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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 December 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 74<sup>th</sup> 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 January 31, 2005 was 18,216,163.

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**PART I. FINANCIAL INFORMATION**

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

	December 31, 2004	September 30, 2004
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 2,056	\$ 2,709
Short-term investments	11,428	16,506
Accounts receivable, net	9,497	8,130
Inventories	1,105	1,040
Deferred tax asset	379	379
Prepays and other	805	805
Total current assets	<u>25,270</u>	<u>29,569</u>
Property and equipment, net	15,299	15,738
Long-term investments	48,349	44,088
Deferred tax asset	5,654	5,579
Other assets, net	16,127	14,807
	<u>\$ 110,699</u>	<u>\$ 109,781</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 598	\$ 683
Accrued liabilities	1,541	6,751
Accrued income taxes payable	4,493	3,827
Deferred revenue	132	528
Total current liabilities	<u>6,764</u>	<u>11,789</u>
Deferred revenue, less current portion	1,573	1,488
Other long-term liabilities	2,000	2,000
Total liabilities	<u>10,337</u>	<u>15,277</u>
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;		
17,614,356 and 17,536,656 shares issued and outstanding	881	877
Additional paid-in capital	59,833	57,849
Unearned compensation	(2,316)	(632)
Accumulated other comprehensive income (loss)	(72)	56
Retained earnings	42,036	36,354
Total stockholders' equity	<u>100,362</u>	<u>94,504</u>
	<u>\$ 110,699</u>	<u>\$ 109,781</u>

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

**Item 1. Financial Statements**

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

	Three Months Ended December 31	
	2004	2003
<b>Revenue</b>		
Royalties and license fees	\$ 10,091	\$ 8,629
Product sales	2,000	2,600
Development	1,978	858
Total revenue	<u>14,069</u>	<u>12,087</u>
<b>Operating costs and expenses</b>		
Product	620	736
Research and development	3,355	3,271
Sales and marketing	262	418
General and administrative	1,194	1,375
Total operating costs and expenses	<u>5,431</u>	<u>5,800</u>
Income from operations	<u>8,638</u>	<u>6,287</u>
<b>Other income</b>		
Investment income	417	276
Gain on sale of investments	0	19
Other income	417	295
Income before income taxes	9,055	6,582
Income tax provision	<u>(3,373)</u>	<u>(2,471)</u>
Net income	<u>\$ 5,682</u>	<u>\$ 4,111</u>
Basic net income per share	\$ 0.32	\$ 0.24
Diluted net income per share	\$ 0.32	\$ 0.23
<b>Weighted average shares outstanding</b>		
Basic	17,574	17,454
Dilutive effect of outstanding stock options	376	312
Diluted	<u>17,950</u>	<u>17,766</u>

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

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

	Three months ended December 31,	
	2004	2003
<b>Operating Activities</b>		
Net income	\$ 5,682	\$ 4,111
Adjustments to reconcile net income to net cash provided by operating activities-		
Depreciation and amortization	996	862
Gain on sale of investments	—	(19)
Noncash compensation	94	48
Deferred taxes	(75)	(79)
Gain on disposal of property and equipment	(195)	—
Change in operating assets and liabilities:		
Accounts receivable	(1,367)	673
Inventories	(65)	9
Accounts payable and accrued liabilities	(275)	(2,969)
Income taxes	666	1,141
Deferred revenue	(311)	(873)
Prepays and other	—	(25)
Net cash provided by operating activities	<u>5,150</u>	<u>2,879</u>
<b>Investing Activities</b>		
Purchases of property and equipment	(194)	(681)
Proceeds from sales of property and equipment	254	—
Purchases of available-for-sale investments	(30,893)	(13,122)
Sales/maturities of available-for-sale investments	31,582	12,936
Investment in InnoRx, Inc.	(1,592)	—
Payment for Abbott and Octoplus licenses	(5,170)	—
Payments received on note receivable	—	1,869
Net cash provided by (used in) investing activities	<u>(6,013)</u>	<u>1,002</u>
<b>Financing Activities</b>		
Issuance of common stock	210	77
Net change in cash and cash equivalents	<u>(653)</u>	<u>3,958</u>
<b>Cash and Cash Equivalents</b>		
Beginning of period	2,709	4,007
End of period	<u>\$ 2,056</u>	<u>\$ 7,965</u>
Cash paid for taxes	<u>\$ 2,723</u>	<u>\$ 1,330</u>

