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 SEPTEMBER 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

87-0447695

(State or other jurisdiction of incorporation or organization)

(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 o

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

Yes 🗵 No o

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

Common Stock

Title or class

26,429,236 Number of Shares Outstanding at November 4, 2004

MERIT MEDICAL SYSTEMS, INC.

INDEX TO FORM 10-Q

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Consolidated Balance Sheets as of September 30, 2004 and December 31, 2003

Consolidated Statements of Operations for the three and nine months ended September 30, 2004 and 2003

Consolidated Statements of Cash Flows for the nine months ended September 30, 2004 and 2003

Notes to Consolidated Financial Statements

<u>Item 2.</u> <u>Management's Discussion and Analysis of Financial Condition</u>

and Results of Operations

<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>

<u>Item 4.</u> <u>Controls and Procedures</u>

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

SIGNATURES

Part I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS SEPTEMBER 30, 2004 AND DECEMBER 31, 2003 (In Thousands - Unaudited)

	September 30, 2004		December 31, 2003
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 34	,434 \$	30,204
Trade receivables - net		,215	17,729
Employee and other receivables		157	267
Inventories	23	,496	21,269
Prepaid expenses and other assets		,071	823
Deferred income tax assets	<u>-</u>	,0,1	221
Income tax refund receivables		2	375
meome tan retain receivables			
Total current assets	76	,375	70,888
Total Carrent assets		,575	7 0,000
PROPERTY AND EQUIPMENT:			
Land	2	,740	2,740
Building		,950	5,268
Manufacturing equipment		,155	29,481
Furniture and fixtures		,620	11,953
Leasehold improvements		,020	4,616
Automobiles	4	88	4,010
Construction-in-progress	20	,859	4,887
Construction-in-progress		,033	4,007
Total	77	,510	59,033
Less accumulated depreciation and amortization		,166)	(29,836)
Less accumulated depreciation and amortization		,100)	(23,030)
Property and equipment—net	44	,344	29,197
OTHER ASSETS:		0.40	
Patents, trademarks and licenses - net		,942	1,846
Goodwill		,765	4,765
Other assets	1	,441	573
Deposits		127	32
Total other assets	8	,275	7,216
		_	
TOTAL ASSETS	\$ 128	,994 \$	107,301
See notes to consolidated financial statements.			

1

LIABILITIES AND STOCKHOLDERS' EQUITY	September 30, 2004	December 31, 2003
CURRENT LIABILITIES:		
Current portion of long-term debt	\$	\$ 17
Trade payables	8,727	5,700

Accrued expenses	7,385	
Advances from employees	132	159
Deferred taxes payable	15	
Income taxes payable	1,076	87
Total current liabilities	17,335	13,957
DEFERRED INCOME TAX LIABILITIES	2,991	3,020
DEFERRED COMPENSATION PAYABLE	1,470	573
DEFERRED CREDITS	1,352	1,507
Total liabilities	23,148	19,057
STOCKHOLDERS' EQUITY:		
Preferred stock—5,000 shares authorized as of June 30, 2004, no shares issued		
Common stock—no par value; 50,000 shares authorized; 26,429 and 26,003 shares issued at September 30,		
2004 and December 31 2003, respectively	41,676	37,702
Retained earnings	64,594	· ·
Accumulated other comprehensive loss	(424	
Accumulated other comprehensive ioss	(424	(417)
Total stockholders' equity	10E 9 <i>46</i>	00 744
Total stockholders' equity	105,846	88,244
TOTAL LIADIUMEC AND COOKING DEDCLEOUMEN	d 100.004	¢ 107.301
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 128,994	\$ 107,301

See notes to consolidated financial statements.

