
UNITED STATES
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 0-23837

SurModics, Inc.

(Exact name of registrant as specified in its Charter)

MINNESOTA
(State of incorporation)

41-1356149
(I.R.S. Employer Identification No.)

9924 West 74th Street
Eden Prairie, Minnesota 55344
(Address of principal executive offices)

Registrant's telephone number, including area code: (952) 829-2700

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

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

Yes No

The number of shares of the registrant's Common Stock, \$.05 par value per share, outstanding as of April 30, 2004 was 17,509,941.

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PART I — FINANCIAL INFORMATION**Item 1. Financial Statements**

SURMODICS, INC.
Condensed Balance Sheets
(In thousands, except share data)
(Unaudited)

	March 31, 2004	September 30, 2003
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 6,492	\$ 4,007
Short-term investments	3,072	2,640
Accounts receivable, net	9,775	9,145
Inventories	1,044	863
Deferred tax asset	345	345
Prepays and other	1,024	759
Total current assets	21,752	17,759
Property and equipment, net	32,957	33,936
Long-term investments	39,450	39,164
Other assets, net	7,546	6,949
	<u>\$ 101,705</u>	<u>\$ 97,808</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 459	\$ 1,118
Accrued liabilities	1,603	6,312
Accrued income taxes payable	1,509	1,558
Deferred revenue	1,207	1,039
Total current liabilities	4,778	10,027
Deferred tax liability	75	27
Deferred revenue, less current portion	1,583	1,640
Total liabilities	6,436	11,694
Commitments and Contingencies		
Stockholders' Equity		
Series A Preferred stock-		
\$.05 par value, 450,000 shares authorized;		
no shares issued and outstanding	—	—
Common stock-		
\$.05 par value, 45,000,000 shares authorized;		
17,498,581 and 17,439,435 shares issued and outstanding	875	872
Additional paid-in capital	57,299	56,453
Unearned compensation	(736)	(466)
Accumulated other comprehensive income	430	337
Retained earnings	37,401	28,918
Total stockholders' equity	95,269	86,114
	<u>\$ 101,705</u>	<u>\$ 97,808</u>

The accompanying notes are an integral part of these condensed financial statements.

SURMODICS, INC.
Condensed Statements of Income
(In thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2004	2003	2004	2003
Revenue				
Royalties and license fees	\$ 8,944	\$ 4,899	\$ 17,572	\$ 8,779
Product sales	2,803	2,893	5,403	5,932
Research and development	991	1,950	1,850	3,079
Total revenue	<u>12,738</u>	<u>9,742</u>	<u>24,825</u>	<u>17,790</u>
Operating costs and expenses				
Product	752	783	1,488	1,371
Research and development	3,124	2,926	6,270	5,586
Sales and marketing	639	534	1,182	1,071
General and administrative	1,545	1,507	2,920	2,915
Total operating costs and expenses	<u>6,060</u>	<u>5,750</u>	<u>11,860</u>	<u>10,943</u>
Income from operations	<u>6,678</u>	<u>3,992</u>	<u>12,965</u>	<u>6,847</u>
Other income				
Investment income	269	366	546	747
Gain on sale of investments	1	48	20	290
Other income	270	414	566	1,037
Income before income taxes	6,948	4,406	13,531	7,884
Income tax provision	(2,576)	(1,656)	(5,048)	(2,963)
Net income	<u>\$ 4,372</u>	<u>\$ 2,750</u>	<u>\$ 8,483</u>	<u>\$ 4,921</u>
Basic net income per share	\$ 0.25	\$ 0.16	\$ 0.49	\$ 0.28
Diluted net income per share	\$ 0.25	\$ 0.15	\$ 0.48	\$ 0.28
Weighted average shares outstanding				
Basic	17,483	17,326	17,468	17,305
Dilutive effect of outstanding stock options	292	477	306	508
Diluted	<u>17,775</u>	<u>17,803</u>	<u>17,774</u>	<u>17,813</u>

The accompanying notes are an integral part of these condensed financial statements.

SURMODICS, INC.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended March 31,	
	2004	2003
Operating Activities		
Net income	\$ 8,483	\$ 4,921
Adjustments to reconcile net income to net cash provided by operating activities-		
Depreciation and amortization	1,770	1,145
Gain on sale of investments	(20)	(290)
Amortization of unearned compensation	107	73
Deferred taxes	48	(72)
Change in operating assets and liabilities:		
Accounts receivable	(630)	368
Inventories	(181)	18
Accounts payable and accrued liabilities	(5,368)	319
Income taxes	(49)	1,427
Deferred revenue	111	446
Prepays and other	(298)	(398)
Net cash provided by operating activities	<u>3,973</u>	<u>7,957</u>
Investing Activities		
Purchases of property and equipment	(780)	(6,230)
Purchases of available-for-sale investments	(20,692)	(40,633)
Sales/maturities of available-for-sale investments	20,088	34,120
Investments in InnoRx, Inc. and Novocell, Inc.	(2,444)	—
Repayment of note receivable	1,869	15
Net cash used in investing activities	<u>(1,959)</u>	<u>(12,728)</u>
Financing Activities		
Issuance of common stock	471	822
Net change in cash and cash equivalents	2,485	(3,949)
Cash and Cash Equivalents		
Beginning of period	4,007	9,207
End of period	<u>\$ 6,492</u>	<u>\$ 5,258</u>
Cash paid for taxes	\$ 5,092	\$ 1,528

The accompanying notes are an integral part of these condensed financial statements.