The accompanying notes are an integral part of these unaudited 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 first quarter ended December 31, 2004, are not necessarily indicative of the results that may be expected for the entire 2005 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, 2004, and footnotes thereto included in the Company's Form 10-K as filed with the United States Securities and Exchange Commission on December 14, 2004.

**(2) New Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board issued a revision to Statement of Financial Accounting Standards 123 (SFAS 123(R)), Share-Based Payment. The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. The statement eliminates the alternative method of accounting for employee share-based payments previously available under Accounting Principles Board Opinion No. 25. The Statement is effective for the Company beginning in the fourth quarter of fiscal 2005. The Company has not completed the process of evaluating the impact that will result from adopting SFAS 123(R).

In March 2004, the FASB issued EITF Issue No. 03-1 ("EITF 03-1"), "The Meaning of Other-Than Temporary Impairment and its Application to Certain Investments." EITF 03-1 includes new guidance for evaluating and recording impairment losses on certain debt and equity investments when the fair value of the investment security is less than its carrying value. The provisions of this rule are required to be applied prospectively to all current and future investments accounted for in accordance with FAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and other cost method investments beginning in the third quarter of 2004. In September 2004, the FASB delayed the effective date for the measurement and recognition provisions until the issuance of additional implementation guidance. The Company is currently evaluating the impact of this new accounting standard on its process for determining other-than-temporary impairments of applicable debt and equity securities, but does not expect the impact to be material.

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### **(3) Other assets**

Other assets consist principally of investments and acquired patents. The balance in other assets increased primarily due to an additional investment in InnoRx of approximately \$1.6 million in the first quarter of fiscal 2005 less accumulated amortization on patents and other intangibles.

### **(4) Inventories (dollars in thousands)**

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:

	December 31, 2004	September 30, 2004
Raw materials	\$ 589	\$ 634
Finished goods	516	406
	<u>\$ 1,105</u>	<u>\$ 1,040</u>

### **(5) Operating Segments (dollars in thousands)**

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance.

SurModics manages its business on the basis of the operating segments noted in the table below, which are comprised of the Company's five business units. The three operating segments are aggregated into one reportable segment. The "Drug Delivery" operating segment contains the Drug Delivery business unit. The "Hydrophilic and Other" operating segment consists of three business units: (1) Hydrophilic Technologies, (2) Regenerative Technologies and (3) SurModics New Ventures. The "Diagnostics" operating segment contains the Diagnostics and Drug Discovery business unit. Each operating segment has similar economic characteristics, technology, manufacturing processes, customers, regulatory environments, and shared infrastructures. The Company manages its expenses on a company-wide basis, as many costs and activities are shared among the business units and a majority of the Company's employees reside in shared resource units. The focus of the business units is providing



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solutions to customers and maximizing revenue over the long-term. The accounting policies for segment reporting are the same as for the Company as a whole (*in thousands*):

	Three months ended December 31,	
	2004	2003
Operating segment:		
Drug Delivery	\$ 7,121	\$ 6,899
Hydrophilic and Other	4,233	3,186
Diagnostics	2,715	2,002
Total Revenue	<u>\$ 14,069</u>	<u>\$ 12,087</u>

### **(6) 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 earnings per share would have changed to the following pro forma amounts for the three months ended December 31, 2004 and 2003:

	Three months ended December 31,	
	2004	2003
Net income		
As reported	\$ 5,682	\$ 4,111
Fair value compensation expense, net of tax	(584)	(460)
Pro forma	<u>\$ 5,098</u>	<u>\$ 3,651</u>
Basic net income per share:		
As reported	\$ 0.32	\$ 0.24
Fair value compensation expense, net of tax	(.03)	(.03)
Pro forma	<u>\$ 0.29</u>	<u>\$ 0.21</u>
Diluted net income per share:		
As reported	\$ 0.32	\$ 0.23
Fair value compensation expense, net of tax	(.04)	(.02)
Pro forma	<u>\$ 0.28</u>	<u>\$ 0.21</u>

The fair market 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 December 31, 2004 and December 31, 2003, respectively: risk-free interest rates of 3.53% and 3.44%; expected lives of 7 years and 7 years; and expected volatility of 65% and 69%.