2

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003
(In Thousands Except Share Data and Unaudited)

		Three Months Ended September 30,			Nine Months Ended September 30,			
		2004		2003		2004		2003
NET SALES	\$	35,476	\$	34,506	\$	112,059	\$	100,826
COST OF SALES		19,683		18,529		61,825		56,396
GROSS PROFIT		15,793		15,977		50,234		44,430
OPERATING EXPENSES:								
Selling, general, and administrative		8,457		7,766		25,789		22,607
Research and development		1,210		1,127		3,674		3,422
Total operating expenses		9,667		8,893		29,463		26,029
OTHER OPERATING INCOME:								
Gain on sale of land								508
INCOME FROM OPERATIONS		6,126		7,084		20,771		18,909
OTHER INCOME (EXPENSE):								
Litigation settlement						100		475
Interest Income		143		108		399		263
Gain (loss) on sale of land		1				(2)		
Other income(expense) - net		(41)		17		(47)		6
Other income - net		103		125		450		744
INCOME BEFORE INCOME TAXES		6,229		7,209		21,221		19,653
INCOME TAX EXPENSE		2,040		2,557	_	7,586		7,043
NET INCOME	\$	4,189	\$	4,652	\$	13,635	\$	12,610
	*	.,230	<u> </u>	.,552	<u> </u>	13,300	*	12,010
EARNINGS PER COMMON SHARE:	ф	10	ď	10	ď	FO	ď	F.0
Basic Diluted	<u>\$</u> \$.16	\$ \$.18	\$ \$.52	<u>\$</u> \$.50 .47
Diffuteu	ψ	.13	φ	.17	φ	.49	φ	.47

AVERAGE COMMON SHARES:

Basic	26,380,059	25,516,923	26,249,212	25,252,324
Diluted	27,760,219	27,238,920	27,756,826	26,838,568

See notes to consolidated financial statements.

3

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003 (In Thousands and Unaudited)

		Nine Mon Septem			
		2004		2003	
CASH FLOWS FROM OPERATING ACTIVITIES:					
Net income	\$	13,635	\$	12,61	
Adjustments to reconcile net income to net cash provided by operating activities:	<u></u>		_		
Depreciation and amortization		3,544		3,362	
Losses (gains) on sales of property and equipment		2		(508	
Bad debt expense		45		23	
Write-off of certain patents and trademarks		243		10	
Amortization of deferred credits		(152)		(120	
Deferred income taxes		206		34	
Tax benefit attributable to appreciation of common stock options exercised		2,698		2,667	
Changes in operating assets and liabilities:		,		,	
Trade receivables		467		(1,866	
Employee and other receivables		110		1,29	
Inventories		(2,226)		(1,32)	
Prepaid expenses and other assets		(248)		(23	
Income tax refund receivables		372			
Deposits		(95)			
Other assets		(869)		(28	
Trade payables		3,027		1,58	
Accrued expenses		(514)		2,45	
Advances from employees		(27)		3	
Income taxes payable		989		92	
Deferred compensation payable		897		6	
Total adjustments		8,469		8,32	
Net cash provided by operating activities		22,104		20,93	
CASH FLOWS FROM INVESTING ACTIVITIES:					
Capital expenditures for:					
Property and equipment		(18,673)		(6,13	
Patents and trademarks		(456)		(1	
Proceeds from the sale of property and equipment		2		56	
Net cash used in investing activities		(19,127)		(5,57	
See notes to consolidated financial statements.					

See notes to consolidated financial statements.

4

	Nine Months Ended September 30,				
	 2004	2003			
CASH FLOWS FROM FINANCING ACTIVITIES:					
Proceeds from:					
Issuance of common stock	\$ 1,277	1,559			
Principal payments on long-term debt	(17)	(329)			
Net cash provided by financing activities	1,260	1,230			
EFFECT OF EXCHANGE RATES ON CASH	(7)	54			
	<u> </u>				
NET INCREASE IN CASH AND CASH EQUIVALENTS	4,230	16,639			
CASH AND CASH EQUIVALENTS:					

Beginning of period		30,204		9,684
End of period	\$	34,434	\$	26,323
Lift of period	Ψ	51,151	<u> </u>	20,323
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION—Cash paid during the period for:				
Interest	\$	4	\$	20
Income taxes	\$	3,321	\$	2,754

SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

- During the nine months ended September 30, 2004 and 2003, 24,114 and 50,704 matured shares, respectively, (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 \$459,000 and \$781,000, respectively, 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 nine months ended September 30, 2004 and 2003, 14,820 and 33,568 matured shares of the Company's common stock, with a value of approximately \$265,000 and \$526,000, respectively, were surrendered in exchange for the exercise of stock options.

