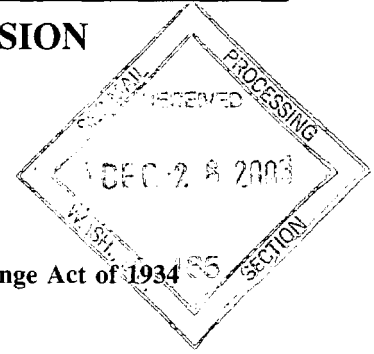


SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM ~~10-K~~ *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, 2005

Commission file number 0-23837



05075863

SURMODICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Minnesota
(State of Other Jurisdiction of
Incorporation or Organization)

41-1356149
(IRS Employer
Identification No.)

9924 West 74th Street
Eden Prairie, Minnesota
(Address of Principal Executive Offices)

55344
(Zip Code)

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

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

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark 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 No

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes 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, 2005 was approximately \$494 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 9, 2005 was 18,545,836.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the Registrant's 2006 Annual Meeting of Shareholders are incorporated by reference into Part III.

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

PART I

ITEM 1. BUSINESS.

Overview

SurModics, Inc. (referred to as “SurModics,” “the Company,” “we,” “us,” “our” and other like terms) is a leading provider of surface modification and drug delivery technologies to the healthcare industry. Our technologies, which primarily include our PhotoLink® surface modification coatings and our drug delivery polymer matrices, modify and enhance the surface characteristics of medical devices and other biomedical products, improving performance and, in some cases, enabling development of new products and applications. We collaborate with our customers, who include the world’s foremost medical device, pharmaceutical and life science companies as well as smaller, development stage companies attempting to develop new technologies, to bring innovation together to improve patient outcomes. Some of the innovations we have developed for the benefit of our customers include polymer coatings for drug-eluting stents, lubricious (slippery) coatings, and cell encapsulation technology for islet cell implantation. Our strategy is to continue to demonstrate technical leadership in the field of surface modification and drug delivery technologies, such that we are viewed as a leading edge product development partner to the healthcare industry.

Our surface modification and drug delivery technologies are utilized by our medical device customers to either alter the characteristics of the surfaces of devices and biological materials (e.g., lubricity or hemocompatibility) or create new functions for the surfaces of the devices (e.g., drug delivery or promotion of healing). For example, our patented PhotoLink technology enhances the maneuverability of guide catheters or guidewires by improving the lubricity of the device surface. Similarly, our patented drug delivery technologies can create new device capabilities by enabling site specific, controlled release drug delivery in cases where devices are themselves necessary to treat a problem (e.g., stents) and in cases where devices serve only as a vehicle to deliver a drug (e.g., ophthalmology implants).

We believe that site specific drug delivery has the potential to change the landscape of the current medical device industry. Drug-eluting stents are one of the first manifestations of how drugs and devices can be combined to produce outstanding patient benefits. We also believe that significant opportunities exist for site specific drug delivery from a wide range of other medical devices. Working with both pharmaceutical and medical device companies, we believe we are poised to exploit this growing market opportunity as drugs and devices converge to create improved products and therapies.

We commercialize our surface modification and drug delivery technologies primarily through licensing and royalty arrangements with medical device manufacturers who typically apply the coatings to their products in their own manufacturing facilities. Additionally, we now have the capability to partner with pharmaceutical and ophthalmology companies to integrate their proprietary ophthalmic drugs with our unique drug delivery technologies and coating processes and our InnoRx implant platform technologies. We believe this approach allows us to focus our resources on further development of our technology and expansion of our licensing activities into new markets, while leveraging the manufacturing, sales and marketing capabilities of our customers.

Revenues from our licensing arrangements typically include research and development revenue, license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees’ product sales. In addition, we manufacture and sell the chemical reagents used in the coating process. We also manufacture and sell coated glass slides to the genomics market and offer a line of stabilization products used to extend the shelf life of immunoassay diagnostic tests. We also license a format for in vitro diagnostics tests, which has found broad application in the area of rapid point-of-care diagnostic testing, such as pregnancy and strep tests.