SURMODICS, INC.
Notes to Condensed Financial Statements
(Unaudited)

(1) Basis of Presentation

In the opinion of management, the accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States and reflect all adjustments, consisting solely of normal recurring adjustments, needed to fairly present the financial results for these interim periods. These financial statements include some amounts that are based on management's best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of earnings in the period in which the change in estimate is identified. The results of operations for the three months and six months ended March 31, 2004, are not necessarily indicative of the results that may be expected for the entire fiscal year.

According to the rules and regulations of the United States Securities and Exchange Commission, the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited financial statements of the Company. These unaudited condensed financial statements should be read together with the financial statements for the year ended September 30, 2003, and footnotes thereto included in the Company's Form 10-K as filed with the United States Securities and Exchange Commission on December 22, 2003.

(2) New Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables," which provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or right to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have an impact on the Company's financial statements.

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on the remaining portions of EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, with an effective date of June 15, 2004. EITF 03-01 provides new disclosure requirements for other-than-temporary impairments on debt and equity investments. Investors are required to disclose quantitative information about: (i) the aggregate amount of unrealized losses, and (ii) the aggregate related fair values of investments with unrealized losses, segregated into time periods during which the investment has been in an unrealized loss position of less than 12 months and greater than 12 months. In addition, investors are required to disclose the qualitative information that supports their conclusion that the impairments noted in the qualitative disclosure are not other-than temporary. The adoption of the remaining portions is not expected to have a material impact on our results of operations or financial condition.

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Inventories are stated at the lower of cost or market using the specific identification method and include direct labor, materials and overhead. Inventories consisted of the following components:

	March 31, 2004	September 30, 2003
Raw materials	\$ 515	\$ 413
Finished goods	529	450
	<u>\$ 1,044</u>	<u>\$ 863</u>

(4) Operating Segments (dollars in thousands)

	Licensing	Manufacturing	Research & Development	Corporate	Consolidated
Three Months Ended March 31, 2004					
Revenue:					
Coating	\$ 8,172	\$ 1,982	\$ 860	\$ —	\$ 11,014
Diagnostic	772	—	—	—	772
Stabilization & other	—	821	—	—	821
Government research	—	—	131	—	131
Total revenue	8,944	2,803	991	—	12,738
Expenses	—	752	3,124	2,184	6,060
Operating income (loss)	8,944	2,051	(2,133)	(2,184)	6,678
Other income, net				270	270
Income tax provision				(2,576)	(2,576)
Net income					<u>\$ 4,372</u>
Three Months Ended March 31, 2003					
Revenue:					
Coating	\$ 4,293	\$ 1,990	\$ 1,833	\$ —	\$ 8,116
Diagnostic	606	—	—	—	606
Stabilization & other	—	903	—	—	903
Government research	—	—	117	—	117
Total revenue	4,899	2,893	1,950	—	9,742
Expenses	—	783	2,926	2,041	5,750
Operating income (loss)	4,899	2,110	(976)	(2,041)	3,992
Other income, net				414	414
Income tax provision				(1,656)	(1,656)
Net income					<u>\$ 2,750</u>

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	Licensing	Manufacturing	Research & Development	Corporate	Consolidated
Six Months Ended March 31, 2004					
Revenue:					
Coating	\$ 16,457	3,736	1,634	\$ —	21,827
Diagnostic	1,115	—	—	—	1,115
Stabilization & other	—	1,667	—	—	1,667
Government	—	—	216	—	216
Total Revenue	17,572	5,403	1,850	—	24,825
Expenses	—	1,488	6,270	4,102	11,860
Operating income (loss)	17,572	3,915	(4,420)	(4,102)	12,965
Other income				566	566
Income tax provision				(5,048)	(5,048)
Net income					\$ 8,483
Six Months Ended March 31, 2003					
Revenue:					
Coating	\$ 7,310	4,499	2,859	\$ —	14,668
Diagnostic	1,469	—	—	—	1,469
Stabilization & other	—	1,433	—	—	1,433
Government	—	—	220	—	220
Total Revenue	8,779	5,932	3,079	—	17,790
Expenses	—	1,371	5,586	3,986	10,943
Operating income (loss)	8,779	4,561	(2,507)	(3,986)	6,847
Other income				1,037	1,037
Income tax provision				(2,963)	(2,963)
Net income					\$ 4,921

