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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2004.

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 0-18592

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. 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

26,275,722

TITLE OR CLASS

Number of Shares Outstanding at May 3, 2004

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Item 1. FINANCIAL STATEMENTS

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

MARCH 31, 2004 AND DECEMBER 31, 2003 (Unaudited)

	March 31, 2004	December 31, 2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 33,893,118	\$ 30,204,083
Short-term investments	1,039,908	572,988
Trade receivables—net	19,030,958	17,728,457
Employee and other receivables	236,167	267,288
Inventories	22,193,521	21,269,380
Prepaid expenses and other assets	777,896	823,221
Deferred income tax assets	435,369	220,625
Income tax refund receivable	179,113	374,644
Total current assets	77,786,050	71,460,686
PROPERTY AND EQUIPMENT:		
Land	2,740,394	2,740,394
Building	5,269,821	5,268,260
Manufacturing equipment	29,947,120	29,480,421
Furniture and fixtures	12,253,658	11,953,358
Leasehold improvements	4,683,068	4,615,947
Automobiles	87,536	87,536
Construction-in-progress	7,002,596	4,886,530
Total	61,984,193	59,032,446
Less accumulated depreciation and amortization	(30,915,636)	(29,835,769)
Property and equipment—net	31,068,557	29,196,677
OTHER ASSETS:		
Patents, trademarks and licenses—net	2,119,584	1,846,392
Goodwill	4,764,596	4,764,596
Deposits	126,874	32,163
Total other assets	7,011,054	6,643,151
TOTAL ASSETS	\$ 115,865,661	\$ 107,300,514

See notes to consolidated financials statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

MARCH 31, 2004 AND DECEMBER 31, 2003 (Unaudited)

	<u>March 31,</u> <u>2004</u>	<u>December 31,</u> <u>2003</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	\$	\$ 16,693
Trade payables	6,412,107	5,700,491
Accrued expenses	8,965,608	8,567,093
Advances from employees	192,087	158,885
Income taxes payable	947,446	86,973
Total current liabilities	16,517,248	14,530,135
DEFERRED INCOME TAX LIABILITIES	2,929,300	3,020,217
DEFERRED CREDITS	1,455,241	1,506,753
Total liabilities	20,901,789	19,057,105
STOCKHOLDERS' EQUITY:		
Preferred stock—5,000,000 shares authorized as of March 31, 2004, no shares issued		
Common stock—no par value; 50,000,000 shares authorized; 26,265,141 and 26,002,544 shares issued at March 31, 2004 and December 31 2003, respectively	40,042,719	37,701,629
Retained earnings	55,334,257	50,958,481
Accumulated other comprehensive loss	(413,104)	(416,701)
Total stockholders' equity	94,963,872	88,243,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 115,865,661	\$ 107,300,514

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 2004, AND 2003 (Unaudited)

	Three Months Ended March 31,	
	2004	2003
NET SALES	\$ 37,662,689	\$ 31,741,573
COST OF SALES	21,229,751	18,470,384
GROSS PROFIT	16,432,938	13,271,189
OPERATING EXPENSES:		
Selling, general, and administrative	8,535,802	7,189,547
Research and development	1,191,580	1,116,402
Total operating expenses	9,727,382	8,305,949
INCOME FROM OPERATIONS	6,705,556	4,965,240
OTHER INCOME:		
Litigation settlement	(100,000)	(475,000)
Gain on sale of land		(325,495)
Other income—(net)	(106,600)	(68,106)
Other income	(206,600)	(868,601)
INCOME BEFORE INCOME TAXES	6,912,156	5,833,841
INCOME TAX EXPENSE	2,536,380	2,081,644
NET INCOME	\$ 4,375,776	\$ 3,752,197
EARNINGS PER COMMON SHARE:		
Basic	\$.17	\$.15
Diluted	\$.16	\$.14
WEIGHTED AVERAGE COMMON SHARES:		
Basic	26,057,803	25,032,924
Diluted	27,771,834	26,553,735

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2004, AND 2003 (Unaudited)

