

MERIT MEDICAL SYSTEMS INC
Form 10-Q/A
October 04, 2004

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004.

OR

o

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

FOR THE TRANSITION PERIOD FROM TO .

Commission File Number 0-18592

MERIT MEDICAL SYSTEMS, INC.

(Exact name of Registrant as specified in its charter)

Utah
(State or other jurisdiction of incorporation or organization)

87-0447695
(I.R.S. Identification No.)

1600 West Merit Parkway, South Jordan, UT, 84095
(Address of Principal Executive Offices)

(801) 253-1600
(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Sections 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.

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Yes No

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of the latest practicable date.

| | |
|---------------------|---|
| Common Stock | 26,351,836 |
| Title or class | Number of Shares Outstanding at August 2, 2004 |

MERIT MEDICAL SYSTEMS, INC.

INDEX TO FORM 10-Q/A

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EXPLANATORY NOTE

The purpose of this Amendment No. 1 on Form 10-Q/A (this Amendment) to the Quarterly Report on Form 10-Q of Merit Medical Systems, Inc. for the quarter ended June 30, 2004 is to refile the certifications of the principal executive officer and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Exhibits 31.1 and 31.2, respectively.

All subsequent references to the Quarterly Report on Form 10-Q for Merit Medical Systems, Inc. for the quarter ended June 30, 2004 shall refer to the initial Form 10-Q, as amended by this Amendment.

Part I - FINANCIAL INFORMATION**Item 1. FINANCIAL STATEMENTS****MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**

CONSOLIDATED BALANCE SHEETS

JUNE 30, 2004 AND DECEMBER 31, 2003 (Unaudited)

| | June 30, | December 31, |
|--|---------------|---------------|
| | 2004 | 2003 |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 35,865,142 | \$ 30,204,083 |
| Trade receivables net | 19,918,295 | 17,728,457 |
| Employee and other receivables | 339,287 | 267,288 |
| Inventories | 22,888,456 | 21,269,380 |
| Prepaid expenses and other assets | 1,082,323 | 823,221 |
| Deferred income tax assets | 677,212 | 220,625 |
| Income tax refund receivable | 28,227 | 374,644 |
| Total current assets | 80,798,942 | 70,887,698 |
| PROPERTY AND EQUIPMENT: | | |
| Land | 2,740,394 | 2,740,394 |
| Building | 5,269,821 | 5,268,260 |
| Manufacturing equipment | 30,646,287 | 29,480,421 |
| Furniture and fixtures | 12,430,876 | 11,953,358 |
| Leasehold improvements | 4,715,444 | 4,615,947 |
| Automobiles | 87,536 | 87,536 |
| Construction-in-progress | 12,620,085 | 4,886,530 |
| Total | 68,510,443 | 59,032,446 |
| Less accumulated depreciation and amortization | (32,077,675) | (29,835,769) |
| Property and equipment net | 36,432,768 | 29,196,677 |
| OTHER ASSETS: | | |

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| | | |
|--------------------------------------|----------------|----------------|
| Patents, trademarks and licenses net | 2,106,451 | 1,846,392 |
| Goodwill | 4,764,596 | 4,764,596 |
| Other assets | 1,268,768 | 572,988 |
| Deposits | 126,874 | 32,163 |
| Total other assets | 8,266,689 | 7,216,139 |
| TOTAL ASSETS | \$ 125,498,399 | \$ 107,300,514 |

See notes to consolidated financials statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

JUNE 30, 2004 AND DECEMBER 31, 2003 (Unaudited)

| | June 30, 2004 | December 31, 2003 |
|--|-----------------------|-----------------------|
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| CURRENT LIABILITIES: | | |
| Current portion of long-term debt | \$ | \$ 16,693 |
| Trade payables | 8,600,311 | 5,700,491 |
| Accrued expenses | 7,884,561 | 7,994,105 |
| Advances from employees | 208,097 | 158,885 |
| Income taxes payable | 2,239,977 | 86,973 |
| Total current liabilities | 18,932,946 | 13,957,147 |
| DEFERRED INCOME TAX LIABILITIES | 3,218,893 | 3,020,217 |
| DEFERRED COMPENSATION PAYABLE | 1,281,982 | 572,988 |
| DEFERRED CREDITS | 1,404,884 | 1,506,753 |
| Total liabilities | 24,838,705 | 19,057,105 |
| STOCKHOLDERS EQUITY: | | |
| Preferred stock 5,000,000 shares authorized as of June 30, 2004, no shares issued | | |
| Common stock no par value; 50,000,000 shares authorized; 26,334,864 and 26,002,544 shares issued at June 30, 2004 and December 31 2003, respectively | 40,678,352 | 37,701,629 |
| Retained earnings | 60,405,915 | 50,958,481 |
| Accumulated other comprehensive loss | (424,573) | (416,701) |
| Total stockholders equity | 100,659,694 | 88,243,409 |
| TOTAL LIABILITIES AND STOCKHOLDERS EQUITY | \$ 125,498,399 | \$ 107,300,514 |

