

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2001

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, Inc.

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

Delaware

(State or other jurisdiction of incorporation or organization)

330-827-593

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

6740 Top Gun Street San Diego, California

(Address of principal executive offices)

92121

(Zip code)

(858) 458-0900

(Registrant's telephone number, including area code)

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 November 5, 2001, MacroPore, Inc. had 15,101,623 shares of common stock outstanding.

MACROPORE, INC.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Review Report of Independent Public Accountants

To MacroPore, Inc.

We have reviewed the accompanying condensed balance sheet of MacroPore, Inc. (a Delaware corporation) as of September 30, 2001, and the related condensed statements of operations and comprehensive income for the three-month and nine-month periods ended September 30, 2001 and 2000 and the related condensed statements of cash flows for the nine-month periods ended September 30, 2001 and 2000. These 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 generally accepted auditing standards, 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 financial statements referred to above for them to be in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

San Diego, California
November 2, 2001

MACROPORE, INC. CONDENSED BALANCE SHEETS

	September 30, 2001 <u>(Unaudited)</u>	December 31, 2000
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,787,000	\$ 7,476,000
Short-term investments, available for sale	31,054,000	37,008,000
Accounts receivable, related party, net of allowance for bad debts of \$35,000 and \$75,000 in 2001 and 2000, respectively	877,000	693,000
Inventories	2,419,000	2,278,000
Other current assets	1,013,000	882,000
Total current assets	<u>38,150,000</u>	<u>48,337,000</u>
Property and equipment, net	5,333,000	3,691,000
Other assets	1,080,000	241,000
Total assets	<u>\$ 44,563,000</u>	<u>\$ 52,269,000</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,402,000	\$ 1,364,000
Current portion of capital lease obligations	115,000	115,000
Total current liabilities	<u>1,517,000</u>	<u>1,479,000</u>
Deferred revenue, related party	975,000	1,200,000
Capital lease obligations, less current portion	167,000	255,000
Total liabilities	<u>2,659,000</u>	<u>2,934,000</u>
Stockholders' equity:		
Preferred stock; \$0.001 par value; 5,000,000 authorized; -0- shares issued and outstanding in 2001 and 2000	-	-
Common stock; \$0.001 par value; 95,000,000 shares authorized in 2001 and 2000; 15,099,123 and 14,814,346 issued and outstanding in 2001 and 2000, respectively	15,000	15,000
Additional paid-in capital	68,387,000	68,126,000
Unearned compensation	(2,381,000)	(3,094,000)
Accumulated deficit	(24,184,000)	(15,892,000)
Treasury stock; 143,561 and 0 shares in 2001 and 2000, respectively	(384,000)	-
Other accumulated comprehensive income	451,000	180,000
Total stockholders' equity	<u>41,904,000</u>	<u>49,335,000</u>

Total liabilities and stockholders' equity \$ 44,563,000 \$ 52,269,000

See notes to condensed financial statements

MACROPORE, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Revenues:				
Sales to related party	\$ 1,381,000	\$ 1,007,000	\$ 4,134,000	\$ 4,007,000
Sales to distributors and end-users	19,000	107,000	63,000	572,000
	<u>1,400,000</u>	<u>1,114,000</u>	<u>4,197,000</u>	<u>4,579,000</u>
Cost of revenues:				
Cost of revenues (including stock based compensation)	653,000	354,000	1,578,000	1,489,000
Inventory provision	-	-	1,228,000	-
	<u>747,000</u>	<u>760,000</u>	<u>1,391,000</u>	<u>3,090,000</u>
Gross profit				
	747,000	760,000	1,391,000	3,090,000
Operating expenses:				
Research and development, net of stock based compensation expense of \$29,000 and \$1,334,000 for the three month periods ended September 30, 2001 and 2000, respectively; \$89,000 and \$2,206,000 for the nine month periods ended September 30, 2001 and 2000, respectively	1,345,000	717,000	4,041,000	1,700,000
Sales and marketing, net of stock based compensation expense of \$121,000 and (\$7,000) for the three month periods ended September 30, 2001 and 2000, respectively; \$131,000 and \$1,823,000 for the nine month periods ended September 30, 2001 and 2000, respectively	1,412,000	712,000	3,791,000	1,585,000
General and administrative, net of stock based compensation expense of \$185,000 and \$412,000 for the three month periods ended September 30, 2001 and 2000, respectively; \$623,000 and \$1,562,000 for the nine month periods ended September 30, 2001 and 2000, respectively	858,000	647,000	2,762,000	1,832,000
Stock based compensation (excluding cost of revenues stock based compensation)	335,000	1,739,000	843,000	5,591,000
Total operating expenses	<u>3,950,000</u>	<u>3,815,000</u>	<u>11,437,000</u>	<u>10,708,000</u>
Other income (expenses):				
Interest income	511,000	372,000	1,850,000	565,000
Interest and other expense	(20,000)	(291,000)	(55,000)	(338,000)
Equity loss in investment	(24,000)	-	(41,000)	-
Net loss	<u>(2,736,000)</u>	<u>(2,974,000)</u>	<u>(8,292,000)</u>	<u>(7,391,000)</u>
Other comprehensive income:				
Unrealized holding gains arising during period	192,000	-	451,000	-
Comprehensive loss	<u>\$ (2,544,000)</u>	<u>\$ (2,974,000)</u>	<u>\$ (7,841,000)</u>	<u>\$ (7,391,000)</u>
Basic and diluted net loss per share	<u>\$ (0.18)</u>	<u>\$ (.50)</u>	<u>\$ (.55)</u>	<u>\$ (1.23)</u>
Shares used in calculating basic and diluted net loss per share	<u>14,964,926</u>	<u>5,998,000</u>	<u>14,964,926</u>	<u>5,998,000</u>

See notes to condensed financial statements.

