## SECURITIES AND EXCHANGE COMMISSION

## **WASHINGTON, DC 20549**

# **FORM 10-K**

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended September 30, 2003

Commission file number 0-23837

# SURMODICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Minnesota (State of Other Jurisdiction of Incorporation or Organization) 41-1356149 (IRS Employer Identification No.)

9924 West 74<sup>th</sup> Street Eden Prairie, Minnesota 55344 (Address of Principal Executive Offices) (Zip Code)

(952) 829-2700 (Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.05 par value

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 by file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes [X] No[]

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of December 12, 2003 was approximately \$298 million (based upon the closing sale price of the registrant's Common Stock on such date).

The number of shares of the registrant's Common Stock outstanding as of December 12, 2003 was 17, 467,965.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the Registrant's 2004 Annual Meeting of Shareholders are incorporated by reference into Part III

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We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act on our web site, www.surmodics.com, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our web site as a part of, or incorporating it by reference into, our Form 10-K.

#### PART I

## ITEM 1. BUSINESS

#### Overview

SurModics, Inc. (referred to as "SurModics," "the Company," "we," "us," "our" and other like terms) is a leading provider of surface-modification solutions for medical-device and biomedical applications. The company's patented PhotoLink® chemistry is the core technology platform on which many of SurModics' 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 PhotoLink®, another key platform is SurModics' drug-delivery polymer matrix technology. Drug-eluting coronary stents are just one example of how this technology can be applied to medical devices to deliver pharmaceutical agents from the surface of a device. SurModics coatings often make medical devices easier for physicians to use, more compatible with the human body and more suitable for a wide range of health care applications.

SurModics' strategy is to create strong relationships and coating technology license agreements with the world's leading medical-device manufacturers as well as emerging companies with promising technology. By collaborating with the foremost medical-device and technology companies, SurModics has leveraged and intends to continue to leverage its core technology into high-growth, high-value opportunities, including genomics, tissue engineering and drug-delivery coatings.

Our surface-modification coatings are based upon versatile underlying technology platforms: our patented drug-delivery matrix technology and our patented PhotoLink® technology. Coatings developed from our drug-delivery matrix technology allow for the controlled release of drugs from the surface of medical devices. Therapeutic drugs can be entrapped within the polymer matrix coating to provide controlled, site-specific release of the drug into the surrounding tissue.

PhotoLink® coating technology is a versatile, easily applied, light-activated coating technology that modifies medical-device surfaces. PhotoLink® coatings can impart many performance-enhancing characteristics, such as lubricity and hemocompatibility, onto the surface of a medical device without materially changing the dimensions or physical properties of the device.

Our customers currently use our surface-modification coatings on a variety of medical devices. For example, our coating technologies are used on pacemaker leads, drug infusion catheters, laser and balloon angioplasty catheters, urinary drainage catheters, vascular closure devices, wound drains, guidewires, stent delivery catheters, cardiovascular stents, angiography catheters, ureteral stents and hydrocephalic shunts, among other devices.

We intend to continue to invest in research and development to continue to expand uses for our technology base. We believe that drug delivery has the potential to change the landscape of the current medical-device industry. Drug-eluting stents are simply the first manifestation of how drugs and devices can be combined to produce outstanding patient benefits. Significant opportunities exist to deliver drugs from a wide range of other medical devices. Working with both pharmaceutical and medical-device companies, SurModics is poised to leverage this new market opportunity as drugs and devices converge to create improved products and therapies.

In 2003, we extended our reach beyond the cardiovascular market, where our drug-delivery matrix first gained prominence, into the ophthalmology market, where we signed an agreement for a novel drug-delivery application now in the very early stages of evaluation and development. We believe this agreement holds strong promise and is further evidence that our drug-delivery technology is applicable not just to stents, but across many medical specialties. We are seeing heightened activity in a number of other areas as interest in SurModics' drug-delivery technology continues to increase.

The Company commercializes its surface-modification technologies through licensing and royalty arrangements with medical-device manufacturers who apply coatings to their own products. The Company believes this approach allows it to focus its resources on further development of its technology and expansion of its licensing activities, while leveraging the established manufacturing, sales and marketing capabilities of its customers. Revenues from these arrangements include license fees, development revenue, minimum royalties, and royalties based on a percentage of licensees' product sales. In addition, the Company manufactures and sells the chemical reagents used in the coating process. The Company also manufactures and sells coated glass slides to the genomics market and offers a line of stabilization products used to extend the shelf life of immunoassay diagnostic tests.

The Company was organized as a Minnesota corporation in June 1979 and became a public company, with shares of our common stock becoming listed for trading on the Nasdaq National Market, in 1998.

## **Healthcare Industry**

Recent trends in healthcare toward improved patient outcomes and reduced costs have resulted in intense competition for the development of medical devices that demonstrate superior product performance, reduced procedure times, improved outcomes and patient comfort and overall cost effectiveness. In an effort to further differentiate their products through improved product performance, a growing number of medical-device manufacturers are turning to the emerging field of surface-modification technology. Surface modification enables device manufacturers to provide medical devices with beneficial characteristics including improved lubricity and hemocompatibility, as well as the ability to deliver drugs and promote cell growth and tissue integration. As the benefits of surface modification become increasingly apparent in connection with improving the performance of medical devices, surface-modification technologies are contributing to, and in some cases driving, advances in the commercialization of new medical devices and treatments.

The convergence of the pharmaceutical and medical-device industries presents a powerful opportunity for major advancements in health care. Medical devices, which have traditionally been considered mechanical solutions for preventing or repairing physical health problems, can offer a whole new range of benefits when combined with pharmaceuticals.

The dramatic success of biological products in spine therapies and the enormous potential of drug-eluting stents in interventional cardiology have captured the attention of the pharmaceutical and medical-device industries. The rewards of combining drugs and biologics with implantable devices are becoming increasingly apparent.

## **Our Technologies**

SurModics is strategically positioned at the intersection of both medical-device and pharmaceutical-based therapies, where technologies are rapidly merging to support and enable a new generation of advanced medical treatments. As an industry-leading provider of surface-modification

solutions, SurModics can uniquely capitalize on this convergence — where technologies and markets overlap to create new opportunities. SurModics has already established technologies, market expertise and strong business relationships needed to enable the convergence of pharmaceuticals with medical devices.

PhotoLink® coating technology is a versatile, easily applied, light-activated coating technology that modifies medical-device surfaces by creating covalent bonds between those surfaces and a variety of chemical agents. The PhotoLink® technology utilizes proprietary, light sensitive (photochemical) reagents, which can consist of advanced polymers or active biomolecules having desired surface characteristics and an attached light-reactive chemical compound (photogroup). When the reagent is exposed to a direct light source, typically ultraviolet light, a photochemical reaction creates a covalent bond between the photogroup and the surface of the medical device, thereby imparting the desired property to the surface. A covalent bond is a very strong chemical bond which results from the sharing of electrons between carbon molecules of the substrate and the applied coating.

The Company's drug delivery technology differs from the PhotoLink® technology in that it involves non-photochemical reagents. Therapeutic drugs can be entrapped within the polymer matrix to provide controlled, site-specific release of the drug into the surrounding tissue. On a wide range of devices, drug-eluting coatings can help improve device performance, increase patient safety and enable innovative new treatments. SurModics works with companies in the pharmaceutical and medical-device industries to develop specialized coatings that allow for the controlled release of drugs from a device surface. SurModics sees three primary areas with strong future potential: (1) improving the function of a device which itself is necessary to treat the problem; (2) enabling drug delivery in cases where the device serves only as a vehicle to deliver a drug to a specific site in the body; and (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

Our patented drug delivery technology utilizes a combination of polymers which are then mixed with drugs to prepare drug-eluting coatings. Release of the drug from these coatings can be controlled by the amount of drug loading and the relative composition of the polymer components, both of which influence the rate at which the drug diffuses out of the coating. The release of the drug can be tuned to elute quickly, in a few days, or slowly, over several months, illustrating the wide range of release profiles that can be achieved with our coating system.

Our proprietary PhotoLink® reagents work directly on most polymer-based (e.g., plastic) and biological substrates (latex rubber, cellulose, tissue and natural fibers). Metal and glass substrates generally require a pretreatment to make a hydrocarbon-containing surface for bonding prior to the application of our reagents. The reagents are easily applied to a clean material surface by dipping, spraying, roll coating, ink jetting or brushing. SurModics continues to develop proprietary reagents providing new product features while expanding the number and type of substrates on which the reagents can be applied.

*Surface-Modification Features.* The Company believes that its proprietary coating process provides its customers with a number of benefits. The main features that are most likely to permit broad incorporation of our technologies into customers' product development and manufacturing include:

• Flexibility. Coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents, which allows customers to be innovative in the design of their products without significantly changing the dimensions or physical properties of the device.

- *Multiple Surface Properties*. The surface-modification process can be tailored to provide customers with the ability to improve the performance of their devices by choosing the specific coating properties desired for particular applications. Our surface-modification technologies also can be combined to deliver multiple surface-enhancing characteristics on the same device.
- *Ease of Use.* Unlike other coating processes, the SurModics coating process is relatively simple and is easily integrated into the customer's manufacturing process. In addition, it does not subject the coated products to harsh chemical or temperature conditions, produces no hazardous byproducts, and does not require lengthy processing or curing time. Further, the coatings are compatible with generally accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized prior to packaging.

*Surface Properties*. The surface-modification process can be tailored to provide medical-device manufacturers with the following surface property characteristics:

- Lubricity. Low friction or lubricious coatings reduce the force and time required for insertion, navigation and removal of devices in vascular, neurological and urogenital applications. Lubricity also reduces tissue irritation and damage caused by products such as catheters, guidewires and endoscopy devices. Based on Company and customer testing, when compared to uncoated surfaces, the PhotoLink® process has reduced the friction on surfaces by more than 90%, depending on the substrate being coated.
- Hemocompatibility. Hemocompatible coatings help reduce adverse reactions that may be created when a device is inserted into the body and comes in contact with blood. Heparin has been used for decades as an injectable drug to reduce blood clotting in patients. PhotoLink can be used to immobilize heparin on the surface of medical devices, thereby inhibiting blood clotting on the device surface, minimizing patient risk and enhancing the performance of the device. PhotoLink® technology heparin coatings have been shown in Company and customer testing to reduce blood clotting by greater than 90% compared to uncoated surfaces. We have also developed synthetic, non-biological coatings that provide medical-device surfaces with improved blood compatibility without the use of heparin.
- Infection Resistance. Anti-adherence coatings are advantageous for most implantable medical devices where the risk of infection is a concern. PhotoLink® technology can provide passive coatings which significantly reduce microbial adhesion to the device. Testing by the Company has demonstrated that a PhotoLink® coating can reduce the adherence of microorganisms to biomaterial surfaces by up to 99% depending on the base material of the device.
- Drug-Eluting Coatings. We provide coatings that address a fundamental challenge of coronary stents: restenosis, or the progressive narrowing of vessels due to tissue growth. To address restenosis, we have developed proprietary polymer coating reagents and application methods, that do not require light activation (i.e. non-PhotoLink® methods), to create durable stent coatings which serve as reservoirs for therapeutic drugs. The drugs can then be released from the coating on a controlled basis. When a drug-eluting stent is implanted into a patient, the drug diffuses out from the surface of the stent into the blood vessel wall where it can act to inhibit unwanted tissue growth, thereby

reducing the occurrence of restenosis. Cordis Corporation is currently selling a SurModics-coated drug-eluting stent in Europe and the U.S. The Company also believes that drug-eluting devices have significant potential in the orthopedics market, where surface-modification coatings might be used to reduce inflammation and promote tissue healing in patients that have received knee, hip or other joint replacements, and in the ophthalmology market where drug-eluting ophthalmic implants may someday be implanted to deliver site-specific drugs in minimally invasive procedures.

- Wettability. PhotoLink® hydrophilic coatings have been shown in tests by the Company and its licensees to accelerate liquid flow rates on normally hydrophobic (water repelling) materials by 75%. For example, some rapid point-of-care diagnostic tests, such as home monitoring or physician monitoring of glucose levels in diabetics, are currently done by pricking a patient's finger and placing a drop of blood onto a polymer strip which is then inserted into a blood glucose reader. The Company believes that the time it takes for the blood to flow up the strip to provide a readout can be dramatically reduced and the consistency can be greatly improved with PhotoLink® technology.
- *Tissue Engineering.* Studies have shown that attachment of extracellular matrix proteins and peptides onto surfaces of implantable medical devices improves host cell attachment, growth and subsequent tissue integration. Company studies have shown that biomedical devices (such as vascular grafts and ocular implants) coated with photoreactive collagen and other proteins have improved attachment, growth of cells and acceptance by surrounding tissues. In fiscal 2002, and again in fiscal 2003, the Company made an investment in Novocell, Inc., which is pursuing a treatment for diabetes by implanting encapsulated islet cells. We have performed research using similar techniques.
- Biomolecule Immobilization. During a DNA gene analysis, typically thousands of different probes need to be placed in a pattern on a surface, called a DNA microarray. These microarrays are used by the pharmaceutical industry to screen for new drugs, by genome mappers to sequence human, animal or plant genomes, or by diagnostic companies to search a patient sample for disease-causing bacteria or viruses. However, DNA does not readily adhere to most surfaces. The Company has developed a versatile method for immobilizing biomolecules.

The table below identifies several market segments where surface modification is desired to improve medical devices and the surface properties the Company believes are desired by each segment.