	Three Months Ended March 31,	
	2004	2003
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 4,375,776	\$ 3,752,197
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,153,904	1,118,482
Gains on sales of property and equipment	(31)	(325,495)
Bad debt expense	10,000	65,597
Write-off of certain patents and trademarks	27,017	
Amortization of deferred credits	(57,515)	(41,398)
Deferred income taxes	(305,661)	(5,620)
Tax benefit attributable to appreciation of common stock options exercised	1,804,158	157,069
Changes in operating assets and liabilities:		
Short-term investments	(466,920)	(55,807)
Trade receivables	(1,312,501)	(1,006,574)
Employee and other receivables	31,121	230,747
Inventories	(924,141)	998,047
Prepaid expenses and other assets	45,325	(187,561)
Income tax refund receivable	195,531	212,039
Deposits	(94,711)	1,050
Trade payables	711,616	(2,632)
Accrued expenses	398,515	266,674
Advances from employees	33,202	27,311
Income taxes payable	860,473	1,865,915
Total adjustments	2,109,382	3,317,844
Net cash provided by operating activities	6,485,158	7,070,041
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures for:		
Property and equipment	(2,987,352)	(2,084,379)
Patents and trademarks	(339,323)	29,654
Proceeds from the sale of property and equipment	713	353,825
Net cash used in investing activities	(3,325,962)	(1,700,900)

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2004, AND 2003 (Unaudited)

	Three Months Ended March 31,	
	2004	2003
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from:		
Issuance of common stock	536,932	1,213,631
Deferred credits	6,003	
Principal payments on long-term debt	(16,693)	(107,880)
Net cash provided by financing activities	526,242	1,105,751
EFFECT OF EXCHANGE RATES ON CASH	3,597	6,959
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,689,035	6,481,851
CASH AND CASH EQUIVALENTS:		
Beginning of year	30,204,083	9,683,578
End of quarter	\$ 33,893,118	\$ 16,165,429
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION—Cash paid during the period for:		
Interest	\$ 3,138	\$ 11,130
Income taxes	\$ 10,464	\$ 154,548

SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES:

- During the three months ended March 31, 2004, matured shares to purchase 13,293 shares of the company's common stock were surrendered in exchange for the Company's recording of payroll tax liabilities in the amount of approximately \$289,000.
- During the three months ended March 31, 2004, 5,295 matured shares of Company common stock with a value of approximately \$115,000 were surrendered in exchange for the exercise of stock options.

See notes to consolidated financial statements.

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Basis of Presentation. The interim financial statements of Merit Medical Systems, Inc. ("Merit," "we" or "us") for the three months ended March 31, 2004 and 2003 are not audited. The 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 March 31, 2004, and our results of operations and cash flows for the three months ended March 31, 2004 and 2003. The results of operations for the three months ended March 31, 2004 and 2003 are not necessarily indicative of the results for a full-year period.

Stock-Based Compensation. We account for stock compensation arrangements under the provisions of 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 March 31,	
	2004	2003
Net income, as reported	\$ 4,375,776	\$ 3,752,197
Compensation cost under fair value-based accounting method, net of tax	497,996	592,786
Net income, pro forma	3,877,780	3,159,411
Net income per common share:		
Basic:		
As reported	\$ 0.17	\$ 0.15
Pro forma	0.15	0.13
Diluted:		
As reported	0.16	0.14
Pro forma	0.14	0.12

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 2003 and 2002: dividend yield of 0%; expected volatility of 63.81% and 63.24% for 2003 and 2002, respectively; risk-free interest rates ranging from 2.32% to 6.71%; and expected lives ranging from 2.33 to 4.98 years.

2. Inventories. Inventories at March 31, 2004 and December 31, 2003 consisted of the following:

	March 31, 2004	December 31, 2003
Finished goods	\$ 10,995,123	\$ 11,996,307
Work-in-process	4,369,944	3,581,197
Raw materials	6,828,454	5,691,876
Total	\$ 22,193,521	\$ 21,269,380

3. Reporting Comprehensive Income. Comprehensive income for the three months ended March 31, 2004 and 2003 consisted of net income and foreign currency translation adjustments. As of March 31, 2004 and December 31, 2003, the cumulative effect of such adjustments reduced stockholders' equity by \$413,104 and \$416,701, respectively. Comprehensive income for the three months ended March 31, 2004 and 2003 has been computed as follows:

	Three Months Ended March 31,	
	2004	2003
Net income	\$ 4,375,776	\$ 3,752,197
Foreign currency translation	3,597	6,959
Comprehensive income	\$ 4,379,373	\$ 3,759,156

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

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" or "believes," "estimates," "potential," or "continue," or the negative thereof or other 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 Securities and Exchange Commission (the "SEC"). 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

During the three months ended March 31, 2004 we reported net income of \$4.4 million, or approximately \$0.16 per share, on revenues of \$37.7 million, which included a gain from the settlement of a legal dispute of \$64,750 (net of tax), or less than \$0.01 per share. For the comparable period of 2003, we reported net income of \$3.8 million, or \$.14 per share, on revenues of \$31.7 million, which included a gain from settlement of a legal dispute and sale of land in the amount of \$512,317 (net of tax), or approximately \$0.02 per share. During the three months ended March 31, 2004, our sales increased by approximately 19% compared to the same period in 2003.

