# 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, 2003**

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 | 41-1356149 |
|---|---|
| (State of incorporation) | (I.R.S. Employer Identification No.) |

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

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

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

Yes ☒ No 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 January 30, 2004 was 17,472,765.

**TABLE OF CONTENTS**

**PART I — FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

| | December 31, 2003 | September 30, 2003 |
|---|---|---|
| **ASSETS** | | |
| Current Assets | | |
| Cash & cash equivalents | $ 7,965 | $ 4,007 |
| Short-term investments | 1,700 | 2,640 |
| Accounts receivable, net | 8,472 | 9,145 |
| Inventories | 854 | 863 |
| Deferred tax asset | 345 | 345 |
| Prepaids and other | 751 | 759 |
| Total current assets | 20,087 | 17,759 |
| Property and equipment, net | 33,760 | 33,936 |
| Long-term investments | 40,180 | 39,164 |
| Deferred tax asset | 52 | — |
| Other assets, net | 5,108 | 6,949 |
| | $99,187 | $97,808 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities | | |
| Accounts payable | $ 724 | $ 1,118 |
| Accrued liabilities | 3,737 | 6,312 |
| Accrued income taxes payable | 2,699 | 1,558 |
| Deferred revenues | 194 | 1,039 |
| Total current liabilities | 7,354 | 10,027 |
| Deferred tax liability | — | 27 |
| Deferred revenue, less current portion | 1,612 | 1,640 |
| Total liabilities | 8,966 | 11,694 |
| 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; 17,465,965 and 17,439,435 shares issued and outstanding | 873 | 872 |
| Additional paid-in capital | 56,842 | 56,453 |
| Unearned compensation | (732) | (466) |
| Accumulated other comprehensive income | 209 | 337 |
| Retained earnings | 33,029 | 28,918 |
| Total stockholders' equity | 90,221 | 86,114 |
| | $99,187 | $97,808 |

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

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

| | Three Months Ended December 31, | |
|---|---|---|
| | **2003** | **2002** |
| Revenue | | |
| Royalties and license fees | $ 8,629 | $ 3,880 |
| Product sales | 2,600 | 3,039 |
| Research and development | 858 | 1,129 |
| Total revenue | 12,087 | 8,048 |
| Operating costs and expenses | | |
| Product | 736 | 587 |
| Research and development | 3,146 | 2,660 |
| Sales and marketing | 543 | 538 |
| General and administrative | 1,375 | 1,408 |
| Total operating costs and expenses | 5,800 | 5,193 |
| Income from operations | 6,287 | 2,855 |
| Other income | | |
| Investment income, net | 276 | 381 |
| Gain on sale of investments | 19 | 242 |
| Other income, net | 295 | 623 |
| Income before income taxes | 6,582 | 3,478 |
| Income tax provision | (2,471) | (1,307) |
| Net income | 4,111 | 2,171 |
| Basic net income per share | $ 0.24 | $ 0.13 |
| Diluted net income per share | $ 0.23 | $ 0.12 |
| Weighted average shares outstanding | | |
| Basic | 17,454 | 17,285 |
| Dilutive effect of outstanding stock options | 312 | 530 |
| Diluted | 17,766 | 17,815 |

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

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

| | Three Months Ended December 31, | |
|---|---|---|
| | **2003** | **2002** |
| Operating Activities | | |
| Net income | $ 4,111 | $ 2,171 |
| Adjustments to reconcile net income to net cash provided by operating activities- | | |
| Depreciation and amortization | 862 | 487 |
| Gain on sale of investments | (19) | (242) |
| Amortization of unearned compensation | 48 | 37 |
| Deferred taxes | (79) | (83) |
| Change in operating assets and liabilities: | | |
| Accounts receivable | 673 | 2,015 |
| Inventories | 9 | (66) |
| Accounts payable and accrued liabilities | (2,969) | (1,407) |
| Income taxes | 1,141 | 1,303 |
| Deferred revenue | (873) | (434) |
| Prepaids and other | (25) | 433 |
| Net cash provided by operating activities | 2,879 | 4,214 |
| Investing Activities | | |
| Purchases of property and equipment | (681) | (3,046) |
| Purchases of available-for-sale investments | (13,122) | (17,663) |
| Sales/maturities of available-for-sale investments | 12,936 | 17,462 |
| Repayment of notes receivable | 1,869 | 7 |
| Net cash provided by (used in) investing activities | 1,002 | (3,240) |
| Financing Activities | | |
| Issuance of common stock | 77 | 136 |
| Net change in cash and cash equivalents | 3,958 | 1,110 |
| Cash and Cash Equivalents | | |
| Beginning of period | 4,007 | 9,207 |
| End of period | $ 7,965 | $ 10,317 |
| Cash paid for taxes | $ 1,330 | $ 390 |