In January 2005, we extended our drug delivery technologies beyond the cardiovascular market, where our drug delivery polymer matrix first gained prominence, into the ophthalmology market by acquiring all of the assets of InnoRx, Inc., including its innovative device platform technologies for drug delivery to treat a variety of serious eye diseases. (For more information on the InnoRx acquisition, see Liquidity and Capital Resources elsewhere in this report.) A Phase I clinical trial for the I-vation™ intravitreal implant for the treatment of diabetic macular edema was initiated during the year. The I-vation implant is one of the principal InnoRx technologies we acquired. If our clinical trials are successful, and the I-vation implant remains a viable commercial prospect, we believe we will

have the capability to partner with pharmaceutical and ophthalmology companies to integrate their proprietary ophthalmic drugs with our ophthalmic device platforms and our unique coating systems. We intend to continue internally investing in our technologies to expand our core capabilities for ophthalmic drug delivery implants. We also anticipate entering into one or more strategic relationships with others to further advance our ophthalmic technologies and eventually commercialize such technologies if they lead to viable, approved treatment solutions.

We manage our business through the following six technology- and market-focused business units:

- ***Drug Delivery***, creating and supporting site specific drug delivery polymers and coating technologies for use in drug/device combination products in our chosen markets, such as drug-eluting stents for the treatment of vascular disease, ophthalmic implants, orthopedics, and wound treatment, among others.
- ***Ophthalmology***, developing drug delivery systems intended to enhance performance, safety, patient convenience and patient compliance for a variety of drugs and other bioactive agents that are being developed by the pharmaceutical and biotech sectors for the treatment of serious eye diseases.
- ***Hydrophilic Technologies***, specializing in advanced lubricity (slippery) coatings that can enhance the function of medical devices, facilitating and easing their placement and maneuverability in the body.
- ***Regenerative Technologies***, developing platforms intended to augment or replace tissue/organ function (e.g., cell encapsulation applications), or to modify medical devices to facilitate tissue/organ recovery through natural repair mechanisms (e.g., hemo/biocompatible coatings).
- ***Diagnostics and Drug Discovery***, consisting of our biosciences group (including the genomics and slide technologies licensed to GE Healthcare), stabilization business and diagnostic format intellectual property (currently licensed to Abbott Laboratories and used in strep, pregnancy and other test kits). The Diagnostics business unit is also responsible for our collaboration with the Donaldson Company in the area of synthetic cell culture products.
- ***Orthopedics***, developing innovative solutions for orthopedics patients using proven SurModics technologies, and creating new technology solutions for existing patient care needs in the orthopedics field.

We believe we have sufficient financial resources available to continue developing and growing our business. We intend to continue investing in research and development to advance our surface modification and drug delivery technologies and to expand uses for our technology bases. In addition, we continue to pursue access to products and 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.

Medical Device Industry

Advances in medical device technology have helped drive improved medical device efficacy and patient outcomes. Pacemakers and defibrillators have dramatically reduced deaths from cardiac arrhythmias. Stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures, and they have diminished the need for more invasive cardiac bypass surgery. Hip, knee and spine implants have relieved pain and increased mobility. Acceptance of these innovations by patients, physicians and insurance companies has helped the U.S. medical device industry grow at a faster pace than the economy as a whole. The attractiveness of the industry has drawn intense competition among the companies participating in this area. In an effort to improve their existing products or develop entirely new devices, a growing number of medical device manufacturers are exploring or using surface modification and drug delivery technologies as product differentiators or device enablers. In addition, the continuing trend toward minimally invasive surgical procedures, which often employ catheter-based delivery technologies, has increased the demand for hydrophilic, lubricious coatings and other technologies.

The convergence of the pharmaceutical, biologics and medical device industries, often made possible by surface modification and drug delivery technologies, presents a powerful opportunity for major advancements in healthcare. The dramatic success of drug-eluting stents in interventional cardiology has 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.