(5) Stock-based Compensation (in thousands, except per share data)

The Company accounts for stock options under the intrinsic value method as described in APB Opinion No. 25, "Accounting for Stock Issued to Employees", under which no compensation expense has been recognized. Had compensation expense for the options been determined using the fair value method described in SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure", the Company's net income and diluted net income per share for the three and six months ended March 31, 2004 and March 31, 2003 would have been as follows:

	Three months ended March 31,		Six months ended March 31,	
	2004	2003	2004	2003
Net income				
As reported	\$ 4,372	\$ 2,750	\$ 8,483	\$ 4,921
Fair value compensation expense	(488)	(358)	(947)	(675)
Pro forma	\$ 3,884	\$ 2,392	\$ 7,536	\$ 4,246
Basic net income per share:				
As reported	\$ 0.25	\$ 0.16	\$ 0.49	\$ 0.28
Fair value compensation expense	(.03)	(.02)	(.06)	(.03)
Pro forma	\$ 0.22	\$ 0.14	\$.43	\$ 0.25
Diluted net income per share:				
As reported	\$ 0.25	\$ 0.15	\$ 0.48	\$ 0.28
Fair value compensation expense	(.03)	(.02)	(.06)	(.04)
Pro forma	\$ 0.22	\$ 0.13	\$.42	\$ 0.24

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for the three months ended March 31, 2004 and March 31, 2003, respectively: risk-free interest rates of 3.11% and 3.04%; expected lives of 7.0 and 7.3; and expected volatility of 68%, and 71%. The weighted-average assumptions for the six months ended March 31, 2004 and March 31, 2003, respectively: risk-free interest rates of 3.21% and 3.04%; expected lives of 7.0 and 7.3; and expected volatility of 68%, and 71%.

(6) Comprehensive Income (dollars in thousands)

The components of comprehensive income for the three-month and six-month periods are as follows:

	Three months ended March 31,		Six months ended March 31,	
	2004	2003	2004	2003
Net income	\$ 4,372	\$ 2,750	\$ 8,483	\$ 4,921
Other comprehensive income:				
Unrealized holding gains (losses) on available-for-sale securities arising during the period, net of tax	222	48	106	23
Less reclassification adjustment for realized gains included in net income, net of tax	(1)	(30)	(13)	(181)
Other comprehensive income (loss)	221	18	93	(158)
Comprehensive income	\$ 4,593	\$ 2,768	\$ 8,576	\$ 4,763

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

General

The Company is a leading provider of surface modification and drug delivery solutions for medical-device and biomedical applications. One of the Company's core surface-modification technology platforms is its patented drug-delivery polymer matrix technology. This technology can be applied to medical devices to deliver pharmaceutical agents from the surface of a device to a targeted area of the body, often enabling sustained release of the pharmaceutical agents. In addition, the Company's patented PhotoLink® technology is another core technology platform on which many of the Company's leading surface-modification capabilities are based. This technology platform helps modify and enhance the surface characteristics of medical devices and biomedical applications improving performance and, in some cases, enabling the development of new products. In addition to these surface-modification technologies, the Company also generates revenue from the licensing of in vitro diagnostic technology developed in the early stages of the Company's development that is used in rapid point-of-care diagnostic testing (diagnostic royalties) and from the sale of stabilization products used by manufacturers of immunoassay diagnostic tests to improve performance, stability and shelf life (stabilization products).

The Company's revenue is derived from three primary activities: (1) royalties and license fees from licensing its patented or proprietary technologies to customers; (2) product sales (reagent chemical compounds to licensees, stabilization products to the diagnostics industry, and coated slides to the genomics market) from our manufacturing activities; and (3) research and development fees generated on projects for commercial customers and pursuant to government grants. For more information on each of these Licensing, Manufacturing and Research & Development activities, presented as individual operating segments, refer to Note 4 to the Company's unaudited condensed financial statements included in this quarterly report and Note 8 to the Company's audited financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2003.

Critical Accounting Policies and Estimates

Critical accounting policies are those policies that require the application of management's most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgements and uncertainties that are sufficiently sensitive to result in materially different results under different assumptions and conditions. For a detailed description of our critical accounting policies, see the notes to the financial statements included in our Annual Report on Form 10-K for the year ended September 30, 2002.