MACROPORE, INC.
CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2001	2000
Cash flows from operating activities:		
Net loss	\$ (8,292,000)	\$ (7,391,000)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	838,000	305,000
Inventory provision	1,228,000	-
Stock based compensation	853,000	5,604,000
Equity loss in investment	41,000	-
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable, related party	(184,000)	(213,000)
Inventories	(1,369,000)	(1,112,000)
Other current assets	(131,000)	(868,000)
Other assets	120,000	(293,000)
Accounts payable and accrued expenses	38,000	837,000
Deferred revenue, related party	(225,000)	1,275,000
Net cash used in operating activities	(7,083,000)	(1,856,000)
Cash flows from investing activities:		
Proceeds from the sale and maturity of short-term investments	78,763,000	-
Purchase of short-term investments	(72,538,000)	(31,631,000)
Purchases of property and equipment	(2,480,000)	(1,511,000)
Equity investment	(1,000,000)	-
Net cash provided by (used in) investing activities	2,745,000	(33,142,000)
Cash flows from financing activities:		
Principal payments on capital leases	(88,000)	(78,000)
Proceeds from sale of common stock	121,000	-
Purchase of treasury stock	(384,000)	-
Proceeds from sale of Series D preferred stock, net of issuance costs	-	4,292,000
Proceeds from initial public offering, net of offering cost	-	43,278,000
Net cash (used in) provided by financing activities	(351,000)	47,492,000
Net (decrease) increase in cash and cash equivalents	(4,689,000)	12,494,000
Cash and cash equivalents at beginning of period	7,476,000	2,471,000
Cash and cash equivalents at end of period	\$ 2,787,000	\$ 14,965,000
Supplemental disclosure of cash flow information:		
Cash paid during period for:		
Interest	\$ 39,000	\$ 66,000
Taxes	800	800
Supplemental schedule of noncash investing and financing activities:		
Equipment acquired under capital leases	\$ -	\$ 81,000

See notes to condensed financial statements.

MACROPORE, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2001
(Unaudited)

1. Basis of presentation

The accompanying unaudited financial statements for the three and nine months ended September 30, 2001 and 2000 have been prepared in accordance with generally accepted accounting principles for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for audited financial statements. The condensed balance sheet at December 31, 2000 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles 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, Inc. ("MacroPore" or the "Company") have been included. Operating results for the three and nine months ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. For further information, refer to the financial statements for the year ended December 31, 2000 and footnotes thereto which were included in the Company's registration statement on Form 10, dated March 30, 2001, as amended.

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. Reclassification

Certain amounts reported under interest income and interest and other expense for the periods ended September 30, 2000 have been reclassified to conform to the presentation for the periods ended September 30, 2001.

4. 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.

5. Inventories

Inventories are valued at the lower of average cost (determined on a FIFO basis) or market. Provisions, when necessary, are made to reduce excess and obsolete inventories to their estimated net realizable values (see footnote 11).

The composition of inventory is as follows:

	September 30, 2001	December 31, 2000 (Audited)
Raw materials	\$ 1,048,000	\$ 706,000
Finished goods	1,371,000	1,572,000
	<u>\$ 2,419,000</u>	<u>\$ 2,278,000</u>

6. Revenue Recognition

The Company generally sells its products to hospitals and distributors. Revenue from sales to hospitals is recognized upon delivery of the product. The Company has agreements with its distributors which provide that title and risk of loss pass to the distributor upon shipment of the products. The Company warrants that its products are free from manufacturing defects at the time of shipment to the distributor. Revenue is recognized upon shipment of products to distributors following receipt and acceptance of a distributor's purchase order.

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

7. Stock Based Compensation

The Company measures compensation expense for its employee stock based compensation plans using the intrinsic value method and provides pro forma disclosures of net loss and net loss per share as if fair value methods had been applied in measuring compensation expense. Accordingly, compensation cost for stock awards is measured as the excess, if any, of the deemed market value for financial reporting purposes of the Company's common stock at the date of grant over the amount an employee must pay to acquire the stock. Compensation cost is amortized using the straight-line method over the related vesting periods. Unearned compensation costs for awards that are forfeited are reversed against additional paid-in capital in the period of forfeiture. Earned and previously expensed compensation costs for awards that are forfeited are reversed against stock based compensation expense in the period of forfeiture.

On May 1, 2001, the Company rehired certain members of its sales force who had previously been terminated. These employees held stock options that continued to vest during the termination period. These options were remeasured using the intrinsic value method as of the rehire date, resulting in approximately \$455,000 of additional stock based compensation cost being recorded as unearned compensation in the three month period ended June 30, 2001. This additional stock based compensation cost is being amortized over the remaining vesting periods of the options.