SurModics' Coating Technologies — Overview

We believe SurModics is uniquely positioned to exploit the continuing trend of incorporating surface modification and drug delivery technologies into medical device design, leading to more efficient and effective medical devices as well as creating entirely new applications for medical devices. We have a growing portfolio of proprietary technologies, market expertise and insight, and unique collaborative research and development capabilities — all key ingredients to bring innovation together for the benefit of the industry and the Company.

Our PhotoLink coating technology is a versatile, easily applied, light activated coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. PhotoLink coatings can impart many performance enhancing characteristics, such as advanced lubricity (slippery) and hemocompatibility (preventing clot formation), by becoming bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or physical properties of devices. Our PhotoLink technology utilizes proprietary, light sensitive (photochemical) reagents, which 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 that results from the sharing of electrons between carbon atoms of the substrate and the applied coating.

Our proprietary PhotoLink reagents work directly on most polymer based (e.g., plastic) and biological substrates (e.g., latex rubber, cellulose, tissue and natural fibers). Metal and glass substrates typically require a pretreatment to provide a hydrocarbon-containing surface for bonding prior to the application of our PhotoLink reagents. Our reagents are easily applied to a clean material surface by dipping, spraying, roll coating, ink jetting or brushing. We continue to expand our portfolio of proprietary reagents for use by our customers. These reagents enable our customers to develop novel surface features for their devices, satisfying the expanding requirements of the healthcare industry. We are also continually working to expand the list of materials that are compatible with our surface modification and drug delivery reagents. Additionally, to deliver the best value added technologies, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput and cost requirements of our customers.

Our drug delivery technologies differ from PhotoLink in that they involve non-photochemical reagents. Therapeutic drugs are incorporated within our proprietary polymer matrices 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. We work with companies in the pharmaceutical, biotechnology and medical device industries to develop specialized coatings that allow for the controlled release of drugs from device surfaces. We see 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 technologies utilize 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, each of which influences 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 systems.

We offer customers several distinct polymer families for site specific drug delivery. Our Bravo™ Drug Delivery Polymer Matrix is utilized on the CYPHER® Sirolimus-eluting Coronary Stent from Cordis Corporation, a Johnson & Johnson company. The Bravo polymer is also used on our I-vation Intravitreal Implant within our Ophthalmology Division. Our Encore™ Drug Delivery Polymer Matrix and Accolade™ Microparticle Drug Eluting System, both developed internally, deliver a wider variety of therapeutic agents, including Rapamycin analogs, from more types of

devices than previously possible. In addition, we have rights to several biodegradable polymers developed outside the Company, and continue to evaluate others. Because some biodegradable polymers can deliver proteins and other large molecule therapeutic agents, they have the potential to expand the breadth of drug delivery applications we can pursue. Biodegradable polymers can be combined with one or more drugs and applied to a medical device, and the drug is then released as the polymer degrades in the body over time. Finally, our PhotoLink technology also offers drug delivery capabilities.

SurModics' Coating Technologies — Product Development Benefits

We believe that our proprietary coating technologies provide our customers with a number of benefits, including:

- *Flexibility.* Coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents, which allow 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.

SurModics' Coating Technologies — Clinical Benefits

- *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 internal and customer testing, when compared with uncoated surfaces, our PhotoLink coatings have reduced the friction on surfaces by more than 90%, depending on the substrate being coated.
- *Wettability.* PhotoLink hydrophilic coatings have been shown in internal and customer tests 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. We believe 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.
- *Hemo/biocompatibility.* Hemocompatible/biocompatible 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 reagents 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. We have also developed synthetic, non-biological coatings that provide medical device surfaces with improved blood compatibility without the use of heparin. These coatings prevent undesirable cells and proteins that lead to clot formation from adhering to the device surface. These coatings may also reduce fibrous encapsulation.
- *Prohealing.* We are developing biologically based extracellular matrix (ECM) protein coatings that may accelerate blood clotting in a controlled fashion, thereby minimizing thromboembolism (blood clots that detach from the device surface and travel downstream). Moreover, these coatings may improve device-site healing through specific protein-cell interactions. Such surfaces may be useful for endovascular grafts and neuroaneurysm devices where it is important to seal off blood clots before serious life threatening