Results of Operations

Three Months Ended March 31, 2004 and 2003

Revenue. The Company's revenue was \$12.7 million in the second quarter of fiscal 2004, an increase of \$3.0 million, or 31%, compared with the same period of fiscal 2003. The revenue components were as follows (in thousands):

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(Dollars in thousands)	Fiscal 2004	Fiscal 2003	Increase (Decrease)	% Increase (Decrease)
Revenue:				
Royalties and license fees	\$ 8,944	\$ 4,899	\$ 4,045	83%
Product sales	2,803	2,893	(90)	-3%
Research and development	991	1,950	(959)	-49%
Total revenue	\$ 12,738	\$ 9,742	\$ 2,996	31%

The growth in total revenue for the second quarter was the result of an 83% increase in royalties and license fees driven largely by an increase in royalties from Cordis Corporation (a Johnson & Johnson company) on its Cypher stent. The Cypher stent incorporates a proprietary SurModics coating that delivers a therapeutic drug that is designed to reduce the occurrence of restenosis in coronary artery lesions. Fiscal 2003 second quarter results include royalties on Cypher stents sold only outside the U.S. because Cordis received U.S. Food and Drug Administration (FDA) approval in April 2003 (our third fiscal quarter). The increase in royalties from the Cypher stent in the second quarter of fiscal 2004 was partially offset by a significant decrease in minimum royalties from Amersham plc (now part of GE Healthcare's Biosciences Division). In the last quarter we discussed that for the balance of the fiscal year 2004, minimum royalties from Amersham would be lower compared with the prior year periods because of contractual decreases. On a sequential basis, total non-Cordis revenue increased modestly compared with the first quarter, and on a sequential basis, we anticipate that non-Cordis revenue will be roughly flat for the balance of the fiscal year.

On March 4, 2004, Boston Scientific Corp., was granted approval by the FDA to begin marketing in the U.S. a drug-eluting stent that competes directly with the Cypher stent. As such, we anticipate that while the overall market for drug-eluting stents will increase, quarterly royalty revenue from the current generation Cypher stent will decline sequentially in 2004 and did decline slightly from the first quarter to the second quarter of our current fiscal year. Royalties from the Cypher stent are expected to constitute a significant portion of our revenue.

There is currently pending litigation involving Boston Scientific Scimed, Inc. and Cordis in U.S. District Court for the District of Delaware in which each alleges its patent rights are being infringed by the other's drug-eluting stent, and each has been denied the preliminary injunction it has requested against the other. Cordis has appealed the denial of its requested preliminary injunction against Boston Scientific's coronary drug-eluting stent. On April 5, 2004, a hearing was held before the Court of Appeals for the Federal Circuit on Cordis' motion to obtain a preliminary injunction against further sales of Boston Scientific's drug-eluting stent until the full trial (scheduled for June 2005). The Court of Appeals has not yet ruled on Cordis' motion.

Fiscal 2004 second quarter product sales decreased 3% to \$2.8 million from the same period in fiscal 2003. Revenue from reagent chemical sales was \$2.0 million, on par with the same period in 2003. While overall reagent revenue was stable, sales to Cordis decreased slightly as a result of contractually lower reagent prices. For the remainder of fiscal 2004, management expects revenue from sales of reagents to Cordis to decline as a result of a contractually-specified step-down in reagent prices that began in the second quarter of fiscal 2004 and because Cordis may continue improving its manufacturing efficiency, thus requiring a smaller quantity of reagent for each stent Cordis

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manufactures. Cordis continues to purchase a substantial majority of the reagents we sell. Our reagents are a critical raw material component of the Cypher stent and any substantial decrease in the number of Cypher stent units sold could have a material adverse impact on reagent sales.

In addition to the sale of reagents, product sales results include revenue generated from the sale of stabilization products and coated glass slides. Results from the sale of these products decreased modestly, with increased stabilization revenue more than offset by a decrease in slide sales. Management expects the current quarter's results (on a dollar basis) to be a reasonable indicator of the Company's near-term quarterly stabilization product and coated glass slide revenue. One factor that may influence stabilization product sales going forward is the recent signing of an exclusive distribution agreement. SeraCare Life Sciences, Inc. began distributing SurModics' stabilization products in the U.S. and Puerto Rico during the second fiscal quarter of 2004. SeraCare has a larger sales force and currently distributes a broad line of biological diagnostic components that are complementary to the Company's stabilization products and distributes to the same customer base: diagnostic kit manufacturers, pharmaceutical companies and research labs. Stabilization product margins will likely decrease as a result of the agreement, however; management believes this margin decrease may be more than offset over time by increased sales through SeraCare.

Development revenue was \$1.0 million in the second quarter of 2004, a 49% decrease from the same period in 2003. This decrease results principally from the lower level of clinical coating work on the Cypher stent since Cordis received U.S. FDA approval for the Cypher stent in April 2003. The Company continues to perform other paid development work for Cordis and other customers, but on a smaller scale. Cordis accounted for less than half of the paid development work performed by the Company during the second quarter, all of which was related to Cordis' drug-eluting stent program. Management expects the current quarter's results (on a dollar basis) to be a reasonable indicator of the Company's near-term quarterly development revenue

Product costs and margins. The Company's product costs were \$752,000 for the second quarter of fiscal 2004, a decrease of \$31,000, or 4%, compared with the same period of fiscal 2003. Overall product gross margins were stable at approximately 73%. Since we anticipate sales of stabilization and slide products will continue to constitute an increasing percentage of our product sales (as sales of reagents are anticipated to continue their modest decline), we expect that combined product margins are likely to decline modestly.