On September 17, 2001, the Company terminated certain members of its sales force and modified the vesting and exercise period of their stock options. These options were remeasured using the intrinsic value method as of the termination date, resulting in approximately \$149,000 of unearned compensation cost being forfeited and reversed against additional paid-in capital, and approximately \$46,000 of unearned compensation cost being accelerated and charged to stock based compensation expense in the three month period ended September 30, 2001.

Stock based awards issued to non-employees are accounted for using a fair value method and are remeasured to estimated fair value at each period end until the earlier of the date that performance by the counterparty is complete or the awards are fully vested.

8. Segment Information

The Company follows the provisions of Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information." The Company believes that all of its material operations are managed under the medical device industry, with similar purpose, production processes, markets, and regulatory requirements, and it currently reports as a single industry segment.

9. Loss Per Share

Basic loss per share is computed by dividing loss 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 loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding if potential common shares had been issued. The dilutive effect of outstanding stock options and unvested common stock

subject to repurchase is reflected in diluted loss per share by application of the treasury stock method. Potentially dilutive securities have been excluded from the computations as their inclusion would be antidilutive.

10. Composition of Certain Financial Statement Captions

Accounts Payable and Accrued Expenses

	September 30, 2001	December 31, 2000 (Audited)
Accounts payable	\$ 170,000	\$ 784,000
Accrued expenses	1,021,000	459,000
Accrued vacation	211,000	121,000
	<u>\$ 1,402,000</u>	<u>\$ 1,364,000</u>

11. Inventory Provision

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 potential excess and obsolete inventory is due to an anticipated reduction in expected future revenues of these products. This provision includes inventory held on-hand as of September 30, 2001.

12. Short-Term Investments

Investments are accounted for in accordance with 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 and reevaluate such designation as of each balance sheet date. As of September 30, 2001, the Company considered all investments as available for use in its current operations, and therefore classified them short-term, available-for-sale investments. Available-for-sale investments are stated at fair value, with unrealized gains and losses, if any, net of tax, reported as a separate component of stockholders' equity. The cost of securities sold is based on the specific identification method.

13. Equity Investment in StemSource

On May 2, 2001, the Company invested \$1,000,000 in cash in exchange for shares of Series A preferred stock of StemSource, Inc. ("StemSource"), a development stage company primarily engaged in biomedical research. StemSource has continued to rely on the Company's cash investment for the continuance of its operations. As the Company may be able to exercise significant influence over the operations of StemSource, the investment is accounted for under the equity method of accounting. Realization of this investment depends on the successful development of products and the future operating results of StemSource.

14. Subsequent Event

In October 2001, the Company entered into a Master Security Agreement to provide financing for equipment purchases. In connection with the agreement, the Company has issued two promissory notes to its lender under the agreement for a total of approximately \$2,434,000. Both notes bear interest at 9.3% per annum. Principal and interest are due in monthly payments of approximately \$55,000 and \$7,000 and mature over 48 and 36 month periods, respectively.

Item 2. Management's Discussion And Analysis Of Financial Condition And Results Of Operations

When used in this report and in other public statements by Macropore, Inc. ("Macropore." or the "Company") and Company officers, the words "may", "will", "expect", "anticipate", "continue", "forecast", "estimate", "project", "intend", and similar expressions are intended to identify forward-looking statements regarding events and financial trends which may affect the Company's future operating results and financial position. Such statements are subject to risks and uncertainties that could cause the Company's actual results and financial position to differ materially. Among these factors are those discussed below and in the Company's financial statements for the year ended December 31, 2000 which were included in the Company's registration statement on Form 10, dated March 30, 2001, as amended, and the Company's periodic reports and other filings. The release of forward-looking statements will not impose an obligation upon the Company to maintain or update these statements in the future. The Company assumes no responsibility to publicly release the results of any revision of forward-looking statements to reflect trends or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

Overview

MacroPore, Inc. was initially formed as a California general partnership on July 1, 1996. On May 16, 1997, the Company was incorporated in the State of Delaware. On August 8, 2000, the Company completed its initial public offering in Germany and listed its common stock for trading on the *Neuer Markt* segment of the Frankfurt Stock Exchange in Frankfurt, Germany.

The Company develops, commercializes and manufactures biodegradable surgical implants to aid in the reconstruction, repair and regeneration of bone. The Company's resorbable products are made from a lactic acid copolymer which is composed of a lactic acid similar to that which occurs naturally in the human body. The lactic acid copolymer used by the Company, while maintaining its strength during the bone healing process, is slowly broken down in the body through hydrolysis into lactic acid molecules and ultimately metabolized into carbon dioxide and water, which are then released from the body through the lungs and the kidneys. The Company believes that its products are easier to use and more cost-effective than products made from alternative materials, such as titanium, among other things, by eliminating the need for a second, later surgery to remove the implant. The Company has received regulatory clearance or approval to market and sell certain of its products in the United States and Europe, and has entered into an exclusive worldwide marketing and distribution agreement with Medtronic, Inc. ("Medtronic") for the global marketing and distribution of some of its products for use in the craniofacial skeleton.