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

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

**(1) Basis of Presentation**

In the opinion of management, the accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States and reflect all adjustments, consisting solely of normal recurring adjustments, needed to fairly present the financial results for these interim periods. These financial statements include some amounts that are based on management's best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of earnings in the period in which the change in estimate is identified. The results of operations for the three months ended December 31, 2003, are not necessarily indicative of the results that may be expected for the entire fiscal year.

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

**(2) New Accounting Pronouncements**

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

**(3) Subsequent Events**

On February 3, 2004, the Company invested $2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing unique drug delivery devices and therapies for the ophthalmology market. The Company has agreed to invest a total of $3.5 million, the remaining $1.4 million of which will be invested subject to InnoRx completing certain development and regulatory milestones. The $2.1 million investment, which is accounted for under the cost method, is included in other assets and, together with the remaining $1.4 million to be invested, would represent an ownership interest of less than 20%.

On February 10, 2004, the Company loaned $285,000 to Novocell, Inc., a privately-held Irvine, California-based biotech firm that is developing a unique treatment for diabetes using cell-encapsulation. This note receivable is secured by Novocell assets and is convertible into Novocell equity at a future date. The Company has previously invested $4.9 million in Novocell, which investment is accounted for under the cost basis, is included in other assets and represents an ownership interest of less than 15%.

**(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, 2003 | September 30, 2003 |
|---|---|---|
| Raw materials | $469 | $413 |
| Finished goods | 385 | 450 |
| | $854 | $863 |

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

| | Licensing (royalties & license fees) | Manufacturing (products) | Research & Development (development) | Corporate (sales & mktg., G&A) | Consolidated |
|---|---|---|---|---|---|
| Three Months Ended December 31, 2003 | | | | | |
| Revenue: | | | | | |
| Coating | $8,286 | $1,754 | $ 773 | $ — | $10,813 |
| Diagnostic | 343 | — | — | — | 343 |
| Stabilization & other | — | 846 | — | — | 846 |
| Government research | — | — | 85 | — | 85 |
| Total revenue | 8,629 | 2,600 | 858 | — | 12,087 |
| Expenses | — | 736 | 3,146 | 1,918 | 5,800 |
| Operating income (loss) | 8,629 | 1,864 | (2,288) | (1,918) | 6,287 |
| Other income, net | | | | 295 | 295 |
| Income tax provision | | | | (2,471) | (2,471) |
| Net income | | | | | $ 4,111 |
| Three Months Ended December 31, 2002 | | | | | |
| Revenue: | | | | | |
| Coating | $3,017 | $2,509 | $ 1,026 | $ — | $ 6,552 |
| Diagnostic | 863 | — | — | — | 863 |
| Stabilization & other | — | 530 | — | — | 530 |
| Government research | — | — | 103 | — | 103 |
| Total revenue | 3,880 | 3,039 | 1,129 | — | 8,048 |
| Expenses | — | 587 | 2,660 | 1,946 | 5,193 |
| Operating income (loss) | 3,880 | 2,452 | (1,531) | (1,946) | 2,855 |
| Other income, net | | | | 623 | 623 |
| Income tax provision | | | | (1,307) | (1,307) |
| Net income | | | | | $ 2,171 |