complications can occur. Certain ECM proteins specifically stimulate the migration and proliferation of endothelial cells (cells that line blood vessels). Covalently attaching the appropriate ECM proteins to stent surfaces with PhotoLink coatings may signal endothelial cells to migrate to the surface where they can rapidly form a stable endothelial lining. Thus, the overgrowth of unwanted cells that lead to narrowing of the stented vessel (restenosis) may be prevented.

- *Drug Delivery.* We provide drug delivery polymer matrix coating technology to enable controlled, site specific delivery of therapeutic agents. Our proprietary polymer reagents and coating methods do not require light activation (i.e., they are non-PhotoLink methods), to create biodurable 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 drug-eluting stent incorporating SurModics technology in Europe, the U.S. and Japan. In addition to our biodurable polymer technologies, we offer a number of biodegradable polymer technologies. We also believe that drug-eluting devices have significant potential in the ophthalmology market, where drug-eluting ophthalmic implants can provide sustained release of drugs using minimally invasive procedures.
- *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 implants (such as vascular grafts and ocular implants) coated with photoreactive collagen and other proteins may improve attachment, cell growth and acceptance by surrounding tissues. We have developed several coating and matrix technologies for tissue engineering applications, such as naturally biodegradable matrix forming polymers to provide scaffolds for cells, proteins, and genes for a variety of applications. For example, biocompatible coatings that form a semipermeable barrier may be used to encapsulate transplant cells, rendering them invisible to a patient's immune system. Accordingly, we have licensed technology to and have made an investment in Novocell, Inc., which is pursuing a treatment for diabetes by implanting encapsulated islet cells. Novocell received FDA approval of its IND application and expects to commence the first-in-man Phase I/II trial in December 2005.
- *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. We have developed a slide coating that specifically and covalently attaches DNA, resulting in highly sensitive DNA microarray assays. GE Healthcare has licensed our technology in this area and sells genomics slides under the trade name CodeLink.

SurModics' Coating Technologies — Applications

The table below identifies several market segments where surface modification and drug delivery technologies are desired to improve and enable both existing and new medical devices.

<u>Market Segment Served</u>	<u>Desired Surface Property and Examples of Applications</u>
Interventional cardiology and vascular access	<i>Lubricity:</i> catheters, guidewires <i>Hemocompatibility:</i> vascular stents, catheters, distal protection devices <i>Site specific drug/biologics delivery:</i> vascular stents, catheters <i>Prohealing:</i> vascular stents, vascular grafts
Cardiac rhythm management	<i>Lubricity:</i> pacemaker and defibrillator leads, electrophysiology devices <i>Hemocompatibility:</i> electrophysiology devices
Cardiothoracic surgery	<i>Prohealing:</i> heart valves, septal defect repair devices <i>Hemocompatibility:</i> minimally invasive bypass devices, vascular grafts, ventricular assist devices
Interventional neurology and neurosurgery	<i>Lubricity:</i> catheters, guidewires
Urology and gynecology	<i>Lubricity:</i> urinary catheters, incontinence devices, ureteral stents, fertility devices
Ophthalmology	<i>Site specific drug/biologics delivery:</i> drug delivery implants
Orthopedics	<i>Cell growth and tissue integration:</i> bone and cartilage growth <i>Infection resistance:</i> orthopedic implants <i>Site specific drug/biologics delivery:</i> orthopedic implants

Our coating technologies are currently 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.