See notes to consolidated financial statements.

5

MERIT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

NOTES 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 nine-month periods ended September 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 of normal recurring accruals, necessary for a fair presentation of our financial position as of September 30, 2004, and our results of operations and cash flows for the three and nine-month periods ended September 30, 2004 and 2003. The results of operations for the three and nine-month periods ended September 30, 2004 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").

<u>Stock-Based Compensation</u>. 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 (in thousands, except per share data):

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2004		2003		2004	_	2003
Net income, as reported	\$	4,189	\$	4,652	\$	13,635	\$	12,610
Compensation cost under fair value-based accounting method, net	Ψ	1,100	Ψ	1,002	Ψ	10,000	Ψ	12,010
of tax		459		423		2,722		1,625
Net income, pro forma	\$	3,730	\$	4,229	\$	10,913	\$	10,985
Net income per common share:								
Basic:								
As reported	\$	0.16	\$	0.18	\$	0.52	\$	0.50
Pro forma		0.14		0.17		0.42		0.43
Diluted:								
As reported		0.15		0.17		0.49		0.47
Pro forma		0.13		0.16		0.39		0.41

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 55.97% and 63.97% for 2004 and 2003, respectively; risk-free interest rates ranging from 2.32% to 6.71%; expected life of 5 years. For options with a vesting period, compensation expense is recognized on a ratable basis over the service period which corresponds to the vesting period. Compensation expense is recognized immediately for options that are fully vested on the date of grant.

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

6

2. Inventories. Inventories at September 30, 2004 and December 31, 2003 consisted of the following (in thousands):

	ember 30, 2004	 December 31, 2003
Finished goods	\$ 11,649	\$ 11,996
Work-in-process	4,544	3,581
Raw materials	7,303	5,692
Total	\$ 23,496	\$ 21,269

3. Reporting Comprehensive Income. Comprehensive income for the three and nine-month periods ended September 30, 2004 and 2003 consisted of net income and foreign currency translation adjustments. As of September 30, 2004 and December 31, 2003, the cumulative effect of such adjustments reduced stockholders' equity by \$423,518 and \$416,701, respectively. Comprehensive income for the three and nine-month periods ended September 30, 2004 and 2003 has been computed as follows (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,				
		2004		2003	_	2004		2003	
Net income	\$	4,189	\$	4,652	\$	13,635	\$	12,610	
Foreign currency translation		(1)		(12)		(7)		54	
Comprehensive income	\$	4,188	\$	4,640	\$	13,628	\$	12,664	

- **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. In September 2004, the Financial Accounting Standards Board approved FSP 03-1, which delayed the effective date for recognition and measurement guidance contained in EITF 03-1 until certain issues are resolved. We believe that these issues will be resolved in the fourth quarter of 2004 and we will adopt the guidance at the time it is issued. We will assess the impact on our consolidated financial statements when final issuance of EITF 03-1 occurs.

7

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 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, without limitation, 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

For the quarter ended September 30, 2004, we reported net income of \$4.2 million, or \$0.15 per share, on revenues of \$35.5 million, up three percent, for the three months ended September 30, 2003. For the comparable period of 2003, we reported net income of \$4.7 million, or \$0.17 per share, on revenues of \$34.5 million. Net income for the third quarter of 2004 was down slightly, as the result of lower gross margins and higher selling, general and administrative expenses as a percentage of sales, when compared to the year ago period.

We reported record sales and earnings for the nine-month period ended September 30, 2004. For the nine months ended September 30, 2004, we reported net income of \$13.6 million, or \$0.49 per share, on revenues of \$112.1 million, up 11%, for the nine-month period ended September 30, 2003. For the comparable period of 2003, we reported net income of \$12.6 million, or \$0.47 per share, on revenues of \$100.8 million. During the nine months ended September 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 nine months ended September 30, 2004 was up 13% over the prior period. Net income for the nine months ended September 30, 2004 was positively effected by higher sales and gross margins, when compared to the same period in 2003.

