# 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, 2005

OR

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-23837

# 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 o

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

Yes 🗹 No o

The number of shares of the registrant's Common Stock, \$.05 par value per share, outstanding as of April 29, 2005 was 18,290,359.

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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, 2005	September 30, 2004 (Restated)
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 974	\$ 2,709
Short-term investments	7,869	16,506
Accounts receivable, net	11,277	8,130
Inventories	992	1,040
Deferred tax asset	379	379
Prepaids and other	1,060	805
Total current assets	22,551	29,569
Property and equipment, net	15,155	15,738
Long-term investments	47,832	44,088
Deferred tax asset	8,205	5,579
Other assets, net	15,744	14,613
	\$109,487	\$ 109,587
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 464	\$ 683
Accrued liabilities	1,433	6,751
Accrued income taxes payable	2,096	3,827
Deferred revenue	577	528
Total current liabilities	4,570	11,789
Deferred revenue, less current portion	1,433	1,488
Other long-term liabilities	10,090	2,000
Total liabilities	16,093	15,277
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; 18,289,319 and 17,536,656 shares issued and outstanding	914	877
Additional paid-in capital	78,007	57,849
Unearned compensation	(2,239)	(632)
Accumulated other comprehensive income (loss)	(314)	56
Retained earnings	17,026	36,160
Total stockholders' equity	93,394	94,310
	\$109,487	\$ 109,587

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

# SURMODICS, INC.

# Condensed Statements of Operations

(In thousands, except per share data) (unaudited)

		Three Months Ended March 31,		ns Ended n 31,
	2005	2004 (Restated)	2005	2004 (Restated)
Revenue		(Resiated)		(Restated)
Royalties and license fees	\$ 12,268	\$ 8,944	\$ 22,359	\$ 17,572
Product sales	2,321	2,803	4,321	5,403
Research and development	1,116	991	3,094	1,850
Total revenue	15,705	12,738	29,774	24,825
Operating costs and expenses				
Product	730	752	1,349	1,488
Research and development	3,890	3,140	7,246	6,411
Sales and marketing	307	588	569	1,006
General and administrative	1,649	1,580	2,843	2,955
Purchased in-process research & development	30,277	<u> </u>	30,277	<u> </u>
Total operating costs and expenses	36,853	6,060	42,284	11,860
Income (loss) from operations	(21,148)	6,678	(12,510)	12,965
Other income				
Investment income	434	269	851	546
Gain (loss) on sales of investments	(64)	1	(64)	20
Loss on equity method investment in InnoRx	(55)	(67)	(500)	(67)
Other income	315	203	287	499
Income (loss) before income taxes	(20,833)	6,881	(12,223)	13,464
Income tax provision	(3,538)	(2,576)	(6,911)	(5,048)
Net income (loss)	(\$ 24,371)	\$ 4,305	(\$ 19,134)	\$ 8,416
Basic net income (loss) per share	(\$ 1.34)	\$ 0.25	(\$ 1.07)	\$ 0.48
Diluted net income (loss) per share	(\$ 1.34)	\$ 0.24	(\$ 1.07)	\$ 0.47
Weighted average shares outstanding				
Basic	18,135	17,483	17,851	17,468
Dilutive effect of outstanding stock options		292		306
Diluted	18,135	17,775	17,851	17,774

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

# SURMODICS, INC.

## Condensed Statements of Cash Flows (In thousands)

(unaudited)