Licensing Arrangements

We commercialize our surface modification and drug delivery technologies primarily through licensing arrangements with medical device manufacturers, who typically apply the surface modifications to their products in their own facilities. We believe this approach allows us to focus our resources on further developing new technologies and expanding our licensing activities rather than making substantial capital investments in contract coating and surface modification equipment. Our technologies have been designed to allow manufacturers to easily implement them into their own manufacturing processes so customers can control production and quality internally without the need to send their products to SurModics or a coating contract manufacturer.

We generate the largest portion of our revenue from commercializing our surface modification and drug delivery technologies for use in connection with medical devices, primarily through licensing and royalty arrangements. Revenue from these licensing and royalty arrangements typically includes research and development revenue, license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees' product sales. We also generate revenue from sales of chemical reagents to licensees for use in their coating processes, and from licensing our proprietary diagnostic formats for use in point-of-care testing.

The licensing process begins with the customer specifying a desired product feature to be created by surface modification, e.g., lubricity, drug delivery, etc. Because each device is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating research and development revenue. 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, a license agreement may be executed granting the licensee rights to use our technology. We also manufacture and sell the chemical reagents used by licensees in the coating process, generating another source of recurring revenue. We often support our customers by providing coating assistance for parts required in animal tests and human clinical trials. However, most customers perform the coating work internally once a product has received regulatory approval and is being actively marketed.

The term of a license agreement is generally for a specified number 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. Our license agreements may include certain license fees and/or milestone payments. The license can be either exclusive or nonexclusive, but a significant majority of our licensed applications are nonexclusive, allowing us to license technology to multiple customers. 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 fees, milestone payments, and the royalty rate are based on various factors including whether the arrangement is exclusive or nonexclusive, the perceived expected value of the coating application to the device, the size of the potential market, and customer preferences. Most of our agreements also incorporate a minimum royalty to be paid by the licensee. 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.

We currently have 80 licensed products (customer products utilizing SurModics technology) already on the market generating royalties and 72 customer products incorporating our technology pending regulatory approval. These 152 products are being sold or developed by 76 licensed customers. We signed a record 20 new licenses in fiscal year 2005.

Licensed customers include Abbott Laboratories, Boston Scientific Corporation, CardioMind, Inc., Cordis Corporation (a Johnson & Johnson company), ev3 Inc., FoxHollow Technologies, Inc., GE Healthcare, Guidant Corporation, Medtronic, Inc., Novocell, Inc., Rubicon Medical, Spectranetics Corporation, St. Jude Medical, Inc., and ThermopeutiX, among others. Under most of our licensing agreements, we are required to keep confidential the identity of our customers unless they approve such disclosure.

Genomics Products

During fiscal year 1999, we launched our 3D-Link® Activated Slide to the genomics market. Coated glass slides are used by genomics researchers to prepare microarrays for DNA analysis. General Electric Company, through GE Healthcare, has an exclusive license to our coated glass slide technology. In addition to license fees, we generate revenue under this license from the manufacture and sale of coated glass slides to GE Healthcare, who markets the slides under their CodeLink brand.

Diagnostic/Stabilization Products

We sell stabilization products for use by manufacturers of immunoassay diagnostic tests. Our StabilCoat®, StabilGuard® and StabilZyme® Stabilizers are designed to maintain the activity of biological components of 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 the past two years, we have introduced new products to improve the stability and performance of protein microarrays, and bead-based assays, a rapidly growing area in the diagnostics and drug discovery. We also introduced StabilZyme® Noble, a BSA-free biomolecule stabilizer, which improves stabilization without the complications of bovine proteins.

Diagnostic Royalties

We have also licensed patent rights to Abbott Laboratories involving a format for in vitro diagnostic tests. This format was developed during the early years of the Company and has found broad application in the area of rapid point-of-care diagnostic testing, such as pregnancy and strep tests. At the end of fiscal year 2004, we expanded

our agreement with Abbott by purchasing the future royalty streams under certain of Abbott's sublicenses until the expiration of our patents in fiscal year 2009. Prior to such expansion, we were receiving only a portion of the royalties under such sublicenses.