Market Segment Served	Desired Surface Property and Examples of Applications
Interventional cardiology and vascular access	Lubricity: catheters, guidewires  Hemocompatibility: vascular stents, catheters, distal protection devices  Therapeutic drug incorporation and release: vascular stents, catheters  Infection resistance: catheters, implantable ports
Cardiac rhythm management	Lubricity: pacemaker and defibrillator leads, electrophysiology devices  Hemocompatibility: electrophysiology devices
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Desired Surface Property and Examples of Applications

Hemocompatibility: minimally invasive bypass devices, vascular grafts, ventricular assist devices

Cell growth and tissue integration: heart valves, vascular grafts

Interventional neurology and neurosurgery

Market Segment Served

Lubricity: catheters, guidewires
Infection resistance: catheters, shunts

**Urology and gynecology**\*\*Lubricity: urinary catheters, incontinence devices, ureteral stents, fertility devices

*Infection resistance*: urinary catheters, incontinence devices, ureteral stents, fertility devices, penile implants

**Ophthalmology** Site specific drug delivery

**Orthopedics** *Cell growth and tissue integration*: bone and cartilage growth

Infection resistance: orthopedic implants

In addition to the above-identified market segments, the Company's technologies are also relevant in genomics applications. During fiscal 1999, we launched our 3D-Link® Activated Slide to the genomics market. These coated glass slides are used by genomics researchers to prepare microarrays for DNA analysis. During fiscal 2000, we licensed the genomics technology to Motorola Life Sciences. In addition to providing exclusive rights to our genomics technology, the agreement calls for collaborative research on further technology advances. During fiscal 2002, Motorola's genomics business, including our agreement, was purchased by Amersham plc. On October 10, 2003, General Electric Company announced its intention to acquire Amersham plc.

## **Current Licensing Arrangements**

The Company has commercialized its technologies through licensing arrangements with medical-device manufacturers who apply the coatings to their products in their own facility. The Company believes this approach allows it to focus its resources on further developing its technologies and expanding its licensing activities, while leveraging the established manufacturing, sales and marketing capabilities of its customers for the marketing of the specific medical device utilizing the coating technologies. The Company's licensing agreements are designed to allow manufacturers to incorporate the process into their own manufacturing processes so the customer can control production and quality without the need to send product outside their facility.

The licensing process begins with the customer specifying the surface characteristics it desires. Because each surface is unique, the Company routinely conducts a feasibility study at no charge to the customer to qualify each new potential product application. Once the feasibility has been proven, the customer typically funds a development project to optimize the coating formulation to meet the customer's specific technical needs. Once the customer is satisfied with the performance of the coating, a license agreement is executed granting the licensee the rights to use the technology. Our technical personnel then transfer the coating technology into the customer's manufacturing process. The Company also manufactures and sells the chemical reagents used by all licensees in the coating process, thus creating another source of recurring revenue. The Company often supports its customers by providing coating assistance for parts required in animal and human clinical trials. However, the customer

generally performs all coating work internally once the product has been approved and is being sold on the market.

The term of a license agreement is generally for a period of 10 to 15 years or the life of our patents, whichever is longer, although a license generally may be terminated by the licensee for any reason upon 90 days written notice. The worldwide license can be either exclusive or nonexclusive, but a significant majority of the Company's licensed applications are nonexclusive. We generally require the payment of a non-refundable license fee that has historically ranged from \$25,000 to \$1,000,000 and quarterly "earned" royalties on the sales of products incorporating our technologies. The royalty rate on a substantial number of the contracts is in the 2% to 3% range, but there are certain contracts with lower or higher rates. The amount of the license fee and the royalty rate are based on various factors including whether the arrangement is exclusive or nonexclusive, the perceived value of the coating application to the device and the size of the potential market. Most of our agreements also incorporate a minimum royalty to be paid by the licensee. In most cases, payment of these minimum royalties will not commence until several months after the execution of an agreement for a particular application. On a quarterly basis, a customer will pay the greater of earned or minimum royalties to us. The earned royalties are generally paid on a quarter-lag basis, and are based on the customer's actual sales of coated products in the prior quarter.

Revenue from Cordis Corporation (48%), Amersham plc (13%) and Abbott Laboratories (10%) together represented approximately 71% of the Company's total revenue for the year ended September 30, 2003. The loss of one or more of these customers could have a material adverse effect on our business, financial condition, results of operations, and cash flow as discussed in more detail below.

#### **Other Products**

#### Stabilization Products

Although the primary focus of the Company is the development and marketing of its coating technologies, the Company also markets stabilization products for use by manufacturers of immunoassay diagnostic tests. Our StabilCoat®, StabilGuard® and StabilZyme® Stabilizers are designed to maintain the activity of biological components of the immunoassays, resulting in longer shelf life. These products offer our customers the benefit of product differentiation and improvement while providing the ultimate end users the benefit of a faster test with fewer steps and fewer errors. Throughout fiscal 2003 the Company formulated new reagents to improve the performance of protein arrays used in diagnostics and drug discovery. In addition, the Company developed new products to improve the stability of proteins bound to microparticles stored in solution. Management expects to begin marketing both products in fiscal 2004.

## Diagnostic Royalties

We have also licensed patent rights to a third party involving a format for *in vitro* diagnostic tests developed during the early years of the Company. This format has found broad application in the area of rapid point-of-care diagnostic testing, such as pregnancy and strep tests, and generated \$3.0 million of royalty revenue in fiscal 2003 pursuant to an exclusive license agreement with Abbott Laboratories. Limited additional research and development is being undertaken in this area.

#### **Research and Development**

Our research and development personnel support the sales staff in performing feasibility studies, providing technical assistance to potential customers, optimizing the coating methodologies for specific customer applications, training customers and integrating the Company's technologies and know-how into customer manufacturing operations. In addition, these personnel work to enhance and expand the coating technologies through the development of new reagents and new applications.

As medical devices become more sophisticated and complex, the Company believes the need for surface modification will grow. The Company intends to continue its development efforts to expand its surface-modification technologies to provide additional optimized surface properties to meet these needs. The Company's technical strategy is to target selected coating characteristics for further development, in order to facilitate and shorten the license cycle. The Company continues to perform research into applications for future products both on its own and in conjunction with some of its customers. Some of the research and development projects currently being worked on include additional coatings for site-specific drug delivery, enhanced tissue growth, long-term blood compatibility and new DNA immobilization methods. The Company is also working with microparticles that offer similar benefits. In addition to expanding the number of medical applications that may use the Company's technologies, we are working on improving the coating process for metals, developing a process for coating the interior diameter of medical devices and developing coatings activated with sources other than UV light.

The technical staff of the Company, including manufacturing personnel, consists of 113 employees, including 12 with Ph.D. degrees, 10 with Masters degrees and over 50 with Bachelor degrees, with expertise in chemistry, chemical engineering, biomedical engineering, biology, microbiology, cell biology and biochemistry. The technical staff is organized into several specialization areas: hydrophilicity, hemocompatibility, biochemistry, tissue engineering, drug delivery and surface characterization. In addition, a chemistry group supports the synthesis of new reagents needed by the other groups.

In fiscal 2003 and 2002, the Company's research and development expenses were \$11.8 million and \$9.7 million, respectively. A portion of these expenses is billed to customers for coating optimization and other development work on customer product applications. Research and development revenue was approximately \$5.6 million in fiscal 2003 and \$8.0 million in fiscal 2002.

Since its founding in 1979, the Company has actively participated in the federal government's Small Business Innovative Research ("SBIR") program to fund development efforts. Since 1979, 145 research contracts resulting in revenues of over \$27 million have been awarded to SurModics, including approximately \$390,000 in fiscal 2003 and \$543,000 in fiscal 2002, primarily under the SBIR program. Grant proposals are generally directed toward the overall business strategies of the Company. The Company retains commercial rights to discoveries and technologies resulting from the research and development efforts funded by these grants. Where possible, licensees' products or substrates are used when performing research under the grant; thus the results are often directly applicable to our customers. Grant funding has allowed us to maintain a larger and more technologically diverse employee base than would otherwise be possible.

## **Patents and Proprietary Rights**

The Company has taken steps intended to protect its surface-modification technologies and related inventions through a series of patents covering a variety of coating methods, reagents and formulations, as well as particular medical-device applications. The Company has 40 issued U.S.

patents, 24 pending U.S. patent applications, 91 issued foreign patents, and 76 pending foreign patent applications related to its surface-modification technologies, including 3 issued and 11 pending patents on its drug delivery matrix technology. The Company generally files international patent applications (primarily in Australia, Canada, Europe, Japan, and Mexico) in parallel with its U.S. applications. In addition to the patents related to its surface-modification technologies, we have 10 issued and 6 pending U.S. patents, 14 issued foreign patents and 32 pending foreign patent applications related to its diagnostic and genomics technology. There can be no assurance that any of the pending patent applications will be allowed.

The Company also relies heavily upon trade secrets and unpatented proprietary technologies. The Company seeks to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of this information or that others will not be able to independently develop such information. Additionally, there can be no assurance that any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to the Company.

#### **Marketing and Sales**

The Company markets its technologies and products throughout the world using a direct sales force consisting of five business development managers who focus on specific markets and companies. This specialization fosters an in-depth knowledge of the issues faced by our customers within these markets such as industry trends, technology changes, biomaterial changes and the regulatory environment.

Because the sales cycle can take several months from feasibility demonstration to the execution of a license agreement, the Company generally focuses its sales efforts on potential customers with established market positions rather than those with only development-stage products that may never come to market. Generally, the Company's technologies are licensed on a non-exclusive basis to medical -device manufacturers for use on specific products. This strategy enables the Company to license its technologies to multiple customers in the same market. We also target new product applications within existing customers. We believe the sales cycle is much faster in these situations because the licensee is already familiar with the technologies and the general terms of the license have already been negotiated.

As part of its marketing strategy, the Company publishes technical literature on each surface capability of its coating technologies (*i.e.*, lubricity, hemocompatibility, etc.). In addition, the Company exhibits at major trade shows and technical meetings, advertises in trade journals and through its website, and conducts direct mailings to appropriate target markets.

The Company also offers ongoing customer service and technical support throughout a licensee's relationship with us. This service and support begins with a coating feasibility study at no charge to the licensee and includes additional services such as assistance in the transfer of the technology to the licensee, further coating optimization, process control and trouble shooting, coating of product for clinical studies, and assistance with regulatory submissions for coated product approval. Most of these services are billable to the customer.

#### Competition

Competition in the medical-device industry has resulted in increased competition in the surface-modification market. The Company's coating technologies compete with technologies developed by Biocompatibles International plc, Carmeda (a division of Norsk Hydro, ASA), AST, Specialty Coatings Systems, and STS Biopolymers Inc. (recently purchased by Angiotech Pharmaceuticals, Inc.), among others. In addition, many medical-device manufacturers have developed or are engaged in efforts to develop surface-modification technologies for use on their own products. Overall, the Company believes the worldwide market is very fragmented with no competitor having more than a 10% market share. Some of the Company's existing and potential competitors (especially medical-device manufacturers pursuing coating solutions through their own research and development efforts) have greater financial, technical and marketing resources than the Company.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value-added approach to surface modification. The Company believes that the primary factors customers consider in choosing a particular surface-modification technology are performance, ease of manufacturing, ability to produce multiple properties from a single process, compliance with manufacturing regulations, customer service and pricing. The Company believes that its surface-modification technologies compete favorably with respect to these factors, enabling it to charge a premium price. The Company believes that the cost and time required to obtain the necessary regulatory approvals significantly reduces the likelihood of a manufacturer changing the coating process it uses once a device has been approved for sale.

Because a significant portion of the Company's revenue is dependent on the receipt of royalties based on sales of medical devices incorporating the Company's coatings, we are also affected by competition within the markets for such devices. The Company believes that the intense competition within the medical-device markets creates opportunities for the Company's coating technologies as medical-device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Because the Company seeks to license its technologies on a non-exclusive basis, the Company may further benefit from competition within the medical-device markets by offering its technologies to multiple competing manufacturers of a device. However, competition in the medical-device markets could also have an adverse effect on the Company. While the Company seeks to license its products to established manufacturers, in certain cases the Company's licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities. The Company also is unable to control other factors that may impact commercialization of coated devices, such as the marketing and sales efforts of its licensees or competitive pricing pressures within the particular device market. There can be no assurance that products coated with our technologies will be successfully commercialized by our licensees or that such licensees will otherwise be able to compete effectively.

## Manufacturing

In accordance with its licensing strategy, the Company generally does not coat medical devices to be sold by its licensees. However, the Company often supports its customers by coating products for human clinical trials. The Company also manufactures most of the reagent chemicals used by its customers in the coating process, allowing it to maintain the quality of the reagents and their proprietary nature, while providing an additional source of revenue. Reagents are polymer chemicals that are prepared using a proprietary formula in relatively small batch processes (as contrasted with commodity chemicals prepared by large continuous methods). The reagents are sold in dry form, requiring the licensee, in most cases, to simply add water, a water and isopropyl alcohol mix, or a solvent to put them

into solution before application. The Company has developed proprietary testing and quality assurance standards for manufacturing the reagents and does not disclose the reagent formulas or manufacturing methods. Although licensees may purchase the requisite chemical reagents from any source, all have elected to purchase them from the Company.

The Company also manufactures its 3D-Link® Activated Slides for sale to Amersham. Standard glass slides are cleaned and pretreated in a multiple-step process. The Company applies its proprietary PhotoLink® coating in a clean room environment, tests the slides to assure they meet quality standards, packages slides in specialized containers and seals them in moisture-proof packaging. In addition, the Company manufactures activated slides that Amersham processes further and markets under the name CodeLink.

The Company also produces its stabilization products. These products are sterile-filtered liquids that generally share a three-step production process. Component chemicals are mixed in high purity water, these liquids are sterile-filtered into specific container sizes under aseptic conditions, and the resultant finished goods are sealed and labeled.

