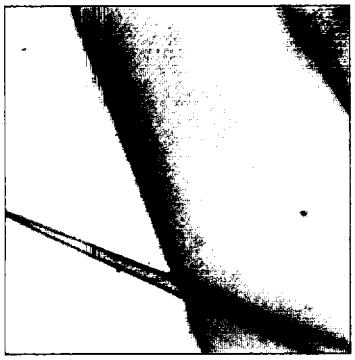
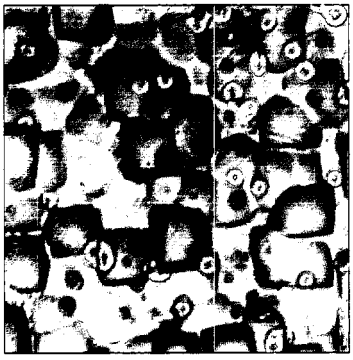
SurModics, Inc.

Bringing Innovation Together™





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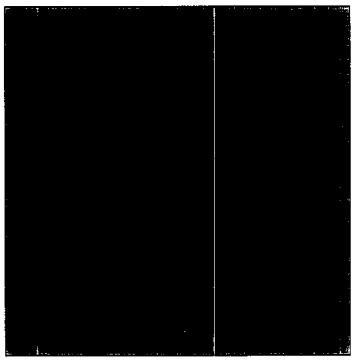
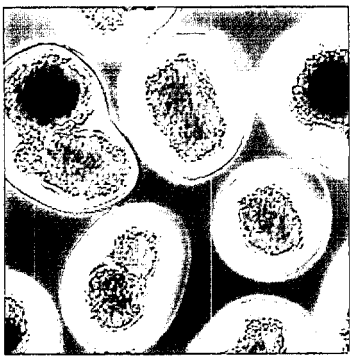
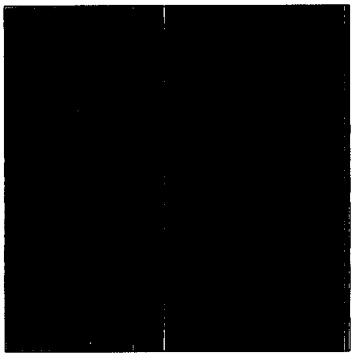


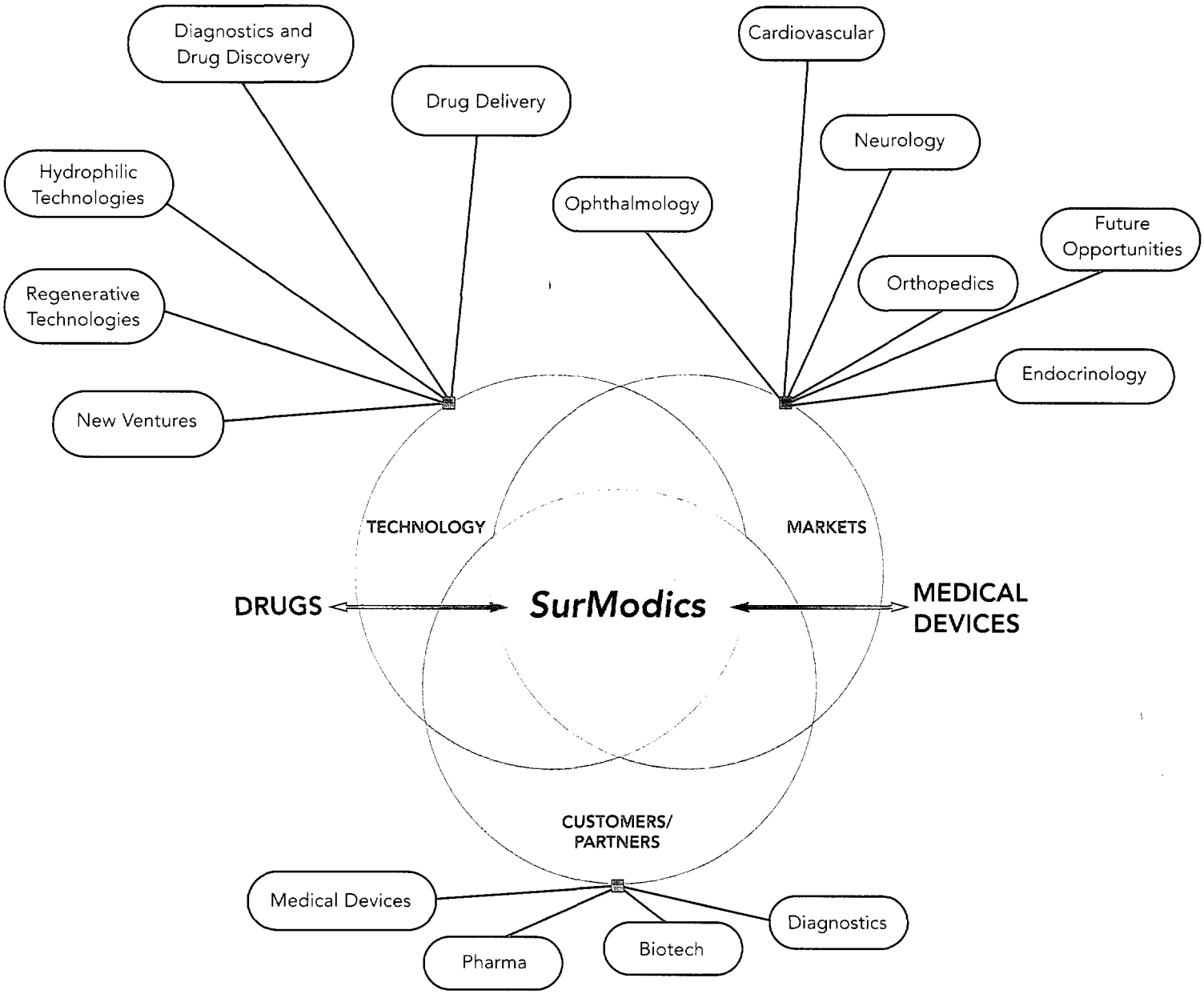




It begins with a question: Can a medical device be made invisible to the body's immune system? Can it be 90 percent more lubricious? Can it deliver a drug in the desired dosage over a precise period of time at a specific location? Questions like these drive SurModics innovation. With unparalleled experience in the science of surface modification and drug delivery, SurModics brings leading edge technology together with our customers' innovative medical devices to turn tomorrow's possibilities into today's headlines.

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 physica health problems, can offer a whole new range of benefits when combined with pharmaceuticals.

SurModics is uniquely positioned to exploit the convergence of drugs and medical devices. SurModics has a growing portfolio of relevant technologies, market expertise and insight, strong custome relationships and a collaborative R&D mentality – all key ingredients to bring innovation together and drive toward success.



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, 2004

Commission file number 0-23837

SURMODICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

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

9924 West 74th 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 March 31, 2004 was approximately $287 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 10, 2004 was 17,605,796.

DOCUMENTS INCORPORATEL BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the Registrant's 2005 Annual Meeting of Shareholders are incorporated by reference into Part III.

Table of Contents

		Page No.
	Part I	
Item 1.	Business	1
Item 2.	Properties	19
Item 3.	Legal Proceedings	20
Item 4.	Submission of Matters to a Vote of Security Holders	20
	Executive Officers	20
	Part II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	23
Item 6.	Selected Financial Data	24
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operation	24
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	32
Item 8.	Financial Statements and Supplementary Data	33
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	33
Item 9A.	Controls and Procedures	33
Item 9B.	Other Information	33
	Part III	
Item 10.	Directors and Executive Officers of the Registrant	34
Item 11.	Executive Compensation	34
Item 12.	Security Ownership of Certain Beneficial Owners and Management	34
Item 13.	Certain Relationships and Related Transactions	34
Item 14.	Principal Accounting Fees and Services	34
	Part IV	
Item 15.	Exhibits, Financial Statement Schedules	35

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 and drug delivery technologies to the medical device industry. Our technologies modify and enhance the surface characteristics of medical devices and biomedical applications, improving performance and, in some cases, enabling development of new products. 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 doing so, SurModics leverages its core technologies into high growth, high value opportunities, including drug delivery coatings, genomics and tissue engineering.

Our surface modification and drug delivery coatings are based upon versatile underlying technology platforms: our patented drug delivery matrix technology and our patented PhotoLink® coating technology. Coatings developed from our drug delivery matrix technology allow for the controlled, site specific 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, by becoming bound 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 various guidewires, angiography catheters, IVUS catheters, neuro microcatheters/infusion catheters, PTCA/PTA laser and balloon angioplasty catheters, atherectomy systems, chronic total occlusion catheters, stent delivery catheters, cardiovascular stents, embolic protection devices, vascular closure devices, EP catheters, pacemaker leads, drug infusion catheters, wound drains, ureteral stents, urological catheters and implants, hydrocephalic shunts and ophthalmic implants, among other devices.

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 exploit this new market opportunity as drugs and devices converge to create improved products and therapies.

In 2003, we extended our drug delivery coating applications beyond the cardiovascular market, where our drug delivery matrix first gained prominence, into the ophthalmology market, when we signed an agreement with InnoRx, Inc. for a novel drug delivery application. In January 2004, we announced an agreement to invest up to $3.5 million in InnoRx to support the continued development of its implantable drug delivery platform. Although commercialization of products containing InnoRx technology is not expected for at least several years, we believe the InnoRx technology and the ophthamology market hold strong promise and offer further evidence that our drug delivery technology is applicable not just in the vascular market, but across many medical specialties including ophthalmology. We are seeing heightened activity in a number of other areas as interest in SurModics' drug delivery technology continues to increase.

In June 2004, SurModics announced four new polymer families for site specific drug delivery. The Encore™ Drug Delivery Polymer Matrix and the Accolade™ Microparticle Drug Eluting System, both developed internally at SurModics, deliver a wider variety of therapeutic agents, including Rapamycin analogs, from more types of devices than previously possible. In addition, SurModics obtained an exclusive license from OctoPlus, a Dutch company, for two novel classes of biodegradable polymers: PolyActive™ and OctoDEX™. Because biodegradable polymers can deliver proteins and other large molecule therapeutic agents, they expand the breadth of drug delivery applications SurModics can pursue. Biodegradable polymers can be combined with one or more drugs and applied to a medical device, yet naturally degrade in the body over time. Combined with its existing Bravo™ polymer matrix and PhotoLink® technology, SurModics now offers six drug delivery platforms.

The Company commercializes its drug delivery and PhotoLink® coating 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 into new markets, 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.