	Six months ended March 31,	
	2005	2004 (Restated)
Operating Activities		(Restated)
Net income (loss)	(\$ 19,134)	\$ 8,416
Adjustments to reconcile net income to net cash provided by operating activities-		
Depreciation and amortization	1,934	1,770
Loss on sales of investments	564	47
Noncash compensation	244	107
Purchased in-process research & development	30,277	
Deferred taxes	(219)	48
Gain on disposals of property and equipment	(193)	
Change in operating assets and liabilities:		
Accounts receivable	(3,147)	(630
Inventories	48	(181
Accounts payable and accrued liabilities	(569)	(5,368
Income taxes	(1,732)	(49
Deferred revenue	(6)	111
Prepaids and other	(255)	(298
Net cash provided by operating activities	7,812	3,973
Investing Activities Purchases of property and equipment	(224)	(780
Purchases of available-for-sale investments	(58,610)	(20,692
Sales/maturities of available-for-sale investments	62,569	20,088
Investments in OctoPlus & other	(3,910)	(287
Purchase of licenses	(5,223)	(
Investment in and acquisition costs for InnoRx, net of cash acquired	(5,180)	(2,157
Payments received on note receivable	(0,200)	1,869
Net cash used in investing activities	(10,578)	(1,959
	(10,070)	(1,000
Financing Activities		
Issuance of common stock	1,031	471
Net cash provided by financing activities	1,031	471
Net change in cash and cash equivalents	(1,735)	2,485
Cash and Cash Equivalents		
Beginning of period	2,709	4,007
End of period	\$ 974	\$ 6,492
Cash paid for taxes	\$ 8,655	\$ 5,092
	ψ 0,000	ψ 0,002

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 three and six month periods ended March 31, 2005, are not necessarily indicative of the results that may be expected for the entire 2005 fiscal year.

In accordance with 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 first quarter of fiscal 2006. 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.

#### (3) Other assets

Other assets consist principally of investments and acquired intellectual property. The balance in other assets increased primarily as a result of the Company's \$3.9 million investment in OctoPlus in the second quarter of fiscal 2005, less accumulated amortization on patents and other intangibles and the restatement and reclassification of the value of our investment in InnoRx, Inc as a result of our acquisition of all of the assets of InnoRx, Inc. in January 2005. See Note 8 for additional information.

#### (4) Inventories

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 (*in thousands*):

	March 31, 2005	tember 30, 2004
Raw materials	\$ 517	\$ 634
Finished goods	475	 406
	\$ 992	\$ 1,040

#### (5) Operating Segments

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 six business units. The three operating segments are aggregated into one reportable segment. The "Drug Delivery" operating segment contains the Drug Delivery business unit and the Ophthalmology 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 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 March 31,		ths ended ch 31,
	2005	2005 2004		2004
Operating segment				
Drug Delivery	\$ 7,266	\$ 7,318	\$ 14,387	\$ 14,217
Hydrophilic and Other	4,761	3,389	8,994	6,575
Diagnostics	3,678	2,031	6,393	4,033
Total revenue	\$ 15,705	\$ 12,738	\$ 29,774	\$ 24,825

#### (6) Stock-based Compensation

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,

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"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 and six months ended March 31, 2005 and 2004 (*in thousands, except per share data*):

		Three months ended March 31,		hs ended h 31,
	2005	2004	2005	2004
Net income (loss)				
As reported	(\$ 24,371)	\$ 4,305	(\$ 19,134)	\$ 8,416
Fair value compensation expense	(759)	(488)	(1,343)	(947)
Pro forma	(\$ 25,130)	\$ 3,817	(\$ 20,477)	\$ 7,469
Basic net income (loss) per share:				
As reported	(\$ 1.34)	\$ 0.25	(\$ 1.07)	\$ 0.48
Fair value compensation expense	(.04)	(.03)	(.08)	(.06)
Pro forma	(\$ 1.38)	\$ 0.22	(\$ 1.15)	\$ 0.42
Diluted net income (loss) per share:				
As reported	(\$ 1.34)	\$ 0.24	(\$ 1.07)	\$ 0.47
Fair value compensation expense	(.04)	(.03)	(.08)	(.06)
Pro forma	(\$ 1.38)	\$ 0.21	(\$ 1.15)	\$ 0.41

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 March 31, 2005 and March 31, 2004, respectively: risk-free interest rates of 3.71% and 3.11%; expected lives of 7 years and 7 years; and expected volatility of 64% and 68%. The weighted-average assumptions for the six months ended March 31, 2005 and March 31, 2004, respectively: risk-free interest rates of 3.70% and 3.21%; expected lives of 7 years and 7 years; and expected volatility of 64% and 68%.

As described in Note 2, 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 Statement is effective for the Company beginning in the first quarter of fiscal 2006. The Company has not completed the process of evaluating the impact that will result from adopting SFAS 123(R).