The Company recently received regulatory clearance for the use of its MX System in surgical management of jaw fractures, the use of its LP System in reconstructive surgery to correct pediatric skeletal birth defects and in cranial reconstruction, and for the use of its OS Spine System bone graft containment system in spinal fusion procedures. The Company has also received regulatory clearance for the expanded use of some of its product lines, including MacroPore FX, MacroPore PS and MacroPore NS, in specified craniomaxillofacial procedures. The Company's Shadow CR, a cement restrictor system for use in orthopedic applications is currently in limited release with Medtronic. The Company is continuing to seek patents on its technology and recently received a U.S. patent for the design of its High Torque Resorbable StarBurst Screws, and an additional U.S. patent for the design of its resorbable sheets, both of which are used in many of the Company's products.

The Company is also developing additional products for use in spinal fusion procedures, neurosurgery plating, long-bone repair, healing of non-union fractures and cyst or tumor site removal 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.

The Company incurred a net loss of \$8,292,000 for the nine months ended September 30, 2001 and net losses for the years ended December 31, 2000, 1999 and 1998 of \$8,645,000, \$4,571,000 and \$2,090,000, respectively. As of September 30, 2001, the Company had an accumulated deficit of \$24,184,000. Such losses have resulted to a large extent from expenses associated with developing resorbable implant designs, performing preclinical studies, preparing submissions to the FDA and foreign regulatory agencies, expanding marketing and distribution channels, further developing the Company's manufacturing capabilities, securing intellectual property rights and trademarks and supporting the Company's public status, as traded on the *Neuer Markt*. The Company expects to expend substantial financial resources to expand marketing, training and customer support needed to generate and support higher sales, expand its manufacturing capabilities, regulatory clearances and to develop new products. This investment is likely to result in lower gross margins until production efficiencies are reached.

For the nine months ended September 30, 2001 and 2000, the majority of the Company's revenues came from the sales of its resorbable protective sheets, plates, screws and tacks, which are high revenue dollar and volume items. A smaller percentage of the Company's revenues for the nine months ended September 30, 2001 and 2000 came from accessories used by surgeons to form, mold and manipulate the Company's resorbable products during surgical procedures, which are lower revenue dollar and volume items. The Company expects to continue to realize the majority of its revenues from the sale of its resorbable protective sheets, plates, screws and tacks.

Results of Operations

Three months ended September 30, 2001 compared to three months ended September 30, 2000

Revenues. For the three months ended September 30, 2001, revenues were \$1,400,000 compared to \$1,114,000 for the three months ended September 30, 2000. The increase in revenues was primarily attributable to new product introductions that occurred in the three months ended September 30, 2001. Revenues from Medtronic, the Company's principal distributor which owns approximately 6.7% of the outstanding common stock in the Company, represented approximately 98.6% of the Company's revenues for the three months ended September 30, 2001 compared to 90.4% for the three months ended September 30, 2000, respectively.

Cost of revenues. For the three months ended September 30, 2001, cost of revenues was \$653,000 or 46.6% of revenues, compared to \$354,000 or 31.8% of revenues for the three months ended September 30, 2000. Cost of revenues includes material, manufacturing labor and overhead costs. The increase in cost of revenues for the three months ended September 30, 2001 is primarily attributable to increased costs to support the increased base and the expensing of excess capacity costs. The increase in cost as a percentage of revenues was primarily attributable to an inability to absorb certain fixed manufacturing overhead costs due to revenue volume.

Gross profit. For the three months ended September 30, 2001, gross profit was \$747,000 or 53.4% of revenues, compared to \$760,000 or 68.2% of revenues for the three months ended September 30, 2000. The decrease in gross profit as a percentage of revenues was primarily attributable to an inability to absorb certain fixed manufacturing overhead costs due to revenue volume.

Research and development expenses. For the three months ended September 30, 2001, research and development expenses excluding related stock based compensation expenses were \$1,345,000, compared to \$717,000 for the three months ended September 30, 2000. Research and development expenses include costs associated with the design, development, testing, enhancement of the Company's products, regulatory fees, the purchase of laboratory supplies and clinical trials. The Company expenses research and development costs as incurred. The increase in research and development expenses in the three months ended September 30, 2001 is primarily attributable to additional personnel costs related to the hiring of 12 employees causing an increase of approximately \$331,000 and other costs associated with the research into the development of new product lines causing an increase of approximately \$297,000. In addition, stock based compensation related to research and development was \$29,000 for the three months ended September 30, 2001 and \$1,334,000 for the three months ended September 30, 2000. For further information regarding fluctuations in research and development inclusive of stock based compensation, see the section entitled "Stock based compensation expenses." The Company expects research and development spending to continue to increase for the year ending December 31, 2001 as the Company continues to expand its product development efforts and seek further regulatory approvals.