In fiscal 2004, SurModics completed a corporate reorganization designed to accelerate its technology development and sharpen its focus on customer needs. The Company created the following five technology-centered business units:

- ***Drug Delivery***, dedicated to creating and supporting site specific drug delivery coatings and technologies for use in drug/device combination products in our chosen markets, such as drug eluting stents for the treatment of vascular disease and ophthalmic implants, among others.
- ***Hydrophilic Technologies***, which specializes in advanced lubricious coatings that can enhance the function of medical devices, facilitating and easing their placement and maneuverability in the body.
- ***Regenerative Technologies***, a business unit encompassing SurModics' work in hemocompatibility, tissue engineering and cell encapsulation technologies.
- ***Diagnostics and Drug Discovery***, which combines the Company's biosciences group (including the genomics and slide technologies licensed to GE Healthcare), stabilization business (including distribution relationships with SeraCare and Diarect) and diagnostic format intellectual property (currently licensed to Abbott Laboratories and used in strep, pregnancy and other test kits).
- ***SurModics New Ventures***, which is dedicated to identifying, researching and developing new technologies outside of research and development conducted in other business units.

Our drug delivery polymer matrix technology is the key coating technology used in the Drug Delivery business unit, and our PhotoLink® technology is the key coating technology (though not the exclusive technology) used in the Hydrophilic Technologies, Regenerative Technologies and Diagnostics and Drug Discovery business units. The most significant difference between each business unit is the varying surface properties that each unit's coatings impart to the surfaces of medical devices or biomedical applications. Multiple coatings can be combined to deliver multiple surface-enhancing characteristics on the same device or biomedical application.

We believe we have sufficient financial resources available to continue developing and growing our business. We intend to continue to invest in research and development to continue to develop new surface modification and drug delivery technologies and to expand uses for our technology bases. In

addition, we continue to pursue access to technologies developed outside the Company as appropriate to complement our internal research and development efforts.

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 improving patient outcomes and reducing 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 surface modification technology. Surface modification enables device manufacturers to develop medical devices with beneficial characteristics including improved lubricity and hemocompatability, as well as the ability to deliver drugs site-specifically 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 successes of biological products in spine therapies and drug-eluting stents in interventional cardiology have captured the attention of the pharmaceutical and medical device industries. We believe the rewards of combining drugs and biologics with implantable devices are becoming increasingly apparent.

Our Drug Delivery and PhotoLink® Coating Technologies

We believe SurModics is uniquely positioned to exploit the convergence of drugs and medical devices and the continuing trend to incorporate coating technology to create more efficient and effective medical devices and biomedical applications. SurModics has a growing portfolio of relevant technologies, market expertise and insight, strong customer relationships and a collaborative R&D mentality – all key ingredients to bring innovation together and drive toward success.

Our 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.

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. SurModics also develops coating processes and designs equipment to ensure proper coating integrity, performance and consistency.

Our drug delivery technology differs from our 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/biotechnology 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, ranging from several months to over a year, illustrating the wide range of release profiles that can be achieved with our coating system.

Surface Modification Features. The Company believes that its proprietary coating technologies provide its customers with a number of benefits. The main features that are most likely to permit broad incorporation of our coating 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 PhotoLink® 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. Our processes 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® based 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 Delivery.* We provide drug delivery polymer matrix coating technology to enable site specific delivery of therapeutic agents. In one application, our coatings address a fundamental challenge of coronary stents: restenosis, or the progressive narrowing of vessels due to tissue growth. Our proprietary polymer coating reagents and application methods do not require light activation (i.e., they are 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 releases 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, a division of Johnson & Johnson, is currently selling a SurModics coated drug-eluting stent in Europe, the U.S. and Japan. 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 up to 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 the use of 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. The Company has made an investment in Novocell, Inc., which is pursuing a treatment for diabetes by implanting encapsulated islet cells.

- *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 and enable both existing and new medical devices.

Market Segment Served	Desired Surface Property and Examples of Applications
Interventional cardiology and vascular access	*Lubricity*: catheters, guidewires *Hemocompatability*: 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 *Hemocompatability*: electrophysiology devices
Cardiothoracic surgery	*Infection resistance*: heart valves *Hemocompatability*: minimally invasive bypass devices, vascular grafts, ventricular assist devices *Cell growth and tissue integration*: heart valves, vascular grafts
Interventional neurology and neurosurgery	*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:* drug delivery implants
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 coating 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 April 8, 2004, General Electric Company acquired Amersham plc and today operates as GE Healthcare using our genomics technology.

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 our coating technologies into their own manufacturing processes so the customer can control production and quality without the need to send their products outside their facility.

The licensing process begins with the customer specifying the product surface characteristics it desires. Because each surface is unique, the Company routinely conducts a feasibility study, sometimes at no charge to the customer, to qualify each new potential product application. Once the feasibility has been completed in a manner satisfactory to the customer, the customer funds a development project to optimize the coating formulation to meet the customer's specific technical needs. At any time prior to commercialization and once the customer is satisfied with the performance of the coating, a license agreement is executed granting the licensee rights to use our technology. Our technical personnel then transfer the coating technology into the customer's manufacturing facility. The Company also manufactures and sells the chemical reagents used by all licensees in the coating process, generating another source of recurring revenue. The Company often supports its customers by providing coating assistance for parts required in animal tests 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 specified period of 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 advance 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 nonrefundable 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 agreements has traditionally been in the 2% to 3% range, but there are certain contracts with lower or higher rates. Royalty rates in certain more recent agreements have been trending higher, especially where the relevant SurModics technology is an enabling component of the customer's device (i.e., the device could not perform as desired without our technology). 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.

The Company currently has 77 licensed products (customer products coated using SurModics technology) already on the market generating royalties to the Company and 64 licensed products awaiting launch (pending regulatory approval). These 141 products are being sold or developed by 69 licensed customers. The Company signed a record 17 new licenses in fiscal 2004.

Licensed customers include Abbott Laboratories, Boston Scientific Corporation, Cordis Corporation (a Johnson & Johnson company), FoxHollow Technologies, Inc., GE Healthcare, Guidant

Corporation, Medtronic, Inc., St. Jude Medical, Inc., among others. Under most agreements, the Company is required to keep confidential the identity of its customers unless they approve such disclosure.

Revenue from Cordis Corporation represented approximately 52% of the Company's total revenue for the year ended September 30, 2004, which was the only customer that accounted for 10% or more of our total revenue in fiscal 2004. The loss of one or more of our largest 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 drug delivery and PhotoLink® coating technologies, the Company also markets stabilization products for use by manufactures of immunoassay diagnostic tests. Our StabilCoat, StabilGuard and StabilZyme Stabilizers are designed to maintain the activity of biological components of the immunoassays, and other bioanalytical techniques, resulting in longer shelf life and improved performance. 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. In fiscal 2004, the Company introduced new reagents to improve the stability and performance of protein microarrays, and bead-based assays, a rapidly growing area in the diagnostics and drug discovery.

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, pursuant to an exclusive license agreement with Abbott Laboratories. At the end of fiscal 2004, the Company expanded its agreement with Abbott by purchasing the future royalty streams under certain of Abbott's sublicenses until the expiration of SurModics patents in fiscal 2009. Prior to such expansion, the Company was receiving only a portion of the royalties under such sublicenses.

Research and Development

Our research and development personnel support the sales staff and business units 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 our technologies through internal research and development as well as evaluation of external technologies that we might access via business development activities.

SurModics works together with medical device manufacturers to integrate the best possible coatings with their devices, not only to meet their performance requirements, but also to perform services quickly so that the product may reach the market ahead of the competition. To quickly solve problems that might arise during the development process and optimization of the coating formulation and process, we have developed comprehensive capabilities in analytical chemistry and surface characterization. Our state-of-the-art instrumentation plus extensive experience allow us to test the purity of coating reagents, to monitor the elution rate of drug from coatings, to measure coating thickness and smoothness, and to map the distribution of chemicals at the surface and within the coating. The Company believes its capabilities far exceed those of its direct competitors, and sometimes even exceed those of its large-company customers.

As medical devices become more sophisticated and complex, the Company believes the need for surface modification will continue to 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. In addition, the Company intends to expand its drug delivery and surface modification technology expertise to capture more of the final product value. The Company intends to do this by, in selected cases, developing or acquiring pharmaceuticals or devices to develop from feasibility, up to and including animal and human clinical tests. There can be no assurance that the Company will be successful in developing or acquiring such pharmaceuticals or devices.

The Company's technical strategy is to target selected coating characteristics for further development, 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.

In fiscal 2004 and 2003, the Company's research and development expenses were $12.6 million and $12.0 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 $4.4 million in fiscal 2004 and $5.6 million in fiscal 2003.

Since its founding in 1979, the Company has actively participated in the federal government's Small Business Innovative Research ("SBIR") program to fund a portion of its development efforts. Since 1979, research contracts resulting in revenues of over $27 million have been awarded to SurModics, including approximately $309,000 in fiscal 2004, $390,000 in fiscal 2003 and $543,000 in fiscal 2002, primarily under the SBIR program. In fiscal 2004, we discontinued our research and development activities under SBIR grants because we do not meet certain ownership eligibility requirements of the SBIR program. We do not expect that our inability to participate in the SBIR program will materially affect the scope or amount of our research and development efforts in the future.

Patents and Proprietary Rights

The Company has taken steps intended to protect its surface modification and drug delivery technologies and its other technologies through a number of patents covering a variety of coating methods, reagents and formulations, as well as particular medical device applications. The Company generally files international patent applications in the locations matching the major markets of its customers (primarily in North America, Europe, and Japan) in parallel with its U.S. applications. Related to its surface modification technologies, the Company has 39 issued U.S. patents, 29 pending U.S. patent applications, 93 issued foreign patents, and 61 pending foreign patent applications. Within this list are 3 issued U.S. patents, 19 pending patent applications, 19 foreign issued patents, and 20 pending foreign patent applications all relating to various drug delivery matrices. In addition to the patents related to its surface modification technologies, the Company has significant intellectual property related to its diagnostic and genomics technologies. For these applications, there are 11 issued U.S. patents and 9 pending U.S. patent applications, as well as 2 issued foreign patents and 51 pending foreign patent applications. There can be no assurance that any of the pending patent applications will be allowed.

The Company also relies upon trade secrets and other 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 four sales professionals who focus on specific markets and companies. These sales professionals work in concert with business unit personnel to coordinate customer activities. Business unit general managers are also integrally involved in sales and marketing activities. The specialization of our sales professionals 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. In fiscal 2004, we signed a marketing agreement with JVS Sales & Technical Consultants, GmbH to help us pursue customer opportunities in Europe while also providing increased service and support to existing customers in the region.