During the quarter ended December 31, 2004, SurModics awarded 57,000 shares of restricted stock which increased the balance of unearned compensation by \$1.7 million. The stock will vest over five years.

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

	Three months ended December 31,	
	2004	2003
Net income	\$ 5,682	\$ 4,111
Other comprehensive income:		
Unrealized holding losses on available-for-sale securities arising during the period, net of tax	(85)	(116)
Less reclassification adjustment for realized gains included in net income, net of tax	(43)	(12)
Other comprehensive loss	(128)	(128)
Comprehensive income	<u>\$ 5,554</u>	<u>\$ 3,983</u>

**(8) Subsequent Events**

On January 18, 2005, SurModics entered into a merger agreement whereby SurModics acquired all of the assets of InnoRx, Inc. by paying approximately \$4.1 million in cash and issuing 600,064 shares of SurModics common stock to InnoRx stockholders. The closing sale price of SurModics common stock on the date of the acquisition was \$28.78 per share. Upon the successful completion of certain development and commercial milestones involving InnoRx technology acquired by SurModics, SurModics will be required to issue up to an additional 600,073 shares of its common stock to the stockholders of InnoRx. The assets of InnoRx consisted almost exclusively of in-process research and development assets, therefore management expects it will expense virtually all of the purchase price as in-process research and development in the Company's second fiscal quarter.

On January 20, 2005, the Company announced that it made an investment of approximately \$3.9 million in OctoPlus, a privately owned company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers. The \$3.9 million investment, which is accounted for under the cost method, represents an ownership interest of less than 20%. Previously, the Company entered into exclusive license agreements with OctoPlus for two classes of biodegradable polymers.

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

### Overview

SurModics is a leading provider of surface modification and drug delivery technologies to the medical device industry. The Company is organized into five technology-centered business units. The operating results from three of the business units are combined into one operating segment, "Hydrophilic and Other" as explained below. Each of the two remaining business units constitutes an operating segment. The "Drug Delivery" operating segment contains the Drug Delivery business unit, which is responsible for technologies dedicated to site specific delivery of drugs. The "Hydrophilic and Other" operating segment consists of three business units: (1) Hydrophilic Technologies unit which focuses on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) Regenerative Technologies unit which encompasses the Company's hemocompatibility, tissue engineering and cell encapsulation technologies; and (3) SurModics New Ventures unit which is dedicated to the identification, research and development of new technologies outside the research conducted in the other business units. The "Diagnostics" operating segment contains the Diagnostics and Drug Discovery business unit which includes the Company's genomics and slide technologies, the Company's stabilization products for immunoassay diagnostics test, and its in vitro diagnostic format technology.

Revenue in each of our operating segments is derived from three primary sources: (1) royalties and license fees from licensing our patented surface modification technologies to customers; (2) the sale of reagent chemicals to licensees of our coating technologies, stabilization products to the diagnostics industry and coated glass slides to the genomics market; and (3) research and development fees generated on projects for commercial customers. Revenue should be expected to fluctuate from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our coating technologies; the timing of introductions of coated products by customers; the timing of introductions of products that compete with our customers' products; the number and size of development projects that are entered into; the number of new license agreements that are finalized; the value of reagent chemicals and other products sold to licensees; and the timing of future acquisitions completed by the Company, if any.

For financial accounting and reporting purposes, we treat our three operating segments as one reportable segment. We made this determination because each of our operating segments uses the same facilities, a significant percentage of our employees provide support services (including research and development) to each operating segment, technology and products from each operating segment are marketed to the same or similar customers, each operating segment uses the same sales and marketing resources and each operating segment operates in the same regulatory environment.