During the quarter ended March 31, 2005, SurModics awarded 2,500 shares of restricted stock. During the six month period ended March 31, 2005, SurModics awarded an aggregate of 59,500 shares of restricted stock, which increased the balance of unearned compensation by approximately \$1.6 million. Each restricted stock award will fully vest after five years.

#### (7) Comprehensive Income

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

	Three months ended March 31,		Six month March	
	2005	2004	2005	2004
Net income (loss)	(\$24,371)	\$ 4,305	(\$19,134)	\$ 8,416
Other comprehensive income: Unrealized holding gains (losses) on available-for-sale securities arising during the period,				
net of tax	(282)	222	(410)	106
Less reclassification adjustment for realized gains included in net income, net of tax	40	(1)	40	(13)
Other comprehensive income (loss)	(242)	221	(370)	93
Comprehensive income (loss)	(\$24,613)	\$ 4,526	(\$19,504)	\$ 8,509

#### (8) InnoRx, Inc. Acquisition

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. Upon the successful completion of all development and commercial milestones involving InnoRx technology acquired in the transaction, SurModics will be required to issue up to a maximum of 600,064 additional shares of its common stock to the stockholders of InnoRx. As the transaction was accounted for as a purchase of assets, SurModics was required to determine the fair value of contingent payments for purposes of valuing the assets acquired. In the three-month period ended March 31, 2005, we recorded an \$8.1 million liability to record the aggregate estimated value of these contingent payment obligations. The aggregate value of the liability was determined by an outside valuation consultant and is recorded in other long-term liabilities at March 31, 2005. We may be required from time to time in future periods to record additional in-process research and development expense if the aggregate fair value of the contingent payment obligations exceeds the value of this liability. Prior to the acquisition, SurModics held an ownership interest in InnoRx of less than 20% and accounted for the investment under the cost method. Upon completion of the InnoRx acquisition, we restated our previously reported results to show the impact of accounting for InnoRx under the equity method. The net impact was an approximate \$67,000 reduction in net income for the three months and six months ended March 31, 2004 from previously reported results. The assets of InnoRx we acquired consisted almost exclusively of in-process research and development assets. In the three-month period ended March 31, 2005, we recorded a charge of \$30.3 million to write-off the value of these in-process research and development assets. The fair value of the in-process research and development was determined by an outside valuation consultant using the excess earnings method. SurModics purchased InnoRx primarily to acquire all of InnoRx's rights to a sustained-release intravitreal implant. The implant is designed to deliver drugs to the eye to treat retinal diseases, such as age-related macular degeneration and diabetic macular edema. Management expects to begin Phase I clinical trials in connection with the intravitreal implant in our third fiscal quarter. Assuming

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successful completion of clinical trials, and assuming the implant continues to be a viable opportunity, SurModics believes it could commence commercial sale of the implant in 2009.

#### (9) Income Taxes

The charge for purchased in-process research and development (IPR&D) described in Note 8 is not deductible for income tax purposes. Excluding the IPR&D charge, SurModics would have reported income for the periods ended March 31, 2005. As a result, SurModics recorded an income tax provision for the period ended March 31, 2005. Excluding the effect of the IPR&D charge, SurModics, effective tax rate was 38.3 % for the six month period ended March 31, 2005.

#### 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 healthcare industry. The Company is organized into six technology-centered business units. The "Drug Delivery" operating segment contains the Drug Delivery business unit, which is responsible for technologies dedicated to site specific delivery of drugs, and the Ophthalmology business unit, which is dedicated to the advancement of treatments for eye diseases, such as age-related macular degeneration (AMD) and diabetic macular edema (DME), two of the leading causes of blindness. 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 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 and drug delivery technologies to customers; (2) the sale of reagent chemicals to licensees of our technologies, stabilization products to the diagnostics industry and coated glass slides to the genomics market; and (3) research and development fees generated on commercial projects. Revenue should be expected to fluctuate from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our 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.

On January 18, 2005, we acquired all of the assets of InnoRx, Inc. by paying cash and issuing shares of SurModics common stock to InnoRx stockholders. InnoRx was an early-stage company developing drug delivery devices and therapies for the ophthalmology market. The assets we acquired were folded into our newly created Ophthalmology business unit.