Cash flow from operations was strong for the nine months ended September 30, 2004 at \$22.1 million, up \$1.2 million from the comparable period in 2003.

8

Results of Operations

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

	Three Months I September 3		Nine Months E September 3	
	2004	2003	2004	2003
Sales	100.0%	100.0%	100.0%	100.0%
Gross profit	44.5	46.3	44.8	44.1
Selling, general and administrative expenses	23.8	22.5	23.0	22.4
Research and development expenses	3.4	3.3	3.3	3.4
Other operating income				0.5
Income from operations	17.3	20.5	18.5	18.8
Other income	0.3	0.4	0.4	0.7
Net income	11.8	13.5	12.2	12.5

Sales. Sales for the three months ended September 30, 2004 increased by 3%, or approximately \$1.0 million, compared to the same period of 2003. Compared to the third quarter of 2003, inflation device sales rose 9%; catheter sales grew 8%; custom kit sales remained about the same; and stand alone device sales fell 2%. Sales for the nine months ended September 30, 2004 increased by 11%, or approximately \$11.2 million. Relative to the comparable nine-month period of 2003, catheter sales grew 16%; custom kit sales rose 12%; inflation device sales grew 11%; and stand alone device sales increased 9%. Our revenues increased during the three and nine-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 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 0.9% and 1.3% for the three and nine-month periods ended September 30, 2004, respectively, when compared to the same periods in 2003. We believe our quarterly sales growth rate slowed during the third quarter of 2004, primarily due to fewer procedures being conducted, an increase in competitive pressures, and, to a lesser extent, weather-related disturbances in the Southeastern United States.

Gross Profit. During the third quarter of 2004, gross profit decreased to 44.5% of sales, compared to 46.3% of sales for the same period of 2003. The decline in the gross margin percentage for the third quarter of 2004 was primarily the result of higher fixed costs and lower production compared to the third quarter of 2003. For the nine months ended September 30, 2004, gross profit improved to 44.8%, compared to 44.1% for the comparable period in 2003. The increase in the gross margin percentage for the nine months ended September 30, 2004, when compared to the same periods of 2003, was primarily 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 we believe was encouraged by our 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 0.2% and 0.4% for the three and nine-month periods ended September 30, 2004, respectively, when compared to the same periods in 2003.

Operating Expenses. Operating expenses increased to 27.2% and 26.3% of sales for the three and nine-month periods ended September 30, 2004, compared with 25.8% of sales for both the three and nine-month periods ended September 30, 2003. Selling, general and administrative expenses as a percentage of sales were 23.8% and 23.0% for the three and nine-month periods ended September 30, 2003, respectively, compared to 22.5% and 22.4% in the prior year's comparable periods. The increase in selling, general and administrative expenses as a percentage of sales during the three and nine-month periods ended September 30, 2004, was due primarily to the write-off of certain patent costs and expenses associated with our efforts to comply with requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Research and development expenses increased slightly to 3.4% of sales during the third quarter of 2004, compared to 3.3% of sales for the same period in 2003. For the nine months ended September 30, 2004, research and development expenditures decreased to 3.3% of sales, compared to 3.4% of sales for 2003.

Other Income. Other income for the third quarter of 2004 was approximately \$103,000, compared to approximately \$125,000 for the same period in 2003. The decrease in other income during the third quarter of

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2004, when compared to the same period in 2003, was primarily the result of mutual fund losses associated with our deferred compensation plan. Other income for the nine months ended September 30, 2004 was approximately \$450,000, compared to other income of \$744,000 for the nine months ended September 30, 2003. The decrease in other income for the nine months ended September 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 nine months ended September 30, 2004 would have increased primarily as the result of an increase in interest income of approximately \$136,000, when compared to the same period in 2003.