The increase in net income for the three months ended March 31, 2004, was favorably affected by increased sales and higher gross margins, when compared to the comparable period in 2003.

Management has continued its efforts to increase inventory turns, which improved during the three months ended March 31, 2004 to 3.9 times per year from 3.7 times per year for the same period of 2003. Our cash flow from operations was \$6.5 million for the first three months of 2004, compared

to \$7.1 million for the comparable period of 2003. Our cash position was \$33.9 million at March 31, 2004, compared to \$16.2 million at March 31, 2003.

Results of Operations

Our sales increased to record levels for the three months ended March 31, 2004. We reported record net income of \$4.4 million for the three months ended March 31, 2004, compared to net income of \$3.8 million for the same period of 2003. The following table sets forth certain operational data as a percentage of sales for the three months ended March 31, 2004 and 2003:

	Three Months Ended March 31,	
	2004	2003
Sales	100.0%	100.0%
Gross profit	43.6	41.8
Selling, general and administrative expenses	22.7	22.7
Research and development expenses	3.2	3.5
Income from operations	17.8	15.6
Other (income) expense	(.5)	(2.7)
Net income	11.6	11.8

Sales. Sales for the three months ended March 31, 2004 increased by 19%, or \$5.9 million, compared to the same period of 2004. All product categories of our business contributed to our sales growth during the first three months of 2004. Custom kits sales rose 30%, catheter sales grew 22%, stand alone device sales grew by 19%, and inflation device sales rose 8%. Our revenues increased 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, except for an increase in the exchange rate between the EURO and the U.S. Dollar which increased sales by 1.8% for the three months ended March 31, 2004, when compared to the same period in 2003. Increases in custom kits sales in the first quarter of 2004, compared to the comparable quarter of 2003, represent the implementation of our strategy of focusing on a core strength of building high-quality, innovative products that can be packaged together in custom kits.

Gross Profit. Gross profit as a percentage of sales increased during the first three months of 2004 to 43.6%, compared to 41.8% for the same period of 2003. The increase in the gross margin percentage for the three months ended March 31, 2004, when compared to the same period, of 2003, was favorably affected by an increase in efficiency and productivity gains achieved by our operations groups and an increase of the exchange rate of the EURO against the U.S. Dollar when compared to the same period in 2003, resulting in an increase in gross profit of .2%.

Operating Expenses. Operating expenses decreased slightly as a percentage of sales to 25.8% of sales for the three months ended March 31, 2004, compared to 26.2% for the same period of 2003. Selling, general and administrative expenses as a percentage of sales were 22.7% for both the quarter ended March 31, 2004 and the same period of 2003. The decrease in operating expenses as a percentage of sales during the three months ended March 31, 2004 was due primarily to our increased revenues during the three months ended March 31, 2004. Research and development expenses increased slightly by \$75,178 and decreased as a percentage of sales to 3.2% of sales during the three months ended March 31, 2004, compared to 3.5% of sales for the same period of 2003.

Other Income. Other income for the three months ended March 31, 2004 was \$206,600, compared to \$868,601 for the same period in 2003. During the three months ended March 31, 2004, other income consisted of multiple items, including a gain from settlement of a legal dispute of \$100,000. In contrast,

other income for the same period of 2003 consisted primarily of a gain from the settlement of a legal dispute of \$475,000 and a gain on sale of land adjacent to the Company's South Jordan, Utah facility for \$325,495. During the quarter ended March 31, 2004, interest income was \$122,665, compared to \$66,851 for the same period in 2003.

Income Taxes. Our effective tax rate for the three months ended March 31, 2004 and 2003 was 36.7% and 35.7%, respectively. The increase in the effective tax rate for the three months ended March 31, 2004, as compared to the same period of the prior year was the result of a greater loss from our Galway, Ireland operations. These losses are booked as a deferred tax asset but at a lower tax rate benefit for Irish purposes than U.S. purposes. The increase in losses for our Irish operations was principally the result of increased costs associated with the development of two new products which are scheduled to be released during 2004 and 2005. Our overall research and development costs are not increasing significantly, primarily because our U.S. research and development department is performing contract research for our Galway operations, which has increased our Ireland research and development costs.