The Company maintains multiple sources of supply for the key raw materials used to manufacture its products. The Company does, however, purchase some raw materials from single sources, but it believes that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, the Company believes that it could manufacture such raw materials.

Although not regulated by Good Manufacturing Practice, we do follow quality management procedures in part to respond to requests of licensees to establish compliance with their criteria. The Company is pursuing ISO 13485:2003 and ISO 9001:2000 certification and it expects to certify its quality system sometime during fiscal 2004.

#### **Government Regulation**

Although the Company's coating technologies themselves are not directly regulated by the U.S. Food and Drug Administration ("FDA"), the medical devices incorporating our technologies are subject to FDA regulation. The burden of demonstrating safety and efficacy of such medical devices, the ultimate criteria applied by the FDA, rests with our customers (the medical-device manufacturers). Medical products incorporating the coating technologies may generally be marketed only after 510(k) or PMA applications have been submitted to and approved by the FDA, which process can take anywhere from six months for a 510(k) application, to two or three years for a PMA application. These applications are prepared by the manufacturer and contain results of extensive biocompatibility and clinical evaluations conducted by the manufacturer.

The Company maintains confidential "Device Master Files" at the FDA regarding the nature, chemical structure and biocompatibility of its reagents. Although the Company's licensees do not have direct access to these files, the licensees may, with the permission of the Company, reference these files in their medical device submission to the FDA. This approach allows the FDA to understand in confidence the details of the coating technologies without the Company having to share this highly confidential information with its licensees.

Recent U.S. legislation allows device manufacturers, prior to obtaining FDA approval to manufacture the device in the U.S. and export it for sale in international markets. This generally allows us to realize earned royalties sooner. However, sales of medical devices outside the U.S. are subject to

international requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required by the FDA.

#### **Employees**

As of December 1, 2003, we had 155 employees, of whom 97 were engaged in technical and 16 in manufacturing positions, with the remainder in sales, marketing, quality or administrative positions. Fourteen of our employees hold Ph.D. degrees and 16 hold Masters degrees. The Company is not a party to any collective bargaining agreements and believes that its employee relations are good.

Management believes that the future success of the Company will depend in part on its ability to attract and retain qualified technical, management and marketing personnel. Such experienced personnel are in high demand, and the Company must compete for their services with other firms which may be able to offer more favorable benefits.

#### **Forward-Looking Statements**

Certain statements contained in this Form 10-K, in the Company's annual report to shareholders or in other reports of the Company 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," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" 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 and other significant customer agreements. You should 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:

- the Company's significant dependence upon Cordis, which causes our financial results and stock price to be subject to factors affecting Cordis and its Cypher stent program, including among others, the rate of market penetration by Cordis, the timing 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 in which each alleges its patent rights are being infringed by the other's stent and each has been denied the preliminary injunction it has requested against the other;
- frequent intellectual property litigation in the medical-device industry that may directly or indirectly adversely affect our customers' ability to market their products incorporating our technologies;

- our ability to protect our own intellectual property;
- 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 our technologies;
- 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;
- market acceptance of products sold by customers incorporating our technologies and the timing of new product introductions by licensees;
- market acceptance of products sold by customers' competitors and the timing and pricing of new product introductions by customers' competitors;
- 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;
- efficacy or safety concerns with respect to products marketed by us and our licensees, whether scientifically justified or not, that may lead to product recalls, withdrawals or declining sales;
- product liability claims not covered by insurance;
- the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;
- 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;
- · economic and other factors over which the Company has no control, including changes in inflation and consumer confidence;
- acts of God or terrorism which impact the Company's personnel or facilities; and
- other factors described below in "Risk Factors."

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 statements and to consult any further disclosures by the Company on this subject in its filings with the Securities and Exchange Commission. Many of the factors identified above are discussed in more detail below under "Risk Factors."

#### Risk Factors

#### The loss of one or more of our major customers could significantly reduce our revenue and earnings.

Revenue from Cordis Corporation (48%), Amersham plc (13%), and Abbott Laboratories (10%) together represented approximately 71% of our total revenue for the year ended September 30, 2003. There can be no assurance that revenue from any customer will continue at their historical levels. Loss of one or more of our current customers, particularly the three companies listed above, could have a material adverse effect on our business, financial condition and results of operations. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenue.

We rely on third parties to market, distribute and sell the products incorporating our coating technologies and those third parties may not perform or agreements with those parties could be terminated.

The principal element of our business strategy is to enter into licensing arrangements with medical-device companies that manufacture products incorporating our technologies. For the fiscal years ended September 30, 2003, 2002 and 2001, we derived approximately 57%, 40% and 49% of our revenue, respectively, from royalties. We do not currently manufacture, market or sell our own medical devices nor do we intend to do so in the foreseeable future. Thus, our prospects are substantially dependent on the receipt of royalties from licensees of our technologies. The amount and timing of such royalties are, in turn, dependent on the ability of our licensees to successfully gain regulatory approval for, market and sell products incorporating our technologies. Failure of certain licensees to gain regulatory approval or market acceptance for such products could have a material adverse effect on our business, financial condition and results of operations.

Our customers manufacture, market and sell the products incorporating our licensed technologies. If one or more of our licensees fails to pursue the development or marketing of these products as planned, our revenue and profits may not reach our expectations, or may decline. We do not control the timing and other aspects of the development or commercialization of products incorporating our licensed technologies because our customers may have priorities that differ from ours or their development or marketing efforts may be unsuccessful, resulting in delayed or discontinued products. Hence, the amount and timing of royalty payments received by us will fluctuate, and such fluctuations could have a material adverse effect on our business, financial condition and results of operations.

Under our standard license agreements, licensees can terminate the license for any reason upon 90 days' prior written notice. Existing and potential licensees have no obligation to deal exclusively with the Company in obtaining surface-modification technologies and may pursue parallel development or licensing of competing surface modification solutions on their own or with third parties. A decision by a licensee to terminate its relationship with us could materially adversely affect our business, financial condition and results of operations.

# We need to expand our licensing base to reduce our reliance upon several major customers.

We intend to continue pursuing a strategy of licensing our technologies to a diversified base of medical-device manufacturers, thereby expanding the licensing base for our coating technologies. Success will depend, in part, on our ability to attract new licensees, to enter into agreements for additional applications with existing licensees and to develop and market new applications. There can be

no assurance that we will be able to identify, develop and adapt our technologies for new applications in a timely and cost effective manner; that new license agreements will be executed on terms favorable to us; that new applications will be accepted by manufacturers in our target markets; or that products incorporating newly-licensed technology, including new applications, will gain regulatory approval, be commercialized or gain market acceptance. Delays or failures in these efforts could have an adverse effect on our business, financial condition and results of operations.

## Surface modification is a competitive market and carries the risk of technological obsolescence.

We operate in a competitive and evolving field and new developments are expected to continue at a rapid pace. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the field of surface modification. Our surface-modification technologies compete with technologies developed by Biocompatibles International plc, Carmeda (a division of Norsk Hydro ASA), AST, Specialty Coatings Systems, and STS Biopolymers Inc. (recently acquired by Angiotech Pharmaceuticals, Inc.), among others. In addition, many medical-device manufacturers have developed or are engaged in efforts to develop surface-modification technologies for use on their own devices. Some of our existing and potential competitors (especially medical-device manufacturers pursuing coating solutions through their own research and development efforts) have greater financial and technical resources and production and marketing capabilities than us. Competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. Products incorporating our competitors' technologies may gain market acceptance more rapidly than products using ours. Developments by competitors may render our current and potential products noncompetitive or obsolete. Furthermore, there can be no assurance that new products or technologies developed by others, or the emergence of new industry standards, will not render our products or technologies or licensees' products incorporating our technologies noncompetitive or obsolete. Any new technologies which make our coating technologies less competitive or obsolete would have a material adverse effect on our business, financial condition and results of operations.

#### If we cannot adequately protect our technologies and proprietary information, we may be unable to sustain a competitive advantage.

Our success depends, in large part, on our ability to obtain and maintain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and protect our proprietary rights against infringement by third parties. We have been granted U.S. and foreign patents and have U.S. and foreign patent applications pending related to our coating technologies. There can be no assurance that any pending patent application will be approved; that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties, or that the patents of others will not prevent the commercialization of products incorporating our technologies. Furthermore, there can be no assurance that others will not independently develop similar technologies, duplicate any of our technologies or design around our patents. There can be no assurance that our trade secrets or confidentiality agreements with employees, potential licensees or other parties will provide meaningful protection for our unpatented proprietary information.

Our commercial success also will depend, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property rights in the medical-device industry, and intellectual property litigation may be used against us as a means of gaining a competitive advantage. Intellectual property litigation is complex, time-consuming and expensive, and the outcome of such litigation is difficult to predict. If we were found to be infringing any third-party patent or other intellectual property right, we could be

required to pay significant damages, alter our products or processes, obtain licenses from others, which we may not be able to do on commercially reasonable terms, if at all, or cease commercialization of our products and processes. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

Patent litigation or U.S. Patent and Trademark Office interference proceedings may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third-party proprietary rights. These activities could result in substantial cost to us, even if the eventual outcome is favorable to us. An adverse outcome of any such litigation or interference proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using its technology. Any action to defend or prosecute intellectual property would be costly and result in significant diversion of the efforts of our management and technical personnel, regardless of outcome, and could have a material adverse effect on our business, financial condition and results of operations.

#### We may face product liability claims related to participation in clinical trials or the use or misuse of our products.

The development and sale of medical devices and component products involves an inherent risk of product liability claims. Although we expect that devices incorporating our technologies will be manufactured by others and sold under their own labels, there can be no assurance that product liability claims will not be filed against us for such devices or that such manufacturers will not seek indemnification or other relief from us for any such claims. In addition, there can be no assurance that product liability claims will not be filed directly against us with respect to our own products. There can be no assurance that our current product liability insurance will continue to be available to us on acceptable terms, if at all, or that, if available, the coverages will be adequate to protect us against any future product liability claims. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any recall of products or devices incorporating our technologies due to alleged defects, whether such recall is instituted by a device manufacturer or us or required by a regulatory agency. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

# We have a single manufacturing facility and we may lose revenue and be unable to maintain our customer relationships if we lose our production capacity.

We manufacture all of the products we sell in our existing production labs in our Eden Prairie, Minnesota facility. If our existing production facility becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our licensees. Without our existing production facility, we would have no other means of manufacturing products incorporating our coating technologies until we were able to restore the manufacturing capability at our facility or develop an alternative manufacturing facility. Although we carry business interruption insurance to cover lost revenue and profits in an amount we consider adequate, this insurance does not cover all possible situations. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing licensees resulting from our inability to produce products for them. Although we are currently in the process of moving portions of our manufacturing to a second site at our Bloomington, Minnesota facility to reduce this risk, we may encounter unforeseen difficulties or delays in doing so. Furthermore, in order for us to produce reagent chemicals at our Bloomington facility, we

will need affirmation from our customers that reagents are equivalent to those produced in our Eden Prairie facility.

#### We are dependent upon key personnel and may not be able to attract qualified personnel in the future.

Our success is dependent upon our ability to retain and attract highly qualified management and technical personnel. We face intense competition for such qualified personnel. We do not maintain key person insurance nor do we have employment agreements with any of our employees. Although we have non-compete agreements with most employees, there can be no assurance that such agreements will be enforceable. The loss of the services of one or more key employees or the failure to attract and retain additional qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

## Our products are subject to continuing regulations and we may be subject to adverse consequences if we fail to comply with applicable regulations.

Although coating technologies themselves are not directly regulated by the FDA, the medical devices incorporating the technologies are subject to FDA regulation. The burden of securing FDA approval for these medical devices rests with our licensees (the medical-device manufacturers). However, we have prepared Device Master Files which may be accessed by the FDA to assist it in its review of the applications filed by our licensees. Historically, most medical devices incorporating a coating have been subject to the FDA's 510(k) marketing approval process, which typically lasts from six to nine months. Supplemental or full pre-market approval ("PMA") reviews require a significantly longer period, delaying commercialization. Furthermore, sales of medical devices outside the U.S. are subject to international regulatory requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required for FDA approval. There can be no assurance that our licensees will be able to obtain regulatory approval for their coated medical devices on a timely basis, or at all. Regulatory approvals, if granted, may include significant limitations on the indicated uses for which the product may be marketed. In addition, product approval could be withdrawn for failure to comply with regulatory standards or the occurrence of unforeseen problems following initial marketing. Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of products incorporating our technologies or subject us to additional regulation. Failure or delay of our licensees in obtaining FDA and other necessary regulatory approval or clearance or the loss of previously obtained approvals could have a material adverse effect on our business, financial condition and results of operations.

Certain of our activities are regulated by federal and state agencies in addition to the FDA. For example, activities in connection with waste disposal are subject to regulation by the U.S. Environmental Protection Agency. Some of our reagent chemicals must be registered with the agency with basic information filed related to toxicity during the manufacturing process as well as the toxicity of the final product. Failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

### We use hazardous materials in some of our research, development and manufacturing processes.

Our research activities sometimes involve the controlled use of various hazardous materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. While we currently maintain insurance in

amounts which we believe are appropriate in light of the risk of accident, we could be held liable for any damages that might result from any such event. Any such liability could exceed our insurance and available resources and could have a material adverse effect on our business, financial condition and results of operations.