#### **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 March 31, 2005 and 2004

	Fiscal 2005 Fiscal 2004 (Dolla)		Increase (Decrease) n thousands)	% Increase (Decrease)
Revenue:				
Drug Delivery	\$ 7,266	\$ 7,318	(\$ 52)	(1%)
Hydrophilic and Other	4,761	3,389	1,372	40%
Diagnostics	3,678	2,031	1,647	81%
Total revenue	\$ 15,705	\$ 12,738	\$ 2,967	23%

**Revenue**. Second quarter revenue was \$15.7 million, an increase of \$3.0 million or 23% from fiscal 2004. Growth was concentrated in two of our 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 decreased less than 1% to \$7.3 million for the period ending March 31, 2005. Growth in royalties and license fees was offset slightly by a decrease in sales of reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices) and a decrease in research and development revenue. 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 Sirolimus-eluting Coronary 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. Revenue from sales of reagents to Cordis decreased because of volume and unit price decreases. Research and development revenue from Cordis also declined compared to the same period a year ago. In addition, prior to January 18, 2005, a portion of our research and development revenue was attributable to InnoRx. Following our acquisition of InnoRx on January 18, 2005, we no longer record revenue for research and development activities in connection with the InnoRx technology.

We expect the significant decrease in reagent chemical sales to Cordis to continue for the balance of fiscal 2005 when compared to prior year periods resulting from a contractual reduction in reagent pricing and as Cordis continues to become more efficient in its manufacturing. In addition, sequential quarterly royalty revenue could decrease because of 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 second fiscal quarter of 2004. 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.

*Hydrophilic and Other*. Hydrophilic and Other revenue increased 40% to \$4.8 million, driven by growth in all three revenue sources, particularly increased royalties and license fees from many of our several dozen licensees in this operating segment. Second quarter 2005 revenue also includes \$275,000 in back royalties recorded as a result of a settlement with Spectrantics, Inc. Excluding the impact of the settlement, revenue increased 32% from the prior year period. Management expects continued growth in Hydrophilic and Other when compared with prior year periods, but growth for the remainder of fiscal 2005 is unlikely to be as strong as it was in the current three-month period.

*Diagnostics*. Diagnostics revenue increased 81% to \$3.7 million. A substantial majority of the growth resulted from increased royalty revenue under certain sublicenses, whose royalty streams we purchased from Abbott. Prior to the purchase, the Company had been receiving only a portion of the royalty revenue from the sublicenses. Diagnostics derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories.

Effective February 1, 2005, the Company terminated its distribution agreement with SeraCare. SurModics began distributing its line of stabilization products in the U.S. through SeraCare in last year's second quarter. Management believes product sales will increase when compared to prior year results for the balance of fiscal 2005 because of the impact of selling directly to the U.S. diagnostics industry, rather than through a distributor.

**Product costs.** Product costs were \$730,000 for the second quarter, a 3% decrease from \$752,000 last year. Overall product margins averaged 69% compared with 73% for the comparable period last year. The margin decrease was primarily attributable to the contractual reduction in reagent pricing with Cordis discussed above.

**Research and development expenses.** Research and development expenses were \$3.9 million, an increase of 24% compared with the same period in fiscal 2004. A majority of the increase reflects the amortization cost associated with the sublicense royalty stream we purchased in the fourth quarter of fiscal 2004, discussed above in Diagnostics, and additional costs associated with preparing for the upcoming clinical trial of the intravitreal implant we acquired as part of the InnoRx transaction. Management believes research and development expense will increase on a sequential basis for the balance of fiscal 2005 due to anticipated expenses for development activities and clinical trials associated with the recent acquisition of InnoRx.

**Sales and marketing expenses.** Sales and marketing expenses were \$307,000 for the second quarter of fiscal 2005, a 48% decrease from the prior year period. A substantial portion of the decrease resulted from lower payroll costs associated with a reduction in marketing personnel in connection with a company-wide reorganization in last year's second quarter. Management anticipates sales and marketing expense will increase sequentially for the remainder of fiscal 2005 as the Company expands its sales force.