### Critical Accounting Policies

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 judgments 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, 2004.

**Results of Operations****Three Months Ended December 31, 2004 and 2003**

<i>(Dollars in thousands)</i>	<u>Fiscal 2005</u>	<u>Fiscal 2004</u>	<u>Increase</u>	<u>% Increase</u>
Revenue:				
Drug Delivery	\$ 7,121	\$ 6,899	\$ 222	3%
Hydrophilic and Other	4,233	3,186	1,047	33%
Diagnostics	2,715	2,002	713	36%
Total revenue	<u>\$ 14,069</u>	<u>\$ 12,087</u>	<u>\$ 1,982</u>	16%

**Revenue.** First quarter revenue was a record \$14.1 million, an increase of \$2.0 million or 16% over fiscal 2004. Growth was distributed across all operating segments as detailed in the table above. We provide a narrative of revenue for each of our three operating segments in the paragraphs that follow.

*Drug Delivery.* Drug Delivery revenue increased 3% to \$7.1 million for the period ending December 31, 2004 compared with \$6.9 million for the same period last year. Drug Delivery derives a substantial majority of its revenue from royalties and license fees and product sales attributable to Cordis Corporation, a Johnson & Johnson company, on its Cypher stent. The Cypher stent incorporates a proprietary SurModics coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. Significant growth in research and development revenue for the Drug Delivery operating segment more than offset a decrease in sales of reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices) to Cordis resulting from volume and unit price decreases. Research and development revenue from Cordis declined compared to the same period a year ago, and did not constitute a majority of research and development revenue in Drug Delivery during the quarter.

A portion of the growth in research and development revenue was attributable to revenue from InnoRx. Research and development revenue may decrease sequentially in future quarters since, as stated above, SurModics purchased InnoRx in January, our second fiscal quarter. In addition, we expect a significant continuing decrease in reagent chemical sales to Cordis for the balance of fiscal 2005 when compared to prior year resulting from a contractual reduction in reagent pricing and as Cordis continues to become more efficient in its manufacturing. Finally, sequential quarterly royalty revenue could decrease due to possibly lower Cypher sales as a result of continuing competition from Boston Scientific Corporation's Taxus drug-eluting stent.

Boston Scientific was granted approval by the FDA to begin marketing in the U.S. its Taxus drug-eluting stent in our 2004 second fiscal quarter. The Taxus stent competes directly with the Cypher stent and has gained market share leadership. We anticipate that while the overall market for drug-eluting stents will continue to grow, quarterly royalty revenue from the current generation Cypher stent will be volatile as the two sole U.S. marketers of drug-eluting stents compete in the marketplace. Management expects royalties from the Cypher stent to constitute a significant portion of our revenue throughout fiscal 2005.

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. The companies are scheduled for trial in June 2005.

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*Hydrophilic and Other.* Hydrophilic and Other revenue increased 33% to \$4.2 million, driven by increased royalties and research and development revenue attributable to several dozen licensees. Management expects continued growth in Hydrophilic and Other but growth for the remainder of fiscal 2005 is unlikely to be as strong as it was in the current period.

*Diagnostics.* Diagnostics derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories. First quarter revenue increased 36% to \$2.7 million. Substantially all the growth resulted from increased royalty revenue under certain sublicensees with Abbott for which the Company previously had been receiving only a portion of the sublicense royalties.

Effective February 1, 2005, the Company terminated its distributor agreement with SeraCare. SurModics began distributing its line of stabilization products in the U.S. through SeraCare in last year's second quarter. Product sales may decrease in the near-term while the Company transitions back to directly selling its stabilization products, but management believes product sales may increase in the intermediate-term by selling directly to the U.S. diagnostics industry.

**Product costs.** Product costs were \$620,000 for the first quarter, a 16% decrease from the \$736,000 last year. Overall product margins averaged 62% compared with 72% for the comparable period last year. The margin decrease is primarily attributable to a contractual reduction in reagent pricing from Cordis and lower pricing on stabilization products. The decrease in product margins is also attributable to lower margins from sales of stabilization products through SeraCare than the Company realized from direct sales in the first quarter of fiscal 2004.