#### Our stock price has been volatile and may continue to be volatile.

The trading price of our common stock has been, and is likely to continue to be, highly volatile, in large part attributable to developments and circumstances related to factors identified in "Forward-looking Statements" and "Risk Factors." The market value of your investment in our common stock may rise or fall sharply at any time because of this volatility, and also because of significant short-positions taken by investors from time to time in our stock. In the year ended September 30, 2003, the closing sale price for our common stock ranged from \$25.80 to \$41.05 per share. As of December 12, 2003, the last reported sale price of our stock was \$20.74 per share. The market prices for securities of medical technology, drug delivery and biotechnology companies historically have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

#### **ITEM 2. PROPERTIES**

The Company conducts its operations in two facilities located in suburban Minneapolis-St. Paul, Minnesota. In May 1999, we purchased the land and building we currently occupy in Eden Prairie, Minnesota for approximately \$3.2 million. The building has approximately 64,000 square feet of space. Most of the Company's operations take place at the Eden Prairie location. In October 2001, the Company purchased a 135,000 square foot facility on 27 acres of land in Bloomington, Minnesota for approximately \$7.1 million and expended an additional \$4.0 million throughout fiscal 2002 on capital improvements. During fiscal 2003, the Company also enhanced its manufacturing capability with the completion of a \$12.5 million addition to its Bloomington facility. Construction was completed in the fourth quarter of fiscal 2003. The Company will begin to move its reagent manufacturing to the Bloomington site from its current location in Eden Prairie, Minnesota and expects to complete the move within twelve to eighteen months. As of September 30, 2003, the Bloomington facility was largely unoccupied. The Company intends to gradually remodel other portions of this facility and move additional operations to it. The purchases of these two properties were internally funded and remain unencumbered. The Company believes that projected capacity of both the manufacturing area and research and development labs are adequate to service the needs of its customers for the foreseeable future.

#### ITEM 3. LEGAL PROCEEDINGS

The Company is not a party to nor is any of its property subject to any material pending legal proceedings.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the fourth quarter of fiscal 2003.

#### EXECUTIVE OFFICERS OF THE REGISTRANT

The names, ages and positions of the Company's executive officers are as follows:

Name	Age	Position
Dale R. Olseth		Chairman and Chief Executive Officer
Bruce J Barclay	47	President and Chief Operating Officer
Philip D. Ankeny	40	Vice President and Chief Financial Officer
Richard C. Carlson	52	Vice President of Strategic Planning
Lise W. Duran, Ph.D.	48	Vice President of Product Development
Robert W. Elliott, Jr.	49	Vice President, Licensing Counsel
Patrick E. Guire, Ph.D.	67	Senior Vice President and Chief Scientific Officer
Loren R. Miller	38	Vice President and Controller
Jane M. Nichols	57	Vice President of Marketing
Ronald F. Ofstead	65	Vice President of Chemistry Development
Marie J. Versen	42	Vice President of Quality Management and Regulatory Compliance
Gregory T. Yung	54	Vice President of Sales and Business Development

Dale R. Olseth joined the Company in 1986 as its President, Chief Executive Officer and a director of the Company and has served as Chairman since 1988. Mr. Olseth also serves on the Board of Directors of The Toro Company and the boards of Otologics LLC and the University of Minnesota Foundation. He served as Chairman or President and Chief Executive Officer of Medtronic, Inc. from 1976 to 1986. From 1971 to 1976, Mr. Olseth served as President and Chief Executive Officer of Tonka Corporation. Mr. Olseth received a B.B.A. degree from the University of Minnesota in 1952 and an M.B.A. degree from Dartmouth College in 1956.

Bruce J Barclay joined the Company as its President and Chief Operating Officer in December 2003. Prior to joining SurModics, he served as President and Chief Executive Officer of Vascular Architects, Inc., a medical device company that develops, manufactures and sells products to treat peripheral vascular disease, from 2000 to 2003. Mr. Barclay has more than 20 years of experience in the health care industry. Prior to Vascular Architects, he served at Guidant Corporation, most recently as an officer and Senior Vice President from 1998 to 2000. Previously, he was a Vice President of Guidant's Interventional Cardiology division with responsibility for the law division, a new therapies technical development team and business development, charged with the acquisition of new products and technologies for the division. Mr. Barclay also has considerable experience in the pharmaceutical area serving in several positions at Eli Lilly and Company. Mr. Barclay also serves on the Board of Directors of Cardiac Science, Inc., which develops, manufactures and markets automatic external defibrillators. Mr. Barclay received a B.S. in chemistry and a B.A. in biology from Purdue University in 1980 and a J.D. from the Indiana University School of Law in 1984. He is also a registered patent attorney.

Philip D. Ankeny joined the Company as its Vice President and Chief Financial Officer in April 2003. Prior to joining SurModics, he served as Chief Financial Officer for Cognicity, Inc. from 1999 to 2002. Prior to that, Mr. Ankeny served as a Partner at Sherpa Partners, LLC, a venture capital and venture development firm, from 1998 to 1999. He also spent five years in investment banking with Robertson Stephens and Morgan Stanley. In addition, his operating experience includes over five years with IBM and Shiva in sales, marketing and business development roles. Mr. Ankeny received an A.B. degree in economics and engineering from Dartmouth College in 1985 and an M.B.A. from Harvard Business School in 1989.

*Richard C. Carlson* was named Vice President of Strategic Planning in September 2002. He joined the Company in 1998 as Director of Marketing and was named Vice President of Marketing and Sales in 1999. Prior to joining SurModics, he was a European Marketing Manager for Boston Scientific Corporation from 1996 to 1998. Mr. Carlson has also held marketing positions with C.R. Bard, Inc., Medtronic, Inc., and American Medical Systems, Inc. He received a B.A. degree in business and economics from the University of Minnesota in 1973 and an M.B.A. in marketing from the Carlson School of Management in 1976.

Lise W. Duran, Ph.D., came to SurModics in 1990, serving as Director of Microbiology until she was promoted to Vice President of Product Development in 1998. From 1988 to 1990, Dr. Duran served as a Study Director for Microbiological Associates, Inc., in the Biotechnology Services Division. She also did a research fellowship in Immunology at the Mayo Clinic and was a postdoctoral associate in Laboratory Medicine and Pathology at the University of Minnesota. Dr. Duran received her B.S. in microbiology from the University of Maryland and a Ph.D. in microbiology from the Uniformed Services University of the Health Sciences.

Robert W. Elliott, Jr. joined the Company in 2002 and currently serves as Vice President, Licensing Counsel. He worked in various legal positions at Motorola, Inc. from 1993 to 2002, most recently as Director of Contracts for Motorola Life Sciences. He also held legal positions at NovAtel Communications, Inc. from 1990 to 1992, Diversified Energies, Inc. from 1987 to 1990 and Eli Lilly and Company from 1980 to 1987. Mr. Elliott received a B.S. degree in chemistry from Purdue University in 1975 and his law degree from Indiana University School of Law in 1978.

Loren R. Miller joined the Company in 1999 and served as Controller before being promoted to Vice President and Controller in March 2003. Prior to coming to SurModics, Mr. Miller served as Controller of Northwest Athletic Clubs (owned by The Wellbridge Company). From 1996 to 1998 he was the Controller for Executive Aviation Inc. In addition he held various positions at Mesaba Aviation Inc. from 1988 until 1995, most recently as Controller. Mr. Miller is a CPA and received a B.S. degree in Business Administration & Finance and a B.S. degree in Accounting from Minnesota State University in 1988.

Patrick E. Guire, Ph.D. is a co-founder of the Company and has served as Senior Vice President of Research and Chief Scientific Officer and a director since 1980. Dr. Guire is responsible for the research affairs of the Company. Prior to founding SurModics, Dr. Guire was employed by Kallestad Laboratories, Inc. as a senior scientist from 1978 to 1979 and was a researcher at the Midwest Research Institute, Inc. in Kansas City, Missouri from 1972 to 1978. He received a B.S. degree in Chemistry from the University of Arkansas, Fayetteville in 1958 and a Ph.D. in biochemistry from the University of Illinois in 1963.

Jane M. Nichols joined SurModics as Vice President of Marketing in October 2002. Before coming to SurModics, she was Vice President of Marketing and New Business Development for LecTec Corporation where she had worked since 1993. Prior to that, she was a Senior Marketing Manager at Ecolab, Inc. in its Professional Products Division. From 1981 through 1993, Ms. Nichols held a number of significant positions at 3M, the most recent as Business Development Manager in 3M's New Veterinary Products Division. She received a B.S. degree in medical technology and chemistry from the University of Wisconsin LaCrosse in 1968 and an M.B.A. from the Carlson School of Management in 1984.

Ronald F. Ofstead, Ph.D. joined SurModics in 1998 as Director of the Chemistry Department and was promoted to Vice President of Chemistry Development in March 2003. Prior to joining SurModics, he served for four years as Director of Laboratories for Science, Inc., a privately held medical device company, after having served in several research and management positions in the Health Care Group of the 3M Company. Dr. Ofstead received a B.S. degree in chemistry from the College of St. Thomas and M.S. and Ph.D. degrees in organic chemistry from the University of Iowa.

*Marie J. Versen* joined the Company in 1987, and in 1996 became its Vice President of Quality Management and Regulatory Compliance. She was previously employed at Precision-Cosmet Company, Inc. from 1983 to 1986. Ms. Versen received a B.S. degree in chemical engineering from the University of Minnesota in 1983.

*Gregory T. Yung* joined SurModics in 2000 as Director of Sales and Market Development and was named Vice President, Sales and Business Development in 2002. Mr. Yung has over 20 years of experience in the medical device industry, having held management positions at Medtronic, Inc. from 1988 to 2000 and at Boston Scientific, Inc. from 1984 to 1988. Mr. Yung received a B.S. degree in business administration and marketing from the University of Akron in 1979.

The executive officers of the Company are elected by and serve at the discretion of the Board of Directors.

#### PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our stock is traded on the Nasdaq National Market under the symbol "SRDX." The table below sets forth the range of high and low closing sale prices, by quarter, for our Common Stock, as reported by Nasdaq, in each of the last two fiscal years.

Fiscal Quarter ended:	High \$	Low \$
September 30, 2003	37.54	26.15
June 30, 2003	41.05	30.52
March 31, 2003	34.00	25.80
December 31, 2002	37.24	28.68
September 30, 2002	31.77	19.95
June 30, 2002	45.64	22.03
March 31, 2002	46.50	32.40
December 31, 2001	45.20	31.59

According to the records of our transfer agent, as of November 20, 2003, there were 281 holders of record of our Common Stock and approximately 10,039 beneficial owners of shares registered in nominee or street name.

We have never paid any cash dividends on our Common Stock and do not anticipate doing so in the foreseeable future.

We made no sales of unregistered securities during the quarter- ended September 30, 2003.

#### ITEM 6. SELECTED FINANCIAL DATA

The data presented below as of and for the years ended September 30, 2003, 2002, and 2001 are derived from our audited financial statements included elsewhere in this report. The financial data as of and for the years ended September 31, 2000 and 1999 are derived from our audited financial statements that are not included in this report. The information set forth below should be read in conjunction with the Company's consolidated financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Item 7 of this report and our financial statements and related notes beginning in page F-1 and other financial information included in this report.

			Fiscal Year		
(Dollars in thousands, except per share data)	2003	2002	2001	2000	1999
Income Statement Data:					
Total revenue	\$43,232	\$29,488	\$22,693	\$18,279	\$13,494
Operating income	20,640	10,709	7,566	5,333	2,419
Net income	13,936	7,796	5,109	4,240	4,360*
Diluted net income per share	.78	.44	.29	.25	.27*
Pro forma amounts assuming the accounting change** was applied retroactively:					
Net income	13,936	7,796	6,814	3,669	4,199*
Diluted net income per share	.78	.44	.38	.22	.26*
Balance Sheet Data:					
Cash and short-term investments	\$ 6,647	\$13,149	\$14,840	\$17,357	\$ 5,922
Total assets	97,808	77,248	60,583	50,749	31,958
Retained earnings (accumulated deficit)	28,918	14,982	7,186	2,077	(2,163)
Total stockholders' equity	86,114	69,995	55,700	48,303	29,719
Pro forma amounts assuming the accounting change** was applied retroactively:					
Retained earnings (accumulated deficit)	28,918	14,982	7,186	372	(3,297)
Total stockholders' equity	86,114	69,995	55,700	46,598	28,585

<sup>\*</sup> Net income for the year ended September 30, 1999 includes the reversal of an income tax valuation reserve totaling \$2,074,000. To make the results comparable between years, excluding the income tax reversal would result in net income of \$2,286,000 and diluted earnings per share of \$0.14.

<sup>\*\*</sup> Effective October 1, 2000, we adopted Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements." As a result of adopting SAB 101, we recorded a cumulative effect of a change in accounting

principle related to license fees recognized in prior years in the amount of \$1,705,000, net of tax of \$1,000,000, or \$.09 per diluted share.

#### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following discussion and analysis of our financial condition, results of operations and trends for the future should be read together with Selected Financial Data and our audited financial statements and related notes appearing elsewhere in this report. This discussion and analysis regarding trends in our future financial condition and results of operations contains forward-looking statements that involve risks, uncertainties and assumptions, as more fully identified in "Forward-looking Statements" and "Risk Factors." Our actual future financial condition and results of operations may differ materially from those anticipated in the forward-looking statements.

#### Overview

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

## **Critical Accounting Policies**

Our financial statements are based in part on the application of significant accounting policies, many of which require management to make estimates and assumptions (see Note 2 to the consolidated financial statements). Management believes the following are the critical areas in the application of our accounting policies that currently affect our financial condition and results of operations.