Research and Development

Our research and development personnel work to enhance and expand our technology offerings in the area of surface modification and drug delivery through internal scientific investigation. These scientists and engineers also evaluate external technologies in support of our business development activities. All of these efforts are directed by an assessment of the needs of the markets in which we do business. Additionally, the R&D staff 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, supporting clinical trials, training customers, and integrating our technologies and know-how into customer manufacturing operations.

We work together with our customers to integrate the best possible surface modification and drug delivery technologies 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 within our R&D organization. Our state-of-the-art instrumentation and 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. We believe our capabilities far exceed those of our direct competitors, and sometimes even exceed those of our large-company customers.

As medical devices become more sophisticated and complex, we believe the need for surface modification and drug delivery will continue to grow. We intend to continue our development efforts to expand our surface modification and drug delivery technologies to provide additional optimized surface properties to meet these needs across multiple medical markets. In addition, we are expanding our drug delivery and surface modification technology expertise to capture more of the final product value. We are doing 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 we will be successful in developing or acquiring additional pharmaceuticals or devices.

After thorough consideration of each market opportunity, our technical strategy is to target selected coating characteristics for further development, to facilitate and shorten the license cycle. We continue to perform research into applications for future products both on our own and in conjunction with some of our customers. Some of the research and development projects currently being worked on include additional polymer systems for site specific drug delivery, including biodegradable technologies, as well as technologies to improve endothelialization of implantable devices and to improve long-term blood compatibility, nanofiber cell culture technologies and drug delivery platforms for ophthalmic applications.

In fiscal years 2005, 2004, and 2003, our research and development expense was \$16.1 million, \$12.6 million, and \$12.0 million, respectively. A portion of this expense is billed to customers for coating optimization and other development work on customer product applications. Research and development revenue in fiscal years 2005, 2004, and 2003 was approximately \$5.4 million, \$4.4 million, and \$5.6 million, respectively. We intend to continue investing in research and development to advance our surface modification and drug delivery technologies and to expand uses for our technology bases. In addition, we continue to pursue access to products and technologies developed outside the Company as appropriate to complement our internal research and development efforts.

Patents and Proprietary Rights

Patents and other forms of proprietary rights are an essential part of the SurModics business model. We protect our extensive portfolio of technologies through a number of U.S. patents covering a variety of coating methods, reagents, and formulations, as well as particular clinical device applications. We generally file international patent applications in the locations matching the major markets of our customers (primarily in North America, Europe, and Japan) in parallel with U.S. applications. In fiscal year 2005, we filed 51 United States patent applications,

expanding the portfolio protection around our current technologies as well as enabling pursuit of new technology concepts, innovations, and directions. At fiscal year end, we had 94 pending United States patent applications, 10 of which were exclusively licensed from others, and 169 foreign patent applications, of which 22 were exclusively licensed from others. We own 52 issued United States patents, and are the exclusive licensee on 13 additional patents. Internationally, we own 107 patents and are exclusively licensed under 10 additional patents. Extensive in-licensing rights of a more limited nature are available to us from other third party patents, enabling efficient use of such intellectual property in various ways favorable to the Company.

We also rely upon trade secrets and other unpatented proprietary technologies. We seek 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 us.

Marketing and Sales

We market our core technologies and products throughout the world using a direct sales force consisting of five 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. Internationally, we have 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. In addition, we are pursuing additional sales and marketing relationships in other geographies around the world.

In general, we license our technologies on a non-exclusive basis to customers for use on specific products. This strategy enables us to license our technologies to multiple customers in the same market. We also target new product applications with existing customers.

To support our marketing and sales activities, we publish technical literature on our various surface modification technologies (e.g., lubricity, hemocompatibility, drug delivery, etc.). In addition, we exhibit at major trade shows and technical meetings, advertise in selected trade journals and through our website, and conduct direct mailings to appropriate target markets.