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 with 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 AST, Biocompatibles International plc, Carmeda, Hydromer, Specialty Coatings Systems, and STS Biopolymers Inc., a division of 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. 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 technologies, we are also affected by competition within the markets for such devices. The Company believes that the intense competition within the medical device market 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 market 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 regulatory approval, marketing and sales efforts of its licensees or competitive pricing pressures within the particular device market. There can be no assurance that products employing 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 following regulatory approval. 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 proprietary line of activated slides for sale by GE Healthcare under the CodeLink® brand. 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. Marketed and sold as either blank slides or pre-arrayed with up to 40,000 genes, these products are a core technology of the GE Molecular Diagnostic Group.

The Company also produces stabilization products that are distributed by others in the United States and internationally. These products are sterile filtered liquids that generally employ 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 attempts to maintain 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 Practices (GMP's), we do follow quality management procedures in part to respond to requests of licensees to establish compliance with their individual criteria. In an effort to better meet our customers' needs in this area, the Company received ISO 13485:2003 and ISO 9001:2000 certification 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 as 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 three months for a 510(k) application, to two or three years or more 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, 2004, we had 140 employees, of whom 88 were engaged in technical and manufacturing positions, with the remainder in sales, marketing, quality or administrative positions. Twenty nine of our employees hold post-graduate degrees, 12 of whom hold Ph.D. 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 an 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;

- the Company's ability to increase the number of market segments and applications that use its coating technologies through its sales and marketing and research and development efforts;

- the Company's ability to facilitate through strategic investment and research and development support the creation of new medical device market segments and applications that incorporate its coating technologies;

- 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;

- the Company's ability to identify suitable businesses to acquire or with whom to form strategic relationships in order to expand its technology development and commercialization, its ability to successfully integrate the operations of companies it may acquire from time to time and its ability to create synergies from acquisitions and other strategic relationships;

- 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;

- the ability to secure raw materials for reagents the Company sells; 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 represented approximately 52% of our total revenue for the year ended September 30, 2004. 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 Cordis or other large customers, 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, 2004, 2003 and 2002, we derived approximately 70%, 57% and 40% of our revenue, respectively, from royalties and license fees. 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.

A significant portion of our revenue is derived from a relatively small number of customer products. We intend to continue pursuing a strategy of licensing our technologies to a diversified base of medical device manufacturers and other customers, 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 and drug delivery. Our technologies compete with technologies developed by AST, Biocompatibles International plc, Carmeda, Hydromer, 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, and in most cases our customer agreements provide indemnification against such claims, 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.

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, 2004, the closing sale price for our common stock ranged from $18.60 to $28.30 per share. As of December 10, 2004, the last reported sale price of our stock was $30.22 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.

Failure to identify acquisition opportunities and integrate acquired businesses into our operations successfully may limit our growth.

An important part of our growth in the future may involve the acquisition of complementary businesses or technologies. Our identification of suitable acquisition candidates involves risks inherent in assessing the technology, value, strengths, weaknesses, overall risks and profitability, if

any, of acquisition candidates. We may be unable to identify suitable acquisition candidates. If we do not make suitable acquisitions, we may find it more difficult to realize our growth objectives.

The process of integrating new businesses into our operations poses numerous risks, including:

- an inability to assimilate acquired operations, personnel, technology, information systems, and internal control systems and products;
- diversion of management's attention;
- difficulties and uncertainties in transitioning the business relationships from the acquired entity to us; and
- the loss of key employees of acquired companies.

In addition, future acquisitions by us may be dilutive to our shareholders, and cause large one-time expenses or create goodwill or other intangible assets that could result in significant asset impairment charges in the future. In addition, if we acquire entities that have not yet commercialized products but rather are developing technologies for future commercialization, our earnings per share may fluctuate as we expend significant funds for continued research and development efforts for acquired technology necessary to commercialize such technology. We cannot guarantee that we will be able to successfully complete any acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

Our revenue will be harmed if we cannot purchase sufficient reagent components we use in our manufacture of reagents.

We currently purchase some of the components we use to manufacture coating reagents from sole suppliers. If any of our sole suppliers becomes unwilling to supply components to us, incurs an interruption in its production or is otherwise unable to provide us with sufficient material to manufacture our reagents, we will experience production interruptions. If we lose our sole supplier of any particular reagent component or are otherwise unable to procure all components required for our reagent manufacturing for an extended period of time, we may lose the ability to manufacture the reagents our customers require to commercialize our coating technology. This could result in lost royalties and product sales, which would harm our financial results. Adding suppliers to our approved vendor list may require significant time and resources since we typically thoroughly review a supplier's business and operations to become comfortable with the quality and integrity of the materials we purchase for use with our technology, including reviewing a supplier's manufacturing processes and evaluating the suitability of materials and packaging procedures the supplier uses. We routinely attempt to maintain multiple suppliers of each of our significant materials, so we have alternative suppliers if necessary. However, if the number of suppliers of a material is reduced, or if we are otherwise unable to obtain our material requirements on a timely basis and on favorable terms, our operations may be harmed.

ITEM 2. PROPERTIES.

SurModics conducts its operations in two facilities located in suburban Minneapolis-St. Paul, Minnesota. In October 2001, we purchased a facility in Bloomington, Minnesota, situated on 27 acres of land. In May 1999, we purchased the land and building we currently occupy in Eden Prairie, Minnesota. The building has approximately 64,000 square feet of space. Most of the Company's operations take place at the Eden Prairie location. As part of a recent reorganization, the Company announced that after careful examination of its redefined business goals, the Company believes that the Bloomington contract manufacturing facility is not necessary for the execution of its strategic plan. Accordingly, results in the third quarter of fiscal 2004 included a non-cash asset impairment charge of $16.5 million. The Company

is seeking to sell or lease the Bloomington facility and will consolidate operations at its Eden Prairie, Minnesota headquarters. The purchases of these two properties were internally funded and remain unencumbered. The Company believes that projected capacity of the Eden Prairie facility is adequate to service the needs of its customers for the foreseeable future and is in the process of consolidating to one facility which it expects to complete in fiscal 2005,

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 2004.

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	74	Chairman and Chief Executive Officer
Bruce J Barclay	48	President and Chief Operating Officer
Philip D. Ankeny	41	Chief Financial Officer and Vice President, Business Development
Douglas P. Astry	52	General Manager, Diagnostics and Drug Discovery
Lise W. Duran, Ph.D	49	Vice President and General Manager, Regenerative Technologies
Steven J. Keough	49	Vice President and General Manager, New Ventures, and Chief Intellectual Property Counsel
Loren R. Miller	39	Vice President and Controller
Charles W. Olson	40	Vice President and General Manager, Hydrophilic Technologies
Marie J. Versen	43	Vice President, Quality, Regulatory and Facilities
David S. Wood	48	Vice President and General Manager, Drug Delivery
Gregory T. Yung	55	Vice President, Sales and Marketing

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 and became a director of the Company in July 2004. 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 25 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 with the additional responsibilities of Vice President, Business Development added in April 2004. 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.

Douglas P. Astry joined SurModics in June 2003 as Manager, Array Business, and was promoted to General Manager, Diagnostics and Drug Discovery in April 2004. Prior to joining SurModics, from 2002 to 2003, he was Vice President of Marketing and Business Development at HTS Biosystems, and from 1980 through 2001, he held various research and business management positions at 3M, most recently Business Development manager of 3M's Bioanalytical Technologies Group. Mr. Astry received his B.A. degree in Biology from Williams College, an M.S. in Physiology from the University of Connecticut, and an M.B. A. from the University of Minnesota.

Lise W. Duran, Ph.D., became Vice President and General Manager of the Regenerative Technologies business unit in April 2004. Dr. Duran 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.

Steven J. Keough joined SurModics as its Vice President and Chief Intellectual Property Counsel in January 2004 and added the duties of Vice President and General Manager of the SurModics New Ventures business unit in April of that year. Before joining SurModics, Mr. Keough practiced law at Minneapolis-based Fredrikson & Byron, P.A. from 2000-2003, where he was a senior member and past chairman of the intellectual property department. He previously served as president and co-founder of the intellectual property law firm Patterson & Keough, P.A. from 1991-2000. He was also Manager of Asia-Pacific at the Minneapolis law firm of Merchant & Gould, from 1987-1991. Mr. Keough has extensive

business and legal experience involving medical technologies, technology transfer, strategic planning, licensing and high technology business management. Mr. Keough earned a J.D. from Boston College, an M.A. from the Catholic University of America, and a Bachelor of Science degree from the United States Naval Academy.

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.

Charles W. Olson joined the Company in 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. Prior to joining SurModics, Mr. Olson was employed as General Manager at Minnesota Extrusion from 1998 to 2001 and at Lake Region Manufacturing in project management and technical sales from 1993 to 1998. Mr. Olson received a BS degree in Marketing from Winona State University in 1987.

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.

David S. Wood joined the Company as its Vice President and General Manager of the Drug Delivery business unit in November 2004. Prior to joining SurModics, he was a Director of Product Development at Guidant Corporation's Cardiac Rhythm Management Division from 1994 to 2004. Prior to Guidant's formation in 1994 as a spin off from Eli Lilly and Company, Mr. Wood held several management positions between 1989 and 1994 in marketing and product development at Lilly's Cardiac Pacemakers, Inc. subsidiary. Mr. Wood joined Eli Lilly and Company in 1978 as a Chemical Engineer. Between 1978 and 1980 and again from 1982 to 1989 he served in a variety of engineering, financial and medical device business development positions at Lilly. Mr. Wood received his undergraduate degree in Chemical Engineering from Vanderbilt University in 1978 and an M.B.A. from The Wharton School at the University of Pennsylvania in 1981.

Gregory T. Yung joined SurModics in 2000 as Director of Sales and Market Development, was named Vice President, Sales and Business Development in 2002 and Vice President, Sales and Marketing in April 2004. 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, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

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, 2004	24.94	21.32
June 30, 2004	25.20	19.00
March 31, 2004	24.08	18.60
December 31, 2003	28.30	20.10
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

Our transfer agent is:

American Stock Transfer & Trust Company
59 Maiden Lane, Plaza Level
New York, New York 10038
(800) 937-5449

According to the records of our transfer agent, as of November 16, 2004, there were 268 holders of record of our Common Stock and approximately 9,800 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, and made no repurchases of our equity securities, during the quarter ended September 30, 2004.

ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of and for the years ended September 30, 2004, 2003, and 2002 are derived from our audited financial statements included elsewhere in this report. The financial data as of and for the years ended September 31, 2001 and 2000 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)	2004	2003	2002	2001	2000
Income Statement Data:					
Total revenue	$49,738	$43,232	$29,488	$22,693	$18,279
Operating income	10,474	20,640	10,709	7,566	5,333
Net income	7,436	13,936	7,796	5,109	4,240
Diluted net income per share	.42	.78	.44	.29	.25
Pro forma amounts assuming the accounting change* was applied retroactively:					
Net income	7,436	13,936	7,796	6,814	3,669
Diluted net income per share	.42	.78	.44	.38	.22
Balance Sheet Data:					
Cash and short-term investments	$19,215	$6,647	$13,149	$14,840	$17,357
Total assets	109,781	97,808	77,248	60,583	50,749
Retained earnings (accumulated deficit)	36,354	28,918	14,982	7,186	2,077
Total stockholders' equity	94,504	86,114	69,995	55,700	48,303
Pro forma amounts assuming the accounting change* was applied retroactively:					
Retained earnings (accumulated deficit)	36,354	28,918	14,982	7,186	372
Total stockholders' equity	94,504	86,114	69,995	55,700	46,598

* 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

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

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

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

Critical Accounting Policies

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. 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. 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. On June 23, 2004, the Company announced that it expected to record an asset impairment charge against its Bloomington, Minnesota contract manufacturing facility. Results in the third quarter of fiscal 2004 include a non-cash asset impairment charge of $16.5 million. The Company engaged several commercial real estate brokerage firms to assess the market valuation of similar types of commercial property. Management determined the fair value using this real estate market data. The Company is seeking to sell or lease the Bloomington facility and will consolidate operations of all business units at its Eden Prairie, Minnesota headquarters.

Investments. Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities. The Company's policy calls for no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. Investments are classified as available-for-sale, that is, 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, 2004 and 2003

(Dollars in thousands)	Fiscal 2004	Fiscal 2003	Increase (Decrease)	% Increase (Decrease)
Revenue:				
Drug Delivery	$25,690	$20,168	$5,522	27%
Hydrophilic and Other	15,527	12,380	3,147	25%
Diagnostics	8,521	10,684	(2,163)	(20%)
Total revenue	$49,738	$43,232	$6,506	15%

Revenue. Fiscal 2004 revenue was $49.7 million, an increase of 15% over fiscal 2003. The growth in total revenue was attributable to growth in our Drug Delivery and Hydrophilic and Other segments as detailed in the table above. We provide a narrative of revenue for each of our three operating segments in the paragraphs that follow.

Drug Delivery. Drug Delivery revenue increased 27% to $25.7 million in fiscal 2004. Drug Delivery derives a substantial majority of its revenue from all three primary sources (royalties and license fees, product sales and research and development fees) from Cordis Corporation (a Johnson & Johnson company) on its Cypher stent. The Cypher stent incorporates a proprietary SurModics coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. Fiscal 2004 Drug Delivery revenue growth was attributable to a significant increase in royalties and license fees compared with the prior year. Cordis' Cypher stent received U.S. FDA approval in April 2003 (our prior year third fiscal quarter). Accordingly, 2004 results reflect a full year of Cypher sales in the United States, whereas fiscal 2003 results include U.S. sales of Cypher for slightly less than 6 months. This increase in royalties and license fees more than offset a significant reduction in research and

development revenue and a decrease in sales of reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices). Research and development revenue decreased in 2004 principally as a result of the lower level of clinical coating work following FDA approval of Cypher. We continue to provide development services to Cordis and other drug delivery customers, but on a smaller scale than that provided to Cordis in 2003. Although Cordis purchased a substantial majority of reagents sold in fiscal 2004, reagent chemical sales to Cordis decreased in 2004 as both volume and unit prices decreased. In fiscal 2005, we expect a significant decrease in reagent chemical sales to Cordis as a result of a contractual reduction in reagent pricing and as Cordis continues to become more efficient in its manufacturing, and possibly lower Cypher sales as a result of Boston Scientific Corporation having its Taxus drug-eluting stent available for sale in the U.S. for our full 2005 fiscal year as opposed to only a portion of our 2004 fiscal year.

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

Cordis' Cypher stent was approved for sale in Japan in fiscal 2004, and was launched in our fourth fiscal quarter. Increased reimbursement for Japanese Cypher sales went into effect in October 2004 (our fiscal 2005). Cypher is expected to be the sole drug-eluting stent available for sale in Japan until the second half of calendar 2006 (based on public disclosure by Boston Scientific that approval for sale of Taxus stent in Japan is not expected until such time).

There is currently pending litigation involving Boston Scientific Scimed, Inc. and Cordis in U.S. District Court for the District of Delaware in which each alleges its patent rights are being infringed by the other's drug-eluting stent, and each has been denied the preliminary injunction it has requested against the other. The companies are scheduled for trial in June 2005.

Hydrophilic and Other. In fiscal 2004, overall Hydrophilic and Other revenue increased 25% to $15.5 million, with growth contributed from all three primary revenue sources. Royalties and license fees increased modestly compared with fiscal 2003. While a significant percentage of revenue in Drug Delivery is attributable to Cordis, in Hydrophilic and Other there are several dozen licensees and even more coated products generating royalties. Sales of reagent chemicals for Hydrophilic and Other increased substantially from fiscal 2003. Management expects continued growth in Hydrophilic and Other but growth in fiscal 2005 is unlikely to be as strong as it was in 2004.

Diagnostics. Diagnostics derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories. Overall fiscal 2004 revenue decreased about 20% to $8.5 million with nearly all of the decrease caused by lower royalties from GE Healthcare stemming from scheduled contractual royalty decreases. In addition, fiscal 2003 results include a $500,000 payment related to the achievement of a technical milestone while 2004 results include a similar milestone payment of $250,000. Historical growth in Diagnostics may not be indicative of future results in light of discussions concerning possible renegotiation of certain agreements. Offsetting this uncertainty is an expected increase in royalty revenue resulting from the Company's purchase at the end of fiscal 2004 of the future royalty stream under certain sublicenses for which the Company previously has been receiving only a portion of the sublicense royalties.

Product costs. The Company's product costs were $3.0 million for fiscal 2004, an increase of 15%, from the $2.6 million recorded in fiscal 2003. Overall product margins averaged 71%, a decrease from the 78% margins in fiscal 2003. Higher cost non-Cordis reagents made up a higher percentage of total product sales in fiscal 2004. Management continues to expect downward pressure on margins in fiscal 2005 resulting from the SeraCare stabilization product distribution agreement signed in the second quarter of fiscal 2004 and a contractual reduction in reagent prices for Cordis.

Research and development expense. Research and development expense for fiscal 2004 was $12.6 million, an increase of $633,000, or 5%, compared with the same period in fiscal 2003. Management believes research and development expense will increase modestly in 2005 as the Company makes increased investments in research and development and resulting from the amortization cost associated with the recently purchased sublicense royalty stream discussed above in *Diagnostics*. Some of this increased spending will be partially offset by lower depreciation expense on the Bloomington facility.

Sales and marketing expense. Sales and marketing expense was $1.7 million for fiscal 2004, a decrease of $331,000, or 16%, from fiscal 2003. A substantial portion of the decrease resulted from lower payroll costs related to a reduction in senior marketing personnel in connection with a company-wide reorganization. Management anticipates increased sales and marketing expense in fiscal 2005 as the Company expands the size of its sales force.

General and administrative expense. General and administrative expense was $5.4 million for fiscal 2004, a decrease of $513,000, or 9%, compared with fiscal 2003. The decrease reflects efficiencies gained in the reorganization as well as lower legal costs. Management anticipates general and administrative expense will increase modestly in fiscal 2005.

Asset impairment charge. Results in fiscal 2004 included a non-cash asset impairment charge of $16.5 million against our Bloomington, Minnesota contract manufacturing facility. In order to determine the fair value of the facility, the Company engaged several commercial real estate brokerage firms to assess the market valuation of similar types of commercial property among other data and factors. The Company is seeking to sell or lease the Bloomington facility and plans to consolidate operations at its Eden Prairie, Minnesota headquarters.

Other income, net. The Company's other income was $1.4 million for fiscal 2004, a decrease of $487,000, or 26%, from fiscal 2003. Investment income decreased as a result of lower investment yields and the early payoff of a $1.9 million note receivable. In addition, much of the decrease reflects lower capital gains generated from our investment portfolio. In fiscal 2003, the Company's investment advisor sold and reinvested a portion of the Company's bond portfolio generating gains of $461,000. Results in fiscal 2004 reflect approximately $187,000 in gains from such sales.

Income tax expense. The Company's income tax provision was $4.4 million in fiscal year 2004 compared to $8.6 million in fiscal 2003. The effective tax rate was 37.2% in fiscal 2004, a decrease from 38% in fiscal 2003.

(Dollars in thousands)	Fiscal 2003	Fiscal 2002	Increase (Decrease)	% Increase (Decrease)
Revenue:				
Drug Delivery	$20,168	$10,871	$9,297	86%
Hydrophilic and Other	12,380	10,804	1,576	15%
Diagnostics	10,684	7,813	2,871	37%
Total revenue	$43,232	$29,488	$13,744	47%

Revenue. The Company's total revenue was $43.2 million in fiscal 2003, an increase of 47% over fiscal 2002. The majority of the overall growth came from our Drug Delivery segment as detailed in the table above. We provide a narrative of revenue for each of our three operating segments in the paragraphs that follow.

Drug Delivery. In fiscal 2003, Drug Delivery revenue increased 86% to $20.2 million. Substantially all of this total revenue increase in fiscal 2003 reflects the growth in royalties and license fees resulting primarily from the royalty obligations of Cordis on its Cypher stent. In April 2003 (the third quarter of our 2003 fiscal year), Cordis received U.S. Food and Drug Administration (FDA) approval to begin marketing its Cypher stent in the U.S. Sales of reagent chemicals increased significantly as a result of increased demand by Cordis in support of their Cypher stent manufacturing. The third source of Drug Delivery revenue, research and development fees, decreased principally reflecting the lower level of clinical coating work following FDA approval of Cypher.

Hydrophilic and Other. Overall revenue for this segment increased 15% to $12.4 million in fiscal 2003. The increase includes a royalty back-payment of $1.1 million on product sales by a single licensee recorded in 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.

Diagnostics. Overall revenue for this segment increased 37% to $10.7 million in fiscal 2003. All three revenue sources contributed to the growth, which included an increase in minimum royalties from Amersham plc (now GE Healthcare) on its coated glass slide and a $500,000 milestone payment from Amersham plc for a product that it introduced to the market during the third quarter of 2003.

Product costs. The Company's product costs were $2.6 million for fiscal 2003, a 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.

Research and development expense. Research and development expense for fiscal 2003 was $12.0 million, an increase of $2.3 million, or 24%, compared with the same period in fiscal 2002. The increase primarily reflects compensation and benefits associated with technical personnel we added during fiscal 2003 and increased depreciation and facilities expenses. We moved segments of our research and development activities to a portion of the Bloomington contract manufacturing facility early in fiscal year 2003, which increased depreciation expense attributable to research and development.

