
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported):

November 15, 2004

MacroPore Biosurgery, Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-32501

33-0827593

(State or other jurisdiction
of incorporation)

(Commission
File Number)

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

6740 Top Gun Street, San Diego, California

92121

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(858) 458-0900

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On November 15, 2004, MacroPore Biosurgery, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2004. A copy of this press release is furnished as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

Exhibit 99.1 -- Press release issued by MacroPore Biosurgery, Inc. on November 15, 2004, announcing financial results for the quarter ended September 30, 2004.

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 hereunto duly authorized.

MacroPore Biosurgery, Inc.

November 15, 2004

By: *Christopher J. Calhoun*

Name: Christopher J. Calhoun
Title: Chief Executive Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by MacroPore Biosurgery, Inc. on November 15, 2004, announcing financial results for the quarter ended September 30, 2004.

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MacroPore Biosurgery Announces Third Quarter 2004 Financial Results; Reports on Progress of Regenerative Cell Technology Program

San Diego, CA, November 15, 2004 — MacroPore Biosurgery, Inc. (Frankfurt: XMP), a company developing therapies for cardiovascular disease, spine and orthopedic disorders and reconstructive surgery using adult stem cells from adipose tissue, today announced financial results for the three and nine months ended September 30, 2004.

In the third quarter, MacroPore Biosurgery continued to shift its business focus toward its regenerative cell technology. During this time, the Company received its first patent related to stem cells from adipose tissue; received its first regulatory clearance related to its regenerative cell technology system; expanded its NIH research grant funding; and reported positive preclinical study results in cardiovascular disease. To support the regenerative cell technology development program, MacroPore Biosurgery is generating cash from the sale of its bioresorbable technology assets. In the third quarter and early in the fourth quarter of 2004, the Company received \$4.25 million from bioresorbable-related licensing and asset sale agreements.

“Over the next year, we look forward to reporting on the progress of our ongoing preclinical studies for cardiovascular disease; submitting additional regulatory filings related to the bedside system; advancing our research into clinical trials; and broadening our patent position,” said Christopher J. Calhoun, Chief Executive Officer for MacroPore Biosurgery. “Strategically, we will pursue regenerative cell technology partnerships in a variety of clinical areas, which will allow us to accelerate our development efforts and enter into multiple therapeutic markets.”

Third Quarter Highlights

Key developments during the third quarter of 2004 include the following:

- An award of up to \$850,000 of additional funding to continue with the second phase of our NIH grant to study the potential role of adipose-derived regenerative cells in treating cardiovascular disease.
- A patent from the U.S. Patent and Trademark Office (U.S. Patent No. 6,777,231), to which MacroPore Biosurgery is the exclusive, worldwide licensee, was issued to the University of California related to stem cells isolated from adipose tissue that can differentiate into a variety of cell types.
- Reporting of preclinical safety study results, which demonstrated that infusion of adipose tissue-derived regenerative cells improved heart function following heart attack. This study, performed in swine, confirms previous preclinical work by MacroPore Biosurgery and others suggesting that this technology is safe and may be clinically useful.
- Receipt of a 510(k) clearance from the U.S. Food and Drug Administration (FDA) for a point-of-care adipose tissue extraction system, which is designed to extract and collect adipose tissue. The clearance is one of multiple components that will require clearance or approval by the FDA prior to commercialization.
- Receipt of \$1.5 million for completing the final milestone related to the September 2002 sale of the Craniomaxillofacial (CMF) product line to Medtronic, Inc. by transferring to them certain know-how, including manufacturing processes.
- Receipt of CE Mark approval to market HYDROSORB™ Cornerstone™ HSR, the first and only resorbable cervical interbody device approval in Europe.
- Licensing Thin Film distribution rights in Japan to Senko Medical Trading Co. (Senko) for \$1.5 million plus regulatory milestone payments, minimum purchase requirements and royalties for a three-year period following commercialization of the products in Japan.
- Receipt of a \$1.25 million regulatory milestone payment from Senko, subsequent to the end of the quarter, upon submitting a regulatory application related to the Thin Film licensing agreement in September 2004 to the Japanese Ministry of Health, Labour and Welfare.

Financial Results

Total revenues for the three months ended September 30, 2004 were \$1.8 million compared to \$4.5 million for the same period in 2003, a decrease of 60%. Total revenues for the nine months ended September 30, 2004 were \$5.7 million compared to \$9.3 million for the same period in 2003, a decrease of 39%.