Sales and marketing expenses. For the three months ended September 30, 2001, sales and marketing expenses excluding related stock based compensation expenses were \$1,412,000, compared to \$712,000 for the three months ended September 30, 2000. Sales and marketing expenses include costs for marketing personnel, tradeshow expenses, and promotional activities and materials. The increase in sales and marketing expenses in the three months ended September 30, 2001 is primarily attributable to additional personnel costs related to the hiring of 7 employees causing an increase of approximately \$679,000 and other costs such as tradeshow expenses and promotional activities and materials expenses related to the promotion of product lines causing an increase of approximately \$21,000. In addition, stock based compensation related to sales and marketing was \$121,000 for the three months ended September 30, 2001 and (\$7,000) for the three months ended September 30, 2000. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, see the section entitled "Stock based compensation expenses." The Company expects sales and marketing expenses to remain at current levels for the remainder of the year ending December 31, 2001.

General and administrative expenses. For the three months ended September 30, 2001, general and administrative expenses excluding related stock based compensation expenses were \$858,000, compared to \$647,000 for the three months ended September 30, 2000. General and administrative expenses include costs for administrative personnel, legal and other professional expenses and general corporate expenses. The increase in general and administrative expenses in the three months ended September 30, 2001 is primarily attributable to the hiring of 5 employees causing an increase in personnel costs of approximately \$154,000, as well as increased administrative costs of approximately \$57,000 for professional services and other general corporate expenditures related to all areas of the Company's operations, as well as costs to support the Company's status as traded on the *Neuer Markt*. In addition,

stock based compensation related to general and administrative expenses was \$185,000 for the three months ended September 30, 2001 and \$412,000 for the three months ended September 30, 2000. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, see the section entitled "Stock based compensation expenses." The Company expects general and administrative expenses to remain at current levels for the remainder of the year ending December 31, 2001.

Stock based compensation expenses. For the three months ended September 30, 2001, non-cash stock based compensation expenses were \$335,000, compared to \$1,739,000 for the three months ended September 30, 2000. Stock based compensation results from options issued to employees and non-employees. Stock based compensation expenses are amortized over the remaining vesting periods of the options, generally four years from the date of grant. The overall decrease in stock based compensation is related to accelerated vesting and modifications to compensatory stock options granted to employees and consultants. Approximately \$1,238,000 of the decrease in research and development stock based compensation was due to management's decision on August 9, 2000 to accelerate options granted to doctors who performed consulting services, as the services for which they were granted were deemed complete and the compensation expense related to all the accelerated options was recognized. The increase in sales and marketing stock based compensation of \$128,000 primarily resulted from the rehiring on May 1, 2001 of certain members of the Company's sales force who had previously been terminated. These employees held stock options that continued to vest during the termination period. In addition, on September 17, 2001 the Company terminated certain members of its sales force and modified the vesting and exercise period of their stock options. The options were remeasured using the intrinsic value method as of the rehire date and modification date and approximately \$306,000 in additional compensation expense is being deferred and amortized over the remaining vesting period of the options. Approximately \$166,000 of the decrease in general and administrative stock based compensation was due to management's decision in January 2001 and April 2001 to accelerate options granted to an employee and a consultant, as the services for which they were granted were deemed complete and the compensation expense related to the accelerated options was recognized.

Interest income. For the three months ended September 30, 2001, interest income was \$511,000, compared to \$372,000 for the three months ended September 30, 2000. The increase in interest income resulted from cash equivalents and short-term investments being invested for three months in the three months ended September 30, 2001 compared to cash equivalents and short-term investments of cash provided by the Company's initial public offering in August 2000 being invested for only one and a half months in the three months ended September 30, 2000.

Interest and other expense. For the three months ended September 30, 2001, interest expense and other expense was \$20,000, compared to \$291,000 in expense for the three months ended September 30, 2000. The decrease in interest and other expense is primarily related to the conversion loss of euros to U.S. dollars in connection with the net proceeds realized by the Company from the sale of equity in the Company's initial public offering in August 2000.

Equity loss in investment. For the three months ended September 30, 2001, the Company's equity loss in investment was \$24,000, for which there was no comparable charge in the three months ended September 30, 2000 since the investment related to the equity loss was made in May 2001.

Nine months ended September 30, 2001 compared to nine months ended September 30, 2000

Revenues. For the nine months ended September 30, 2001, revenues were \$4,197,000 compared to \$4,579,000 for the nine months ended September 30, 2000. The decrease in revenues was primarily attributable to the initial inventory purchase of \$1,162,000 by Medtronic, the Company's principal distributor, in the three months ended June 30, 2000. Excluding the initial inventory purchase during the three months ended June 30, 2000, the Company's revenues increased by \$780,000 which was attributable to new product introductions that occurred in the nine months ended September 30, 2001. Revenues from this distributor, which owns approximately 6.7% of the outstanding common stock in the Company, represented approximately 98.5% and 87.5% of the Company's revenues for the nine months ended September 30, 2001 and September 30, 2000, respectively.

Cost of revenues. For the nine months ended September 30, 2001, cost of revenues, excluding the inventory provision, was \$1,578,000 or 37.6% of revenues, compared to \$1,489,000 or 32.5% of revenues for the nine months ended September 30, 2000. Cost of revenues includes material, manufacturing labor and overhead costs. The dollar increase in cost of revenues for the nine months ended September 30, 2001 is primarily attributable to the expensing of excess capacity costs. The increase in cost as a percentage of revenue was primarily attributable to an inability to absorb certain fixed manufacturing overhead costs due to revenue volume.