Research and development expenses. Research and development expenses were \$3.1 million for the second quarter of fiscal 2004, an increase of \$198,000, or 7%, compared with the same period of fiscal 2003. The increase was primarily a result of higher depreciation and facilities costs at our Bloomington facility as well as increased patent-related legal costs. Management expects a modest increase in development expenses for the balance of the fiscal year.

Sales and marketing expenses. Sales and marketing expenses were \$639,000 for the second quarter of fiscal 2004, a \$105,000 or 20% increase from the same period of fiscal 2003. A substantial portion of the increase results from compensation and benefits related to marketing personnel. Management expects the increase in sales and marketing expenses to moderate for the remainder of the fiscal year.

General and administrative expenses. General and administrative expenses were \$1.5 million for the second quarter of fiscal 2004, an increase of 3% compared with the same period of fiscal 2003. Lower legal costs in the second quarter of fiscal 2004 were offset by a substantial increase in directors and officers insurance premiums, as well as increased utilities costs. For the balance of the fiscal year, management anticipates modest sequential quarterly growth in general and administrative expense.

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Other income, net. The Company's other income was \$270,000 for the second quarter of fiscal 2004, a decrease of \$144,000 or 35%, compared with the same period of fiscal 2003. Investment income decreased as a result of lower investment yields and the early payoff of a \$1.8 million note receivable.

Income tax expense. The Company's income tax provision was \$2.6 million for the second quarter of fiscal 2004 compared with \$1.7 million in the same period of fiscal 2003. The effective tax rates were 37.0% in fiscal 2004 and 37.5% in fiscal 2003.

Six Months Ended March 31, 2004 and 2003

Revenue. The Company's revenue was \$24.8 million for the first six months of fiscal 2004, an increase of \$7.0 million, or 40%, compared with the same period of fiscal 2003. The revenue components were as follows (in thousands):

(Dollars in thousands)	Fiscal 2004	Fiscal 2003	Increase (Decrease)	% Increase (Decrease)
Revenue:				
Royalties and license fees	\$ 17,572	\$ 8,779	\$ 8,793	100%
Product sales	5,403	5,932	(529)	-9%
Research and development	1,850	3,079	(1,229)	-40%
Total revenue	\$ 24,825	\$ 17,790	\$ 7,035	40%

The revenue growth in the first six months was the result of a 100% increase in royalties and license fees driven largely by an increase in royalties from Cordis Corporation (a Johnson & Johnson company) on its Cypher stent. This growth was partially offset by decreasing product sales and development revenue as shown in the table above. The increase in royalties from the Cypher stent in the first half of fiscal 2004 was partially offset by a \$503,000 decline in license fees compared with the same period in fiscal 2003. The first quarter of fiscal 2003 included a one-time recognition of \$340,000 of deferred revenue resulting from the termination by the Company of a non-performing license agreement.

Product revenue decreased 9% in the first six months of fiscal 2004 from the same period last year. Revenue from reagent chemical sales was \$3.7 million, a decrease of \$763,000, or 17%, from the same period in fiscal 2003. The decrease primarily reflects reduced revenue from reagents sold to Cordis resulting from lower reagent prices. As stated earlier, for the remainder of fiscal 2004, management expects revenue from sales of reagents to Cordis to decline. Cordis continues to purchase a substantial majority of the reagents we sell and our reagents are a critical raw material component of the Cypher stent so any substantial decrease in the number of Cypher stent units sold could have a material adverse impact on reagent sales.

Partially offsetting lower reagent sales in the first half of fiscal 2004 was a \$234,000, or 16% increase in sales of stabilization products and coated glass slides. While the Company expects continued growth in the sale of these products in the near-term, management does not anticipate the growth in the second half of fiscal 2004 to occur at the same rate as in the first half of fiscal 2004. One factor that may influence stabilization product sales going forward is the recent signing of an exclusive distribution agreement with SeraCare Life Sciences, Inc. as described above.

Finally, development revenue in the first half of fiscal 2004 decreased 40% to \$1.9 million. This decrease results principally from the lower level of clinical coating work on the Cypher stent as stated above. Cordis accounted for a less than half of the paid development work performed by the Company during the first half of fiscal 2004.

