shares. The grant of an Option or other right to acquire Shares pursuant to the Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, reorganizations or changes of its capital or business structure, to merge or consolidate or to dissolve, liquidate, sell or transfer all or any part of its business or assets.

## SECTION 10. LEGAL REQUIREMENTS.

Shares shall not be issued under the Plan unless the issuance and delivery of such Shares complies with (or is exempt from) all applicable requirements of law, including (without limitation) the Securities Act of 1933, as amended, the rules and regulations promulgated thereunder, state securities laws and regulations, and the regulations of any stock exchange on which the Company's securities may then be listed, and the Company has obtained the approval or favorable ruling from any governmental agency which the Company determines is necessary or advisable.

## SECTION 11. NO EMPLOYMENT RIGHTS.

No provision of the Plan, nor any Option granted or other right to acquire Shares awarded under the Plan, shall be construed to give any person any right to become, to be treated as, or remain an Employee. The Company and its Subsidiaries reserve the right to terminate any person's Service at any time and for any reason.

## SECTION 12. DURATION AND AMENDMENTS.

(a) *Term of the Plan* The Plan, as set forth herein, shall become effective on the date, of its adoption by the Board of Directors, subject to the approval of the Company's shareholders. In the event that the shareholders fail to approve the Plan within twelve (12) months after its adoption by the Board of Directors, any Option grants or other right to acquire Shares already made shall be null and void, and no additional Option grants or other right to acquire Shares shall be made after such date. The Plan shall terminate automatically ten (10) years after its adoption by the Board of Directors and may be terminated on any earlier date pursuant to Subsection (b) below.

(b) *Right to Amend or Terminate the Plan.* The Board of Directors may amend the Plan at any time and from time to time. Rights and obligations under any Option granted or other right to acquire Shares awarded before amendment of the Plan shall not be materially altered, or impaired adversely, by such amendment, except with consent of the Optionee or Offeree. An amendment of the Plan shall

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be subject to the approval of the Company's shareholders only to the extent required by applicable laws, regulations or rules.

(c) *Effect of Amendment or Termination* No Shares shall be issued or sold under the Plan after the termination thereof, except upon exercise of an Option granted prior to such termination. The termination of the Plan, or any amendment thereof, shall not affect any Share previously issued or Option previously granted under the Plan.

## SECTION 13. EXECUTION

To record the amended and restatement of the Plan by the Board of Directors as of January 24, 2002 the Company has caused its authorized officer to execute the same.

MACROPORE, INC.

By: /s/ CHRISTOPHER J. CALHOUN

Name: Christopher J. Calhoun

Title: Vice-Chairman, Chief Executive Officer, Secretary

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EXHIBIT 15.1

**LETTER RE UNAUDITED INTERIM FINANCIAL INFORMATION**

August 9, 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 August 2, 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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## RISK FACTORS

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

### ***We have a limited operating history, so 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. 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 \$4,537,000 for the first six months of 2002. These losses have resulted primarily from expenses associated with our research and development activities, including preclinical and clinical trials 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.

### ***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 orthopedics, spine, 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.

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

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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 through 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. We cannot guarantee that this sales force 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.

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 price 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.

Medtronic may terminate its agreement to purchase MacroPore FX or MacroPore PS from us should we be unable to provide an adequate supply, and Medtronic may itself then manufacture MacroPore FX or MacroPore PS and only pay us royalties on sales. In addition, although we have given exclusive distribution rights to Medtronic for craniomaxillofacial and spinal implants, Medtronic is free to pursue existing or alternative technologies in preference to our technology in the spine, and any non poly-lactic acid alternatives in craniomaxillofacial.

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.

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

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

***We do not have much manufacturing experience***

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

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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 six months prior notice which may also result in a substantially increased material cost. There can be no assurance that we will be able to obtain adequate increased commercial quantities 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 resorbable sheets 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 and diversion of effort by 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,

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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 resorbable 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 resorbable surgical implants for humans are subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices. 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 postmarket 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.

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### ***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 June 30, 2002, we had \$24,977,000 of cash, cash equivalents and short-term investments; we have always had negative cash flow from operations. Other than our current equipment financing lines of credit, we currently have no commitments for any additional financing, and there can be no guarantee that adequate funds for our operations from any additional 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 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

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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 very liquid***

In the United States, our stock is traded on the OTC Bulletin Board. Investors trading in this market may be disadvantaged in comparison to investors trading in our stock on the Neuer Markt.

### ***We pay no dividends***

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

### ***We must incur expenses to comply with new corporate governance and reporting laws***

The Sarbanes-Oxley Act of 2002 requires public companies to implement a wide variety of financial reporting and corporate governance processes and procedures. Complying with this Act's requirements may strain our management resources and result in cash expenditures which will penalize our quarterly earnings comparisons. The effect on us will be disproportionately large because we are a smaller company and did not previously have some of the newly required processes and procedures in place.

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