We also offer ongoing customer service and technical support throughout our licensees' relationships with us. This service and support begins with a coating feasibility study, 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 customers.

Significant Customers

We have two customers that each provided more than 10% of our revenue in fiscal year 2005. Revenue from Cordis Corporation and Abbott Laboratories represented approximately 46% and 14%, respectively, of our total revenue for the year ended September 30, 2005. 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.

Competition

The ability for surface modification and drug delivery technologies to improve the performance of medical devices and to enable new product categories has resulted in increased competition in these markets. Our surface modification and drug delivery technologies compete with technologies developed by AST, Biocompatibles

International plc, BioSensors, Carmeda (recently acquired by W.L. Gore), Control Delivery Systems (recently acquired by pSivida Limited), Hydromer, MediVas, Oculex Pharmaceuticals, Inc. (acquired by Allergan, Inc.), Specialty Coatings Systems, and STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., among others. Some of these companies offer drug delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target ophthalmology applications, while others target cardiovascular medical device applications. In addition, due to the many product possibilities afforded by surface modification technologies, many of the large medical device manufacturers have developed or are engaged in efforts to develop internal competency in the area of surface modification and drug delivery. Some of our 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 we have.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value added approach to surface modification and drug delivery technology. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility, etc.), ease of manufacturing, time-to-market, ability to produce multiple properties from a single process, compliance with manufacturing regulations, customer service and total cost of goods (including manufacturing process labor). We believe our technologies deliver exceptional performance in these areas, allowing us to compete favorably with respect to these factors. We believe 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 our revenue is dependent on the receipt of royalties based on sales of medical devices incorporating our technologies, we are also affected by competition within the markets for such devices. We believe that the intense competition within the medical device market creates opportunities for our technologies as medical device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Because we seek to license our technologies on a non-exclusive basis, we may further benefit from competition within the medical device markets by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us. While we seek to license our products to established manufacturers, in certain cases our licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities. We also are unable to control other factors that may impact commercialization of coated devices, such as regulatory approval, marketing and sales efforts of our 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 our licensing strategy, we generally do not coat medical devices to be sold by our customers following regulatory approval. However, we often support our customers by coating products for human clinical trials. We also manufacture most of the reagent chemicals used by our customers in the coating process, allowing us to control the quality of the reagents and maintain 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/isopropyl alcohol mix, or other solvent to put them into solution before application. We have developed proprietary testing and quality assurance standards for manufacturing our reagents and do not disclose the reagent formulas or manufacturing methods.

We also manufacture our proprietary line of activated coated glass slides for sale by GE Healthcare under the CodeLink® brand. Standard glass slides are cleaned and pretreated in a multiple-step process. We apply our proprietary PhotoLink coating in a clean room environment, test the slides to assure they meet quality standards, package slides in specialized containers and seal 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 GE Healthcare.

We also manufacture stabilization products employing a three-step production process. First, component chemicals are mixed in high purity water; next, these liquids are sterile-filtered into specific container sizes under aseptic conditions; and finally, the resultant finished goods are sealed and labeled.

We attempt to maintain multiple sources of supply for the key raw materials used to manufacture our products. We do, however, purchase some raw materials from single sources, but we believe that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, we believe that we could manufacture such raw materials.

Although not regulated by Good Manufacturing Practices (GMP), we do follow quality management procedures in part to respond to requests of customers to establish compliance with their individual criteria. In an effort to better meet our customers' needs in this area, we received ISO 13485:2003 and ISO 9001:2000 certification in fiscal year 2004.

Government Regulation

Although our 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. New medical products utilizing our coating technologies can only be marketed in the United States after a 510(k) application has been cleared, or PMA application approved, by the FDA. This process can take anywhere from three months for a 510(k) application, to two or three years or more for a PMA application. The burden of demonstrating to the FDA that a new device is either equivalent to a previously marketed device (510k process), or in the case implantable devices, safe and effective, (PMA process) rests with our customers as the medical device manufacturers. If the primary mode of action for a product is as a drug, customers are typically required to submit an Investigational New Drug (IND) application to initiate clinical studies that will support their marketing application, which is called a New Drug Application (NDA) or Biologics License Application (BLA). These applications contain the results of design verification and validation testing, biocompatibility testing, and clinical evaluations conducted with the device.