**General and administrative expenses.** General and administrative expenses were \$1.6 million for the second quarter of fiscal 2005, a 4% increase compared with the same period in fiscal 2004 reflecting increased compensation cost. Management anticipates general and administrative expense will increase modestly on a sequential basis for the balance of fiscal 2005.

**Purchased in-process research and development.** On January 18, 2005, the Company acquired all of the assets of InnoRx, Inc. by paying cash and issuing shares of SurModics common stock to InnoRx stockholders. Results in the second quarter of fiscal 2005 include a non-cash in-process research and development charge of \$30.3 million. The fair value of the in-process research and development was determined by an outside valuation consultant using the excess earnings method. We may be required from time to time in future periods to increase or decrease the amount of the \$30.3 million charge we recorded for in-process research and development to reflect changes in the fair market value of aggregate contingent payment obligations we may become obligated to satisfy in the future upon the successful completion of development and commercial milestones related to the InnoRx assets we acquired.

**Other income, net.** Other income was \$315,000 for the second quarter of fiscal 2005, an increase of \$112,000, or 55%, compared with the same period of fiscal 2004. The increase reflects increased levels of investable cash and higher yields generated from our investment portfolio. Previously reported fiscal 2004 results have been restated to show the impact of accounting for InnoRx under the equity method. Prior to completing the acquisition of InnoRx in January 2005, we accounted for our investment in InnoRx under the cost method. See Note 8 to the financial statements included in this report.

**Income tax expense.** The Company's income tax provision was \$3.5 million for the second quarter of fiscal 2005 compared with \$2.6 million in the same period of fiscal 2004. Excluding the impact of the \$30.3 million in-process research and development charge, which is not tax deductible, the effective tax rate was 37.5% for the second quarter of fiscal 2005, compared with 37.4% for the second quarter of fiscal 2004. See Note 9 to the financial statements included in this report.

#### Six Months Ended March 31, 2005 and 2004

	Fiscal 2005	<u>Fiscal 2004</u> (Dollars in	Increase (Decrease) thousands)	% Increase (Decrease)
Revenue:				
Drug Delivery	\$ 14,387	\$ 14,217	\$ 170	1%
Hydrophilic and Other	8,994	6,575	2,419	37%
Diagnostics	6,393	4,033	2,360	59%
Total revenue	\$ 29,774	\$ 24,825	\$ 4,949	20%

**Revenue**. The Company's revenue was \$29.8 million for the first six months of fiscal 2005, an increase of \$5.0 million, or 20%, compared with the same period of fiscal 2004. We provide a narrative of revenue for each of our three operating segments in the paragraphs that follow.

*Drug Delivery*. Drug Delivery revenue increased 1% to \$14.4 million for the first half of fiscal 2005 compared with \$14.2 million for the same period last year. Growth in royalties and license fees as well as increased research and development revenue offset a decrease in reagent sales. A portion of the growth in research and development revenue was attributable to revenue from InnoRx prior to our acquisition of all of InnoRx's asset on January 18, 2005. Research and development revenue is expected to decrease sequentially in future quarters partially as a result of the InnoRx acquisition. In addition, we expect the significant decrease in reagent chemical sales to Cordis to continue for the balance of fiscal 2005 when compared to prior year periods 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.

*Hydrophilic and Other.* Hydrophilic and Other revenue increased 37% to \$9.0 million for the first six months of fiscal 2005, driven primarily by increased royalties and research and development revenue. Second quarter 2005 revenue also includes \$275,000 in back royalties recorded as a result of a settlement with Spectrantics, Inc. Management expects continued growth in Hydrophilic and Other when compared with prior year periods, but growth for the remainder of fiscal 2005 is unlikely to be as strong as it was in the first half of fiscal 2005.

*Diagnostics*. Diagnostics revenue increased 59% to \$6.4 million. A substantial majority of the growth resulted from increased royalty revenue under sublicenses, whose royalty streams we purchased from Abbott. Prior to the purchase, the Company had been recording only a portion of the royalty revenue from the sublicenses. Management expects continued growth in this royalty stream compared with prior periods throughout the remainder of fiscal 2005. However, growth in the second half of the year may not be as strong as it was in the first six months of 2005.