Inventory provision. For the nine months ended September 30, 2001, the Company recorded an inventory provision of \$1,228,000 or 29.3% of revenues, for which there was no comparable charge in the nine months ending September 30, 2000. The inventory provision was a result of potential excess and obsolete inventory due to an anticipated reduction in expected future revenues of the Company's craniofacial skeleton implant and instrument products.

Gross profit. For the nine months ended September 30, 2001, gross profit was \$1,391,000 or 33.1% of revenues, compared to \$3,090,000 or 67.5% of revenues for the nine months ended September 30, 2000. Excluding the inventory provision, the gross profit would have been \$2,619,000 or 62.4% of revenues in the nine months ended September 30, 2001.

Research and development expenses. For the nine months ended September 30, 2001, research and development expenses excluding related stock based compensation expenses were \$4,041,000, compared to \$1,700,000 for the nine months ended September 30, 2000. The increase in research and development expenses in the nine months ended September 30, 2001 is primarily attributable to additional personnel costs related to the hiring of employees causing an increase of approximately \$1,090,000 and other costs associated with the research into the development of new product lines causing an increase of approximately \$1,251,000. In addition, stock based compensation related to research and development was \$89,000 for the nine months ended September 30, 2001 and \$2,206,000 for the nine months ended September 30, 2000. For further information regarding fluctuations in research and development inclusive of stock based compensation, see the section entitled "Stock based compensation expenses." The Company expects research and development spending to continue to increase for the year ending December 31, 2001 as the Company continues to expand its product development efforts and seek further regulatory approvals.

Sales and marketing expenses. For the nine months ended September 30, 2001, sales and marketing expenses excluding related stock based compensation expenses were \$3,791,000, compared to \$1,585,000 for the nine months ended September 30, 2000. The increase in sales and marketing expenses in the nine months ended September 30, 2001 is primarily attributable to additional personnel costs related to the hiring of employees causing an increase of approximately \$1,467,000 and other costs such as tradeshow expenses and promotional activities and materials expenses related to the promotion of product lines causing an increase of approximately \$739,000. In addition, stock based compensation related to sales and marketing was \$131,000 for the nine months ended September 30, 2001 and \$1,823,000 for the nine months ended September 30, 2000. For further information regarding fluctuations in sales and marketing inclusive of stock based compensation, see the section entitled "Stock based compensation expenses." The Company expects sales and marketing expenses to remain at current levels for the remainder of the year ending December 31, 2001.

General and administrative expenses. For the nine months ended September 30, 2001, general and administrative expenses excluding related stock based compensation expenses were \$2,762,000, compared to \$1,832,000 for the nine months ended September 30, 2000. The increase in general and administrative expenses in the nine months ended September 30, 2001 is primarily attributable to increased personnel costs of approximately \$496,000, as well as increased administrative costs of approximately \$434,000 such as professional services and other general corporate expenditures related to all areas of the Company's operations, as well as costs to support the Company's status, as traded on the *Neuer Markt*. In addition, stock based compensation related to general and administrative expenses was \$623,000 for the nine months ended September 30, 2001 and \$1,562,000 for the nine months ended September 30, 2000. For further information regarding fluctuations in general and administrative expenses inclusive of stock based compensation, see the section entitled "Stock based compensation expenses." The Company expects general and administrative expenses to remain at current levels for the remainder of the year ending December 31, 2001.

Stock based compensation expenses. For the nine months ended September 30, 2001, non-cash stock based compensation expenses were \$843,000, compared to \$5,591,000 for the nine months ended September 30, 2000. Stock based compensation results from options issued to employees and non-employees. Stock based compensation expenses are amortized over the remaining vesting periods of the options, generally four years from the date of grant. The overall decrease in stock based compensation is related to accelerated vesting and modifications to compensatory stock options granted to employees and consultants. The decrease of \$2,117,000 in research and development stock based compensation was due to management's decision on August 9, 2000 to accelerate options granted to doctors who performed consulting services, as the services for which they were granted were deemed complete and the compensation expense related to all the accelerated options was recognized. The decrease in sales and marketing stock based compensation was due to approximately \$1,775,000 in additional expense in the three months ended March 31, 2000, which was a result of a modification to extend the expiration date of certain stock options granted to members of the sales force upon their termination. The decrease in general and administrative stock based compensation was primarily due to approximately \$520,000 in additional expense recorded in the nine months ended September 30, 2000 as a result of significant options granted to senior management with immediate vesting and at exercise prices below fair market value.

Interest income. For the nine months ended September 30, 2001, interest income was \$1,850,000, compared to \$565,000 for the nine months ended September 30, 2000. The increase in interest income was primarily attributable to the increase in higher average cash balances and short-term investments.

Interest and other expense. For the nine months ended September 30, 2001, interest expense and other expense were \$55,000, compared to \$338,000 for the nine months ended September 30, 2000. The decrease in interest and other expense is primarily related to the conversion loss of euros to U.S. dollars in connection with the net proceeds realized by the Company from the sale of equity in August 2000.