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Product costs and margins. The Company's product costs were \$1.5 million for the first six months of fiscal 2004, an increase of 9%, compared with the same period of fiscal 2003. Overall product margins were 73% in the first six months of fiscal 2004 compared with 77% in the same period of fiscal 2003. Management continues to expect downward pressure on margins due to the recently signed SeraCare distribution agreement and a contractual reduction in reagent prices for Cordis.

Research and development expenses. Research and development expenses were \$6.3 million for the first six months of fiscal 2004, an increase of \$684,000, or 12%, compared with the same period of fiscal 2003. A significant portion of this increase was attributable to higher depreciation and facilities costs of the Bloomington facility and increased patent-related legal costs.

Sales and marketing expenses. Sales and marketing expenses were \$1.2 million for the first six months of fiscal 2004, an increase of 10% from the same period of fiscal 2003. As explained earlier, most of the increase can be attributed to compensation and benefits expenses related to marketing personnel.

General and administrative expenses. General and administrative expenses were \$2.9 million for the first six months of fiscal 2004 and fiscal 2003. While overall expense was flat year over year, an increase in recruiting, utilities and directors and officers insurance costs offset a decrease in legal expense.

Other income, net. The Company's other income was \$566,000 for the first six months of fiscal 2004, a decrease of \$471,000, or 45%, compared with the same period of fiscal 2003. While investment income decreased as a result of lower investment yields and the early payoff of a \$1.8 million note receivable, much of the decrease reflects lower gains generated from our investment portfolio. In the first half of fiscal 2003, the Company's investment adviser sold and reinvested a portion of the Company's bond portfolio generating gains of \$290,000. Results in the first quarter of fiscal 2004 reflect approximately \$20,000 in gains from such sales.

Income tax expense. The Company's income tax provision was \$5.0 million for the first six months of fiscal 2004 compared with \$3.0 million in the same period of fiscal 2003. The effective tax rates were 37.25% in fiscal 2004 and 37.5% in fiscal 2003.

As a result of our current technology and existing relationships with customers in large, attractive markets, we believe we are well positioned to pursue long-term growth opportunities. We believe that drug delivery has the potential to change the landscape of the current medical-device industry. We believe drug-eluting stents are simply the first example of how drugs and medical devices can be combined to produce improved medical results and patient benefits. Significant opportunities exist to deliver drugs from a wide range of other medical devices. In the first quarter of 2004, we completed a new strategic plan to help guide the long-term management of the Company. The strategic plan outlines opportunities and highlights long-term growth potential in four key markets: cardiovascular, ophthalmology, orthopedics and neurology. In the cardiovascular market, the Company intends to continue to leverage its expertise in drug-eluting coatings, hemocompatible (i.e., blood compatible) coatings that prevent blood components from attaching to medical devices and lubricity coatings. In the ophthalmology market, we intend to expand our drug-eluting technology to ophthalmic implants to treat certain eye diseases. We believe that our drug-eluting

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technologies also have significant opportunities in the orthopedic market, where our coatings may reduce inflammation and promote healing of patients receiving orthopedic devices such as hip, knee and joint implants. In the neurology market, we believe our lubricity and drug-eluting coatings have broad applicability as well.

The Company currently has 58 customers licensing the Company's patented or proprietary technology with respect to 135 product applications, 72 of which are generating royalties. The Company continues to sign new license and development agreements involving our patented or proprietary technology, including seven in the first half of fiscal 2004. Further, we expect that our customers will launch for sale (commercialize) at least 10 products in fiscal 2004. While we have numerous customers and products in our portfolio, revenue continues to be concentrated. In fiscal year 2003, our top 3 customers accounted for 71% of total revenue. However, we do not anticipate that this new product activity will generate sufficient royalty revenue in the near future to replace that which may be lost as a result of increased competition in the drug-eluting stent market or to allow the Company's growth rate to remain at historical levels in the near future.

While the Company has undertaken and will continue its research and development efforts internally, with customers and through strategic investments in third parties, the development of new medical devices and therapies may take years for our customers to commercialize and is often outside our control. As a result, we expect that our royalty revenue and its corresponding impact on our net income are likely to be cyclical depending upon the timing of the development of new surface-modification technologies or applications by us or our collaboration partners as well as the timing of commercialization of new medical devices and applications by our customers that achieve significant market acceptance.

The Company recently announced a corporate reorganization intended to sharpen its focus on customer needs and accelerate its technology leadership. The Company is now organized into five technology centered business units. In addition, management created a new business development function to support the Company's increasing interest in evaluating and gaining rights to new technologies created outside the Company. Management expects to implement the organizational changes during the Company's third fiscal quarter; as such, the operating segment results, reported under footnote 4 above, will reflect this change.

Liquidity and Capital Resources

As of March 31, 2004, the Company had working capital of \$17.0 million and cash, cash equivalents and investments totaling \$49.0 million. The Company's investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. The Company generated positive cash flows from operating activities of \$4.0 million in the first six months of fiscal 2004, a decrease of 50% from the same period of last year.