Net income for the three and nine months ended September 30, 2004 was \$4.5 million, or \$0.31 per diluted share, and \$2.2 million, or \$0.15 per diluted share, respectively. This compares to a net loss of \$2.8 million, or \$0.19 per diluted share, and \$8.1 million, or \$0.56 per diluted share, respectively for the same periods in 2003. The 2004 quarter and year-to-date results benefited from the following items:

- The receipt and recognition of the previously mentioned \$1.5 million know-how payment in the third quarter of 2004 as a result of completing the final milestone related to the 2002 sale of the CMF product line;
- The recognition of \$7.4 million in the third quarter of 2004 associated with the completion of our obligations from the CMF product line sale, which was previously reported as deferred gain on sale of assets, related party, on our balance sheet; and
- A \$5.0 million gain in the second quarter of 2004 related to the completion of the clinical research regarding Faster Resorbing Polymers, a milestone under the CMF product line sale agreement.

MacroPore Biosurgery ended the third quarter of 2004 with \$17.0 million in cash and cash equivalents and short term investments. The Company has since received \$1.25 million from Senko. During the third quarter, MacroPore Biosurgery was also awarded a grant of up to \$850,000 to continue with the second phase of our National Institutes of Health Small Business Innovation Research (NIH) study, for which we will receive funds during 2004 and 2005.

Conference call information

The management of MacroPore Biosurgery will host a conference call today at 10:30 a.m. EST or 4:30 p.m. CET. The conference call will be webcast live and may be accessed on the Investor Relations section of the Company's website at <http://www.macropore.com>. An archived version of the webcast will be available on the same website 60 minutes after the call. A telephone replay will be available for 24 hours. To access the replay, please call +49 / 69 / 58 99 90 568 (PIN: 132784#) or (303) 590-3000 (PIN: 11013849#).

About MacroPore Biosurgery, Inc.

MacroPore Biosurgery (Frankfurt: XMP) is focused on the discovery and development of regenerative medicine technologies, with two technology platforms, regenerative cell technology and bioresorbable technology. Within its regenerative cell technology program, MacroPore Biosurgery is developing a system to isolate autologous, homologous-use regenerative cells. Simultaneously, the company is generating scientific knowledge through internal research to support the clinical use of these cells. Its most advanced research and development program is in the repair of cardiovascular tissues that are damaged after a heart attack. The company also is researching regenerative cell technology applications in bone repair, spinal disc regeneration and cosmetic and reconstructive surgery. The Company's surgical implants, derived from bioresorbable technology, represent one of the latest advancements in spine and orthopedic medicine. For further information please visit our web site <http://www.macropore.com>.

Cautionary Statement Regarding Forward-Looking Statements

This press release may include forward-looking statements regarding events and trends which may affect MacroPore Biosurgery's future operating results and financial position. Such statements are subject to risks and uncertainties that could cause MacroPore Biosurgery's actual results and financial position to differ materially. Some of these risks and uncertainties are described (under the heading "Risk Factors") in our 2003 Form 10-K annual report for the year ended December 31, 2003, which is available on our web site. Our inability to predict whether and when HYDROSORB™ sales will recover is an additional risk factor. MacroPore Biosurgery assumes no responsibility to update any revision of forward-looking statements to reflect events, trends or circumstances after the date they are made.

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CONSOLIDATED CONDENSED BALANCE SHEETS

	As of September 30, 2004 (Unaudited)	As of December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,986,000	\$ 2,820,000
Short-term investments, available-for-sale	13,991,000	11,448,000
Accounts receivable, net of allowance for doubtful accounts of \$5,000 and \$62,000 in 2004 and 2003, respectively	178,000	1,291,000
Inventories	459,000	831,000
Milestone payment due from distribution agreement.	1,250,000	—
Other current assets	940,000	526,000
Total current assets	<u>19,804,000</u>	<u>16,916,000</u>
Property and equipment, net	3,396,000	3,822,000
Other assets	226,000	332,000
Intangibles, net	2,189,000	2,392,000
Goodwill	4,387,000	4,627,000
Total assets	<u>\$ 30,002,000</u>	<u>\$ 28,089,000</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,248,000	\$ 3,767,000
Current portion of long-term obligations	958,000	717,000
Total current liabilities	<u>3,206,000</u>	<u>4,484,000</u>
Deferred gain on sale of assets, related party	—	7,539,000
Deferred gain on sale of assets	5,694,000	—
Deferred license fee revenue	1,500,000	—
Deferred development revenue	1,092,000	—
Long-term obligations, less current portion	1,347,000	1,157,000
Total liabilities	<u>12,839,000</u>	<u>13,180,000</u>
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; -0- shares issued and outstanding in 2004 and 2003	—	—
Common stock, \$0.001 par value; 95,000,000 shares authorized; 16,800,018 and 16,777,644 shares issued and 13,927,184 and 14,195,062 shares outstanding in 2004 and 2003, respectively	17,000	17,000
Additional paid-in capital	74,734,000	74,698,000
Unearned compensation	—	(109,000)
Accumulated deficit	(47,159,000)	(49,385,000)
Treasury stock, at cost	(10,414,000)	(9,362,000)
Treasury stock receivable	—	(976,000)
Accumulated other comprehensive (loss) income	(15,000)	26,000
Total stockholders' equity	<u>17,163,000</u>	<u>14,909,000</u>
Total liabilities and stockholders' equity.	<u>\$ 30,002,000</u>	<u>\$ 28,089,000</u>

CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)

	<u>For the Three Months Ended September 30,</u>		<u>For the Nine Months Ended September 30,</u>	
	<u>2004</u>	<u>2003</u>	<u>2004</u>	<u>2003</u>
Revenues:				
Sales to related party	\$ 298,000	\$ 4,230,000	\$ 3,113,000	\$ 8,421,000
Sales to third parties	1,189,000	265,000	2,166,000	906,000
Research grant	129,000	—	229,000	—
Development	158,000	—	158,000	—
	<u>1,774,000</u>	<u>4,495,000</u>	<u>5,666,000</u>	<u>9,327,000</u>
Cost of revenues:				
Cost of revenues (including stock based compensation expense of \$-0- and \$3,000 for the three months ended September 30, 2004 and 2003; \$3,000 and \$9,000 for the nine months ended September 30, 2004 and 2003, respectively)	1,184,000	1,438,000	2,375,000	2,864,000
Inventory provision	—	—	242,000	—
Gross profit	<u>590,000</u>	<u>3,057,000</u>	<u>3,049,000</u>	<u>6,463,000</u>
Operating expenses:				
Research and development, excluding stock based compensation expense of \$-0- and \$19,000 for the three months ended September 30, 2004 and 2003, respectively; \$32,000 and \$58,000 for the nine months ended September 30, 2004 and 2003, respectively	2,959,000	2,552,000	8,134,000	6,810,000
Sales and marketing, excluding stock based compensation expense of \$-0- and \$17,000 for the three months ended September 30, 2004 and 2003, respectively; \$22,000 and \$53,000 for the nine months ended September 30, 2004 and 2003, respectively	454,000	1,055,000	2,066,000	3,354,000
General and administrative, excluding stock based compensation expense of \$-0- and \$411,000 for the three months ended September 30, 2004 and 2003, respectively; \$71,000 and \$761,000 for the nine months ended September 30, 2004 and 2003, respectively	1,502,000	1,426,000	4,303,000	3,425,000
Stock based compensation (excluding cost of revenues stock based compensation)	—	447,000	125,000	872,000
Restructuring charge	37,000	458,000	107,000	458,000
Total operating expenses	<u>4,952,000</u>	<u>5,938,000</u>	<u>14,735,000</u>	<u>14,919,000</u>
Total operating loss	<u>(4,362,000)</u>	<u>(2,881,000)</u>	<u>(11,686,000)</u>	<u>(8,456,000)</u>
Other income (expense):				
Gain on the sale of assets, related party	8,883,000	—	13,883,000	—
Interest income	68,000	88,000	180,000	335,000
Interest expense	(44,000)	(24,000)	(131,000)	(88,000)
Other income (expense)	1,000	18,000	(20,000)	71,000
Total other income (expense)	<u>8,908,000</u>	<u>82,000</u>	<u>13,912,000</u>	<u>318,000</u>
Net income (loss)	<u>4,546,000</u>	<u>(2,799,000)</u>	<u>2,226,000</u>	<u>(8,138,000)</u>
Other comprehensive income (loss): unrealized holding loss	9,000	(44,000)	(41,000)	(96,000)
Comprehensive income (loss)	<u>\$ 4,555,000</u>	<u>\$ (2,843,000)</u>	<u>\$ 2,185,000</u>	<u>\$ (8,234,000)</u>
Net income (loss) per common share:				
Basic	\$ 0.33	\$ (0.19)	\$ 0.16	\$ (0.56)
Diluted	\$ 0.31	\$ (0.19)	\$ 0.15	\$ (0.56)
Weighted average common shares:				
Basic	13,929,326	14,605,273	13,929,895	14,557,167
Diluted	14,661,303	14,605,273	14,779,478	14,557,167