**Research and development expenses.** Research and development expenses were \$3.4 million, an increase of 3% compared with the same period in fiscal 2004. Management believes research and development expense will increase modestly for the balance of 2005 as the Company makes increased investments in such research and development in addition to the amortization cost associated with the recently purchased sublicense royalty stream discussed above in Diagnostics. In addition, management anticipates increased research and development expenses approximating \$500,000 per quarter related to development activities and clinical trials associated with the recent acquisition of InnoRx.

**Sales and marketing expenses.** Sales and marketing expenses were \$262,000 for the first quarter of fiscal 2005, a 37% decrease from last year. A substantial portion of the decrease resulted from lower payroll costs related to a reduction in senior marketing personnel in connection with a company-wide reorganization. Management anticipates increased sales and marketing expense in fiscal 2005 as the Company expands the size of its sales force.

**General and administrative expenses.** General and administrative expenses were \$1.2 million for the first quarter of fiscal 2005, a 13% decrease compared with the same period in fiscal 2004 reflecting efficiencies gained in the reorganization. Management anticipates general and administrative expense will increase modestly throughout fiscal 2005.

**Other income, net.** Other income was \$417,000 for the first quarter of fiscal 2005, an increase of \$141,000, or 51%, compared with the same period of fiscal 2004. The increase reflects increased levels of investable cash and higher yields generated from our investment portfolio. Management expects investment income to decrease for the balance of the fiscal year due to lower investment balances as a result of recent strategic investments in development stage companies and the acquisition of InnoRx.

**Income tax expense.** The Company's income tax provision was \$3.4 million for the first quarter of fiscal 2005 compared with \$2.5 million in the same period of fiscal 2004. The effective tax

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rate was 37.2% for the first quarter of fiscal 2005, compared with 37.5% for the first quarter of fiscal 2004.

### **Liquidity and Capital Resources**

As of December 31, 2004, the Company had working capital of \$18.5 million and cash, cash equivalents and investments totaling \$61.8 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's policy requires that no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while generating an above benchmark (Lehman Brothers 1-3 Year Government Index) total rate of return. Management plans to continue to direct its investment advisor to manage the Company's investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments. The Company had positive cash flows from operating activities of approximately \$5.2 million in the first three months of fiscal 2005, compared to \$2.9 million in the first three months of fiscal 2004.

SurModics conducts a significant majority of its operations at its Eden Prairie, Minnesota headquarters. In addition, the Company owns a facility in Bloomington, Minnesota. Management believes the Company has adequate office space and manufacturing capacity in its Eden Prairie headquarters to support its business and strategic plan. As such the Company is seeking to sell or lease the Bloomington facility and plans to consolidate operations in Eden Prairie.

In February 2004, the Company invested \$2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing drug delivery devices and therapies for the ophthalmology market. SurModics made an additional investment of approximately \$1.6 million in the first quarter of fiscal 2005. On January 18, 2005, SurModics acquired all of InnoRx's assets through a merger of InnoRx into SurModics by paying approximately \$4.1 million in cash and issuing 600,064 shares of SurModics common stock to InnoRx stockholders. Upon the successful completion of certain development and commercial milestones involving InnoRx technology acquired by SurModics, SurModics will be required to issue up to an additional 600,073 shares of its common stock to the stockholders of InnoRx.

SurModics has invested a total of \$5.2 million in Novocell, Inc., a privately-held Irvine, California-based biotech firm that is developing a unique treatment for diabetes. 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 \$5.2 million investment, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 5%.

In September 2004, we made a commitment to purchase for \$7 million certain additional sublicense rights and the accompanying future royalty revenue streams under certain sublicenses through an amendment to our diagnostic format patent license with Abbott Laboratories. Prior to such amendment, we were receiving only a portion of the royalties under such sublicenses. The first \$5 million installment was paid in November 2004. The remaining installments are reflected in Other Long-Term Liabilities in the December 31, 2004 balance sheet.