<u>Income Taxes.</u> Our effective tax rate for the three months ended September 30, 2004 was 32.7%, compared to 35.5% for the same period of 2003. For the nine months ended September 30, 2004, our effective tax rate was 35.7%, compared to 36.0% for the same period of 2003. The decrease in the effective tax rate for the three and nine months ended September 30, 2004, as compared to the same periods of the prior year, was principally the result of increased tax benefits associated with the Company's foreign sales.

<u>Income</u>. During the third quarter of 2004, we reported income from operations of \$6.1 million, a decrease of 14% from \$7.1 million for the comparable period in 2003. The decrease in income from operations for the third quarter of 2004, when compared to the same period in 2003, was primarily the result of

lower gross margins and higher selling, general and administrative expenses as a percentage of sales. For the nine months ended September 30, 2004, we reported income from operations of \$20.8 million, an increase of 10% from \$18.9 million for the comparable period in 2003. The increase in operating income for the nine-month period ended September 30, 2004 was attributable primarily to increased sales and higher gross margins. These factors contributed to net income of \$4.2 million for the three months ended September 30, 2004, compared to net income of \$4.7 million for the same period of 2003, and net income for the nine months ended September 30, 2004 of \$13.6 million compared to \$12.6 million for the nine months of 2003.

Liquidity and Capital Resources

On September 30, 2004, our working capital was \$59.0 million, and our current ratio was 4.4 to 1. Our cash balance at September 30, 2004 was \$34.4 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. The Company has already spent \$14.1 million through September 30, 2004 on these expansions. 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. Management believes that there is an increasing possibility for material cash requirements in the event of one or more acquisitions. Our principal sources of funding for these and other expenses has been cash generated from operations, sales of equity principally resulting from the exercise of options granted to our employees under our stock incentive plan, cash from loans on equipment and bank lines of credit. We believe 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:

<u>Inventory Obsolescence Reserve.</u> 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 \$2.5 million as of September 30, 2004.

10

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 \$792,319 at September 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:

We May Be Unable To Compete In Our Markets, Particularly If There Is A Significant Change In Relevant Procedures Or Technology, Or Increase In Competitive Pressures.

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 Merit. Such resources and market presence may enable our competitors to more effectively market competing products or market competing products at reduced prices in order to gain market share. Further, such resources and market presence may enable our competitors to market products beyond the scope of Merit's current business strategy.

Our ability to compete successfully is dependent, in part, upon our ability to respond effectively to changes in technology and procedures, as well as 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 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. Our inability to develop or introduce new products may also have an adverse effect on our ability to compete effectively.

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 voluntarily withdraw such products from the market or be required to withdraw them by order of the FDA. 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 or 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.

We May Be Unable To Successfully Manage Growth, Particularly If Accomplished Through Acquisitions.

We may attempt to acquire businesses, assets, products, or technologies that we believe will be strategic complement to our business model. Successful implementation of our business model 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

11

condition. These acquisitions may also require significant management attention that would otherwise be available for ongoing development of our business. Further, we may never realize the anticipated benefits of any acquisition. We may also make dilutive issuances of equity securities, incur debt or experience a decrease in the amount of cash available for our operations, or incur contingent liabilities in connection with any future acquisitions

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. 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.

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 current 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.

While We Believe That We Currently Have Adequate Internal Control Procedures In Place, We Are Still Exposed To Potential Risks From Recent Legislation Requiring Companies To Evaluate Controls Under Section 404 Of The Sarbanes-Oxley Act of 2002.

We are currently evaluating our internal controls systems in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. We are performing the system and process evaluation and testing required in an effort to comply with the management certification and auditor attestation requirements of Section 404. As a result, we are incurring additional expenses and a diversion of management's time. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there is no precedent available by which to measure compliance adequacy. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to investigation by regulatory authorities and a loss of public confidence in our internal controls, which could adversely affect our financial results and the market price of our common stock.

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 nine-month periods ended September 30, 2004, sales of our inflation devices (including inflation devices sold in custom kits) accounted for approximately 34% and 33%, 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.