**Revenue recognition.** Royalty revenue is generated when a licensed customer sells products incorporating our technologies. Royalty revenue is recognized as our licensees report it to us, and payment is typically submitted concurrently with the report. We recognize initial license fees over the term of the related agreement. Effective October 1, 2000, we adopted Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements." As a result of adopting SAB 101, we recorded a cumulative effect of a change in accounting principle related to license fees recognized in prior years in the amount of \$1,705,000, net of tax of \$1,000,000, or \$.09 per diluted share. Revenue related to a performance milestone is recognized upon the achievement of the milestone, as defined in the respective agreements. Revenue on sales of the Company's products is recognized when persuasive evidence of an agreement exists, delivery has occurred, the fee is fixed and determinable and collectibility is probable. Generally, these criteria are met at the time our product is shipped. Revenue for research and development is recorded as performance progresses under the applicable contract.

*Valuation of long-lived assets.* We periodically evaluate whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of long-lived assets, such as property and equipment and our investment in Novocell, Inc. If such events or circumstances were to indicate that the carrying amount of these assets would not be recoverable, we

would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) or other measure of fair value was less than the carrying amount of the assets, we would recognize an impairment loss

*Investments.* Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities and are classified as available-for-sale. Available-for-sale investments are reported at fair value with unrealized gains and losses excluded from operations and reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations and result in a new cost basis for the investment.

#### **Results of Operations**

#### Years Ended September 30, 2003 and 2002

**Revenue.** The Company's total revenue was \$43.2 million in fiscal 2003, an increase of 47% over fiscal 2002. The revenue components were as follows:

(Dollars in thousands)	Fiscal 2003	Fiscal 2002	Increase (Decrease)	% Increase (Decrease)
Revenue:				
Royalties and license fees	\$25,833	\$12,493	\$13,340	107%
Product sales	11,804	9,004	2,800	31%
Development	5,595	7,991	(2,396)	-30%
Total revenue	\$43,232	\$29,488	\$13,744	47%

Substantially all of the total revenue increase in fiscal 2003 reflects the 107% growth in royalties and license fees. The growth resulted primarily from the royalty obligations of Cordis Corporation on its Cypher stent, an increase in minimum royalties from Amersham plc on its coated glass slide, and a one-time royalty payment of \$1.1 million on product sales by a single licensee recorded in the third quarter of 2003. On April 24, 2003, Cordis received U.S. Food and Drug Administration (FDA) approval to begin marketing its Cypher stent in the U.S. 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. License fees totaled \$1.3 million in fiscal 2003, up from \$684,000 last year. Substantially all of the increase was attributable to a \$500,000 milestone payment from Amersham for a product that it introduced to the market during the third quarter of 2003 and a non-performing license we cancelled in the first quarter of fiscal 2003 that resulted in the recognition of approximately \$340,000 of deferred license fee revenue. Taking into account the one-time nature of the cancelled license and the milestone payment, management expects current year license fee results to be a good indication of licensing activity for fiscal 2004. The uncertainty surrounding when the FDA will grant approval for a drug-eluting stent in competition with Cordis' Cypher stent, from which a significant portion of our royalty revenue was derived in fiscal 2003, and the subsequent dynamics that will play out in the U.S. marketplace when a competing stent is available constrains management's ability to project with confidence how such competition will affect royalty revenue for fiscal 2004.

Product sales increased 31% to \$11.8 million compared to \$9.0 million last year. Sales of reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices) made up \$8.9 million of product sales, up from \$6.1 million last year. A substantial majority of product sales

growth over fiscal 2003 reflects increased demand by Cordis in support of their Cypher stent manufacturing. In addition, Cordis purchased a substantial majority of reagents sold in fiscal 2003. Management anticipates reduced reagent sales to Cordis in fiscal 2004 as their manufacturing process becomes more efficient. However, management expects Cordis to continue to purchase a substantial percentage of the reagents sold in fiscal year 2004, in addition to being a significant source of royalty revenue. In fiscal 2003, Cordis Corporation represented 48% of our total revenue, up from 38% in fiscal 2002.

Commercial development revenue decreased 30% to \$5.6 million. Substantially all of the decrease results from a lower level of clinical coating work performed on the Cypher stent project since Cordis received FDA approval. Despite this decrease, the Cordis Cypher stent project accounted for a substantial majority of the development work we performed during fiscal year 2003. However, when Cordis results are excluded from both fiscal 2003 and 2002, development revenue from work on all other customers increased 22% over fiscal 2002. We continue to perform other development work for Cordis and for other customers, but on a smaller scale because in many cases the projects are at earlier stages of development. Since the Cordis Cypher stent project accounted for a substantial majority of the development work we performed during fiscal year 2003, but the product received FDA approval in fiscal year 2003, we expect total development revenue to decrease in fiscal 2004 as well.

**Product costs.** The Company's product costs were \$2.6 million for fiscal 2003, a slight decrease of 1%, from the \$2.7 million recorded in fiscal 2002. Overall product margins averaged 78%, a significant increase from the 70% margins in fiscal 2002 attributable in part to reduced scrap costs but mostly to the fact that higher margin reagent product sales constituted an even greater percentage of total product sales than in fiscal 2002. During fiscal 2004 and 2005, we plan to move portions of our manufacturing operations to our newly-completed manufacturing addition in Bloomington, Minnesota. Much of the activity related to the move will also revolve around qualifying the facility and newly-installed equipment. Management anticipates increased reagent production costs while we optimize our manufacturing operations at the new location and until we can discontinue manufacturing activities at our Eden Prairie facility.

**Research and development expense.** Research and development expense for fiscal 2003 was \$11.8 million, an increase of \$2.1 million, or 21%, compared with the same period in fiscal 2002. The change was primarily a result of compensation and benefits associated with technical personnel we added during the past year and increased depreciation and facilities expenses. We moved segments of our research and development activities to a portion of the renovated Bloomington facility early in fiscal year 2003. Management expects research and development expenses to increase in 2004 as we complete more renovations and move additional research and development and manufacturing activity to the Bloomington facility.

*Sales and marketing expense.* Sales and marketing expense was \$2.2 million for fiscal 2003, an increase of \$656,000, or 42%, from fiscal 2002. The increase reflects higher promotional costs, increased compensation, benefits, and business travel related to marketing personnel added in the first quarter of fiscal 2003 and licensing costs. Management expects sales and marketing expenses to increase throughout fiscal 2004, although at a lower rate of growth.

*General and administrative expense.* General and administrative expense was \$5.9 million for fiscal 2003, an increase of \$1.1 million, or 23%, over fiscal 2002. The increase was primarily a result of costs associated with contract negotiations and a 156% increase in directors and officers insurance.

*Other income, net.* The Company's other income was \$1.9 million for fiscal 2003, an increase of \$171,000, or 10%, from fiscal 2002. Interest earned on our investments decreased 13% to \$1.4 million mostly because of lower yields.

*Income tax expense.* The Company's income tax provision was \$8.6 million in fiscal year 2003 compared to \$4.6 million in fiscal 2002. The effective tax rate was 38% in fiscal 2003, a slight increase from 37% in fiscal 2002.

#### Years Ended September 30, 2002 and 2001

*Revenue.* The Company's revenue was \$29.5 million in fiscal 2002, an increase of 30% over fiscal 2001. The revenue components were as follows:

(Dollars in thousands)	Fiscal 2002	Fiscal 2001	Increase (Decrease)	% Increase (Decrease)
Revenue:				
Royalties and license fees	\$12,493	\$12,828	\$ (335)	-3%
Product sales	9,004	5,685	3,319	58%
Development	7,991	4,180	3,811	91%
Total revenue	\$29,488	\$22,693	\$6,795	30%

The revenue growth in fiscal 2002 was primarily because of strong increases in product sales and development revenue. Within product sales, reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices) increased 131% over last year due mostly to increased demand by Cordis Corporation. During fiscal 2002, Cordis began manufacturing stents utilizing a SurModics coating for sale in Europe and in anticipation of U.S. FDA approval. As Cordis' demand grew, internal manufacturing efficiencies were passed on to Cordis in the form of lower reagent prices.

Cordis also largely influenced the 91% growth in development revenue. Cordis represented a significant majority of the Company's development revenue as we coated stents in support of their various clinical trials and performed other development projects. Additionally, Cordis Corporation represented 38% of the Company's total revenue in fiscal 2002, up from 16% in fiscal 2001.

Overall royalties and license fees decreased 3%. Within this category, royalty revenue from coatings licenses ended the year 20% above fiscal 2001. Revenue from license fees declined 62% to \$684,000 in fiscal 2002 from nearly \$1.8 million in fiscal 2001. Included in fiscal 2001 results was a \$1.0 million milestone payment from Motorola Life Sciences (Motorola Life Sciences was sold to Amersham plc during fiscal 2002). No similar milestone payment was received in 2002. Excluding this payment, license fee revenue would have ended fiscal 2002 down 14%. Finally, diagnostic royalties decreased 25% from fiscal 2001. Revenue in the prior year included proceeds from patent infringement settlements that offset an overall trend of decreasing revenue. The sole licensee of these diagnostic patents has been subject to regulatory issues that have prevented it from manufacturing certain royalty-generating products resulting in decreased revenue.

**Product costs.** The Company's product costs were \$2.7 million for fiscal 2002, an increase of \$243,000, or 10%, from fiscal 2001. Overall product margins averaged 70%, a significant increase from the 57% margins in fiscal 2001. The significant increase in relatively higher margin reagent sales boosted overall product margins despite a slight decrease in margins from stabilization and slide products.

**Research and development expense.** Research and development expense was \$9.7 million for fiscal 2002, an increase of \$1.7 million, or 21%, from fiscal 2001. Most of this increase was because of compensation and benefit expenses associated with the technical personnel hired by the Company during the last two years. In addition, the Company incurred increased depreciation related to new equipment purchased during the same time period.

*Sales and marketing expense.* Sales and marketing expense was \$1.6 million for fiscal 2002, a decrease of \$130,000, or 8%, from fiscal 2001. Increased recruiting costs were partially offset by a decrease in business travel and promotional expense.

*General and administrative expense.* General and administrative expense was \$4.8 million for fiscal 2002, an increase of \$1.8 million, or 61%, over fiscal 2001. The increase was primarily because of operating costs associated with the Bloomington property acquired in early 2002. While the property was undergoing improvements, the holding cost was allocated to corporate general and administrative expense. The balance of the increase was attributed to higher bonus expenses, benefit costs, employer taxes on stock option exercises and increased professional fees and legal costs.

*Other income*, *net*. The Company's other income was \$1.7 million for fiscal 2002, a decrease of \$1.4 million, or 45%, from fiscal 2001. Interest earned on the Company's investments decreased 32% to \$1.6 million. Approximately \$750,000 of the decrease was due to lower yields and smaller investment balances related to capital expenditures made during the year. The remaining decrease was the result of lower capital gains on investment sales. In fiscal 2001, the Company sold investments to generate \$700,000 of gains to utilize fully a tax capital loss carryforward before it expired.

*Income tax expense.* The Company's income tax provision was \$4.6 million in fiscal year 2002 compared to \$3.8 million in fiscal 2001. The effective tax rate was 37% in fiscal 2002, a slight increase from 36% in fiscal 2001 because the Company entered a higher federal tax bracket and utilization of the capital loss carryforward discussed above.

#### **Liquidity and Capital Resources**

As of September 30, 2003, the Company had working capital of \$7.7 million and cash, cash equivalents and investments (marketable securities) totaling \$45.8 million. The Company generated positive cash flows from operating activities of \$19.3 million in fiscal 2003, \$14.3 million in fiscal 2002, and \$7.8 million in fiscal 2001. The increase in cash flows in fiscal 2003 primarily reflects the increased net income generated during the year, with the accrued income tax provision more than offsetting a decrease in the income tax benefit from the exercise of employee stock options. During the last several years, a significant source of cash provided by operating activities included the result of income tax benefits from the exercise of employee stock options. Management expects the impact of income tax benefits from option exercise activity to be less significant in fiscal 2004, therefore management expects the cash outlay for income taxes to increase next year.

In October 2001, the Company purchased a facility in Bloomington, Minnesota, situated on 27 acres of land, for approximately \$7.1 million and expended an additional \$4.0 million throughout fiscal 2002 on capital improvements. During fiscal 2003, the Company invested approximately \$12.5 million to construct additional manufacturing capacity at this location. With construction completed in the fourth quarter of fiscal 2003, the Company intends to move its reagent manufacturing to the Bloomington site from its current location in Eden Prairie, Minnesota over the next twelve to eighteen months. During

fiscal 2002, with the planned expansion into the Bloomington facility, the Company sold property located in Orono, Minnesota, for \$2.4 million. Terms of the sale included a \$500,000 cash down payment and a note for \$1.9 million. The note receivable was paid in its entirety on October 31, 2003.

In the first quarter of fiscal 2002, the Company invested \$4.0 million in Novocell, Inc., a privately held Irvine, California-based biotech firm that is developing a potential treatment for diabetes. In the third quarter of fiscal 2003, the Company invested an additional \$925,000 in Novocell. The total \$4.9 million investment, which is accounted for under the cost basis, is included in other assets and represents an ownership interest of less than 15%. Information with respect to our general investment policies regarding debt and certain securities with debt features is located in Item 7A of this report.

As of September 30, 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 its 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 did not have an impact on the Company's financial statements.

In November 2002, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 45 (FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 clarifies the requirements for a guarantor's accounting for and disclosure of certain issued and outstanding guarantees. The initial recognition and initial measurement provisions of FIN 45 are applicable to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements for interim or annual periods ending after December 15, 2002. There was no impact to the Company upon adoption.