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On January 20, 2005, the Company announced that it made an equity investment of approximately \$3.9 million in OctoPlus, a privately owned company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers. The \$3.9 million investment, which is accounted for under the cost method, represents an ownership interest of less than 20%.

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 OctoPlus and the revenue they may ultimately generate. 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 OctoPlus will be met when required. If adverse results occur in Novocell's or OctoPlus's development of its respective technology, or if their respective financing needs are not continually met, the viability of such companies and their ability to be future sources of revenue for the Company will be in jeopardy and the Company's investment in such companies would likely be considered impaired and charged against the Company's earnings at such time.

As of December 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 December 2004, the Financial Accounting Standards Board issued a revision to Statement of Financial Accounting Standards 123 (SFAS 123(R)), Share-Based Payment. The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. The statement eliminates the alternative method of accounting for employee share-based payments previously available under Accounting Principles Board Opinion No. 25. The Statement is effective for the Company beginning in the fourth quarter of fiscal 2005. The Company has not completed the process of evaluating the impact that will result from adopting SFAS 123(R).

In March 2004, the FASB issued EITF Issue No. 03-1 ("EITF 03-1"), "The Meaning of Other-Than Temporary Impairment and its Application to Certain Investments." EITF 03-1 includes new guidance for evaluating and recording impairment losses on certain debt and equity investments when the fair value of the investment security is less than its carrying value. The provisions of this rule are required to be applied prospectively to all current and future investments accounted for in accordance with FAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and other cost method investments beginning in the third quarter of 2004. In September 2004, the FASB delayed the effective date for the measurement and recognition provisions until the issuance of additional implementation guidance. The Company is currently evaluating the impact of this new accounting standard on its process for determining other-than-temporary impairments of applicable debt and equity securities, but does not expect the impact to be material.

### **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

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“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 and product supply 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, (vi) the Company’s ability to attract new licensees in the Company’s current market segments 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) the Company’s ability to increase the number of market segments and applications that use its coating technologies through its sales and marketing and research and development efforts; (viii) the Company’s ability to facilitate through strategic investment and research and development the creation of new medical device market segments and applications that use its coating technologies; (ix) market acceptance of products sold by customers incorporating SurModics’ technologies and the timing of new product introductions by licensees; (x) market acceptance of products sold by customers’ competitors and the timing and pricing of new product introductions by customers’ competitors; (xi) 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; (xii) 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; (xiii) qualification for and/or continuation of government or other funding of research and development work; (xiv) product liability claims not covered by insurance; (xv) the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors; (xvi) economic and other factors over which the Company has no control, including changes in inflation and consumer confidence; (xvii) acts of God or terrorism which impact the Company’s personnel or facilities; (xviii) 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; (xix) the timing and success of acquisitions made by the Company from time to time, including in particular with respect to the Company’s January 2005 acquisition of InnoRx’s assets the factors discussed below, and (xx) other factors described in the “Risk Factors” and other sections of SurModics’ filings with the



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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.

SurModics expects to record significant one-time charges following its acquisition of InnoRx as a result of transaction costs for the acquisition and to write-off purchased in-process research and development. Virtually all of the purchase price in this acquisition is allocated to in-process research and development. The cumulative amount of these one-time charges may exceed the market value of the consideration that SurModics paid to InnoRx's stockholders. These one-time charges are expected to materially decrease SurModics' net earnings in its 2005 fiscal year and may also result in charges in each period thereafter in which milestone payments in shares of SurModics stock are made depending on the value of such shares at such time.

Because of its historical strategy, SurModics has not maintained significant manufacturing operations, managed significant marketing, sales or product branding efforts or developed significant expertise with respect to applying for and receiving governmental and regulatory clearances for marketing products. SurModics may increasingly internally perform certain product development activities and governmental and regulatory compliance activities with respect to technology acquired from InnoRx, but there can be no assurance that SurModics' efforts will be effective in these areas.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company's 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 \$900,000 decrease in the fair value of the Company's available-for-sale securities as of December 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.