**Product costs.** Product costs were \$1.3 million for the six months ended March 31, 2005, a 9% decrease from the \$1.5 million last year. Overall product margins averaged 69% compared with 72% for the comparable period last year. The margin decrease is primarily attributable to a contractual reduction in reagent pricing from Cordis. We expect the significant decrease in reagent chemical sales to Cordis to continue for the balance of fiscal 2005, compared to prior year periods, resulting from the contractual reduction in reagent pricing.

**Research and development expenses.** Research and development expenses were \$7.2 million for the first six months of fiscal 2005, an increase of 13% compared with the same period in fiscal 2004. The increase principally reflects increased patent related legal costs and the amortization cost associated with the purchase from Abbott of the sublicense royalty stream discussed above in Diagnostics and additional costs associated with preparing for the upcoming clinical trial on the intravitreal implant we acquired from InnoRx.

**Sales and marketing expenses.** Sales and marketing expenses were \$569,000 for the six months ending March 31, 2005, a 43% decrease from prior year period. A substantial portion of the decrease resulted from lower payroll costs related to a reduction in marketing personnel in connection with a company-wide reorganization.

**General and administrative expenses.** General and administrative expenses were \$2.8 million for the first six months of fiscal 2005, a 4% decrease compared with the same period in fiscal 2004.

**Purchased in-process research and development.** On January 18, 2005, the Company acquired all of the assets of InnoRx, Inc. by paying cash and issuing shares of SurModics common stock to InnoRx stockholders. Results for the first six months of fiscal 2005 include a non-cash in-process research and development charge of \$30.3 million. The fair value of the in-process research and development was determined by an outside valuation consultant using the excess earnings method.

We may be required from time to time in future periods to increase or decrease the amount of the \$30.3 million charge we recorded for in-process research and development to reflect changes in the fair market value of aggregate contingent payment obligations we may become obligated to satisfy in the future upon the successful completion of development and commercial milestones related to the InnoRx assets we acquired.

**Other income, net.** Other income was \$287,000 for the first six months of fiscal 2005, a decrease of \$212,000, or 42%, compared with the same period of fiscal 2004. The decrease is attributable to investment losses, the bulk of which are related to the impact in the first quarter of 2005 related to the change to equity method treatment of our investment in InnoRx. See Note 8 to the financial statements included in this report.

**Income tax expense.** The Company's income tax provision was \$6.9 million for the first six months of fiscal 2005 compared with \$5.0 million in the same period of fiscal 2004. Excluding the impact of the \$30.3 million in-process research and development charge, which is not tax deductible, the effective tax rate was 38.3% for the first six months of fiscal 2005, compared with 37.5% for the same period last year. See Note 9 to the financial statements included in this report.

#### Liquidity and Capital Resources

As of March 31, 2005, the Company had working capital of \$18.0 million and cash, cash equivalents and investments totaling \$56.7 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 \$7.8 million in the first six months of fiscal 2005, compared with \$4.0 million in the first six 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. Management is currently evaluating plans for up to \$8 million in capital improvements to increase the research and development capabilities at its Eden Prairie location. Once plans are finalized, we expect to begin construction during our fiscal third quarter.

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 all development and commercial milestones involving InnoRx technology acquired by SurModics, SurModics will be required to issue up to a maximum of an additional 600,064 shares of its common stock to the stockholders of InnoRx.

In January 2005, the Company 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%.

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.

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%.

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' 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 March 31, 2005, 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.

#### **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

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) the Company's ability to manage successfully clinical trials and related foreign and domestic regulatory processes for the intravitreal implant or other products in development acquired from InnoRx, whether delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances postpone or preclude product commercialization of the intravitreal implant or other acquired products and whether the intravitreal implant and any other acquired products remain viable commercial prospects; (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, and (xx) 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.

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 \$835,000 decrease in the fair value of the Company's available-for-sale securities as of March 31, 2005, 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 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.

Information regarding matters submitted to a vote of the Company's security holders during the period covered by this report was previously reported in the Company's Form 10-Q for the quarterly period ended December 31, 2004.