In October 2001, the Company purchased a facility in Bloomington, Minnesota, situated on 27 acres of land, for approximately \$7.1 million and expended an additional \$16.5 million throughout fiscal 2002 and 2003 on capital improvements to upgrade laboratories and to complete the construction of additional manufacturing capacity. As part of a recent reorganization, the Company announced that after careful examination of its redefined business goals, the Company does not believe that contract manufacturing, which the Bloomington facility was built to accommodate, warrants a prominent role in its strategic plan. Furthermore, the Company believes it has adequate manufacturing capacity in its Eden Prairie headquarters to support its business. Accordingly, the Company is actively investigating selling

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or leasing the facility. The financial results for the current period do not include any adjustments related to the Bloomington facility, because the Company does not believe that an impairment against book value has occurred.

In October 2003, the Company received prepayment of approximately \$1.9 million due on a note receivable related to property the Company sold in June 2002. With this payment, the note was paid in its entirety.

On February 3, 2004, the Company invested \$2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing unique drug delivery devices and therapies for the ophthalmology market. The Company has agreed to invest a total of \$3.5 million, the remaining \$1.4 million of which will be invested subject to InnoRx completing certain development and regulatory milestones. In collaboration with the Company, InnoRx is developing a patented, implantable coil to deliver therapeutic agents in the eye to treat various retinal diseases. This product utilizes SurModics' site-specific drug delivery technology. While the Company anticipates that its investment in InnoRx will help facilitate the commercialization of its technology and result in revenue for the Company in the future, there can be no assurance that this will occur. InnoRx's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized. The \$2.1 million investment, which is accounted for under the cost method, is included in other assets and, together with the remaining \$1.4 million to be invested, would represent an ownership interest of less than 20%.

On February 10, 2004, the Company loaned \$285,000 to Novocell, Inc., a privately-held Irvine, California-based biotech firm that is developing a unique treatment for diabetes using cell-encapsulation. The loan is in addition to the \$4.9 million the Company has invested in Novocell. Working with Novocell, the Company's researchers have created a coating that encapsulates pancreatic islet cells — the cells that produce insulin in the human body. If successful, this treatment using coated islet cells could dramatically change the treatment of diabetes. While the Company anticipates that its investment in Novocell will help facilitate the commercialization of its technology and result in revenue for the Company in the future, there can be no assurance that this will occur. Novocell's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized. The \$4.9 million investment, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 15%.

Risks and uncertainties surrounding a development-stage company's ability to obtain on a timely and frequent basis financing needed to continue its development activities currently affect, and will continually affect, the prospects of the Company's investments in Novocell and InnoRx and the revenue they may ultimately generate. Neither of these companies has full funding for its development activities. There is no assurance that Novocell's current efforts to meet its immediate financing needs will be successful or that future financing needs of Novocell or InnoRx will be met when required. If adverse results occur in Novocell's or InnoRx's development of its respective technology or if its financing needs are not continually met, the viability of such company and its efforts in providing a future revenue source for the Company will be in jeopardy and the Company's investment in such company would likely be considered impaired and charged against the Company's earnings at such time.

As of March 31, 2004, the Company had no debt, nor did it have any credit agreements. The Company believes that its existing capital resources will be adequate to fund SurModics' operations into the foreseeable future.

New Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables,” which provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or right to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have an impact on the Company’s financial statements.

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on the remaining portions of EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, with an effective date of June 15, 2004. EITF 03-01 provides new disclosure requirements for other-than-temporary impairments on debt and equity investments. Investors are required to disclose quantitative information about: (i) the aggregate amount of unrealized losses, and (ii) the aggregate related fair values of investments with unrealized losses, segregated into time periods during which the investment has been in an unrealized loss position of less than 12 months and greater than 12 months. In addition, investors are required to disclose the qualitative information that supports their conclusion that the impairments noted in the qualitative disclosure are not other-than temporary. The adoption of the remaining portions is not expected to have a material impact on our results of operations or financial condition.

Forward Looking Statements

Certain statements contained in this report and other written and oral statements made from time to time by the Company do not relate strictly to historical or current facts. As such, they are considered “forward-looking statements” that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “could,” “possible,” “plan,” “project,” “will,” “forecast” and similar words or expressions. Any statement that is not a historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, are forward-looking statements. The Company’s forward-looking statements generally relate to its growth strategy, financial results, product development programs, sales efforts, and the impact of the Cordis agreement. One must carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. The Company undertakes no obligation to update any forward-looking statement.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from the Company’s forward-looking statements, such factors include, among others: (i) the trend of consolidation in the medical-device industry, resulting in more significant, complex and long-term contracts than in the past and potentially greater pricing pressures; (ii) frequent intellectual property litigation in the medical-device industry that may directly or indirectly adversely affect our customers’ ability to market their products incorporating SurModics’ technologies; (iii) our ability to protect our own intellectual property; (iv) healthcare reform efforts and reimbursement rates for medical-device products that may adversely affect our customers’ ability to cost-effectively market and sell devices incorporating SurModics’ technologies; (v) the Company’s significant dependence upon Cordis, which causes our financial results and stock