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2004 AND 2003 (Unaudited)

| | Three Months Ended | | Six Months Ended | |
|--------------------------------------|--------------------|---------------|------------------|---------------|
| | June 30, , | | June 30 | |
| | 2004 | 2003 | 2004 | 2003 |
| NET SALES | \$ 38,920,944 | \$ 34,577,305 | \$ 76,583,633 | \$ 66,318,878 |
| COST OF SALES | 20,911,592 | 19,396,384 | 42,141,343 | 37,866,768 |
| GROSS PROFIT | 18,009,352 | 15,180,921 | 34,442,290 | 28,452,110 |
| OPERATING EXPENSES: | | | | |
| Selling, general, and administrative | 8,795,625 | 7,650,977 | 17,331,427 | 14,840,524 |
| Research and development | 1,273,344 | 1,178,491 | 2,464,924 | 2,294,893 |
| Total operating expenses | 10,068,969 | 8,829,468 | 19,796,351 | 17,135,417 |
| OTHER OPERATING INCOME: | | | | |
| Gain on sale of land | | 182,433 | | 507,928 |
| INCOME FROM OPERATIONS | 7,940,383 | 6,533,886 | 14,645,939 | 11,824,621 |
| OTHER INCOME (EXPENSE): | | | | |
| Litigation settlement | | | 100,000 | 475,000 |
| Interest Income | 133,330 | 88,160 | 255,995 | 155,011 |
| Other income(expense) | 6,641 | (12,469) | (9,424) | (11,214) |
| Other income - net | 139,971 | 75,691 | 346,571 | 618,797 |
| INCOME BEFORE INCOME TAXES | 8,080,354 | 6,609,577 | 14,992,510 | 12,443,418 |
| INCOME TAX EXPENSE | 3,008,696 | 2,404,031 | 5,545,076 | 4,485,675 |
| NET INCOME | \$ 5,071,658 | \$ 4,205,546 | \$ 9,447,434 | \$ 7,957,743 |
| EARNINGS PER COMMON SHARE: | | | | |
| Basic | \$.19 | \$.17 | \$.36 | \$.32 |
| Diluted | \$.18 | \$.16 | \$.34 | \$.30 |

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AVERAGE COMMON SHARES:

| | | | | |
|---------|------------|------------|------------|------------|
| Basic | 26,301,004 | 25,201,865 | 26,183,069 | 25,117,861 |
| Diluted | 27,729,654 | 26,717,788 | 27,754,410 | 26,636,228 |

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003 (Unaudited)

| | Six Months Ended June 30, | |
|---|---------------------------|--------------------|
| | 2004 | 2003 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income | \$ 9,447,434 | \$ 7,957,743 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 2,355,125 | 2,235,580 |
| Losses (gains) on sales of property and equipment | 2,279 | (507,756) |
| Bad debt expense | 28,937 | 153,909 |
| Write-off of certain patents and trademarks | 33,493 | |
| Amortization of deferred credits | (107,867) | (81,037) |
| Deferred income taxes | (257,911) | 17,227 |
| Tax benefit attributable to appreciation of common stock options exercised | 2,161,814 | 629,851 |
| Changes in operating assets and liabilities: | | |
| Trade receivables | (2,218,775) | (2,470,628) |
| Employee and other receivables | (71,999) | 1,262,548 |
| Inventories | (1,619,076) | 795,855 |
| Prepaid expenses and other assets | (259,102) | (304,175) |
| Income tax refund receivable | 346,417 | |
| Deposits | (94,711) | 1,050 |
| Other assets | (695,780) | (217,803) |
| Trade payables | 2,899,820 | 1,213,715 |
| Accrued expenses | (109,544) | 615,006 |
| Advances from employees | 49,212 | (2,642) |
| Income taxes payable | 2,153,004 | 1,653,550 |
| Deferred compensation payable | 708,994 | 217,803 |
| Total adjustments | 5,304,330 | 5,212,053 |
| Net cash provided by operating activities | 14,751,764 | 13,169,796 |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Capital expenditures for: | | |
| Property and equipment | (9,515,912) | (4,144,640) |
| Patents and trademarks | (371,848) | (12,707) |
| Proceeds from the sale of property and equipment | 713 | 569,424 |
| Net cash used in investing activities | (9,887,047) | (3,587,923) |

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

MERIT MEDICAL SYSTEMS, INC. SUBSIDIARIES

FOR THE SIX MONTHS ENDED JUNE 30, 2004 AND 2003 (Unaudited)

| | Six Months Ended June 30, | |
|--|---------------------------|---------------|
| | 2004 | 2003 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from: | | |
| Issuance of common stock | 814,909 | 1,688,491 |
| Deferred credits | 5,998 | |
| Principal payments on long-term debt | (16,693) | (217,683) |
| Net cash provided by financing activities | 804,214 | 1,470,808 |
| EFFECT OF EXCHANGE RATES ON CASH | (7,872) | 66,564 |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 5,661,059 | 11,119,245 |
| CASH AND CASH EQUIVALENTS: | | |
| Beginning of period | 30,204,083 | 9,683,578 |
| End of period | \$ 35,865,142 | \$ 20,802,823 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION Cash paid | | |
| during the period for: | | |
| Interest | \$ 3,637 | \$ 16,022 |
| Income taxes | \$ 1,141,752 | \$ 1,487,584 |

SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

During the six months ended June 30, 2004, 19,715 matured shares (i.e. shares owned for more than six months) of the Company's common stock were surrendered in exchange for the Company's recording of payroll tax liabilities in the amount of approximately \$384,000 related to the exercise of stock options. The matured shares were valued based upon the closing price of the Company's common stock on the surrender date.

During the six months ended June 30, 2004 and 2003, 12,146 and 5,406 matured shares of the Company's common stock, with a value of approximately \$219,000 and \$56,256, respectively, were surrendered in exchange for the exercise of stock options.

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIESNOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. **Basis of Presentation.** The interim consolidated financial statements of Merit Medical Systems, Inc. (Merit, we or us) for the three and six month periods ended June 30, 2004 and 2003 are not audited. Our consolidated financial statements are prepared in accordance with the requirements for unaudited interim periods, and consequently, do not include all disclosures required to be in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, the accompanying consolidated financial statements contain all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of our financial position as of June 30, 2004, and our results of operations and cash flows for the three and six month periods ended June 30, 2004 and 2003. The results of operations for the three months ended June 30, 2004 and 2003 are not necessarily indicative of the results for a full-year period. These interim consolidated financial statements should be read in conjunction with the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003 filed with the Securities and Exchange Commission (the SEC).

Stock-Based Compensation. We account for stock compensation arrangements under the intrinsic value method outlined in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB 25) and currently intend to continue to do so. Accordingly, no compensation cost has been recognized for our stock compensation arrangements. If the compensation cost for our compensation plans had been determined consistent with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, our net income and net income per common and common share equivalent would have changed to the pro forma amounts indicated below:

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|--------------|------------------|--------------|
| | June 30, | | June 30, | |
| | 2004 | 2003 | 2004 | 2003 |
| Net income, as reported | \$ 5,071,658 | \$ 4,205,546 | \$ 9,447,434 | \$ 7,957,743 |
| Compensation cost under fair value-based accounting method, net of tax | 1,746,823 | 609,208 | 2,232,640 | 1,201,994 |
| Net income, pro forma | 3,324,835 | 3,596,338 | 7,214,794 | 6,755,749 |
| Net income per common share: | | | | |
| Basic: | | | | |
| As reported | \$ 0.19 | \$ 0.17 | \$ 0.36 | \$ 0.32 |
| Pro forma | 0.13 | 0.14 | 0.28 | 0.27 |
| Diluted: | | | | |
| As reported | 0.18 | 0.16 | 0.34 | 0.30 |
| Pro forma | 0.12 | 0.13 | 0.26 | 0.25 |

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in 2004 and 2003: dividend yield of 0%; expected volatility of 62.54% and 63.81% for 2004 and 2003, respectively; risk-free interest rates ranging from 2.32% to 4.48%; expected life of 5 years.

Reclassifications. Certain amounts have been reclassified in the prior year financials to conform with their year current presentation.

2. **Inventories.** Inventories at June 30, 2004 and December 31, 2003 consisted of the following:

| | June 30, | | December 31, | |
|-----------------|----------|------------|--------------|------------|
| | 2004 | | 2003 | |
| Finished goods | \$ | 11,937,888 | \$ | 11,996,307 |
| Work-in-process | | 4,050,034 | | 3,581,197 |
| Raw materials | | 6,900,534 | | 5,691,876 |
| Total | \$ | 22,888,456 | \$ | 21,269,380 |

3. **Reporting Comprehensive Income.** Comprehensive income for the three month and six month periods ended June 30, 2004 and 2003 consisted of net income and foreign currency translation adjustments. As of June 30, 2004 and December 31, 2003, the cumulative effect of such adjustments reduced stockholders' equity by \$424,573 and \$416,701, respectively. Comprehensive income for the three and six months ended June 30, 2004 and 2003 has been computed as follows:

| | Three Months Ended | | | | Six Months Ended | | | |
|------------------------------|--------------------|-----------|----------|-----------|------------------|-----------|----------|-----------|
| | June 30, | | June 30, | | June 30, | | June 30, | |
| | 2004 | 2003 | 2004 | 2003 | 2004 | 2003 | 2004 | 2003 |
| Net income | \$ | 5,071,658 | \$ | 4,205,546 | \$ | 9,447,434 | \$ | 7,957,743 |
| Foreign currency translation | | (11,469) | | 59,605 | | (7,872) | | 66,654 |
| Comprehensive income | \$ | 5,060,189 | \$ | 4,265,151 | \$ | 9,439,562 | \$ | 8,024,397 |

4. **Stock Split.** On August 15, 2003 and December 3, 2003, we effected a four-for-three forward split of our common stock. All earnings per share and share data have been adjusted to reflect those splits.