In December 2002, FASB issued Statement of Financial Accounting Standards No. 148 (SFAS No. 148), "Accounting for Stock-Based Compensation-Transition and Disclosure", which amends SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirement of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The transition guidance and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on the Company's consolidated balance sheet or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." This Interpretation clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. We have reviewed the provisions of FIN 46 and have determined that it does not have an impact on our financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument with certain defined characteristics as a liability (or an asset in some circumstances). The requirements of this statement apply to an issuer's classification and measurement of freestanding financial instruments, including those that comprise more than one option or forward contract. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. We have reviewed the provision of SFAS No. 150 and have determined that it does not have an impact on our financial position and results of operations.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our investment policy generally requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our 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 our investment policies, the primary market risk associated with these investments is interest rate risk. We do 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 \$625,000 decrease in the fair value of our available-for-sale securities as of September 30, 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 our 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The balance sheets as of September 30, 2003 and 2002 and the statements of income, stockholders' equity an cash flows for each of the three years in the period ended September 30, 2003, together with the independent auditors' report thereon, begin on page F-1 of this Form 10-K.

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### ITEM 9A. 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 Chief Executive Officer and Chief Financial Officer, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under

the Securities Exchange Act of 1934 (the "Exchange Act")). Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. There was no change in the Company's internal control over financial reporting during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

#### **PART III**

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information required by Item 10 relating to directors, codes of ethics and compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated herein by reference to the sections entitled "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" that appear in the Company's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated herein by reference to the section entitled "Executive Compensation and Other Information" that appears in the Company's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by Item 12 is incorporated herein by reference to the sections entitled "Principal Shareholders," "Management Shareholdings" and "Equity Compensation Plan Information" that appear in the Company's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 14 is incorporated herein by reference to the section entitled "Independent Public Accountant" that appears in the Company's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders.

## **PART IV**

# ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) 1. Financial statements

The following statements are included in this report on the pages indicated:

	Page (s)
Report of Independent Accountants	F-1 – F-2
Balance Sheets	F-3
Statements of Income	F-4
Statements of Stockholders' Equity	F-5 – F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8 – F-21

- 2. *Financial Statement Schedules*. All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission other than the ones listed above are not required under the related instructions or are not applicable, and, therefore, have been omitted.
- 3. *Listing of Exhibits*. The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index following the signature page.
- (b) Reports on Form 8-K. A report on Form 8-K dated July 17, 2003 was furnished on July 17, 2003, pursuant to Item 12 and related to the issuance of a press release announcing the results for the Company's third quarter ended June 30, 2003.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SURMODICS, INC. ("Registrant")

Dated: December 15, 2003 By: /s/ Dale R. Olseth

Dale R. Olseth

Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant, in the capacities, and on the dates indicated.

(Power of Attorney)

Each person whose signature appears below constitutes and appoints DALE R. OLSETH and PHILIP D. ANKENY as his true and lawful attorneys-in-fact and agents, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Signature	Title	Date
/s/ Dale R. Olseth	Chairman, Chief Executive Officer and Director (principal executive officer)	December 15, 2003
Dale R. Olseth	(F)	
/s/ Philip D. Ankeny	Vice President and Chief Financial Officer (principal financial officer)	December 15, 2003
Philip D. Ankeny	mancial officer)	
/s/ Loren R. Miller	Vice President and Controller (principal accounting officer)	December 15, 2003
Loren R. Miller	officer)	
/s/ Jose H. Bedoya	Director	December 12, 2003
Jose H. Bedoya		
/s/ John W. Benson	Director	December 15, 2003
John W. Benson		
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Signature	<u> </u>	Title	Date
/s/ Gerald B. Fischer	Director		December 15, 2003
Gerald B. Fischer			
/s/ Patrick E. Guire	Director		December 15, 2003
Patrick E. Guire			
/s/ Kenneth H. Keller	Director		December 15, 2003
Kenneth H. Keller			
/s/ David A. Koch	Director		December 15, 2003
David A. Koch			
/s/ Kendrick B. Melrose	Director		December 16, 2003
Kendrick B. Melrose			
/s/ John A. Meslow	Director		December 12, 2003
John A. Meslow			
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#### **Independent Auditors' Report**

SurModics, Inc. Eden Prairie, Minnesota:

We have audited the accompanying balance sheets of SurModics, Inc. (the "Company") as of September 30, 2003 and 2002 and the related statements of income, stockholders' equity, and cash flows for each of the two years in the period ended September 30, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of the Company for the year ended September 30, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated October 23, 2001.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of SurModics, Inc. as of September 30, 2003 and 2002 and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2003 in conformity with accounting principles generally accepted in the United States of America.

Deloitte & Touche LLP Minneapolis, Minnesota October 29, 2003

#### **Report of Independent Public Accountants**

This is a copy of a report previously issued by Arthur Andersen LLP. This report has not been reissued by Arthur Andersen LLP nor has Arthur Andersen LLP provided a consent to the inclusion of its report in this Annual Report.

To SurModics, Inc.:

We have audited the accompanying balance sheets of SurModics, Inc. (a Minnesota corporation) as of September 30, 2001 and 2000, and the related statements of income, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of SurModics, Inc. as of September 30, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2001 in conformity with accounting principles generally accepted in the United States.

As explained in Note 2 to the financial statements, effective October 1, 2000, the Company changed its method of accounting for revenue recognition of license fees.

Arthur Andersen LLP Minneapolis, Minnesota, October 23, 2001

SurModics, Inc. Balance Sheets As of September 30 (thousands, except share data)

	2003	2002
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 4,007	\$ 9,207
Short-term investments	2,640	3,942
Accounts receivable, net of allowance for doubtful accounts of \$40 as of September 30, 2003 and 2002	9,145	5,506
Inventories	863	746
Deferred tax asset	345	417
Prepaids and other	759	1,058
Total current assets	17,759	20,876
Property and Equipment, net	33,936	18,836
Long-Term Investments	39,164	30,726
Deferred Tax Asset	<del></del>	740
Other Assets, net	6,949	6,070
	\$97,808	\$77,248
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 1,118	\$ 877
Accrued liabilities-		
Compensation	1,635	1,332
Accrued construction-in-progress	3,683	1,922
Accrued income taxes payable	1,558	_
Other	994	645
Deferred revenue	1,039	281
Total current liabilities	10,027	5,057
Deferred Revenue, less current portion	1,640	2,196
Deferred Tax Liability	27 	
Total liabilities	11,694	7,253
Committee and Continuous in (Note C)		
Commitments and Contingencies (Note 6) 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 17,439,435 and 17,271,594 shares issued and		
outstanding	872	864
Additional paid-in capital	56,453	53,936
Unearned compensation	(466)	(460
Accumulated other comprehensive income	337	673
Retained earnings	28,918	14,982
Total stockholders' equity	86,114	69,995
ı v		
	\$97,808	\$77,248

The accompanying notes are an integral part of these balance sheets.

SurModics, Inc.
Statements of Income
For the Years Ended September 30
(thousands, except net income per share)

	2003	2002	2001
Revenue			
Royalties and license fees	25,833	\$12,493	\$12,828
Product sales	11,804	9,004	5,685
Research and development	5,595	7,991	4,180
Total revenue	43,232	29,488	22,693
perating Costs and Expenses			
Product Product	2,649	2,683	2,440
Research and development	11,790	9,714	7,997
Sales and marketing	2,224	1,568	1,698
General and administrative	5,929	4,814	2,992
General and administrative			
Total operating costs and expenses	22,592	18,779	15,127
ncome from Operations	20,640	10,709	7,566
Other Income			
Investment income	1,398	1,609	2,354
Gain on sale of investments and real property	461	79	701
Other income	1,859	1,688	3,055
ncome Before Income Taxes	22,499	12,397	10,621
ncome Tax Provision	8,563	4,601	3,807
ncome before cumulative effect of a change in accounting principle	13,936	7,796	6,814
umulative effect of a change in accounting principle, net of tax			(1,705)
Tet income	\$13,936	\$ 7,796	\$ 5,109
	_	_	
Basic net income per share before cumulative effect of a change in accounting principle	\$ .80	\$ .46	\$ .41
Cumulative effect of a change in accounting principle	_	_	(.10)
Basic net income per share	\$ .80	\$ .46	\$ .31
Saste net meome per snare			
iluted net income per share before cumulative effect of a change in accounting principle	\$ .78	\$ .44	\$ .38
Cumulative effect of a change in accounting principle			(.09)
Diluted net income per share	\$ .78	\$ .44	\$ .29
Veighted Average Shares Outstanding			
Basic	17,363	17,016	16,692
Dilutive effect of outstanding stock options	474	806	1,158
Diluted	17,837	17,822	17,850
	•	•	•

 $\label{thm:companying} \textit{ notes are an integral part of these financial statements.}$ 

# SurModics, Inc.

Statements of Stockholders' Equity
For the Years Ended September 30, 2003, 2002 and 2001 (in thousands)

	Common	Common Stock	
	Shares	Amount	Additional Paid-In Capital
Balance, September 30, 2000	16,556	\$828	\$45,740
Components of comprehensive income, net of tax:			
Net income	_	_	_
Unrealized holding gains on available-for-sale securities arising during the period	_	_	_
Less reclassification for gains included in net income, net of tax	_	_	_
Comprehensive income			
Issuance of common stock	22	1	279
Common stock options exercised, net	177	9	168
Tax benefit from exercise of stock options	_	_	1,392
Restricted stock activity	6	_	198
Net loan activity	_	_	_
Amortization of unearned compensation	_	_	_
•			
Balance, September 30, 2001	16,761	838	47,777
Components of comprehensive income, net of tax:	,		,
Net income	_	_	_
Unrealized holding gains on available-for-sale securities arising during the period	_	_	_
Less reclassification for gains included in net income, net of tax	_	_	_
Comprehensive income			
Issuance of common stock	13	1	335
Common stock options exercised, net	492	25	928
Tax benefit from exercise of stock options	_	_	4,784
Restricted stock activity	6	_	112
Amortization of unearned compensation	_	_	_
Timorazation of ancamea compensation			
Balance, September 30, 2002	17,272	864	53,936
Components of comprehensive income, net of tax:	17,272	004	33,330
Net income	<u></u>	_	<u>_</u>
Unrealized holding losses on available-for-sale securities arising during the period			
Less reclassification for gains included in net income, net of tax			
Comprehensive income			
Issuance of common stock	17	1	404
	149	7	765
Common stock options exercised, net Tax benefit from exercise of stock options	149	/	1,186
Restricted stock activity	<u> </u>	_	1,100
Amortization of unearned compensation	1	_	102
Amoruzation of unearned compensation		_	
Balance, September 30, 2003	17,439	\$872	\$56,453

	Unearned Compensation	Stock Purchase Notes Receivable	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
Balance, September 30, 2000	\$(289)	\$ (7)	\$ (46)	\$ 2,077	\$48,303
Components of comprehensive income, net of tax:	, ,	. ,	, ,		
Net income	_	_	_	5,109	5,109
Unrealized holding gains on available-for-sale securities arising					
during the period	_	_	762	_	762
Less reclassification for gains included in net income, net of tax	_	_	(441)	_	(441)
Comprehensive income					5,430
Issuance of common stock	_	_	_	_	280
Common stock options exercised, net	_	_	_	_	177
Tax benefit from exercise of stock options	_	_	_	_	1,392
Restricted stock activity	(198)	_	_	_	_
Net loan activity	_	7	_	_	7
Amortization of unearned compensation	111	_	_		111 ——
Balance, September 30, 2001	(376)	_	275	7,186	55,700
Components of comprehensive income, net of tax:  Net income	—	_		7,796	7,796
Unrealized holding gains on available-for-sale securities arising				7,730	7,750
during the period	_		511	_	511
Less reclassification for gains included in net income, net of tax	_	_	(113)	_	(113)
Comprehensive income					8,194
Issuance of common stock	_	_	_	_	336
Common stock options exercised, net	_	_	_	_	953
Tax benefit from exercise of stock options	_	_	_	_	4,784
Restricted stock activity	(218)		_	_	(106)
Amortization of unearned compensation	134	_	_	_	134
Balance, September 30, 2002	(460)		673	14,982	69,995
Components of comprehensive income, net of tax:					
Net income	_	_	_	13,936	13,936
Unrealized holding losses on available-for-sale securities arising					
during the period	_	_	(51)	_	(51)
Less reclassification for gains included in net income, net of tax Comprehensive income			(285)		(285) 13,600
Issuance of common stock	_	_	_	_	405
Common stock options exercised, net	_	_	_		772
Tax benefit from exercise of stock options	_	_	_	_	1,186
Restricted stock activity	(162)	_			
Amortization of unearned compensation	156	_	_	_	156
D. L. C. (1. 20. 2002)	#(ACC)	<u> </u>	ф ээ <del>г</del>	#20.040	фос 44.4
Balance, September 30, 2003	\$(466)	\$—	\$ 337	\$28,918	\$86,114

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

# SurModics, Inc.

Statements of Cash Flows For the Years Ended September 30 (in thousands)

	2003	2002	2001
Operating Activities			
Net income	\$ 13,936	\$ 7,796	\$ 5,109
Adjustments to reconcile net income to net cash provided by operating activities-	,	, ,	, -,
Depreciation and amortization	2,583	1,867	1,547
Gain on sale of investments and real property	(461)	(79)	(701)
Amortization of unearned compensation	156	134	111
Tax benefit from exercise of stock options	1,186	4,784	1,392
Deferred tax	839	(214)	(31)
Cumulative effect of a change in accounting principle, net of tax	_		1,705
Change in operating assets and liabilities:			,
Accounts receivable	(3,639)	(2,261)	(1,839)
Inventories	(117)	(22)	(224)
Accounts payable and accrued liabilities	2,654	2,907	(94)
Income taxes	2,043	(842)	
Deferred revenue	202	(181)	470
Prepaids and other	(124)	424	366
•			
Net cash provided by operating activities	19,258	14,313	7,811
recease provided by operating activities			
nvesting Activities			
Purchases of property and equipment	(17,660)	(13,004)	(2,053)
Purchases of available-for-sale investments	(74,300)	(39,513)	(81,907)
Sales/maturities of available-for-sale investments	67,289	40,683	85,708
Purchase of equity in Novocell, Inc. and other	(935)	(4,000)	03,700
Proceeds from sale of real property	(333)	500	
Purchase of real property	_	300	(2,489)
Repayment of notes receivable		1	(2,409)
Repayment of notes receivable	(30)	1	/
AT 1 THE RESERVE OF THE STATE O	(05.000)	(45.000)	(50.4)
Net cash used in investing activities	(25,636)	(15,333)	(734)
Financing Activities			
Issuance of common stock	1,178	1,183	457
Net cash provided by financing activities	1,178	1,183	457
Net increase (decrease) in cash and cash equivalents	(5,200)	163	7,534
Cash and Cash Equivalents			
Beginning of year	9,207	9,044	1,510
End of year	\$ 4,007	\$ 9,207	\$ 9,044
Supplemental Information			
Cash paid for taxes	\$ 4,327	\$ 1,075	\$ 1,232
Noncash transaction-Note receivable from sale of real property	Ψ 4,04/	\$ 1,900	Ψ 1,232

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

#### SurModics, Inc.

Notes to Financial Statements September 30, 2003 and 2002

#### 1. Description

SurModics, Inc. ("the Company") develops, manufactures and markets innovative surface modification solutions to the medical device industry. The Company's revenue is derived from the following: fees from licensing its patented technology to customers and royalties received from licensees; the sale of reagent chemicals to licensees, stabilization products to the diagnostic industry and coated glass slides to the genomics market; and research and development fees generated on projects for commercial customers and government grants. The Company markets its products through a direct sales force primarily in the United States and certain international markets.