Sales and marketing expense. Sales and marketing expense was $2.0 million for fiscal 2003, an increase of $446,000, or 28%, from fiscal 2002. The increase reflects higher promotional costs, increased compensation, benefits, and business travel related to marketing personnel added in fiscal 2003 and licensing costs.

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.

Liquidity and Capital Resources

As of September 30, 2004, the Company had working capital of $17.8 million and cash, cash equivalents and investments (marketable securities) totaling $63.3 million. The Company's investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are three years or less. The Company's policy requires that no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while generating an above benchmark (Lehman Brothers 1-3 Year Government Index) total rate of return. Management plans to continue to direct its investment advisor to manage the Company's investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments. The Company generated positive cash flows from operating activities of $19.5 million in fiscal 2004, $19.3 million in fiscal 2003, and $14.3 million in fiscal 2002. The increase in cash flows in fiscal 2004 primarily reflects the increased net income generated during the year, net of the asset impairment charge and the related deferred taxes.

In October 2001, the Company purchased a facility in Bloomington, Minnesota, situated on 27 acres of land. As part of a reorganization, we announced in June 2004 that after careful examination of our redefined business goals, we determined that the Bloomington contract manufacturing facility was not necessary for the execution of our strategic plan. Management believes the Company has adequate office space and manufacturing capacity in its Eden Prairie headquarters to support its business and strategic plan. Accordingly, results in the third quarter of fiscal 2004 included a non-cash asset impairment charge of $16.5 million. The Company is seeking to sell or lease the Bloomington facility and plans to consolidate operations at its Eden Prairie, Minnesota headquarters.

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

In February 2004, the Company invested $2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing unique drug delivery devices and therapies for the ophthalmology market. The Company invested an additional $0.7 million in October 2004 (our fiscal 2005) and has agreed to invest a total of $3.5 million, the remaining $0.7 million of which will be invested subject to InnoRx completing a regulatory milestone. We expect that such milestone investment will be made in December 2004. In collaboration with the Company, InnoRx is developing a patented, implantable coil to deliver therapeutic agents in the eye to treat various retinal diseases. This product utilizes SurModics' site-specific drug delivery technology. While the Company anticipates that its investment in InnoRx will help facilitate the commercialization of its technology and result in revenue for the Company in the future, there can be no

assurance that this will occur. InnoRx's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized. The Company's investment in InnoRx is accounted for under the cost method and the total $3.5 million to be invested represents an ownership interest of less than 20%.

In February 2004, the Company loaned $285,000 to Novocell, Inc., a privately-held Irvine, California-based biotech firm that is developing a unique treatment for diabetes using cell-encapsulation. In August 2004, the loan was converted into equity. To date, the Company has invested a total of $5.2 million in Novocell. Working with Novocell, the Company's researchers have created a coating that encapsulates pancreatic islet cells — the cells that produce insulin in the human body. If successful, this treatment using coated islet cells could dramatically change the treatment of diabetes. While the Company anticipates that its investment in Novocell will help facilitate the commercialization of its technology and result in revenue for the Company in the future, there can be no assurance that this will occur. Novocell's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized. The $5.2 million investment, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 5%.

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

In September 2004, we made a commitment to purchase for $7 million certain additional sublicense rights and the accompanying future royalty revenue streams under certain sublicenses through an amendment to our diagnostic format patent license with Abbott Laboratories. Prior to such amendment, we were receiving only a portion of the royalties under such sublicenses. The first $5 million installment was paid in November 2004 (our fiscal 2005). The remaining installments are reflected in Other Long-Term Liabilities in the September 30, 2004 balance sheets.

As of September 30, 2004, the Company had no debt, nor did it have any credit agreements. The Company believes that its existing capital resources will be adequate to fund its operations into the foreseeable future.

Off-Balance Sheet Arrangements

The Company did not have any material off-balance sheet arrangements at September 30, 2004 or during the year then ended.

Contractual Obligations

Presented below is a summary of contractual obligations and other minimum commercial commitments. We do not have any long-term debt or any capital or operating leases. See Notes to Financial Statements for additional information regarding the below obligations and commitments.

	Maturity by Fiscal Year						
Contractual obligations	Total	2005	2006	2007	2008	2009	Thereafter
	(in millions)						
Other long-term liabilities reflected on balance sheet under GAAP	$2.0	-	-	$1.0	$1.0	-	-
Total	$2.0	-	-	$1.0	$1.0	-	-

New Accounting Pronouncements

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on the remaining portions of EITF 03-01, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, with an effective date of June 15, 2004. EITF 03-01 provides new disclosure requirements for other-than-temporary impairments on debt and equity investments. Investors are required to disclose quantitative information about: (i) the aggregate amount of unrealized losses, and (ii) the aggregate related fair values of investments with unrealized losses, segregated into time periods during which the investment has been in an unrealized loss position of less than 12 months and greater than 12 months. In addition, investors are required to disclose the qualitative information that supports their conclusion that the impairments noted in the qualitative disclosure are not other-than temporary. The adoption of EITF Issue No. 03-01 did not have an impact on our results of operations or financial condition.

In May 2004, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. 106-2, "Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003" (FSP 106-2), which provides guidance on the accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 for employers that sponsor postretirement healthcare plans that provide prescription drug benefits. FSP 106-2 supersedes FSP 106-1 that was issued in January 2004 under the same title. FSP 106-2 is effective for the first interim period beginning after June 15, 2004. The Company does not sponsor a postretirement healthcare plan so FSP 106-2 did not have an impact on our results of operations or financial condition.

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

The Company's investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company's investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. SurModics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A one percentage point increase in interest rates would result in an approximate $910,000 decrease in the fair value of the Company's available-for-sale securities as of September 30, 2004, but no material impact on the results of operations or cash flows.

Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The balance sheets as of September 30, 2004 and 2003 and the statements of income, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2004, together with the independent auditors' report thereon and related footnotes (including selected unaudited quarterly financial data), 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.

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

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

ITEM 9B. OTHER INFORMATION.

All information required to be disclosed in a report on Form 8-K during the fourth quarter of the year covered by this Form 10-K has been reported.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information required by Item 10 relating to directors, our audit committee, the nature of changes, if any, to procedures by which our shareholders may recommend nominees for 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," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Code of Ethics and Business Conduct" that appear in the Company's definitive Proxy Statement for its 2005 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 2005 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" which appear in the Company's definitive Proxy Statement for its 2005 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 Registered Public Accounting Firm" which appears in the Company's definitive Proxy Statement for its 2005 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) 1. *Financial statements*

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

	Page (s)
Report of Independent Registered Public Accounting Firm	F-1
Balance Sheets	F-2
Statements of Income	F-3
Statements of Stockholders' Equity	F-4 – F-5
Statements of Cash Flows	F-6
Notes to Financial Statements	F-7 – F-16

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.

SIGNATURES

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

SURMODICS, INC.
("Registrant")

Dated: December 14, 2004

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 authorizes DALE R. OLSETH and PHILIP D. ANKENY, and constitutes and appoints said persons 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, authorizing said persons and 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 Dale R. Olseth	Chairman, Chief Executive Officer and Director (principal executive officer)	December 14, 2004
/s/ Philip D. Ankeny Philip D. Ankeny	Vice President and Chief Financial Officer (principal financial officer)	December 14, 2004
/s/ Loren R. Miller Loren R. Miller	Vice President and Controller (principal accounting officer)	December 14, 2004
/s/ Bruce J Barclay Bruce J Barclay	President, Chief Operating Officer and Director	December 14, 2004
/s/ Jose H. Bedoya Jose H. Bedoya	Director	December 10, 2004
/s/ John W. Benson John W. Benson	Director	December 10, 2004

Signature	Title	Date
/s/ Gerald B. Fischer Gerald B. Fischer	Director	December 10, 2004
/s/ Kenneth H. Keller Kenneth H. Keller	Director	December 13, 2004
/s/ David A. Koch David A. Koch	Director	December 10, 2004
/s/ Kendrick B. Melrose Kendrick B. Melrose	Director	December 10, 2004
/s/ John A. Meslow John A. Meslow	Director	December 10, 2004

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
SurModics, Inc.
Eden Prairie, Minnesota

We have audited the consolidated balance sheets of SurModics, Inc. (the "Company") as of September 30, 2004 and 2003 and the related statements of income, cash flows, and changes in stockholders' equity for each of the three years in the period ended September 30, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated 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 consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2004 and 2003 and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2004 in conformity with accounting principles generally accepted in the United States of America.

Deloitte & Touche LLP
Minneapolis, Minnesota
December 10, 2004

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

	2004	*2003*
ASSETS		
Current Assets		
Cash and cash equivalents	$2,709	$4,007
Short-term investments	16,506	2,640
Accounts receivable, net of allowance for doubtful accounts of $40 as of September 30, 2004 and 2003	8,130	9,145
Inventories	1,040	863
Deferred tax asset	379	345
Prepaids and other	805	759
Total current assets	29,569	17,759
Property and Equipment, net	15,738	33,936
Long-Term Investments	44,088	39,164
Deferred Tax Asset	5,579	--
Other Assets, net	14,807	6,949
	$109,781	$97,808
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$683	$1,118
Accrued liabilities-		
Compensation	894	1,635
Accrued income taxes payable	3,827	1,558
Accrued other	5,857	4,677
Deferred revenue	528	1,039
Total current liabilities	11,789	10,027
Deferred Revenue, less current portion	1,488	1,640
Deferred Tax Liability	--	27
Other Long-Term Liabilities	2,000	--
Total liabilities	15,277	11,694
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 17,536,656 and 17,439,435 shares issued and outstanding	877	872
Additional paid-in capital	57,849	56,453
Unearned compensation	(632)	(466)
Accumulated other comprehensive income	56	337
Retained earnings	36,354	28,918
Total stockholders' equity	94,504	86,114
	$109,781	$97,808

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)

	2004	2003	2002
Revenue			
Royalties and license fees	$34,836	$25,833	$12,493
Product sales	10,478	11,804	9,004
Research and development	4,424	5,595	7,991
Total revenue	49,738	43,232	29,488
Operating Costs and Expenses			
Product	3,035	2,649	2,683
Research and development	12,633	12,000	9,714
Sales and marketing	1,683	2,014	1,568
General and administrative	5,416	5,929	4,814
Asset impairment charge	16,497	---	---
Total operating costs and expenses	39,264	22,592	18,779
Income from Operations	10,474	20,640	10,709
Other Income			
Investment income	1,185	1,398	1,609
Gain on sale of investments and real property	187	461	79
Other income	1,372	1,859	1,688
Income Before Income Taxes	11,846	22,499	12,397
Income Tax Provision	4,410	8,563	4,601
Net income	$7,436	$13,936	$7,796
Basic net income per share	$.42	$.80	$.46
Diluted net income per share	$.42	$.78	$.44
Weighted Average Shares Outstanding			
Basic	17,501	17,363	17,016
Dilutive effect of outstanding stock options	299	474	806
Diluted	17,800	17,837	17,822