**(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 2003 and 2002:

| | Three months ended December 31, | |
|---|---|---|
| | **2003** | **2002** |
| Net income | | |
| As reported | $4,111 | $2,171 |
| Fair value compensation expense, net of tax | (460) | (316) |
| Pro forma | $3,651 | $1,855 |
| Basic net income per share: | | |
| As reported | $ 0.24 | $ 0.13 |
| Fair value compensation expense, net of tax | (.03) | (.02) |
| Pro forma | $ 0.21 | $ 0.11 |
| Diluted net income per share: | | |
| As reported | $ 0.23 | $ 0.12 |
| Fair value compensation expense, net of tax | (.02) | (.02) |
| Pro forma | $ 0.21 | $ 0.10 |

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, 2003 and December 31, 2002, respectively: risk-free interest rates of 3.44% and 3.01%; expected lives of 7 years and 7 years; and expected volatility of 69% and 71%.

**(7) Comprehensive Income** (*dollars in thousands*)

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

| | Three months ended December 31, | |
|---|---|---|
| | **2003** | **2002** |
| Net income | $4,111 | $2,171 |
| Other comprehensive income: | | |
| Unrealized holding losses on available-for-sale securities arising during the period, net of tax | (116) | (25) |
| Less reclassification adjustment for realized gains included in net income, net of tax | (12) | (151) |
| Other comprehensive loss | (128) | (176) |
| Comprehensive income | $3,983 | $1,995 |

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

### Overview

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

The Company's revenue is derived from three primary activities: (1) royalties and license fees from licensing its patented or proprietary technologies to customers; (2) product sales (reagent chemical compounds to licensees, stabilization products to the diagnostics industry, and coated slides to the genomics market) from our manufacturing activities; and (3) research and development fees generated on projects for commercial customers and pursuant to government grants. For more information on each of these Licensing, Manufacturing and Research & Development activities, presented as individual operating segments, refer to Note 5 to the Company's unaudited condensed financial statements included in this quarterly report and Note 8 to the Company's audited financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2003.

### Critical Accounting Policies and Estimates

Critical accounting policies are those policies that require the application of management's most challenging, subjective or complex judgment, often as a result of the need to make estimates and assumptions about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments that are sufficiently important to our financial results that materially different financial results may result if slightly different estimates or assumptions are selected when applying such judgments. Management believes that revenue recognition, investments, and the valuation of long-lived assets are the critical areas in the application of our accounting policies that currently affect our financial condition and results of operations. 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 fiscal year ended September 30, 2003.

### Results of Operations

***Three Months Ended December 31, 2003 and 2002***

*Revenue.* The Company's revenue was $12.1 million in the first quarter of fiscal 2004, an increase of $4.0 million, or 50%, compared with the same period of fiscal 2003. The revenue components were as follows (in thousands):

| (Dollars in thousands) | Fiscal 2004 | Fiscal 2003 | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| Revenue: | | | | |
| Royalties and license fees | $ 8,629 | $3,880 | $4,749 | 122% |
| Product sales | 2,600 | 3,039 | (439) | -14% |
| Development | 858 | 1,129 | (271) | -24% |
| Total revenue | $12,087 | $8,048 | $4,039 | 50% |

The revenue growth in the first quarter was the result of a 122% increase in royalties and license fees driven almost entirely by an increase in royalties from Cordis Corporation (a Johnson & Johnson company) on its Cypher stent. The Cypher stent incorporates a proprietary SurModics coating that delivers a therapeutic drug that is designed to reduce the occurrence of restenosis in coronary artery lesions. Fiscal 2003 first quarter results include royalties on Cypher stents sold only outside the U.S. because Cordis received U.S. Food and Drug Administration (FDA) approval in April 2003 (our third fiscal quarter). The increase in royalties from the Cypher stent in the first quarter of fiscal 2004 was partially offset by a $473,000 decline in license fees compared with the same period in fiscal 2003. The first quarter of fiscal 2003 included a one-time recognition of $340,000 of deferred revenue resulting from the termination by the Company of a non-performing license agreement. Minimum royalties from Amersham plc under our license agreement involving genomics technology were at the same level in the first quarter of fiscal 2004 compared with the prior year period. However, for the balance of the fiscal year, minimum royalties from Amersham will be lower compared with the prior year periods because of contractual decreases. Despite this fact, we anticipate growth in revenue from other customers will offset this contractual decrease from Amersham, so that on a sequential quarterly basis total non-Cordis revenue will be roughly flat for the balance of the fiscal year.