#### 2. Summary of Significant Accounting Policies

#### Cash and Cash Equivalents

Cash and cash equivalents consist principally of money market instruments with original maturities of three months or less and are stated at cost which approximates fair value.

#### **Investments**

Investments consist principally of mortgage-backed securities and U.S. government and government agency obligations and are classified as available-for-sale as of September 30, 2003 and 2002. Available-for-sale investments are reported at fair value with unrealized gains and losses excluded from operations and reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations and result in a new cost basis for the investment.

The original cost, unrealized holding gains and losses, and fair value of investments as of September 30 were as follows (in thousands):

	2003			
Original Cost	Unrealized Gains	Unrealized Losses	Fair Value	
\$18,298	\$145	\$(41)	\$18,402	
9,759	280	(27)	10,012	
6,427	13	(10)	6,430	
5,839	179	(7)	6,011	
937	12	_	949	
\$41,260	\$629	\$(85)	\$41,804	
	_	_		
	\$18,298 9,759 6,427 5,839 937	Original Cost         Unrealized Gains           \$18,298         \$145           9,759         280           6,427         13           5,839         179           937         12	Original Cost         Unrealized Gains         Unrealized Losses           \$18,298         \$145         \$(41)           9,759         280         (27)           6,427         13         (10)           5,839         179         (7)           937         12         —	

)	n	n	7
2	υ	u	4

	Original Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government obligations	\$11,260	\$ 471	\$ <i>—</i>	\$11,731
Mortgage-backed securities	10,913	228	(4)	11,137
Municipal bonds	5,036	254	_	5,290
Asset-backed securities	3,766	95	(7)	3,854
Corporate bonds	2,645	11		2,656
			_	
Total	\$33,620	\$1,059	\$(11)	\$34,668

The original cost and fair value of investments by contractual maturity at September 30, 2003, were as follows (in thousands):

	Original Cost	Fair Value
Debt securities due within:		
One year	\$ 2,621	\$ 2,640
One to five years	22,484	22,960
Five years or more	16,155	16,204
m - 1	ф.44. DCO	ф.44.004
Total	\$41,260	\$41,804

The following table summarizes sales of available-for-sale securities for the years ended September 30, 2003, 2002, and 2001(in thousands):

	2003	2002	2001
Proceeds from sales	\$53,634	\$33,227	\$77,131
Gross realized gains	\$ 506	\$ 194	\$ 705
Gross realized losses	\$ (45)	\$ (14)	\$ (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 as of September 30 (in thousands):

	2003	2002
Raw materials	\$413	\$408
Finished products	450	338
Total	\$863	\$746

#### **Property and Equipment**

Property and equipment are stated at cost and are depreciated using the straight-line method over 3 to 20 years, the estimated useful lives of the assets. The September 30, 2002 balance in construction-in-progress included the cost to purchase the Bloomington site and the costs-to-date to remodel a portion of the exiting structure. The balance on September 30, 2003 includes the cost to construct a reagent

manufacturing facility. When placed in service, construction-in-progress is transferred to the specific property and equipment categories and depreciated over the estimated useful lives of the assets. The Company recorded depreciation expense of approximately \$2.6 million and \$1.8 million in 2003 and 2002 respectively. Property and equipment consisted of the following components as of September 30 (in thousands):

	2003	2002	Useful life(in years)
Laboratory fixtures and equipment	\$ 8,529	\$ 6,986	3 to 5
Building and improvements	18,720	6,360	5 to 20
Office furniture and equipment	4,114	2,823	3 to 5
Construction-in-progress	13,529	11,102	
Less-accumulated depreciation and amortization	(10,956)	(8,435)	
Property and equipment, net	\$ 33,936	\$18,836	

#### Other Assets

Other assets consist principally of investments and acquired patents. In December 2001, the Company invested \$4.0 million in Novocell, Inc., a privately held Irvine, California-based biotech firm that is developing a potential cure for diabetes. On April 29, 2003, the Company invested an additional \$925,000 in Novocell. The \$4.9 million investment, which is accounted for under the cost basis, is included in other assets and represents an ownership interest of less than 15%. In June 2002, the Company sold real property for approximately \$2.4 million. The terms of the sale agreement included a \$500,000 cash down payment and a note receivable for \$1.9 million, which is collateralized by the assets. Finally, the cost of patents is amortized over 7 to 12 years. The Company recorded amortization expense of \$23,000 and \$26,000 in 2003 and 2002 respectively. The Company expects to incur approximately \$22,000 of amortization expense per year in fiscal 2004 through 2007 decreasing to \$19,000 in fiscal 2008. Other assets consisted of the following components as of September 30 *(in thousands):* 

	2003	2002
Investment in Novocell	\$4,925	\$4,000
Note receivable	1,836	1,869
Patents and other	350	339
Less-accumulated amortization	(162)	(138)
Other assets, net	\$6,949	\$6,070

#### 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, "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 years ended September 30 (in thousands, except per share data):

	2003	2002	2001
Net income			
As reported	\$13,936	\$ 7,796	\$ 5,109
Fair value compensation expense, net of tax	(1,524)	(1,183)	(1,013)
Pro forma	\$12,412	\$ 6,613	\$ 4,096
Basic net income per share:			
As reported	\$ 0.80	\$ 0.46	\$ 0.31
Fair value compensation expense, net of tax	(.09)	(.07)	(.06)
Pro forma	\$ 0.71	\$ 0.39	\$ 0.25
Diluted net income per share:			
As reported	\$ 0.78	\$ 0.44	\$ 0.29
Fair value compensation expense, net of tax	(80.)	(.07)	(.06)
Pro forma	\$ 0.70	\$ 0.37	\$ 0.23

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in 2003, 2002, and 2001 respectively: risk-free interest rates of 3.05%, 3.69%, and 4.51%; expected lives of 7.4, 7.1, and 7.0; and expected volatility of 69%, 73%, and 77%. See Note 4 for a detailed description of the Company's Equity Incentive Plan.

### Impairment of Long-Lived Assets

We periodically evaluate whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of long-lived assets, such as property and equipment and the investment in Novocell, Inc. If such events or circumstances were to indicate that the carrying amount of these assets would not be recoverable, the Company would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) or other measure of fair value was less than the carrying amount of the assets, the Company would recognize an impairment loss. No such impairment losses were required to be recorded in the years ended September 30, 2003, 2002 and 2001.

#### Revenue Recognition

Royalty revenue is generated when a licensed customer sells products incorporating our technologies. Royalty revenue is recognized as the Company's licensees report it to us, and payment is typically submitted concurrently with the report. The Company recognizes initial license fees over the term of the related agreement. Effective October 1, 2000, we adopted Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements." As a result of adopting SAB 101, the Company recorded a cumulative effect of a change in accounting principle related to license fees recognized in prior years in the amount of \$1,705,000, net of tax of \$1,000,000, or \$.09 per diluted share. Revenue related to a performance

milestone is recognized upon the achievement of the milestone, as defined in the respective agreements. Revenue on sales of the Company's products is recognized when persuasive evidence of an agreement exists, delivery has occurred, the fee is fixed and determinable and collectibility is probable. Generally, these criteria are met at the time the Company's product is shipped. Revenue for research and development is recorded as performance progresses under the applicable contract.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Ultimate results could differ from those estimates.

#### Reclassifications

Certain reclassifications have been made to prior year's financial statements in order to conform to the 2003 presentation. Such reclassifications had no effect on stockholders' equity, net income, or income per share as previously reported.

#### 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 did not have an impact on the Company's financial statements.

In November 2002, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 45 (FIN 45), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 clarifies the requirements for a guarantor's accounting for and disclosure of certain issued and outstanding guarantees. The initial recognition and initial measurement provisions of FIN 45 are applicable to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements for interim or annual periods ending after December 15, 2002. There was no impact to the Company upon adoption.

In December 2002, FASB issued Statement of Financial Accounting Standards No. 148 (SFAS No. 148), "Accounting for Stock-Based Compensation-Transition and Disclosure", which amends SFAS No. 123, "Accounting for Stock-Based Compensation". SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirement of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The transition guidance and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on the Company's consolidated balance sheet or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities." This Interpretation clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to

finance its activities without additional subordinated financial support from other parties. We have reviewed the provisions of FIN 46 and have determined that it does not have an impact on our financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument with certain defined characteristics as a liability (or an asset in some circumstances). The requirements of this statement apply to an issuer's classification and measurement of freestanding financial instruments, including those that comprise more than one option or forward contract. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. We have reviewed the provision of SFAS No. 150 and have determined that it does not have an impact on our financial position and results of operations.

#### 3. Stockholders' Equity

#### 1999 Employee Stock Purchase Plan

Under the 1999 Employee Stock Purchase Plan ("Stock Purchase Plan") the Company is authorized to issue up to 200,000 shares of Common Stock. All full-time and part-time employees can choose to have up to 10% of their annual compensation withheld to purchase the Company's Common Stock at purchase prices defined within the provisions of the Stock Purchase Plan. The Company issued 17,179 and 12,548 shares under the Stock Purchase Plan during fiscal 2003 and 2002, respectively. As of September 30, 2003 and 2002, there was approximately \$251,000 and \$248,000, respectively, of employee contributions included in accrued liabilities in the accompanying balance sheets.

#### Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of Common Stock ("Restricted Stock"). The Restricted Stock will be released to the key employees if they are employed by the Company at the end of a five-year waiting period. Unearned compensation has been recognized for the estimated fair value of the applicable common shares, reflected as a reduction of stockholders' equity, and is being charged to income over the five-year term. Transactions in restricted stock were as follows:

Outstanding at September 30, 2000	95,500
Granted	5,500
Outstanding at September 30, 2001	101,000
Granted	8,000
Canceled	(2,000)
Vested	(52,000)
Outstanding at September 30, 2002	55,000
Granted	5,000
Canceled	(4,000)
Vested	(8,000)
Outstanding at September 30, 2003	48,000

#### 4. Stock-Based Compensation Plan

In fiscal 2003, the Company adopted and shareholders approved the SurModics, Inc. 2003 Equity Incentive Plan (the "2003 Plan").

The 2003 Plan replaced the 1997 Incentive Stock Option Plan, which the shareholders previously approved and the Nonqualified Stock Option Plan and Restricted Stock Plan previously adopted by the Board (collectively referred to as the "Prior Plans"). Upon shareholder approval of the 2003 Plan, no further stock options or restricted stock awards were granted under the Prior Plans, it being the Board's intention that all future options should be granted under the 2003 Plan; however, any options and restricted stock awards outstanding under the Prior Plans shall remain subject to their terms and conditions.

Under the Company's 2003 Plan, the Board or the Compensation Committee may award nonqualified or incentive stock options and restricted stock awards (collectively referred to as an "Award" or "Awards") to those officers, directors, consultants and employees (the "Participants") of the Company. The 2003 Plan called for 600,000 shares of the Company's common stock be made available for grants of Awards to Participants. If any Awards granted under the Plan expire or terminate prior to exercise or otherwise lapse, the shares subject to such portion of the Award are available for subsequent grants of Awards.

The 2003 Plan requires that the option price of Incentive Stock Options ("ISO") be at least 100% of the fair market value of the Common Stock on the date of the grant or 110% with respect to optionees who own more than 10% of the total combined voting power of all classes of stock. Generally, options expire in seven years or upon termination of employment and are exercisable at a rate of 20% per year from the date of grant or 20% per year commencing one year after the date of grant.

Nonqualified stock options issued under the 2003 Plan are granted at fair market value on the date of grant. Generally, options expire in 7 to 10 years and are exercisable at a rate of 20% per year from the date of grant or 20% per year commencing two years after the date of grant.