price to be subject indirectly to factors affecting Cordis and its Cypher stent program, including among others, the rate of market penetration by Cordis, the timing and impact of market introduction of competing products, product safety or efficacy concerns, and intellectual property litigation generally and specifically the litigation involving Boston Scientific Scimed, Inc. and Cordis currently pending in U.S. District Court for the District of Delaware (and scheduled for trial in June 2005) in which each alleges its patent rights are being infringed by the other's drug-eluting stent, and each has been denied the preliminary injunction it has requested against the other, though Cordis has appealed denial of its requested preliminary injunction against Boston Scientific's coronary drug-eluting stent, which appeal was heard on April 5, 2004 (but no decision yet issued) by the Court of Appeals for the Federal Circuit; (vi) the Company's ability to attract new licensees and to enter into agreements for additional product applications with existing licensees, the willingness of potential licensees to sign license agreements under the terms offered by the Company, and the Company's ability to maintain satisfactory relationships with its licensees; (vii) market acceptance of products sold by customers incorporating SurModics' technologies and the timing of new product introductions by licensees; (viii) market acceptance of products sold by customers' competitors and the timing and pricing of new product introductions by customers' competitors; (ix) the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances, which may result in lost market opportunities or postpone or preclude product commercialization by licensees; (x) efficacy or safety concerns with respect to products marketed by SurModics and its licensees, whether scientifically justified or not, that may lead to product recalls, withdrawals or declining sales; (xi) product liability claims not covered by insurance; (xii) the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors; (xiii) economic and other factors over which the Company has no control, including changes in inflation and consumer confidence; (xiv) acts of God or terrorism which impact the Company's personnel or facilities; (xv) any delays or quality problems in the supply of raw materials used by the Company to manufacture its products, including some raw materials that currently are being purchased only from single sources; and (xvi) other factors described in the "Risk Factors" and other sections of SurModics' filings with the Securities and Exchange Commission which are incorporated herein by reference. Many of these factors are outside the control and knowledge of the Company and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon the Company's forward-looking information and to consult any further disclosures by the Company on this subject in its filings with the Securities and Exchange Commission.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

SurModics' investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company's investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. SurModics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A one percentage point increase in interest rates would result in an approximate \$640,000 decrease in the fair value of the Company's available-for-sale securities as of March 31, 2004, but no material impact on the results of operations or cash flows. Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material. Also, the Company's foreign currency exposure is not significant.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer regarding the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rules 13a-15(b) of the Securities Exchange Act of 1934 (the "Exchange Act"). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information that is required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the rules of the Securities Exchange Commission.

Changes in Internal Controls

There were no changes in the Company's internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 2. Changes in Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information.

None.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits -

31.1	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002

- (b) Reports on Form 8-K — A report on Form 8-K dated January 21, 2004 was furnished on January 21, 2004, pursuant to Item 12 and related to the issuance of a press release announcing the results for the Company's first 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.

SurModics, Inc.

May 17, 2004

By: /s/ Philip D. Ankeny
Philip D. Ankeny
Chief Financial Officer

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-Q

For the Quarter Ended March 31, 2004

SURMODICS, INC.

Exhibit	Description
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
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**CERTIFICATION PURSUANT TO SECTION 302
OF SARBANES-OXLEY ACT OF 2002**

I, Dale R. Olseth, Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SurModics, Inc.;

2. Based on my knowledge, this 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 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 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.

5. The registrant's other certifying officer 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.

Dated: May 17, 2004

Signature: /s/ Dale R. Olseth

Dale R. Olseth
Chief Executive Officer

**CERTIFICATION PURSUANT TO SECTION 302
OF SARBANES-OXLEY ACT OF 2002**

I, Philip D. Ankeny, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SurModics, Inc.;

2. Based on my knowledge, this 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 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 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.

5. The registrant's other certifying officer 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.

Dated: May 17, 2004

Signature: /s/ Philip D. Ankeny

Philip D. Ankeny
Chief Financial Officer

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SurModics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2004, as filed with the Securities and Exchange Commission (the "Report"), I, Dale R. Olseth, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §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 the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 17, 2004

/s/ Dale R. Olseth

Dale R. Olseth
Chief Executive Officer

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SurModics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2004, as filed with the Securities and Exchange Commission (the "Report"), I, Philip D. Ankeny, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §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 the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 17, 2004

/s/ Philip D. Ankeny

Philip D. Ankeny
Chief Financial Officer