Boston Scientific Corp., whose drug-eluting stent is being sold in Europe, has publicly predicted that its drug-eluting stent will be approved by the FDA during the Company's fiscal 2004 second quarter. The anticipated FDA approval of a drug-eluting stent in direct competition with the Cypher stent in the U.S. generates uncertainties in that market and constrains our ability to project the timing and magnitude of the impact on our royalties. If a competing drug-eluting stent is approved by the FDA, we anticipate that quarterly royalty revenue from the current generation Cypher stent will decline sequentially in 2004. We expect that when the Cypher stent faces competition in the U.S. market, royalties from the Cypher stent will continue to constitute a significant portion of our revenue, but we do not believe the comparable-period increases in Cypher stent royalties realized in the first quarter of fiscal 2004 can be sustained by Cordis' sale of the current generation Cypher stent.

There is currently pending litigation involving Boston Scientific Scimed, Inc. and Cordis in U.S. District Court for the District of Delaware (and scheduled for trial in June 2005) in which each alleges its patent rights are being infringed by the other's drug-eluting stent, and each has been denied the preliminary injunction it has requested against the other. Cordis has appealed the denial of its requested preliminary injunction against Boston Scientific's coronary drug-eluting stent, which appeal is scheduled to be heard in April 2004 by the Court of Appeals for the Federal Circuit.

Fiscal 2004 first quarter product revenue decreased 14% from last year's first quarter. Revenue from reagent chemical sales was $1.8 million, a decrease of $755,000, or 30%, from the same period in 2003. The decrease primarily reflects reduced revenue from reagents sold to Cordis resulting from lower reagent prices and lower relative volume stemming from increased efficiency by Cordis in its Cypher stent

manufacturing process. For the remainder of fiscal 2004, management expects revenue from sales of reagents to Cordis to decline as a result of a contractually-specified step-down in reagent prices beginning in the second quarter of fiscal 2004 and because Cordis may continue improving its manufacturing efficiency, thus requiring a smaller quantity of reagent for each stent Cordis manufactures. Cordis continues to purchase a substantial majority of the reagents we sell. Our reagents are a critical raw material component of the Cypher stent and any substantial decrease in the number of Cypher stent units sold could have a material adverse impact on reagent sales.

Partially offsetting lower reagent sales in the first quarter of fiscal 2004 was an increase of $316,000, or 60%, (to $846,000) in sales of stabilization products and coated glass slides. While the Company expects continued growth in the sale of these products in the near-term, management does not anticipate the growth to occur at the same rate as in the first quarter. One factor that may influence stabilization product sales going forward is the recent signing of an exclusive distribution agreement. Starting in the second quarter of fiscal 2004, SeraCare Life Sciences, Inc. began distributing SurModics' stabilization products in the U.S. and Puerto Rico. SeraCare has a larger sales force and currently distributes a broad line of biological diagnostic components that are complementary to the Company's stabilization products and distributes to the same customer base: diagnostic kit manufacturers, pharmaceutical companies and research labs. Stabilization product margins will likely decrease as a result of the agreement, however, management believes this margin decrease may be more than offset over time by increased sales through SeraCare.

Commercial development revenue was $858,000 in the first quarter of 2004, down 24% from $1.1 million in the same period in 2003. This decrease results principally from the lower level of clinical coating work on the Cypher stent since Cordis received U.S. FDA approval for the Cypher stent in April 2003. The Company continues to perform other paid development work for Cordis and other customers, but on a smaller scale. Cordis accounted for a less than half of the paid development work performed by the Company during the first quarter, all of which was related to Cordis' drug-eluting stent program. Management expects fiscal 2004 first quarter's results (on a dollar basis) to be a reasonable indicator of the Company's near-term quarterly development revenue.