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

SurModics, Inc.
Statements of Stockholders' Equity
For the Years Ended September 30, 2004, 2003 and 2002
(in thousands)

	Common Stock	
	Shares	Amount
Balance, September 30, 2001	16,761	$838
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
Common stock options exercised, net	492	25
Tax benefit from exercise of stock options	-	-
Restricted stock activity	6	-
Amortization of unearned compensation	-	-
Balance, September 30, 2002	17,272	864
Components of comprehensive income, net of tax:		
Net income	-	-
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
Common stock options exercised, net	149	7
Tax benefit from exercise of stock options	-	-
Restricted stock activity	1	-
Amortization of unearned compensation	-	-
Balance, September 30, 2003	17,439	872
Components of comprehensive income, net of tax:		
Net income	-	-
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	19	1
Common stock options exercised, net	63	3
Tax benefit from exercise of stock options	-	-
Restricted stock activity	16	1
Amortization of unearned compensation	-	-
Balance, September 30, 2004	17,537	$877

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

Additional Paid-In Capital	Unearned Compensation	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
$47,777	$(376)	$275	$7,186	$55,700
-	-	-	7,796	7,796
-	-	511	-	511
-	-	(113)	-	(113)
				8,194
335	-	-	-	336
928	-	-	-	953
4,784	-	-	-	4,784
112	(218)	-	-	(106)
-	134	-	-	134
53,936	(460)	673	14,982	69,995
-	-	-	13,936	13,936
-	-	(51)	-	(51)
-	-	(285)	-	(285)
				13,600
404	-	-	-	405
765	-	-	-	772
1,186	-	-	-	1,186
162	(162)	-	-	-
-	156	-	-	156
56,453	(466)	337	28,918	86,114
-	-	-	7,436	7,436
-	-	(164)	-	(164)
-	-	(117)	-	(117)
				7,155
344	-	-	-	345
350	-	-	-	353
325	-	-	-	325
377	(378)	-	-	-
-	212	-	-	212
$57,849	$(632)	$56	$36,354	$94,504

SurModics, Inc.
Statements of Cash Flows
For the Years Ended September 30
(in thousands)

	2004	2003	2002
Operating Activities			
Net income	$7,436	$13,936	$7,796
Adjustments to reconcile net income to net cash provided by operating activities-			
Depreciation and amortization	3,125	2,583	1,867
Gain on sale of investments and real property	187	(461)	(79)
Asset impairment charge	16,497	-	-
Amortization of unearned compensation	212	156	134
Tax benefit from exercise of stock options	325	1,186	4,784
Deferred tax	(5,640)	839	(214)
Change in operating assets and liabilities:			
Accounts receivable	1,015	(3,639)	(2,261)
Inventories	(177)	(117)	(22)
Accounts payable and accrued liabilities	(5,016)	2,654	2,907
Income taxes	2,269	2,043	(842)
Deferred revenue	(663)	202	(181)
Prepaids and other	(78)	(124)	424
Net cash provided by operating activities	19,492	19,258	14,313
Investing Activities			
Purchases of property and equipment	(1,402)	(17,660)	(13,004)
Purchases of available-for-sale investments	(62,575)	(74,300)	(39,513)
Sales/maturities of available-for-sale investments	43,317	67,289	40,683
Purchase of equity in InnoRx, Inc. and Novocell	(2,633)	(935)	(4,000)
Proceeds from sale of real property	-	-	500
Purchase of license	(64)	-	-
Repayment of notes receivable	1,869	(30)	1
Net cash used in investing activities	(21,488)	(25,636)	(15,333)
Financing Activities			
Issuance of common stock	698	1,178	1,183
Net cash provided by financing activities	698	1,178	1,183
Net increase (decrease) in cash and cash equivalents	(1,298)	(5,200)	163
Cash and Cash Equivalents			
Beginning of year	4,007	9,207	9,044
End of year	$2,709	$4,007	$9,207
Supplemental Information			
Cash paid for taxes	$7,265	$4,327	$1,075
Noncash transaction-purchase Abbott Laboratories sublicense	$7,020	-	-
Noncash transaction-note receivable from sale of real property	-	-	$1,900

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

1. Description

SurModics, Inc. (the Company) develops, manufactures and markets innovative surface modification and drug delivery technologies to the medical device industry. The Company's revenue is derived from three primary sources: (1) royalties and license fees from licensing its patented surface modification technologies to customers; (2) the sale of reagent chemicals to licensees of our technologies, stabilization products to the diagnostics industry, and coated slides to the genomics market; and (3) research and development fees generated on projects for commercial customers. 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 U.S. government and government agency obligations and mortgage-backed securities and are classified as available-for-sale as of September 30, 2004 and 2003. 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)*:

	2004			
	Original Cost	*Unrealized Gains*	*Unrealized Losses*	*Fair Value*
U.S. government obligations	$28,035	$82	$(56)	$28,061
Mortgage-backed securities	15,172	95	(64)	15,203
Asset-backed securities	6,015	6	(16)	6,005
Municipal bonds	9,949	57	(31)	9,975
Corporate bonds	1,350	-	-	1,350
Total	$60,521	$240	$(167)	$60,594

	2003			
	Original Cost	*Unrealized Gains*	*Unrealized Losses*	*Fair Value*
Mortgage-backed securities	$18,298	$145	$(41)	$18,402
U.S. government obligations	9,759	280	(27)	10,012
Asset-backed securities	6,427	13	(10)	6,430
Municipal bonds	5,839	179	(7)	6,011
Corporate bonds	937	12	-	949
Total	$41,260	$629	$(85)	$41,804

The original cost and fair value of investments by contractual maturity at September 30, 2004, were as follows (*in thousands*):

	Original Cost	Fair Value
Debt securities due within:		
One year	$16,488	$16,506
One to five years	28,778	28,794
Five years or more	15,255	15,294
Total	$60,521	$60,594

The following table summarizes sales of available-for-sale securities for the years ended September 30, 2004, 2003, and 2002 (*in thousands*):

	2004	*2003*	*2002*
Proceeds from sales	$26,522	$53,634	$33,227
Gross realized gains	$187	$506	$194
Gross realized losses	$0	$(45)	$(14)

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):*

	2004	*2003*
Raw materials	$634	$413
Finished products	406	450
Total	$1,040	$863

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over 3 to 30 years, the estimated useful lives of the assets. The 2004 and 2003 balances in construction-in-progress include the cost of construction for the contract manufacturing facility at the Bloomington, Minnesota site. Once 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 $3.1 million in 2004, $2.6 million in 2003, and $1.8 million in 2002. Property and equipment consisted of the following components as of September 30 *(in thousands)*:

	2004	*2003*	*Useful life(in years)*
Laboratory fixtures and equipment	$9,954	$8,529	3 to 5
Building and improvements	16,366	18,720	5 to 30
Office furniture and equipment	3,152	4,114	3 to 5
Construction-in-progress	127	13,529	
Less-accumulated depreciation and amortization	(13,861)	(10,956)	
Property and equipment, net	$15,738	$33,936	

Other Assets

Other assets consist principally of investments and acquired patents. The cost of patents is amortized over 4 to 19 years. The Company recorded amortization expense of $22,000 and $23,000 in 2004 and 2003, respectively.

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. In April 2003, the Company invested an additional $925,000 in Novocell. On February 10, 2004, the Company loaned $285,000 to Novocell. This note was converted into Novocell equity in August 2004. The $5.2 million investment, which is accounted for under the cost basis, is included in other assets and represents an ownership interest of less than 5%.

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 was collateralized by the assets and was paid in full in October 2003.

On February 3, 2004, the Company invested $2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing unique drug delivery devices and therapies for the ophthalmology market. The Company invested an additional $0.7 million in October 2004 (the Company's fiscal year 2005) and has agreed to invest a total of $3.5 million, the remaining $0.7 million of which will be invested subject to InnoRx completing a regulatory milestone. It is expected that such milestone investment will be made in December 2004. The Company's investment in InnoRx is accounted for under the cost method and the total $3.5 million to be invested represents an ownership interest of less than 20%.

On September 30, 2004, the Company amended its license agreement with Abbott Laboratories. Pursuant to such amendment, the Company acquired the future royalty streams under certain sublicenses under such license agreement. Prior to such amendment, the Company was receiving only a portion of the royalties under such sublicenses. The terms of such amendment include a $5.0 million cash payment by the Company in November 2004 and two $1.0 million cash payments by it in 2007 and 2008. The $7.0 million cost of the license is recorded in other assets as of September 30, 2004. The two $1.0 million future cash payments are recorded in other long-term liabilities as of September 30, 2004. The cost will be amortized over the approximate four year life of the agreement.

The Company expects to incur approximately $1.7 million of amortization expense in fiscal 2005 through 2008 and $425,000 in fiscal 2009 related to all of its licenses and patents. Other assets consisted of the following components as of September 30 *(in thousands)*:

	2004	2003
Investment in Novocell	$5,210	$4,925
Investment in InnoRx	2,162	--
Abbott license	7,020	--
Patents and other	599	350
Note receivable	--	1,836
Less-accumulated amortization	(184)	(162)
Other assets, net	$14,807	$6,949

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)*:

	2004	2003	2002
Net income			
As reported	$7,436	$13,936	$7,796
Fair value compensation expense, net of tax	(2,062)	(1,524)	(1,183)
Pro forma	$5,374	$12,412	$6,613
Basic net income per share:			
As reported	$0.42	$0.80	$0.46
Fair value compensation expense, net of tax	(.11)	(.09)	(.07)
Pro forma	$0.31	$0.71	$0.39
Diluted net income per share:			
As reported	$0.42	$0.78	$0.44
Fair value compensation expense, net of tax	(.12)	(.08)	(.07)
Pro forma	$0.30	$0.70	$0.37

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 2004, 2003, and 2002 respectively: risk-free interest rates of 3.56%, 3.05%, and 3.69%; expected lives of 7.4, 7.4, and 7.1; and expected volatility of 66%, 69%, and 73%. See Note 4 for a detailed description of the Company's 2003 Equity Incentive Plan.

Impairment of Long-Lived Assets

The Company periodically evaluates 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. 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. On June 23, 2004, the Company announced in a press release that it would record an asset impairment charge against its Bloomington, Minnesota contract manufacturing facility. Fiscal 2004 results include a non-cash asset impairment charge of $16.5 million. The Company is seeking to sell or

lease the Bloomington facility and plans to consolidate operations at its Eden Prairie, Minnesota headquarters. No such impairment losses were required to be recorded in the years ended September 30, 2003 and 2002.