Equity loss in investment. For the nine months ended September 30, 2001, the Company's equity loss in investment was \$41,000, for which there was no comparable charge in the nine months ended September 30, 2000. This was a result of the Company accounting for its investment, which it purchased in May 2001, under the equity method of accounting.

Unearned Compensation

The Company records unearned compensation for options granted to employees as the difference between the exercise price of options granted and the fair value of its common stock at the time 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 September 30, 2001 was \$6,684,000 with an accumulated amortization, net of charges reversed during the period for the forfeiture of unvested awards, of \$4,303,000. The remaining \$2,381,000 as of September 30, 2001 will be amortized using the straight-line method over the remaining vesting periods of the options, generally four years from the date of grant. The Company expects to record amortization expense for unearned compensation of \$269,000 for the period October 1, 2001 to December 31, 2001, \$1,044,000 in 2002, \$854,000 in 2003 and \$214,000 in 2004. The amount of unearned compensation expense recorded in future periods may decrease if unvested options for which unearned compensation has been recorded are forfeited.

Net Operating Loss and Tax Credit Carry Forwards

As of December 31, 2000, the Company had federal net operating loss carryforwards of approximately \$7,962,000 and state net operating loss carryforwards of approximately \$5,683,000, which may be available to offset future taxable income for tax purposes. The federal net operating loss carryforwards begin to expire in 2012, if unused. The state net operating loss carryforwards begin to expire in 2005. A portion of the net operating losses are limited in their annual utilization. As of December 31, 2000, the Company also had research tax credit carryforwards of approximately \$177,000 and \$163,000 for federal and state tax purposes, respectively. As of December 31, 2000, the Company also had California manufacturer's credit carryforwards of approximately \$152,000, which begin to expire in 2007, if unused. For financial reporting purposes, the Company has provided a valuation against its deferred tax assets due to uncertainties regarding their realization.

Property and Facilities

The Company's main facility is located at 6740 Top Gun Street, San Diego, California. The Company currently leases approximately 27,000 square feet of space at this location, which it uses for its corporate headquarters and for manufacturing. Of the 27,000 square feet, approximately 13,000 square feet is laboratory space, 6,000 square feet is office space and 8,000 square feet is manufacturing space. The Company's lease has a five year term and will expire in 2003.

The Company also leases a facility located at 6749 Top Gun Street, San Diego, California. The Company expects to use the 14,000 square foot facility primarily for research and development. The lease has a five year term and expires in 2006.

The Company leases approximately 5,800 square feet of office space in Frankfurt, Germany for use in marketing and administration. The lease has a five year term and expires in 2006.

In addition, the Company collectively leases approximately 400 square feet of office space in Malvern, Pennsylvania and Atlanta, Georgia. These offices have been leased for nine month terms that renew automatically, unless terminated.

The Company pays an aggregate of approximately \$47,000 in rent per month for its properties located in the United States and approximately DM15,770 for its property in Germany.

Recent Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provisions of Accounting Principles Board ("APB") Opinion No. 30, "Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of a business (as previously defined in the APB opinion). The provisions of SFAS 144 are effective for financial statements issued for fiscal years beginning after December 15, 2001, with early application encouraged and generally are to be applied prospectively. The Company does not expect the adoption of SFAS 144 to have a material impact on the financial condition and results of operations.

Staff

As of September 30, 2001, the Company had 72 full-time employees, comprised of 24 employees in research and development, 17 employees in manufacturing, 16 employees in management and finance and administration, and 15 employees in marketing. As of September 30, 2000, the Company had 47 full-time employees, consisting of 12 employees in research and development, 16 employees in manufacturing, 11 employees in management and finance and administration and 8 employees in marketing. The expansion of the Company's research and development as well as sales and administrative activities has resulted in the increase of personnel. From time to time, the Company also employs independent contractors to support its administrative organizations. The Company's employees are not represented by any collective bargaining unit, and the Company has never experienced a work stoppage. The Company believes its relations with its employees are good.

Liquidity and Capital Resources

As of September 30, 2001, the Company had cash, cash equivalents and short-term investments of \$33,841,000 and working capital of \$36,633,000. Since inception, the Company has financed its operations primarily through sales of stock. The sale of preferred stock in 1997, 1998 and 1999 yielded net proceeds of approximately \$14,679,000. On August 8, 2000, the Company completed its initial public offering in Germany and listed its common stock for trading on the *Neuer Markt* segment of the Frankfurt Stock Exchange in Frankfurt, Germany at which time all of the outstanding shares of the Company's preferred stock were converted into shares of common stock. The net proceeds to the Company from the sale of 3,500,000 shares of common stock in the offering were approximately \$43,244,000. A portion of those net proceeds have been used for research and development, to expand the Company's manufacturing operations, to promote the Company's brand and to pursue regulatory approvals for the Company's products. In addition, some of the proceeds have been used for working capital and general corporate purposes. The Company has invested some of the proceeds from the offering in short-term investments, pending other uses of the proceeds in its business.