5. **Recently Issued Accounting Standard.** In March 2004 the Emerging Issues Task Force (EITF) reached a final consensus on Issue 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments. EITF 03-1 requires that when the fair value of an investment security is less than its carrying value, impairment exists for which the determination must be made as to whether the impairment is other-than-temporary. The EITF 03-1 impairment model applies to all investment securities accounted for under Statements of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities and to investment securities accounted for under the cost method to the extent an impairment indicator exists. Under the guidance, the determination of whether an impairment is other than temporary and therefore would result in a recognized loss depends on market conditions and management's intent and ability to hold the securities

with unrealized losses. The Company is required to adopt the impairment evaluation and recognition guidance in EITF 03-1 in the third quarter ending September 30, 2004, and is currently assessing the impact its consolidated financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Disclosure Regarding Forward-Looking Statements

This Report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements, other than statements of historical fact, are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this Report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, intends, believes, estimates, potential, or continue, or the negative or comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that any such expectations or any forward-looking statements will prove to be correct. Our actual results will vary, and may vary materially from those projected or assumed in the forward-looking statements. Future financial condition and results of operations, as well as any forward-looking statements are subject to inherent risks and uncertainties, including market acceptance of our products, product introductions, potential product recalls, delays in obtaining regulatory approvals, or the failure to maintain such approvals, cost increases, fluctuations in and obsolescence of inventory, price and product competition, availability of labor and materials, development of new products and technology that could render our products obsolete, product liability claims, modification or limitation of governmental or private insurance reimbursement procedures, infringement of our technology or the assertion that our technology infringes the rights of other parties, foreign currency fluctuations, challenges associated with the Company's growth strategy, changes in healthcare markets related to healthcare reform initiatives, and other factors referred to in our press releases and reports filed with the SEC, including our Annual Report on Form 10-K for the year ended December 31, 2003. All subsequent forward-looking statements attributable to Merit or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on our operating results are described under Factors That May Affect Future Results beginning on page 11 below.

Overview

We reported record quarterly sales and earnings for the three and six-month periods ended June 30, 2004. For the quarter ended June 30, 2004, we reported net income of \$5.1 million, or approximately \$0.18 per share, on revenues of \$38.9 million. For the comparable period of 2003, we reported net income of \$4.2 million, or approximately \$0.16 per share, on revenues of \$34.6 million, which included a gain from the sale of land of approximately \$117,000 (net of tax). Excluding that gain, net income for the second quarter of 2004 was up 24% for the comparable period. For the six months ended June 30, 2004, net income was \$9.4 million, or \$0.34 per share, on revenues of \$76.6 million, compared to 2003 net income of \$8.0 million, or \$0.30 per share, on revenues of \$66.3 million. During the six months ended June 30, 2003, we recorded a gain from the settlement of a legal dispute and sale of land in the amount of approximately \$629,000 (net of tax), or \$0.02 per share. Excluding that gain, net income for the six months ended June 30, 2004 was up 29% over the prior period. Gross margins improved by 2.4% and 2.1%, respectively, for the three and six-month periods ended June 30, 2004, when compared to the same periods in 2003. Cash flow from operations was strong for the six months ended June 30, 2004 at \$14.8 million, up \$1.6 million from the comparable period in 2003.

Results of Operations

The following table sets forth certain operational data as a percentage of sales for the three and six-month periods ended June 30, 2004 and 2003:

| | Three Months Ended | | Six Months Ended | |
|--|--------------------|--------|------------------|--------|
| | June 30, | | June 30, | |
| | 2004 | 2003 | 2004 | 2003 |
| Sales | 100.0% | 100.0% | 100.0% | 100.0% |
| Gross profit | 46.3 | 43.9 | 45.0 | 42.9 |
| Selling, general and administrative expenses | 22.6 | 22.1 | 22.6 | 22.4 |
| Research and development expenses | 3.3 | 3.4 | 3.2 | 3.5 |
| Other operating income | 0.5 | 0.8 | | |
| Income from operations | 20.4 | 18.9 | 19.1 | 17.8 |
| Other income | 0.4 | 0.2 | 0.5 | 0.9 |
| Net income | 13.0 | 12.2 | 12.3 | 12.0 |

Sales. Sales for the three months ended June 30, 2004 increased by 13%, or \$4.3 million, compared to the same period of 2003. Compared to the second quarter of 2003, catheter sales grew 17%; inflation device sales rose 15%; stand alone device sales grew by 11%; and custom kit sales rose 9%. Sales for the six months ended June 30, 2004 increased by 15%, or \$10.3 million. Compared to the six month period of 2003, catheter sales grew 20%; custom kit sales rose 19%; stand alone device sales increased 15%; and inflation device sales grew 12%. Our revenues increased during the three and six-month periods of 2004 notwithstanding the fact that the markets for many of our products are experiencing slight pricing declines; therefore substantially all of the increase in our revenues was attributable to increased unit sales. Sales were favorably affected by an increase in the exchange rate between the Euro and the U.S. Dollar which increased sales by 1.0% and 2.1% for the three and six-month periods ended June 30, 2004, respectively, when compared to the same periods in 2003.