Revenue Recognition

Royalty revenue is generated when a licensed customer sells products incorporating the Company's technologies. Royalty revenue is recognized as the Company's licensees report it to the Company, and payment is typically submitted concurrently with the report. The Company recognizes initial license fees over the term of the related agreement. 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.

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 2004 presentation. Such reclassifications had no effect on stockholders' equity, net income, or income per share as previously reported.

New Accounting Pronouncements

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on the remaining portions of EITF 03-01, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, with an effective date of June 15, 2004. EITF 03-01 provides new disclosure requirements for other-than-temporary impairments on debt and equity investments. Investors are required to disclose quantitative information about: (i) the aggregate amount of unrealized losses, and (ii) the aggregate related fair values of investments with unrealized losses, segregated into time periods during which the investment has been in an unrealized loss position of less than 12 months and greater than 12 months. In addition, investors are required to disclose the qualitative information that supports their conclusion that the impairments noted in the qualitative disclosure are not other-than temporary. The adoption of EITF Issue No. 03-01 did not have an impact on our results of operations or financial condition.

In May 2004, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. 106-2, "Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement and Modernization Act of 2003" (FSP 106-2), which provides guidance on the accounting for the effects of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 for employers that sponsor postretirement healthcare plans that provide prescription drug benefits. FSP 106-2 supersedes FSP 106-1 that was issued in January 2004 under the same title. FSP 106-2 is effective for the first interim period beginning after June 15, 2004. The Company does not sponsor a postretirement healthcare plan so FSP 106-2 did not have an impact on our results of operations or financial condition.

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 19,169 and 17,179 shares under the Stock Purchase Plan during fiscal 2004 and 2003, respectively. As of September 30, 2004 and 2003, there was approximately $255,000 and $251,000, 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, 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
Granted	20,000
Canceled	(4,000)
Vested	(22,500)
Outstanding at September 30, 2004	41,500

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. 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. 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, 2004, there were 141,580 additional shares available for grant under the 2003 Plan. Information regarding stock options under all plans is summarized as follows:

	2004		*2003*		*2002*	
Options	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	982,965	$19.57	964,215	$14.86	1,383,260	$8.41
Granted	352,700	21.54	241,100	30.01	154,350	34.80
Exercised	(62,052)	5.69	(155,418)	6.30	(515,655)	3.07
Canceled	(126,050)	26.90	(66,932)	20.26	(57,740)	18.82
Outstanding, end of year	1,147,563	$20.12	982,965	$19.57	964,215	$14.86
Exercisable, end of year	568,367	$14.52	505,025	$11.61	493,933	$8.41
Weighted average fair value of options granted	$14.57		$20.69		$24.80	

Exercise Price Range	Shares Outstanding at September 30, 2004	Weighted Average Exercise Price	Weighted average Remaining Contractual Life (in years)	Shares Exercisable at September 30, 2004	Weighted Average Exercise Price
$2.50-$3.88	158,458	$ 2.97	1.28	158,458	$ 2.97
$4.75-$8.44	180,055	7.76	2.45	179,395	7.75
$10.25-$21.82	346,720	21.18	6.68	27,800	17.67
$22.46-$25.09	140,600	25.00	3.33	103,224	25.09
$27.00-$29.50	174,990	29.33	5.78	40,420	29.30
$30.13-$53.00	146,740	35.64	4.57	59,070	36.00
	1,147,563	$20.12	4.45	568,367	$14.52

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)*:

	2004	*2003*	*2002*
Current provision:			
Federal	$8,697	$6,524	$4,611
State and foreign	1,179	1,032	423
Total current provision	9,876	7,556	5,034
Deferred provision (benefit):			
Federal	(4,827)	981	(578)
State	(639)	26	145
Total deferred provision (benefit)	(5,466)	1,007	(433)
Total provision	$4,410	$8,563	$4,601

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

	2004	*2003*	*2002*
Amount at statutory federal income tax rate	$4,146	$7,870	$4,339
Change due to:			
State taxes	351	676	360
Rate difference for deferred tax assets	-	-	68
Other	(87)	17	(166)
Income tax provision	$4,410	$8,563	$4,601

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)*:

	2004	*2003*
Depreciable assets	$4,851	$(97)
Deferred revenue	625	760
Accruals and reserves	379	345
Restricted stock amortization	149	173
Equity items	(33)	(207)
Other	(13)	(656)
Total deferred tax asset	5,958	318
Current deferred tax asset	379	345
Noncurrent deferred tax asset (liability)	$5,579	$(27)

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.

On September 30, 2004, the Company amended its license agreement with Abbott Laboratories. See "Other Assets" under Note 2. In addition to the $5.0 million paid by the Company in November 2004 for such amendment, the amendment calls for a $1.0 million payment in June 2007 and a $1.0 million payment in June 2008. The $2.0 million obligation of the Company is included in "Other Long-Term Liabilities" as of September 30, 2004.

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 $210,000, $204,000, and $193,000 have been charged to income for the years ended September 30, 2004, 2003, and 2002.

8. *Operating Segments*

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

At the end of the second fiscal quarter, the Company announced a corporate reorganization intended to sharpen its focus on customer needs and accelerate its technology leadership. The Company is now organized into five technology-centered business units. In addition, management created a new business development function to support the Company's increasing interest in evaluating and gaining rights to new technologies created outside the Company.

Effective with the reorganization, the Company currently manages its business on the basis of the operating segments noted in the table below, which are comprised of the five business units formed by the reorganization. The three operating segments are aggregated into one reportable segment. The "Drug Delivery" operating segment contains the Drug Delivery business unit. The "Hydrophilic and Other" operating segment consists of three business units: (1) Hydrophilic Technologies, (2) Regenerative Technologies and (3) SurModics New Ventures. The "Diagnostics" operating segment contains the Diagnostics and Drug Discovery business unit. Each operating segment has similar economic characteristics, technology, manufacturing processes, customers, regulatory environments, and shared infrastructures. The Company manages its expenses on a company-wide basis, as many costs and activities are shared among the business units and a majority of the Company's employees reside in shared resource units. The focus of the business units is providing solutions to customers and maximizing revenue over the long-term. The accounting policies for segment reporting are the same as for the Company as a whole (see Note 2) *(in thousands):*

	2004	*2003*	*2002*
Operating segment:			
Drug Delivery	$25,690	$20,168	$10,871
Hydrophilic and Other	15,527	12,380	10,804
Diagnostics	8,521	10,684	7,813
Total Revenue	$49,738	$43,232	$29,488

Major Customers

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

	2004	*2003*	*2002*
Cordis Corporation	52%	48%	38%
Abbott Laboratories	8%	10%	11%
GE Healthcare (formerly Amersham plc)	7%	13%	12%

The revenues from each of the customers are derived from all three primary sources. The results for GE Healthcare include the business acquired from Amersham plc in April 2004.

Geographic Revenue

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

	2004	*2003*	*2002*
Domestic	79%	66%	80%
Foreign	21%	34%	20%

9. *Quarterly Financial Data*

The following is a summary of the unaudited quarterly results for the years ended September 30, 2004, 2003 and 2002 *(in thousands, except per share data)*.

	First Quarter	*Second Quarter*	*Third Quarter*	*Fourth Quarter*
Fiscal 2004				
Revenue	$12,087	$12,738	$11,444	$13,469
Income (loss) from operations	6,287	6,678	(10,787)	8,295
Net income (loss)	4,111	4,372	(6,491)	5,443
Net income (loss) per share:				
Basic	.24	.25	(.37)	.31
Diluted	.23	.25	(.37)	.31
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	.13	.16	.26	.25
Diluted	.12	.15	.26	.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 2004 third quarter results include an impairment charge recorded against the Company's contract manufacturing facility. The $16.5 million impairment charge was included in loss from operations.

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-K

For the Fiscal Year Ended September 30, 2004

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 quarter 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* 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.

10.7 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 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.

10.11 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.

10.12* Form of officer acceptance regarding employment/compensation

23.1 Consent of Deloitte & Touche 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.

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*Management contract or compensatory plan or arrangement

Bruce J Barclay
President and
Chief Operating
Officer

Dale R. Olseth
Chairman and
Chief Executive
Officer

To Our Shareholders:

Fiscal 2004 was a year of exciting change at SurModics. In the midst of this dynamic environment, we delivered record results. We also celebrated the company's 25th anniversary. Emanating from the vision of its founders, SurModics has grown and prospered and today stands as an established and proven leader in surface modification and site specific drug delivery. We are proud of SurModics' achievements and look fondly on its early years, which set the stage for today's accomplishments and instilled a spirit of innovation, dedication and optimism that still thrives.

SurModics built on its legacy of success in 2004, attaining a number of significant milestones. The company set a high-water mark for annual revenue, signed a record number of new licenses, saw an unprecedented number of new products launched by customers and posted record earnings before a non-cash charge. For the fifth consecutive year, SurModics made *Forbes* magazine's annual listing of "The 200 Best Small Companies," this year ranking 20th – the highest in our history.

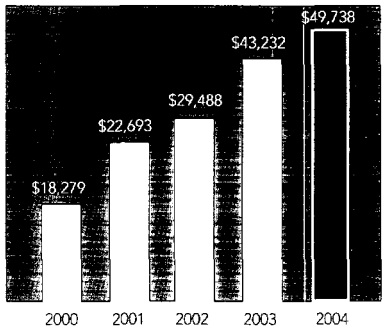
Enhancing the Business Model, Creating New Accountability

SurModics reorganized its corporate structure in 2004, a move designed to accelerate the company's technology leadership and focus more directly on customer needs. The effort organizes the company into five technology-centered business units, each led by a general manager who directs research and development, drives customer projects and coordinates initiatives with the company's operating and financial resources.

Individual business units help diversify our offerings, creating a wider range of products and technology – applicable to many different devices and treatments. Having agile business units also gives us the ability to provide customers with tailored services, a capability that most small companies don't have and most large companies can't duplicate in a timely manner.

To lead SurModics' new business units, we identified key personnel capable of motivating people, delighting customers and driving results. In November, we added the last of five business unit leaders, welcoming David Wood from Guidant Corporation; he now serves as vice president and general manager of the Drug Delivery unit. Under our improved corporate structure, Wood and other business unit leaders have dedicated resources and profit and loss responsibility; they have been given the freedom to make key decisions and pursue promising opportunities.

TOTAL REVENUE
(in thousands)



Bringing Urgency to Business Initiatives

SurModics' corporate reorganization has invigorated the company and strengthened our growth prospects by instilling a sense of urgency and excitement in individuals and teams throughout the organization. We've added a new business development group and expanded our sales presence in California, at headquarters and in Europe. One barometer of our progress: research and development revenue rose 37 percent in fiscal 2004 over the prior year.