12

$Termination\ Of\ Relationships\ With\ Our\ Suppliers,\ Or\ Failure\ Of\ Such\ Suppliers\ To\ Perform,\ Could\ Disrupt\ Our\ Business.$

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 or our costs could increase. 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 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.

Failure To Obtain Or Maintain The Regulatory Approvals Required To Market And Sell Our Products, Could Disrupt Our Business.

We are subject to regulation by government agencies in the United States and international markets with respect to the manufacture, packaging, labeling, advertising, promotion, distribution and sale of our products. For instance, most of our products are subject to FDA clearance and approval prior to marketing in the United States for commercial use. We are also subject to similar approvals for international markets. The process of obtaining and maintaining necessary regulatory approvals and clearances is expensive and time-consuming. If we do not receive required regulatory approvals or clearance to market our products domestically and internationally, or if any approvals we have received are revoked or terminated, we may not be able to develop and-or commercialize our products which could disrupt our business.

We Are Dependent Upon Key Personnel.

The loss of one or more key members of our management team could affect our ability to successfully implement our business strategy. Our success if achieved will be 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 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 will also depend, among other factors, on the successful recruitment and retention of key personnel.

13

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 September 30, 2004, the exchange rate resulted in an increase of gross revenues of \$326,393 and approximately 0.2% increase in gross profit.

For the three months ended September 30, 2004, approximately \$4.2 million, or 11.8%, 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 U.S. Dollars declines, our financial results may be negatively impacted.

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 acquisitions of businesses, assets, products or technologies;
- · 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 operating or 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 Subject To Work Stoppage, Transportation And Related Risks.

We manufacture our products at various locations in the United States and 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.

14

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 September 30, 2004 (\$4.2 million, representing approximately 11.8% 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 \$326,393 and \$1.4 million for the three and nine months ended September 30, 2004, respectively, and 0.2% and 0.4%, respectively, in gross profit.

As of September 30, 2004, we had a net exposure (representing the difference between Euro-denominated receivables and Euro-denominated payables) of approximately \$167,000. In order to partially offset such risk, on August 31, 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 nine months ended September 30, 2004, we experienced a net loss of \$1,449 and \$55,082 on these economic hedging transactions.

As of September 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 our management, including our Chief Executive Officer and our Chief Financial Officer of the effectiveness of the our disclosure controls and procedures, as of September 30, 2004. Based on that evaluation, the our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by Merit in reports filed or submitted by the Merit 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 our internal control s or in other factors that could significantly affect internal controls subsequent to the evaluation.

15

PART II - OTHER INFORMATION

ITEM 6: EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

Exhibit No.	Description		
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002		
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002		
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		

(b) Forms 8-K:

Form 8-K	Date of Event	Description	
Items 7&12	7/22/2004	Merit's financial and operating results for the quarter ended June 30, 2004	
Items 7,9, &12	8/3/2004	Supplier agreement with Premier Purchasing Partners, L.P.	
Items 7.01 and 9.01	9/13/2004	Supplier agreement with Novation, the supply Company of VHA Inc. & University Health System Consortium	

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:

Date: November 8, 2004 /s/ Fred P. Lampropoulos

FRED P. LAMPROPOULOS

PRESIDENT AND CHIEF EXECUTIVE

OFFICER

November 8, 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 September 30, 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 functions):
 - 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: November 8, 2004 /s/ FRED P. LAMPROPOULOS

Fred P. Lampropoulos, Chief Executive Officer

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

I, Kent W. Stanger, certify that:

- I have reviewed this guarterly report on Form 10-Q of Merit Medial Systems, Inc. for the guarter ended September 30, 2004; 1.
- 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;
- The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as 4. defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
 - 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;
 - 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
- The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial 5. reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - 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
 - 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: November 8, 2004 /s/ KENT W. STANGER

Kent W. Stanger, Chief Financial Officer

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 September 30, 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: November 8, 2004 /s/ Fred P. Lampropoulos

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

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 September 30, 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: November 8, 2004

/s/ Kent W. Stanger

Kent W. Stanger

Chief Financial Officer