Gross Profit. During the second quarter of 2004, gross profit increased to 46.3% as a percentage of sales, compared to 43.9% of sales for the same period of 2003. For the six months ended June 30, 2004, gross profit improved to 45.0%, compared to 42.9%, for the comparable period in 2003. The increase in the gross margin percentage for the three and six months ended June 30, 2004, when compared to the same periods of 2003, was favorably affected by an increase in efficiency and productivity gains achieved primarily by our operations groups. These productivity gains have been achieved primarily by enhanced employee productivity, which management believes was encouraged by the Company's bonus program, streamlined production layouts and investments in manufacturing equipment which have improved efficiencies. With these improved efficiencies, our cost per unit for many of our products has decreased as our unit sales have grown notwithstanding slight increases in fixed overhead costs. Gross profit was also favorably affected by an increase of the exchange rate of the Euro against the U.S. Dollar, resulting in an increase in gross profit of 0.3% for the three and six-month periods ended June 30, 2004, when compared to the same periods in 2003.

Operating Expenses. Operating expenses increased slightly to 25.9% of sales for the second quarter 2004, compared to 25.5% of sales for the same period of 2003. For the six months ended June 30, 2004 and 2003, operating expenses remained flat at 25.8% of sales. Selling, general and administrative expenses as a percentage of sales were 22.6% for the second quarter of 2004, compared to 22.1% of sales for the same period of 2003. The slight increase in operating expenses as a percentage of sales during the three months ended March 31, 2004 was due primarily to an increase in sales commission expense commensurate with the increase in sales for the quarter, tax consulting work and increased costs associated with the implementation of readiness procedures required by the Sarbanes-Oxley Act. Research and development expenses decreased slightly to 3.3% of sales during the second quarter of 2004, compared to 3.4% of sales for the same period in 2003. For the six months ended June 30, 2004, research and development expenditures decreased to 3.2% of sales, compared to 3.5% of sales for 2003.

Other Income. Other income for the second quarter of 2004 was \$139,971, compared to \$75,691 for the same period in 2003. The increase in other income during the second quarter of 2004 when compared to the same period in 2003 was principally the result of an increase in interest income of \$45,170. Other income for the six months ended June 30, 2004 was \$346,571, compared to other income of \$618,797 for the six months ended June 30, 2003. The decrease in other income for the six months ended June 30, 2004, when compared to the same period in 2003, was attributable primarily to the result of a gain from the settlement of a legal dispute of \$475,000. Absent this legal settlement, other income for the six months ended June 30, 2004 would have increased primarily as the result of an increase in interest income of \$100,984, when compared to the same period in 2003.

Income Taxes. Our effective tax rate for the three months ended June 30, 2004 was 37.2% compared to 36.4% for the same period of 2003. For the six months ended June 30, 2004, our effective tax rate was 37.0%, compared to 36.0% for the same period of 2003. The increase in the effective tax rate for the three and six months ended June 30, 2004, as compared to the same periods of the prior year, was the result of lower research and development tax credits anticipated for 2004.

Income. During the second quarter of 2004, we reported income from operations of \$7.9 million, an increase of 25% from \$6.4 million for the comparable period in 2003. For the six months ended June 30, 2004, we reported income from operations of \$14.6 million, an increase of 29% from \$11.3 million for the comparable period in 2003. The increase in operating income for the three and six months ended June 30, 2004 was attributable primarily to increased sales and higher gross margins. These factors contributed to our net income of \$5.1 million for the three months ended June 30, 2004, compared to net income of \$4.2 million for the same period of 2003, and net income for the six months ended June 30, 2004 of \$9.4 million compared to \$8.0 million for the first half of 2003.

Liquidity and Capital Resources

On June 30, 2004, our working capital was \$61.9 million, which represented a current ratio of 4.3 to 1, compared to \$56.9 million and a current ratio of 5.1 to 1. Our cash balance at June 30, 2004 was \$35.9 million, compared to \$30.2 million. Historically, we have incurred significant expenses in connection with product development and introduction of new products. Substantial capital has also been required to finance the increase in our receivables and inventories associated with our increased sales. We anticipate that during 2004 and the first half of 2005, we will need substantial funds to construct additional facilities in South Jordan, Utah and in Galway, Ireland. Construction of these facilities is currently estimated to cost approximately \$26 million in the aggregate. We anticipate that an additional \$5 million, in excess of our 2003 annual capital expenditures, will be spent on a finished goods handling system and other production equipment for these new facilities. Our principal source of funding for these and other expenses has been cash generated from operations, sale of equity, cash from loans on equipment and bank lines of credit. Management believes that our present sources of liquidity and capital are adequate for our current and anticipated operations for the foreseeable future.