As of September 30, 2003, there were 470,100 additional shares available for grant under the 2003 Plan. Information regarding stock options under all plans is summarized as follows:

	2003		2002		2001	
Options	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	964,215	\$14.86	1,383,260	\$ 8.41	1,565,560	\$ 7.45
Granted	241,100	30.01	154,350	34.80	16,550	42.29
Exercised	(155,418)	6.30	(515,655)	3.07	(191,510)	3.26
Canceled	(66,932)	20.26	(57,740)	18.82	(7,340)	15.50 ——
Outstanding, end of year	982,965	\$19.57	964,215	\$14.86	1,383,260	\$ 8.41
Exercisable, end of year	505,025	\$11.61	493,933	\$ 8.41	851,190	\$ 4.80
Weighted average fair value of options granted	\$ 20.69		\$ 24.80		\$ 31.11	

Exercise Price Range	Shares Outstanding at September 30, 2003	Weighted Average Exercise Price	Weighted average Remaining Contractual Life (in years)	Shares Exercisable at September 30, 2003	Weighted Average Exercise Price
\$2.50-\$4.75	191,270	\$ 3.05	2.18	187,750	3.06
\$5.78-\$8.44	217,315	7.81	3.37	169,335	7.75
\$10.25-\$27.00	189,590	23.93	4.28	108,630	23.79
\$29.17-\$29.50	207,450	29.34	6.72	4,800	29.17
\$30.13-\$53.00	177,340	35.69	5.54	34,510	36.33
	982,965	\$19.57	4.41	505,025	\$11.61

# 5. Income Taxes

The Company utilizes the liability method to account for income taxes. Deferred taxes are based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of the enacted tax laws.

The deferred income tax provision reflects the net change during the year in deferred tax assets and liabilities. Income taxes in the accompanying statements of income for the years ended September 30 were as follows (in thousands):

	2003	2002	2001
Current provision:			
Federal	\$6,524	\$4,611	\$2,672
State and foreign	1,032	423	362
Total current provision	7,556	5,034	3,034
Deferred provision (benefit):			
Federal	981	(578)	832
State	26	145	(59)
Total deferred provision (benefit)	1,007	(433)	773
Total provision	\$8,563	\$4,601	\$3,807

The reconciliation of the difference between amounts calculated at the statutory federal tax rate and the Company's effective tax rate for the years ended September 30 was as follows (in thousands):

	2003	2002	2001
A	фп опо	# 4 DDO	#D COF
Amount at statutory federal income tax rate	\$7,870	\$4,339	\$3,605
Change due to:			
Reversal of tax valuation allowance	_	_	(161)
State taxes	676	360	201
Rate difference for deferred tax assets	_	68	_
Other	17	(166)	162
Income tax provision	\$8,563	\$4,601	\$3,807

The components of deferred income taxes consisted of the following as of September 30 and result from differences in the recognition of transactions for income tax and financial reporting purposes (in thousands):

	2003	2002
Depreciable assets	\$ (97)	\$ 604
Deferred revenue	760	916
Accruals and reserves	345	360
Restricted stock amortization	173	103
Net operating loss carryforward	_	78
R&D credit carryforward	_	118
Equity items	(207)	(375)
Other	(656)	(647)
Total deferred tax asset	318	1,157
Current deferred tax asset	345	417
Noncurrent deferred tax asset (liability)	\$ (27)	\$ 740

#### 6. Commitments and Contingencies

Under provisions contained in the government research contracts, representatives of the government agencies have the right to access and review the Company's underlying records of contract costs. The government retains the right to reject expenses considered unallowable under the terms of the contract. The Defense Contract Audit Agency has reviewed the contracts through 1989. In the opinion of management, future amounts due, if any, with respect to open contract years will not have a material impact on the financial position or results of operations of the Company.

The Company is involved from time to time in routine legal matters and other claims incidental to the business. The Company believes that the resolution of such routine matters and other incidental claims, taking into account established reserves and insurance, won't have a material adverse impact on its financial position, results of operations, or cash flows.

#### 7. Defined Contribution Plan

The Company has a 401(k) retirement and savings plan for the benefit of qualified employees. The Company matches 50% of each dollar of the first 6% of the tax deferral elected by each employee. Company contributions totaling \$204,000, \$193,000, and \$166,000 have been charged to income for the years ended September 30, 2003, 2002 and 2001, respectively.

#### 8. Operating Segments (Dollars in thousands)

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

The Company manages its business on the basis of three business segments: licensing, manufacturing, and research and development. The licensing segment includes all license fees and royalty revenue generated from the transfer of the Company's technology. No expenses are allocated to the licensing

segment. The manufacturing segment includes revenue from the sale of chemical reagents, stabilization products and DNA slides. The expenses include all production costs, including analytical costs to verify quality of the finished products and certain technical support. The research and development segment includes the revenue generated from development projects for commercial customers and research revenue received from government grants. The expenses include all costs of the Company's technical personnel. Corporate includes all administrative, sales and marketing costs of the Company. These costs, along with interest income and income taxes, are not allocated to the other business segments. The Company's assets are not reviewed by business segment. The accounting policies for segment reporting are the same as for the Company as a whole (see Note 2).

	Licensing	Manufacturing	Research & Development	Corporate	Consolidated
Year Ended September 30, 2003					
Revenues:					
Coating	\$22,881	\$ 8,946	\$ 5,208	\$ —	\$37,035
Diagnostic	2,952	· —	· —	_	2,952
Stabilization & other	, <u> </u>	2,858	_	_	2,858
Government	_	· —	387	_	387
Total revenue	25,833	11,804	5,595	_	43,232
Operating expenses		2,649	11,790	8,153	22,592
- F					
Operating income (loss)	25,833	9,155	(6,195)	(8,153)	20,640
Other income	25,055	3,133	(0,133)	1,859	1,859
Income tax provision				(8,563)	(8,563)
ncome tax provision				(0,303)	(0,505)
Net income					\$13,936
NET HICOHIE					
Year Ended September 30, 2002					
Revenues:				_	
Coating	\$10,044	\$ 6,084	\$ 7,448	\$ —	\$23,576
Diagnostic	2,449	_	_	_	2,449
Stabilization & other	_	2,920	_	_	2,920
Government	_	_	543	_	543
Total revenue	12,493	9,004	7,991	_	29,488
Operating expenses	_	2,683	9,714	6,382	18,779
Operating income (loss)	12,493	6,321	(1,723)	(6,382)	10,709
Other income				1,688	1,688
Income tax provision				(4,601)	(4,601)
•					
Year Ended September 30, 2001					
Net income					\$ 7,796
					. ,
Revenues:					
Coating	\$ 9,575	\$ 2,638	\$ 3,648	\$ —	\$15,861
	3,253	\$ 2,030	\$ 5,040	<b>J</b> —	3,253
Diagnostic	3,233	2.047	_	<del>_</del>	
Stabilization & other	_	3,047		_	3,047
Government	_	_	532	_	532
P-4-1	12.020		4 100		22.602
Total revenue	12,828	5,685	4,180	4.000	22,693
Operating expenses	_	2,440	7,997	4,690	15,127
Operating income (loss)	12,828	3,245	(3,817)	(4,690)	7,566
Other income				3,055	3,055
Income tax provision				(3,807)	(3,807)
income before cumulative effect of a					
change in accounting principle					\$ 6,814

# **Major Customers**

Revenue from customers that exceed 10% of total revenue was as follows for the years ended September 30:

	2003	2002	2001
Cordis Corporation	48%	38%	16%
Amersham plc	13%	12%	15%
Abbott Laboratories	10%	11%	19%

The revenues from each of the customers are derived from all three revenue segments. The results for Amersham plc include the business acquired from Motorola, Inc in fiscal 2002.

# Geographic Revenue

Geographic revenues were as follows for the years ended September 30:

	2003	2002	2001
Domestic	66%	80%	89%
Foreign	34%	20%	11%
	F-20		

# 9. Quarterly Financial Data

The following is a summary of the unaudited quarterly results for the years ended September 30, 2003, 2002 and 2001 (in thousands, except per share data). The results for 2001 reflect the Company's adoption of SAB 101 in the fourth quarter of 2001 (see Note 2).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Fiscal 2003				
Revenue	\$8,048	\$9,742	\$12,819	\$12,623
Income from operations	2,856	3,992	6,958	6,834
Net income	2,171	2,750	4,572	4,443
Net income per share:				
Basic	0.13	0.16	0.26	0.25
Diluted	0.12	0.15	0.26	0.25
Fiscal 2002				
Revenue	\$6,059	\$7,109	\$ 7,601	\$ 8,719
Income from operations	1,819	2,385	2,903	3,602
Net income	1,410	1,758	2,031	2,597
Net income per share:				
Basic	.08	.10	.12	.16
Diluted	.08	.10	.11	.15
Fiscal 2001				
Revenue	\$4,757	\$5,443	\$ 5,675	\$ 6,818
Income from operations	1,256	1,698	1,884	2,728
Net income (loss)	(380)	1,610	1,675	2,204
Net income (loss) per share:				
Basic	(.02)	.10	.10	.13
Diluted	(.02)	.09	.09	.12

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

# EXHIBIT INDEX TO FORM 10-K

For the Fiscal Year Ended September 30, 2003

# SURMODICS, INC.

Exhibit	
3.1	Restated Articles of Incorporation, as amended—incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarter ended December 31, 1999, SEC. File No. 0-23837.
3.2	Bylaws, as amended to date—incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarte ended December 31, 1998, SEC. File No. 0-23837.
10.1*	Company's Incentive 1987 Stock Option Plan, including specimen of Incentive Stock Option Agreement—incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
10.2*	Company's Incentive 1997 Stock Option Plan, including specimen of Incentive Stock Option Agreement—incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
10.3*	Form of Restricted Stock Agreement—incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
10.4*	Form of Non-qualified Stock Option Agreement—incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
10.5	Form of License Agreement—incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
10.6	License Agreement with Abbott Laboratories dated November 20, 1990, as amended—incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
10.7	Purchase and Sale Agreement dated March 31, 1999 between the Company and Prairie View Jack Ltd.—incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-QSB for the quarter ended March 31, 1999, SEC. File No. 0-23837.
10.8*	SurModics, Inc. Executive Income Continuation Plan—incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-QSB for the quarter ended June 30, 1999, SEC. File No. 0-23837.
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Exhibit	
10.9	Purchase Agreement dated August 15, 2001, between Seagate Technology, LLC and DRB#10, LLC (a wholly-owned subsidiary entity of the Company)—incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2001, SEC File No. 0-23837.
10.10	Series C Purchase Agreement between Novocell, Inc. and the Company dated December 10, 2001—incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2001, SEC File No. 0-23837.
10.11	Adjusted License Agreement by and between the Company and Cordis Corporation effective as of January 1, 2003—incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2002, SEC File No. 0-23837.
10.12	Reagent Supply Agreement by and between the Company and Cordis Corporation effective as of January 1, 2003—incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2002, SEC File No. 0-23837.
23.1	Consent of Deloitte & Touche LLP
23.2	Notice Regarding Consent of Arthur Andersen LLP
24	Power of Attorney (included on signature page of this Form 10-K).
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.

<sup>\*</sup>Management contract or compensatory plan or arrangement

#### INDEPENDENT AUDITORS' CONSENT

We consent to the incorporation by reference in Registration Statement Nos. 333-104258, 333-64171, 333-64173, 333-79741, and 333-54266 of SurModics, Inc. (the "Company") on Form S-8 of our report dated October 29, 2003 relating to the consolidated financial statements of the Company as of and for the years ended September 30, 2003 and 2002, appearing in this Annual Report on Form 10-K of the Company for the year ended September 30, 2003.

/s/ Deloitte & Touche LLP

Minneapolis, Minnesota December 19, 2003

#### **Notice Regarding Consent of Arthur Andersen LLP**

On July 2, 2002, SurModics, Inc. (the "Company") filed a Current Report on Form 8-K reporting that on June 28, 2002 the Company discontinued the engagement of Arthur Andersen LLP ("Andersen") as its independent auditors and engaged Deloitte & Touche LLP as new independent auditors for fiscal 2002. This Annual Report on Form 10-K, which includes the report of Andersen on the Company's consolidated balance sheets as of September 30, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended September 30, 2001, is incorporated by reference into the Company's previously filed Registration Statements on Form S-8, File Nos. 333-104258, 333-64171, 333-64173, 333-79741, and 333-54266 (collectively, the "Registration Statements").

After reasonable efforts, the Company has been unable to obtain Andersen's consent to incorporate by reference into the Registration Statements its audit report with respect to the financial statements of the Company as of September 30, 2001 and for the period then ended. Under these circumstances, Rule 437(a) under the Securities Act of 1933, as amended, permits the Company to file this Form 10-K without such consent from Andersen. The absence of such consent may limit recovery by investors on certain claims, including the inability of investors to assert claims against Andersen under Section 11 of the Securities Act of 1933, as amended, for any untrue statements of a material fact contained, or any omissions to state a material fact required to be stated, in those audited financial statements. In addition, the ability of Andersen to satisfy any claims (including claims arising from Andersen's provision of auditing and other services to the Company) may be limited as a practical matter due to Andersen ceasing operations.

# CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

- I, Dale R. Olseth, Chief Executive Officer of SurModics, Inc., certify that:
  - 1. I have reviewed this report on Form 10-K 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  - 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 15, 2003

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

# CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

- I, Philip D. Ankeny, Chief Financial Officer of SurModics, Inc., certify that:
  - 1. I have reviewed this report on Form 10-K 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  - 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 15, 2003 /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 Annual Report of SurModics, Inc. (the "Company") on Form 10-K for the year ended September 30, 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: December 15, 2003

/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 Annual Report of SurModics, Inc. (the "Company") on Form 10-K for the year ended September 30, 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: December 15, 2003

/s/ Philip D. Ankeny

Philip D. Ankeny Chief Financial Officer