#### Item 5. Other Information.

None.

#### Item 6. Exhibits.

Exhibits -

10.1 Amendment to the SurModics, Inc. 2003 Equity Incentive Plan

10.2 SurModics, Inc. Board Compensation Policy effective January 31, 2005

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.

May 10, 2005

# SurModics, Inc.

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, 2005

# SURMODICS, INC.

Exhibit	Description
10.1	Amendment to the SurModics, Inc. 2003 Equity Incentive Plan
10.2	SurModics, Inc. Board Compensation Policy effective January 31, 2005
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

#### Amendment Adopted November 15, 2004 by Board of Directors and Approved by the Shareholders on January 31, 2005 to the SurModics, Inc. 2003 Equity Incentive Plan

The number of shares reserved and available under the Plan is increased from 600,000 shares to 2,400,000 shares by hereby amending the second sentence of Section 6 of the Plan to read in its entirety as follows:

"Two Million Four Hundred Thousand (2,400,000) shares of Option Stock shall be reserved and available for options and stock awards under the Plan; provided, however, that the total number of shares of Option Stock reserved for options and stock awards under this Plan shall be subject to adjustment as provided in Section 12 of the Plan."

#### SurModics, Inc. Board Compensation Policy

To be effective beginning with calendar 2005 and, therefore, these compensation provisions commence as of January 1, 2005.

Non-employee directors shall receive an annual retainer of \$10,000 (\$12,000 for Committee Chairs), payable quarterly at the end of each calendar quarter. If, for any reason, the director does not serve for the entire calendar quarter, the director shall be entitled to a pro rata portion of that quarterly payment.

Non-employee directors shall also receive \$1,000 for each formal Board meeting attended and \$500 for each formal Committee meeting attended. All such fees shall be payable quarterly at the end of each calendar quarter.

When a non-employee director is first elected to the board, such director shall be granted a nonqualified stock option for 10,000 shares of the Company's common stock. In November of each year, each non-employee director shall be granted a nonqualified stock option for 5,000 shares of the Company's common stock; provided, however, that such director shall not be entitled to such annual option grants until he or she has served as a director for at least 12 months.

All such 10,000-share and 5,000-share options shall be granted under the Company's 2003 Equity Incentive Plan, shall have a ten-year term, and shall have an exercise price equal to the fair market value of the Company's common stock on the date of grant. Such options shall be immediately vested for 20% of the shares on the date of grant, shall vest with respect to 20% of the shares on the next four anniversaries of the date of grant, and shall be subject to such other terms and conditions set forth in the individual option agreements. In the event the director's service on the Board terminates for any reason, such options shall continue to vest, and the director shall be entitled to exercise such options until the ten-year expiration date.

For the 2005 calendar year, all meeting fees and retainers shall be paid in cash. For 2006 and future calendar years, the Company will consider offering directors the choice between cash and nonqualified stock options. Any election by a director to receive nonqualified stock options in lieu of a cash payment of retainer and/or meeting fees would have to be made on or before December 31st of each year and would be irrevocable for the next calendar year. If the director should elect to receive nonqualified stock options in lieu of cash, the number of shares subject to each option would be determined according to a formula to be determined by the Board prior to the 2006 calendar year; however, it currently is anticipated that the number of shares would be determined by dividing the director's total cash payment for the calendar quarter by the fair market value of the Company's common stock on the quarterly payment date, and multiplying that number of shares by at least two.

Each of these nonqualified stock options granted in lieu of cash would be granted under the 2003 Equity Incentive Plan on the quarterly payment date. The deferred compensation requirements of the Internal Revenue Code have recently been modified, and IRS guidance as to their application to and impact on the terms and provisions of the options to be granted in lieu of cash is expected in 2005. The terms and provisions of the options granted in lieu of cash are intended by the Board to be the same as those for the 10,000-share and 5,000-share options described above except to the extent the application of the deferred compensation provisions causes the Board to establish prior to 2006 different terms and provisions for the options granted in lieu of cash.

#### 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 10, 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: May 10, 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 March 31, 2005, 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 10, 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 March 31, 2005, 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 10, 2005

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