Critical Accounting Policies

The SEC has requested that all registrants discuss their most critical accounting policies. We understand that a critical accounting policy is one which is both important to the representation of the subject company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We base our estimates on past experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following are our most critical accounting policies:

Inventory Obsolescence Reserve. We write-down our inventory for estimated obsolescence for unmarketable or slow-moving products that may expire prior to being sold. If market conditions become less favorable than those

projected by our management, additional inventory write-downs may be required. Our obsolescence reserve was approximately \$2.4 million as of June 30, 2004.

Allowance for Doubtful Accounts. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of customers to make required payments. The allowance is based upon historical experience and a review of individual customer balances. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. Our bad debt reserve was \$776,662 at June 30, 2004, which is generally in line with our historical collection experience.

Factors that May Affect Future Results

Our business, operations and financial condition are subject to certain risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results will vary, and may vary materially, from those anticipated, estimated, projected or expected. The following are among the key factors that may have a direct bearing on our business, operations and financial condition:

Our products may be subject to recall or product liability claims.

Our products are used in connection with surgical procedures and in other medical contexts in which it is important that those products function with precision and accuracy. If our products do not function as designed, or are designed improperly, we may withdraw such products from the market. In addition, if medical personnel or their patients suffer injury as a result of any failure of our products to function as designed, or a design is inappropriate, we may be subject to lawsuits seeking significant compensatory and punitive damages. Any product recall or lawsuit seeking significant monetary damages may have a material adverse effect on our business and financial condition.

Substantially all of our products are backed by a limited warranty for returns due to defects in quality and workmanship. We maintain a reserve for these future returned products, but the actual costs of such returns may significantly exceed the reserve, which could have a material adverse effect on our operations.

Termination of relationships with our suppliers, or failure of such suppliers to perform, could disrupt our business.

We rely on raw materials, component parts, finished products, and services supplied by outside third parties in connection with our business. For example, substantially all of our products are sterilized by two entities. In addition, some of our products are manufactured or assembled by third parties. If a supplier of significant raw materials, component parts, finished goods or services were to terminate its relationship with Merit, or otherwise cease supplying raw materials, component parts, finished goods or services consistent with past practice, our ability to meet our obligations to our customers may be disrupted. A disruption with respect to numerous products, or with respect to a few significant products, could have a material adverse effect on our business and financial condition.

We may be unable to compete in our markets, particularly if there is a significant change in relevant practices and technology.

The market for each of our existing and potential products is highly competitive. We face competition from several companies, many of which are larger, better established and have greater financial, technical and other resources and greater market presence than does Merit. Such resources and market presence may enable our competitors to more effectively market competing products or to market competing products at reduced prices in order to gain market share.

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Our ability to compete successfully is dependent, in part, upon our ability to respond effectively to changes in technology and to develop and market new products which achieve significant market acceptance. Competing companies with substantially greater resources than Merit are actively engaged in research and development of diagnostic and interventional methods, treatments and procedures that could limit the market for our products and eventually make certain of our products obsolete. A reduction in the demand for a significant number of our products, or a few key products, could have a material adverse effect on our business and financial condition.

We may be unable to protect our proprietary technology or our technology may infringe on the proprietary technology of others.

Our ability to remain competitive is dependent, in part, upon our ability to prevent other companies from using proprietary technology incorporated into our products. We seek to protect our technology through a combination of patents and trade secrets, as well as license, proprietary know-how and confidentiality agreements. We may be unable, however, to prevent others from using our proprietary information, or to use such information ourselves, for numerous reasons, including the following:

Our issued patents may not be sufficiently broad to prevent others from copying our proprietary technologies;

Our issued patents may be challenged by third parties and deemed to be overbroad or unenforceable;

Our products may infringe on the patents of others, requiring us to alter or discontinue our manufacture or sale of such products;

Costs associated with seeking enforcement of our patents against infringement, or defending ourselves against allegations of infringement, may be significant;

Our pending patent applications may not be granted for various reasons, including overbreadth or conflict with an existing patent; and

Other persons may independently develop, or have developed, similar or superior technologies.

A significant adverse change in, or failure to comply with, governing regulations could adversely affect our business.

Substantially all of our products are devices, as defined in the Federal Food, Drug and Cosmetic Act, and the manufacture, distribution, record keeping, labeling and advertisement of our products is subject to regulation by the Food and Drug Administration (the FDA) in the United States and comparable regulatory agencies in various foreign countries in which our products are manufactured, distributed, labeled, offered or sold. Further, we are subject to continual review and periodic inspections at our current facilities with respect to the FDA's Good Manufacturing Practices and similar requirements of foreign countries. Our business and financial condition could be adversely affected if we are found to be out of compliance with governing regulations. In addition, if such regulations are amended to become more restrictive and costly to comply with, the costs of compliance could adversely affect our business and financial condition.