Income. During the three months ended March 31, 2004, we reported income from operations of \$6.7 million, an increase of 35% from income from operations of \$5.0 million for the comparable period in 2003. The increase in operating income for the three months ended March 31, 2004 was attributable primarily to increased sales and higher gross margins. These factors contributed to our net income of \$4.4 million for the three months ended March 31, 2004, compared to net income of \$3.8 million for the same period of 2003.

Liquidity and Capital Resources.

At March 31, 2004, our working capital was \$67.3 million, which represented a current ratio of 4.7 to 1. Our cash balance at March 31, 2004 was \$33.9 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. During 2004, substantial funds will be needed 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. It is anticipated that an additional \$5 million, in excess of our 2003 annual capital expenditures, will be spent on a finished good 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 its 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 \$2.4 million as of March 31, 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 \$757,725 at March 31, 2004, generally in line with our historical experience with collection of receivables.

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 be forced by regulatory agencies to 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 an inappropriate design, 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.

In addition, 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 months ended March 31, 2004, sales of our inflation devices (including inflation devices sold in custom kits) accounted

for approximately 31% 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.

In addition, the products that have accounted for a majority of our historical revenues 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 so as 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 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 key man life insurance with his life. Mr. Lampropoulos announced his candidacy for Governor of Utah in January 2004 and is actively campaigning as one of several candidates vying for that seat. 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.

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 a 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 utilize 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 March 31, 2004, the exchange rate resulted in an increase of gross revenues of \$676,197 and approximately 0.2% increase in gross profit.

For the three months ended March 31, 2004, approximately \$4.0 million, or 10.6%, 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. Furthermore, we may be unable 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. In addition, 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.

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 March 31, 2004 (\$4.0 million, representing approximately 10.6% 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 \$676,197 million and 0.2% in gross profit.

At March 31, 2004, we had a net exposure (representing the difference between Euro-denominated receivables and Euro-denominated payables) of approximately \$2.0 million. In order to partially offset such risk, on February 29, 2004, we entered into a 30-day Euro hedge contract. We enter into similar hedging transactions at various times during the year in an effort to partially offset exchange rate risks we bear throughout the year. We do not purchase or hold derivative financial instruments for speculative or trading purposes. During the three months ended March 31, 2004, we experienced a net loss of \$48,290 on hedging transactions we executed during the three months ended March 31, 2004 in an effort to limit our exposure to fluctuations in the Euro/Dollar exchange rate.

As of March 31, 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 March 31, 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 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 Report on Form 8-K was filed during the quarter ended March 31, 2004:

Form 8-K	Date of Event	Description
Item 7&12	2-20-2004	Company's financial and operating results For the year and quarter ended December 31, 2003

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.

MERIT MEDICAL SYSTEMS, INC.

REGISTRANT

Date: May 6, 2004

/s/ FRED P. LAMPROPOULOS

FRED P. LAMPROPOULOS
PRESIDENT AND CHIEF EXECUTIVE OFFICER

Date: May 6, 2004

/s/ KENT W. STANGER

KENT W. STANGER
SECRETARY AND CHIEF FINANCIAL OFFICER

**Certification of Chief Executive Officer
Pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002**

I, Fred P. Lampropoulos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Merit Medial Systems, Inc. for the quarter ended March 31, 2004;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2004

/s/ FRED P. LAMPROPOULOS

Fred P. Lampropoulos, Chief Executive Officer

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[Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)

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

I, Kent W. Stanger, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Merit Medial Systems, Inc. for the quarter ended March 31, 2004;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2004

/s/ KENT W. STANGER

Kent W. Stanger, Chief Financial Officer

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[Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)

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EXHIBIT 32.1

**Certification of Chief Executive Officer
Pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002**

In connection with this quarterly report on Form 10-Q of Merit Medical Systems, Inc. for the quarter ended March 31, 2004, I, Fred P. Lampropoulos, Chief Executive Officer of Merit Medical Systems, Inc., certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The report fully complies with the requirements of Section 13(a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Merit Medical Systems, Inc.

Date: May 6, 2004

/s/ FRED P. LAMPROPOULOS

Fred P. Lampropoulos
Chairman of the Board, President and Chief Executive Officer

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[Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)

**Certification of Chief Financial Officer
Pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002**

In connection with this quarterly report on Form 10-Q of Merit Medical Systems, Inc. for the quarter ended March 31, 2004, I, Kent W. Stanger, Chief Financial Officer of Merit Medical Systems, Inc., certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The report fully complies with the requirements of Section 13(a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Merit Medical Systems, Inc.

Date: May 6, 2004

/s/ KENT W. STANGER

Kent W. Stanger
Chief Financial Officer

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[Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)