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

The Company currently has 60 customers licensing the Company's patented or proprietary technology with respect to 134 product applications, 70 of which are generating royalties. The Company continues to sign new license and development agreements involving our patented or proprietary technology, including six in the first quarter of fiscal 2004. Further, we expect that our customers will launch for sale

(commercialize) an additional 10-12 products in fiscal 2004. While we have numerous customers and products in our portfolio, revenue continues to be concentrated. In fiscal year 2003, our top 3 customers accounted for 71% of total revenue. However, we do not anticipate that this new product activity will generate sufficient royalty revenue in the near future to replace that which may be lost as a result of increased competition in the drug-eluting stent market or to allow the Company's growth rate to remain at historical levels in the near future.

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

*Product costs and margins.* Product costs were $736,000 for the first quarter of fiscal 2004, an increase of $149,000, or 25%, compared with the same period of fiscal 2003. Combined product margins decreased to 72% in the first quarter of fiscal 2004 from 81% in the same period last year. A greater mix of stabilization and slide sales, both of which carry lower margins than reagents, contributed to some of the decline in margins, in addition to lower prices on reagents sold to Cordis as discussed above. Since we anticipate sales of stabilization and slide products will continue to constitute an increasing percentage of our product sales (as sales of reagents are anticipated to continue declining), we anticipate that combined product margins will continue to decline. If portions of our manufacturing operations are moved to our newly-completed manufacturing facility in Bloomington, Minnesota, we anticipate increased production costs, higher depreciation costs, and higher reagent costs even after manufacturing is fully transitioned to the new facility, depending on the capacity utilization of the facility. We continue to assess our current and long-term facilities needs and usage as we seek to implement our strategic plan. See "Liquidity and Capital Resources."

*Research and development expenses.* Research and development expenses were $3.1 million for the first quarter of fiscal 2004, an increase of $486,000, or 18%, compared with the same period of fiscal 2003. A significant portion of this increase was attributable to higher depreciation and facilities costs as the Company moved segments of its research and development activities to a previously-renovated portion of its Bloomington facility during the first fiscal quarter of 2004. In the first quarter of fiscal 2004, we began to depreciate the full cost of the completed manufacturing facility. Management expects quarterly research and development expense (including depreciation from the two facilities) to increase on a sequential quarterly basis for the balance of the fiscal year.

*Sales and marketing expenses.* Sales and marketing expenses were $543,000 for the first quarter of fiscal 2004, essentially unchanged compared with the same period of fiscal 2003. Management expects sales and marketing expense to remain approximately the same throughout the remainder of the fiscal year.

*General and administrative expenses.* General and administrative expenses were $1.4 million for the first quarter of fiscal 2004, essentially unchanged compared with the same period of fiscal 2003. However, lower legal costs in the first quarter of fiscal 2004 were offset by a substantial increase in directors and officers insurance premiums, as well as an increase in personnel recruiting costs. For the balance of the fiscal year, management anticipates modest sequential quarterly growth in general and administrative expense.

*Other income, net.* Other income was $295,000 for the first quarter of fiscal 2004, a decrease of $328,000, or 53%, compared with the same

period of fiscal 2003. While investment income decreased as a result of lower investment yields and the early payoff of a $1.8 million note receivable, most of the decrease reflects lower gains generated from our investment portfolio. In the first quarter of fiscal 2003, the Company's investment adviser sold and reinvested a portion of the Company's bond portfolio generating a gain of $240,000. Results in the first quarter of fiscal 2004 reflect approximately $19,000 in gains from such sales.

*Income tax expense.* The Company's income tax provision was $2.5 million for the first quarter of fiscal 2004 compared with $1.3 million in the same period of fiscal 2003. The effective tax rates were 37.5% for both fiscal periods.

**Liquidity and Capital Resources**

As of December 31, 2003, the Company had working capital of $12.7 million and cash, cash equivalents and investments totaling $49.8 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 generated positive cash flows from operating activities of $2.9 million in the first three months of fiscal 2004, a decrease of 32% from the same period of last year.

In October 2003, the Company received prepayment of approximately $1.8 million due on a note receivable related to property the Company sold in June 2002. With this payment, the note was paid in its entirety.