A significant portion of our revenues are derived from a few products and procedures.

A significant portion of our revenues are attributable to sales of our inflation devices. During the year ended December 31, 2003, sales of our inflation devices (including inflation devices sold in custom kits) accounted for approximately 33% of our total revenues. During the three and six-month periods ended June 30, 2004, sales of our inflation devices (including inflation devices sold in custom kits) accounted for approximately 33% and 32%, respectively, of our total revenues. Any material decline in market demand for our inflation devices could have an adverse effect on our business and financial condition.

These products have accounted for a majority of our historical revenues and are designed for use in connection with a few related medical procedures, including angiography, angioplasty and stent placement procedures. If subsequent developments in medical technology or drug

therapy make such procedures obsolete, or alter the methodology of such procedures to eliminate the usefulness of our products, we may experience a material decrease in demand for our products and experience deteriorating financial performance.

We are subject to work stoppage, transportation and related risks.

We manufacture our products at various locations in the United States and in Ireland and sell our products throughout the United States, Europe and other parts of the world. We depend on third-party transportation companies to deliver supplies necessary to manufacture Merit products from vendors to our various facilities and to move Merit products to customers, operating divisions and other subsidiaries located within and outside the United States. Our manufacturing operations, and the operations of the transportation companies on which our operations depend, may be adversely affected by natural disasters and significant human events, such as war, terrorist attack, riot, strike, slowdown or similar event. Any disruption in our manufacturing or transportation could materially adversely affect our ability to meet customer demands or conduct our operations.

Limits on reimbursement imposed by governmental and other programs may adversely affect our business.

The cost of a significant portion of medical care is funded by governmental, social security or other insurance programs. Limits on reimbursement imposed by such programs may adversely affect the ability of hospitals and others to purchase Merit products. In addition, limitations on reimbursement for procedures which use Merit products could adversely affect our sales.

Fluctuations in Euro exchange rates may negatively impact our financial results.

Fluctuations in the rate of exchange between the Euro and the U.S. Dollar could have a negative impact on our margins and financial results. For example, during 2003, the exchange rate between the Euro and U.S. Dollar resulted in an increase of the Company's gross revenues of \$2.4 million and 0.3% in gross profit. For the three months ended June 30, 2004, the exchange rate resulted in an increase of gross revenues of \$399,412 and approximately 0.3% increase in gross profit.

For the three months ended June 30, 2004, approximately \$3.8 million, or 9.9%, of our sales were denominated in Euros. If the rate of exchange between the Euro and the U.S. Dollar declines, we may not be able to increase the prices that we charge our European customers for products whose prices are denominated in Euros. We may be unable to, or elect not to enter into hedging transactions which could mitigate the effect of declining exchange rates. As a result, as the rate of exchange between Euros and the U.S. Dollars declines, our financial results may be negatively impacted.

We may be unable to successfully manage growth, particularly if accomplished through acquisitions.

Successful implementation of our business strategy will require that we effectively manage any associated growth. To manage growth effectively, our management will need to continue to implement changes in certain aspects of our business, enhance our information systems and operations to respond to increased demand, attract and retain qualified personnel and develop, train and manage an increasing number of management-level and other employees. Growth could place an increasing strain on our management, financial, product design, marketing, distribution and other resources, and we could experience operating difficulties. Any failure to manage growth effectively could have a material adverse effect on our results of operations and financial condition.

To the extent that we grow through acquisition, we will face the additional challenges of integrating our current operations, culture, information management systems and other characteristics with that of the acquired entity. We may incur significant expenses in connection with negotiating and consummating one or more transactions, and we may inherit certain liabilities in connection with the acquisition as a result of our failure to conduct adequate due diligence or otherwise. We may not realize competitive advantages, synergies or other benefits anticipated in connection with such acquisition(s). If we do not adequately identify targets for, or manage issues related to our future acquisitions, such acquisitions may have a negative adverse effect on our business and financial results.

The market price of our common stock has been, and may continue to be, volatile.

The market price of our common stock has been, and may continue to be, highly volatile for various reasons, including the following:

Our announcement of new products or technical innovations, or similar announcements by our competitors;

Development of new procedures that use, or do not use, our technology;

Quarter-to-quarter fluctuations in our financial results;

Claims involving potential infringement of patents and other intellectual property rights;

Analyst and other projections or recommendations regarding our common stock or medical technology stocks generally;

Any restatement of our financial statements or any investigation into Merit by the SEC or another regulatory authority; and

A general decline, or rise, of stock prices in the capital markets.

We are dependent upon key personnel.