Although we conduct business in foreign countries, our international operations consist primarily of sales of reagent and stabilization chemicals. Additionally, all sales transactions are denominated in U.S. dollars. Accordingly, we do not expect to be subject to material foreign currency risk with respect to future costs or cash flows from our foreign sales. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

### **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 Rule 13a-15(b) of the

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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. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

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

No matters were submitted to a vote of the Company's security holders during the period covered by this Report on Form 10-Q; however, set forth below is information concerning matters submitted to a vote of the Company's security holders at the recent annual meeting of shareholders:

- (a) The Company held its Annual Meeting of Shareholders on January 31, 2005.
- (b) Proxies were solicited pursuant to Regulation 14A under the Securities Act of 1934. The shareholders voted on three matters: (i) to set the number of directors at nine (9), (ii) to elect Class III directors, and (iii) to approve the amendment of the Company's 2003 Equity Incentive Plan to increase the shares available for issuance under the Plan by 1,800,000. The shareholders approved all matters by the following votes:

	<u>Votes For</u>	<u>Votes Against</u>	<u>Votes Abstained</u>	<u>Broker Non-Votes</u>
(i) Set the number of directors at nine (9)	15,670,009	84,841	31,554	25
	<u>Votes For</u>	<u>Votes Withheld</u>	<u>Broker Non-Votes</u>	
(ii) Elect Class III directors				
Dale R. Olseth	15,256,079	530,350	—	
Kenneth H. Keller, Ph.D.	15,136,217	650,212	—	
David A. Koch	15,062,388	724,041	—	
	<u>Votes For</u>	<u>Votes Against</u>	<u>Votes Abstained</u>	<u>Broker Non-Votes</u>
(iii) To approve the amendment of the Company's 2003 Equity Incentive Plan to increase the shares available for issuance under the Plan by 1,800,000	8,541,611	1,499,025	24,770	5,721,023

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**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibits –

- 2.1 Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. — incorporated by reference to Exhibit 2.1 to the Company’s Current Report on Form 8-K dated January 24, 2005.
- 10.1 SurModics 2005 Bonus Plan
- 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

**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.**

February 9, 2005

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 December 31, 2004

SURMODICS, INC.

<u>Exhibit</u>	<u>Description</u>
2.1	Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 24, 2005.
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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

FY 2005 SurModics Bonus Plan

I. Consists of two parts

- A. Corporate objectives
- B. Business Unit or Department objectives

II. Corporate objectives

A. Revenue	Level I	Level II	Level III
And/Or			
B. Earnings Per Share	Level I	Level II	Level III

Such Level I, Level II, and Level III performance levels are as set by the Organization & Compensation Committee for FY 2005.

III. Business Unit or Department objectives

- A. Three (3) to five (5) objectives identified by Senior Staff member and approved by President
- B. One objective for Business Units will be revenue

IV. No bonus payout unless Revenue or EPS initial corporate objective is met

V. Corporate Payout structure – for each of Revenue and EPS (Levels not cumulative)

	<u>Level I</u>	<u>Level II</u>	<u>Level III</u>
CEO/COO	3%	7%	13%
Senior Staff	2%	5%	10%
Director/Manager	1%	3%	5%
Employees	0.5%	1%	2%

VI. Composition of Total Bonus Payout

- 1. Senior Staff: 75% corporate + 25% Business Unit/Department
- 2. All other employees: 50% corporate + 50% Business Unit/Department
- 3. CEO and COO will receive 100% corporate bonus and no Business Unit/Department component.

Example: If corporate Level II revenue and Level III EPS are met, then Senior Staff member gets 15% corporate bonus (5% + 10%). If all Business Unit/Department goals are met, then that person gets an additional 5% bonus, for a total bonus payout of 20% (75% corporate, 25% Business Unit)

**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: February 9, 2005

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: February 9, 2005

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 December 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: February 9, 2005

/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 December 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: February 9, 2005

/s/ Philip D. Ankeny

Philip D. Ankeny  
Chief Financial Officer