In October 2001, the Company purchased a facility in Bloomington, Minnesota, situated on 27 acres of land, for approximately $7.1 million and expended an additional $16.5 million throughout fiscal 2002 and 2003 on capital improvements to upgrade laboratories and to complete the construction of additional manufacturing capacity. The manufacturing facility was completed during the fourth quarter of fiscal 2003, and provides significant capacity to support future growth for the Company. We continue to assess how our new facility, as well as our existing Eden Prairie, Minnesota facility, can best fit within our strategic plan and the manufacturing requirements that can result from emphasis on various components of the plan. As part of this process, we must analyze our near-term and long-term space needs and determine how to manage the higher costs associated with having both facilities.

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

In support of the Company's strategic plan in the ophthalmology market, on February 3, 2004, the Company invested $2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing unique drug delivery devices and therapies for the ophthalmology market. The Company has agreed to invest a total of $3.5 million, the remaining $1.4 million of which will be invested subject to InnoRx completing certain development and regulatory milestones. In collaboration with the Company, InnoRx is developing a patented, implantable coil to deliver therapeutic agents in the eye to treat various retinal diseases. This product utilizes SurModics' site-specific drug delivery technology.

While the Company anticipates that its investment in InnoRx will help facilitate the commercialization of its technology and result in revenue for the Company in the future, there can be no assurance that this will occur. InnoRx's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized. The $2.1 million investment, which is accounted for under the cost method, is included in other assets and, together with the remaining $1.4 million to be invested, would represent an ownership interest of less than 20%.

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

As of December 31, 2003, the Company had no debt, nor did it have any credit agreements. The Company believes that its existing capital resources will be adequate to fund SurModics' operations into the foreseeable future.

**New Accounting Pronouncements**

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

**Forward Looking Statements**

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

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from the Company's forward-looking statements, such factors include, among others: (i) the trend of consolidation in the medical-device industry, resulting in more significant, complex and long-term contracts than in the past and potentially greater pricing pressures; (ii) frequent intellectual property

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

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

SurModics' investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company's investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. SurModics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A one percentage point increase in interest rates would result in an approximate $630,000 decrease in the fair value of the Company's available-for-sale securities as of December 31, 2003, but no material impact on the results of operations or cash flows. Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material. Also, the Company's foreign currency exposure is not significant.

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

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

### Changes in Internal Controls

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

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings.

None.

### Item 2. Changes in Securities and Use of Proceeds.

None.

### Item 3. Defaults Upon Senior Securities.

None.

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

(a) The Company held its Annual Meeting of Shareholders on January 26, 2004.

(b) Proxies were solicited pursuant to Regulation 14A under the Securities Act of 1934. The shareholders voted on two matters: (i) to set the number of directors at nine (9) and (ii) to elect Class II directors. The shareholders approved both matters by the following votes:

| | | Votes For | Votes Against | Votes Abstained | Broker Non-Votes |
|---|---|---|---|---|---|
| (i) | Set the number of directors at nine (9) | 15,655,857 | 117,746 | 17,654 | — |
| | | **Votes For** | **Votes Withheld** | **Broker Non-Votes** | |
| (ii) | Elect Class II directors | | | | |
| | John W. Benson | 15,601,147 | 190,110 | — | |
| | Gerald B. Fischer | 15,559,541 | 231,716 | — | |
| | Kendrick B. Melrose | 15,504,785 | 286,472 | — | |

### Item 5. Other Information.

None.

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

(a) Exhibits —

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

(b) Reports on Form 8-K — A report on Form 8-K dated October 29, 2003 was furnished on October 29, 2003, pursuant to Item 12 and related to the issuance of a press release announcing the results for the Company's fourth quarter and fiscal year ended September 30, 2003.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**SurModics, Inc.**

February 17, 2004

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

**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

**EXHIBIT INDEX TO FORM 10-Q**

**For the Quarter Ended December 31, 2003**

**SURMODICS, INC.**

| Exhibit | Description |
|---|---|
| 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 |

**EXHIBIT 31.1**

**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 17, 2004

Signature: /s/ Dale R. Olseth
Dale R. Olseth
Chief Executive Officer

**EXHIBIT 31.2**

**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 17, 2004

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

**EXHIBIT 32.1**

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, 2003, 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 17, 2004

/s/ Dale R. Olseth
Dale R. Olseth
Chief Executive Officer

**EXHIBIT 32.2**

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, 2003, 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 17, 2004

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