Our continued success is dependent on key management personnel, including Fred P. Lampropoulos, our Chairman of the Board, President and Chief Executive Officer. Mr. Lampropoulos is not subject to any agreement prohibiting his departure, and we do not maintain a key man life insurance with respect to his life. The loss of Mr. Lampropoulos, or of certain other key management personnel, could materially adversely affect our business and operations. Our success also depends, among other factors, on the successful recruitment and retention of key operations, manufacturing, sales and other personnel.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our principal market risk relates to changes in the value of the Euro relative to the value of the U.S. Dollar. Our consolidated financial statements are denominated in, and our principal currency is, the U.S. Dollar. A portion of our revenues for the three months ended June 30, 2004 (\$3.8 million, representing approximately 9.9% of aggregate revenues) came from sales that were denominated in Euros. Certain of our expenses are also denominated in Euros, partially offsetting any risk associated with fluctuations of the Euro/Dollar exchange rate. Because of our Euro-denominated revenues and expenses, in a year in which our Euro-denominated revenues exceed our Euro-based expenses, the value of such Euro-denominated net income increases if the value of the Euro increases relative to the value of the U.S. Dollar, and decreases if the value of the Euro decreases relative to the value of the U.S. Dollar. During 2004, the exchange rate between the Euro and the U.S. Dollar resulted in an increase of our gross revenues of \$399,412 and \$1.1 million for the three and six months ended June 30, 2004, respectively, and 0.3% in gross profit.

At June 30, 2004, we had a net exposure (representing the difference between Euro-denominated receivables and Euro-denominated payables) of approximately \$1.5 million. In order to partially offset such risk, on May 28, 2004, we entered into a 30-day Euro forward hedge contract. We entered into similar hedging transactions at various times during the year in an effort to partially offset exchange rate risks we bore throughout the year. We do not purchase or hold derivative financial instruments for speculative or trading purposes. During the three and six months ended June 30, 2004, we experienced a net loss of \$48,290 and \$5,343 on these economic hedging transactions.

As of June 30, 2004, we had no variable rate debt. As long as we do not have variable rate debt, our interest expense would not be affected by changes in interest rates.

ITEM 4: CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer, or CEO, and the Company's Chief Financial Officer, or CFO, of the effectiveness of the Company's disclosure controls and procedures, as of June 30, 2004. Based on that evaluation, the Company's management, including its CEO and CFO, concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports filed or submitted by the Company under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported as specified in the SEC's rules and forms. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls subsequent to the evaluation.

PART II - OTHER INFORMATION

ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On May 25, 2004, we held our 2004 Annual Meeting of Shareholders at which our shareholders considered and voted as follows on the items described below:

1. The shareholders considered whether to elect the following persons as directors, each to serve until our next annual meeting of shareholders and until his respective successor shall have been duly elected and shall qualify:

| | Votes | |
|--------------------|------------|----------|
| | Received | Withheld |
| Rex C. Bean | 23,890,142 | 802,136 |
| Richard W. Edelman | 23,932,457 | 759,821 |

In addition to Messrs. Bean and Edelman, Fred P. Lampropoulos, Kent W. Stanger, James J. Ellis and Michael E. Stillabower continued to serve as directors of the Company.

2. Our shareholders also considered a proposal to amend the Merit Medical Systems, Inc. 1999 Omnibus Stock Incentive Plan to: (i) change the name of the plan to the Merit Medical Systems, Inc. Stock Incentive Plan, (ii) to increase the number of shares of Common Stock of the Company available for the grant of awards under the plan from 4,678,861 shares to 5,928,861 shares; (iii) establish the minimum vesting periods for grants of restricted stock under the plan, and (iv) limit the discretion of the plan's administrative committee (currently the Compensation Committee of the Company's Board of Directors) to amend the plan or waive certain restrictions set forth in the plan. There were 14,910,011 votes cast in favor of the proposal, 5,234,713 votes cast in opposition, 98,197 votes withheld and 4,709,068 broker non-votes.

3. Our shareholders also considered a proposal to ratify the appointment by our Board of Directors of Deloitte & Touche, LLP as our auditors for the fiscal year ending December 31, 2004. There were 22,744,814 votes cast in favor, 2,182,858 votes cast against, and 23,777 votes withheld.

ITEM 6: EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits -

| Exhibit No. | Description |
|-------------|--|
| 31.1 | Certification of Principal Executive Officer |
| 31.2 | Certification of Principal Financial Officer |
| 32.1 | Certification of Principal Executive Officer |
| 32.2 | Certification of Principal Financial Officer |

(b) The following Current Reports on Form 8-K were filed during the quarter ended June 30, 2004:

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| Form 8-K | Date of Event | Description |
|-----------------|----------------------|---|
| Item 7&12 | 4/20/2004 | Company's financial and operating results for the quarter ended June 30, 2004 |
| Item 9 | 5/10/2004 | Additional information request about fees paid to independent auditors Deloitte and Touche LLP. |
| Item 7&12A | 6/4/2004 | Amendment to Company's 8-K filed on April 20, 2004. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this amendment to be signed on its behalf by the undersigned thereunto duly authorized.

MERIT MEDICAL SYSTEMS, INC.
REGISTRANT

Date: October 1, 2004

/s/ KENT W. STANGER
KENT W. STANGER
SECRETARY AND CHIEF FINANCIAL
OFFICER