With improved product development and service capabilities, we can serve as a powerful product development partner – helping clients all the way from concept to optimization, through clinical trials.

"With improved product development and service capabilities, we can serve as a powerful product development partner – helping clients all the way from concept to optimization, through clinical trials."

– Bruce J Barclay

Transitioning away from contract manufacturing, we are freeing personnel and financial resources to focus on our core business strengths. As part of this effort, we announced plans in 2004 to sell our RiverBluff facility in suburban Minneapolis, consolidating activities at our headquarters in Eden Prairie, Minnesota.

Delivering Results

In 2004, SurModics executed on many of the strategies laid out in last year's annual report. Bringing a strategic focus to the company's business and technology efforts, we worked diligently to generate results. The company posted three consecutive quarters of sequential growth in both R&D revenue and in revenue unrelated to Johnson & Johnson's Cordis stent, demonstrating our ability to develop new revenue sources and heralding a bright future. We developed and acquired new assets that enhance future growth:

- **Investing in new technologies,** by partnering with InnoRx, Inc. to develop a new ophthalmic application, in which a helical implant using SurModics' coating technology provides sustained delivery of therapeutic agents in the eye.
- **Developing and acquiring new polymers** that will help SurModics enter new markets and solidify its position as the leading provider of surface modification and drug delivery solutions.
- **Strengthening SurModics' portfolio of license agreements,** by signing a record 17 new agreements in fiscal 2004. At fiscal year-end, 77 SurModics-coated products were generating royalties, with 64 licensed products awaiting launch and an additional 73 potential commercial products in development. In addition, we now have 69 licensed customers.

Building on Success, Seizing New Opportunities

SurModics' new business units are fostering relationships with high-quality clients – projects and partners that can help create revenue opportunities to sustain growth over the long term. While SurModics is proud of its proven business relationships – notably, the successful relationship with Johnson & Johnson – we continue to diversify our client base. To attract new quality clients, we will continue to expand our technology portfolio, focusing particularly on drug delivery coatings. Our recent agreement with drug delivery and development company OctoPlus is an example of this effort, as we add vital new polymers to our already strong technology portfolio.

SurModics will also continue to build on its market expertise. With significant experience in the cardiovascular field, we're now enhancing our capabilities in other core markets, including orthopedics, ophthalmology and neurology. To broaden our knowledge in these large, attractive markets, we continue to look for prudent investments in companies and technologies where SurModics finds a strategic fit. As we identify these opportunities, we will put our strong balance sheet to work to add to our portfolio of intellectual property, find new strategic investments and consider acquisitions.

With our enlarged technology portfolio, improved organizational structure and renewed sense of urgency, we look confidently ahead. Today, companies from different sectors are seeking a partner with our capabilities. We are diversified, have an established distribution network and an unparalleled service capability. With dedicated employees and a deep commitment to ethics and sound business principles, SurModics will continue as a proven innovator and unmatched leader in its field.

Sincerely,

Dale R. Olseth
Chairman and Chief Executive Officer

Bruce J Barclay
President and Chief Operating Officer

December 1, 2004

Patrick E. Guire, Ph.D.
In late 2004, senior vice president and chief scientific officer Patrick E. Guire, Ph.D., announced his resignation from SurModics. One of the company's original founders, he has served as an officer and director of SurModics since 1980. As leader of SurModics' government-supported research, Dr. Guire's expertise and guidance have helped build a remarkable team of researchers and scientists, creating a pool of individuals who are ready today to build on Dr. Guire's solid record of success, helping lead SurModics to new opportunities and innovations. We gratefully acknowledge Dr. Guire's many positive contributions to the company's success over the past 25 years and wish him well in his future endeavors.

Some of the information contained in this report is forward looking and subject to certain risks and uncertainties as described in the company's SEC reports, including its most recent report on Form 10-K for the year ended Sept. 30, 2004.


SurModics
Bringing Innovation Together™

FACT SHEET

STOCK SUMMARY

As of November 30, 2004

NASDAQ: SRDX

Price per Share: $30.10

Shares Outstanding: 17.5 million

Market Cap.: $529 million

52-week Range: $18.10 - 31.00

Avg. Daily Trading Vol.: 139,000 shares

Insider Holdings: 19.0%

ANALYST COVERAGE

Adams Harkness

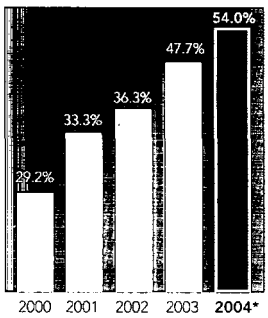
Craig-Hallum

Morgan Keegan

RBC Capital Markets

SunTrust Robinson Humphrey

Operating Margin



Corporate Profile

SurModics, Inc. (SRDX) is a leading provider of surface modification and drug delivery solutions to the medical device industry. SurModics' patented drug delivery polymer matrices and PhotoLink® coating process are two of its core technology platforms. SurModics' technologies modify and enhance the surface characteristics of medical devices and biomedical applications, improving performance and, in some cases, enabling development of new products.

For example, SurModics' Bravo™ drug delivery polymer matrix is a key component in the CYPHER™ drug eluting coronary stent manufactured by Cordis Corporation, a Johnson & Johnson company. SurModics' Bravo polymer matrix is also being used in an innovative ophthalmic helical coil developed by InnoRx, Inc. to deliver therapeutic agents in the eye.

SurModics' coatings:

- Increase ease of use for physicians
- Improve device efficacy
- Increase compatibility with the human body
- Extend the useful lifetime of medical devices
- Enhance device performance
- Improve patient outcomes

Financials

- Record revenue for fiscal year 2004 of $49.7 million – up 15 percent over 2003
- Diluted EPS of $0.42 per share, including impairment charge; excluding the charge, EPS totaled $1.00 vs. $0.78 in 2003
- Record number of new licenses and new product launches

SurModics' Core Business Units

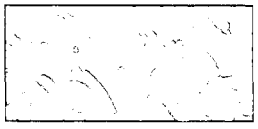
In fiscal 2004, SurModics completed a corporate reorganization designed to accelerate its technology leadership and sharpen its focus on customer needs. The company created five technology-centered business units:

- **Drug Delivery,** dedicated to creating and supporting site specific drug delivery coatings and technologies like those being used by customers in drug eluting stents, ophthalmic implants and other drug coated products.
- **Hydrophilic Technologies,** which specializes in advanced lubricious coatings that can enhance medical devices, facilitating and easing their placement and maneuverability in the body.
- **Regenerative Technologies,** a business unit encompassing SurModics' work in hemocompatibility, tissue engineering and cell encapsulation technologies.
- **Diagnostics and Drug Discovery,** which combines the company's biosciences group (including the genomics and slide technologies licensed to GE Healthcare), stabilization business (including distribution relationships) and diagnostic format intellectual property (currently licensed to Abbott Laboratories and used in strep and pregnancy test kits).
- **SurModics New Ventures,** which is dedicated to identifying, researching and developing new technologies outside of research conducted in other business units. The group also leads a technical advisory board helping SurModics overcome key challenges and target areas of new growth and opportunity.

*Excluding non-cash asset impairment charge.

Some of the information contained in this report is forward looking and subject to certain risks and uncertainties as described in the company's SEC reports, including its most recent report on Form 10-K for the year ended Sept. 30, 2004.








Recent Developments

CYPHER: Driving Drug Coated Stents' Success

The CYPHER stent uses a specialized drug eluting coating developed by SurModics and has been embraced as a revolutionary treatment for cardiovascular disease. In the U.S., the market for coated stents continues to expand, with current market penetration estimated at 77 percent.

Recent clinical studies suggest CYPHER can also be more effective in diabetic patients and in treating longer blockages in coronary arteries – two particularly challenging patient populations.

To boost distribution and market penetration, Cordis is teaming with Guidant Corporation to co-promote CYPHER in the U.S., with an option to add Japan in the future. In 2004, CYPHER became the first and only drug coated stent available in Japan – the second-largest interventional cardiology market after the U.S.

InnoRx: Investing in Innovative New Technologies

In January 2004, SurModics signed an agreement to invest up to $3.5 million in InnoRx, Inc., which is developing a patented, implantable coil utilizing SurModics' Bravo polymer matrix for sustained delivery of therapeutic agents in the eye. If successful, the device will provide a valuable tool for physicians treating eye disorders such as macular degeneration and diabetic macular edema, representing a potential combined market opportunity of $2.5 to $7.0 billion.

Broadening Our Worldwide Distribution

In fiscal 2004, SurModics deepened its U.S. sales coverage. Additionally, the company signed an agreement with JVS Sales & Technical Consultants, GmbH. JVS will help SurModics expand its European customer base while also providing increased service and support to existing SurModics customers there. The company is also evaluating distribution opportunities in other regions of the world.

Building New Polymer Capabilities

In June 2004, SurModics announced four new polymer families for site specific drug delivery:

- The **Encore™ Drug Delivery Polymer Matrix** and the **Accolade™ Microparticle Drug Eluting System**, both developed internally at SurModics, deliver a wider variety of therapeutic agents, *including Rapamycin analogs*, from more types of devices than previously possible.
- SurModics also obtained an exclusive license from OctoPlus for two novel classes of biodegradable polymers: **PolyActive™** and **OctoDEX™**. Because biodegradable polymers can also deliver proteins and other large molecule therapeutic agents, they expand the breadth of drug delivery applications SurModics can pursue. Biodegradable polymers can be combined with one or more drugs and applied to a medical device, yet naturally degrade in the body over time.

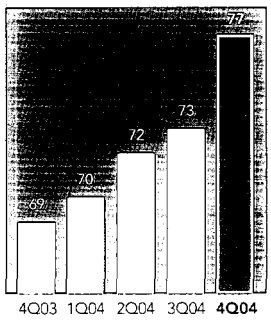
Combined with its existing **Bravo** polymer matrix and **PhotoLink** technology, SurModics now offers six drug delivery platforms.

Partnering with Novocell

SurModics continues its work with Novocell, Inc., an early stage company developing a potential treatment for diabetes. Novocell and SurModics researchers have created a coating that encapsulates pancreatic islet cells – the cells that produce insulin in the human body. If successful, coated islet cells would allow insulin-producing cells to be transplanted into diabetic patients without the need for dangerous immune-suppressive drug regimens. Novocell plans to begin human clinical trials in the first half of 2005.

CURRENT PRODUCTS

SurModics-Coated Products Generating Royalty Revenue



PIPELINE

Licensed Products Not Yet Launched

Major Non-Licensed Opportunities