Net cash used in operating activities was approximately \$7,083,000 for the nine months ended September 30, 2001. Net cash used in operating activities primarily related to the net loss of \$8,292,000 and an increase in inventory of approximately \$1,369,000, offset by non-cash charges for inventory provision, stock based compensation and depreciation and amortization. Net cash used in operating activities was \$1,856,000 for the nine months ended September 30, 2000. Net cash used in operating activities resulted primarily from a net loss of \$7,391,000, offset by an up-front license fee of \$1,275,000 paid to the Company by a distributor for exclusive worldwide distribution rights on all of the Company's products for use in the craniofacial areas and from a non-cash charge for stock based compensation expenses of \$5,604,000.

Net cash provided by investing activities was approximately \$2,745,000 for the nine months ended September 30, 2001. Net cash provided by investing activities primarily consisted of the purchase and sale of short-term investments, capital expenditures and the Company's investment in StemSource, Inc. Net cash used in investing activities was \$33,142,000 for the nine months ended September 30, 2000 and primarily related to the purchase of short-term investments with the proceeds from the initial public offering.

Net cash used in financing activities was approximately \$351,000 for the nine months ended September 30, 2001 and resulted primarily from the purchase of approximately \$384,000 in treasury stock. Net cash provided by financing activities was approximately \$47,492,000 for the nine months ended September 30, 2000 and primarily resulted from the sale of Series D preferred stock and the initial public offering.

The Company's revenues, operating results and cash flow are affected by product pricing, fixed costs of sales and fluctuations in variable cost of sales and sales volumes. In January 2000, the Company entered into an exclusive distribution agreement with Medtronic for the marketing, distribution and sale of MacroPore FX and MacroPore PS products for use in the craniofacial skeleton. The distribution agreement has a term of five years. Under the terms of the distribution agreement, the Company sells its products to Medtronic at fixed prices that are subject to adjustment upon biannual reviews. Although the Medtronic distribution agreement provides that direct selling costs are borne by the distributor, cash flow may be adversely affected if fixed costs increase and the Company is unable to negotiate an increase in product pricing with the distributor.

The Company has 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 all equipment lease obligations are \$13,000. In October 2001, the Company obtained \$2,434,000 of equipment financing that matures in October 2005 at an interest rate of 9.3%. The total monthly payments under the equipment financing arrangement are \$62,000.

As of September 30, 2001, the Company had property and equipment of \$6,925,000 less accumulated depreciation of \$1,592,000 to support its clinical, research, development, manufacturing and administrative activities. For the nine month periods ended September 30, 2001 and September 30, 2000, the Company's capital expenditures were \$2,480,000 and \$1,511,000, respectively. For the next twelve months, the Company expects capital expenditures to be approximately \$2,000,000, as the Company acquires additional equipment and expands its facilities. The Company is in the process of obtaining a collateralized line of credit for capital expenditures. The Company intends to pay for future capital expenditures with available working capital until the line of credit becomes available.

In May 2001, the Company acquired an ownership interest in StemSource, Inc. StemSource, which is in its early stages of development, was formed to principally engage in biomedical research. The Company is negotiating the terms of a collaborative agreement with StemSource for the purpose of engaging in joint research and development activities. From time to time, the Company may enter into collaborative arrangements with, and acquire ownership interest in, other companies for the purpose of engaging in joint research and development activities.

The Company's capital requirements depend on numerous factors, including market acceptance of its products and regulatory approvals, the resources the Company devotes to developing and supporting its products and other factors. The Company expects to devote substantial capital resources to continue its research and development efforts, to expand its support and product development activities and for other general corporate activities. The Company

believes that its current cash and investment balances and revenue to be derived from the sale of its products will be sufficient to fund its operations at least through December 31, 2002.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

The Company is exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

Interest Rate Exposure. The Company's exposure to market risk due to fluctuations in interest rates relates primarily to short-term investments, which consist primarily of investments in debt instruments of financial institutions, corporations with strong credit ratings and United States government obligations, reported at an aggregate fair market value of \$31,054,000 as of September 30, 2001. These securities are subject to interest rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at September 30, 2001, for example, and assuming an average investment duration of ten months, the fair value of the portfolio would not decline by a material amount. The Company does not use derivative financial instruments to mitigate the risk inherent in these securities. However, the Company does attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying its investments and limiting the amount of credit exposure with any one issuer. The Company believes that it currently has the ability to hold these investments until maturity and, therefore, believes that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect its financial position, results of operations or cash flows.

Foreign Currency Exchange Rate Exposure. The Company's exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to sales of the Company's products in Europe and other foreign markets. Although the Company transacts business in various foreign countries, settlement amounts are usually based on U.S. dollars or the Euro. Transaction gains or losses resulting from sales revenues have not been significant in the past and there is no hedging activity on the Euro or other currencies. Based on the Company's revenues derived from markets other than the United States for the nine months ended September 30, 2001, a hypothetical 10% adverse change in the Euro against the U.S. dollar would not result in a material foreign exchange loss. Consequently, the Company does 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 its financial position, results of operations or cash flows.

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

None

Item 5. Other Information

None

Item 6. Exhibits and Reports on Form 8-K

- a. Exhibits - - None
- b. Reports on Form 8-K – Form 8-K filed on August 13, 2001 with respect to Item 5.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in San Diego, California, on November 9, 2001.

MACROPORE, INC.

By: /s/ Christopher J. Calhoun
Christopher J. Calhoun
Vice-Chairman, Chief Executive Officer and Secretary