In support of our customers' regulatory filings, we maintain confidential Device Master Files at the FDA regarding the nature, chemical structure and biocompatibility of our reagents. Although our licensees do not have direct access to these files, they may, with our permission, 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 us having to share this highly confidential information with our customers.

U.S. legislation allows device manufacturers, prior to obtaining FDA approval, to manufacture devices in the U.S. and export them 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.

SurModics is currently conducting a Phase I safety trial for the I-variation implant. The study is being conducted at five clinical sites under an IND according to Good Clinical Practices. The Phase I trial plans to enroll 30 patients who will be subject to follow-up monitoring for three years.

Employees

As of December 1, 2005, we had 135 employees, of whom 85 were engaged in product development, quality, and manufacturing positions, with the remainder in sales, marketing, or administrative positions. Post-graduate degrees are held by 23 of our employees, 10 of whom hold Ph.D. degrees. We are not a party to any collective bargaining agreements and we believe that our employee relations are good.

We believe that future success will depend in part on our ability to attract and retain qualified technical, management and marketing personnel. Such experienced personnel are in high demand, and we must compete for their services with other firms that 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 in the U.S. District Court for the District of Delaware in which each was reported in June and July 2005 to have infringed the patent rights of 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;
- the ability to secure raw materials for reagents the Company sells;
- the Company’s ability to manage successfully clinical trials and related foreign and domestic regulatory processes for the I-vation intravitreal implant or other acquired products from InnoRx under development by the Company’s ophthalmology division, whether delays, difficulties or failures in achieving acceptable

clinical results or obtaining foreign or FDA marketing clearances postpone or preclude product commercialization of the intravitreal implant or other acquired products, and whether the intravitreal implant and any other acquired products remain viable commercial prospects;

- 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 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;
- the Company's ability to successfully internally perform certain product development activities and governmental and regulatory compliance activities with respect to acquired technology, including InnoRx technology, which activities the Company has not previously undertaken in any significant manner;
- economic and other factors over which the Company has no control, including changes in inflation and consumer confidence;
- acts of God or terrorism which impact the Company's personnel or facilities; and
- other factors described below in "Risk Factors."

Many of these factors are outside the control and knowledge of the Company, and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon the Company's forward-looking statements and to consult any further disclosures by the Company on this subject in its filings with the Securities and Exchange Commission. Many of the factors identified above are discussed in more detail below under "Risk Factors."

Risk Factors

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

We have two customers that each provided more than 10% of our revenue in fiscal year 2005. Revenue from Cordis Corporation and Abbott Laboratories represented approximately 46% and 14%, respectively, of our total revenue for the year ended September 30, 2005. 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. 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, Abbott, 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 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, 2005, 2004 and 2003, we derived approximately 76%, 70% and 60% 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. (Assuming completion of successful clinical trials with the I-vation intravitreal implant, we believe we could commence commercial sale of the implant no sooner than 2010.) 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 gain successful 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 or drug delivery technologies and may pursue parallel development or licensing of competing technological 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, BioSensors, Carmeda (recently acquired by W.L. Gore), Control Delivery Systems (recently acquired by pSivida Limited), Hydromer, MediVas, Oculex Pharmaceuticals, Inc. (acquired by Allergan, Inc.), 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 or drug delivery 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 existing 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 our 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 because of 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.

Any adverse results in our Phase I trials for our I-vation intravitreal implant could harm our ability to commercialize the implant in a timely, cost-effective manner, if at all.

We are currently conducting a Phase I safety trial for our I-vation intravitreal implant. Our Phase I trial is intended to help assess the safety and tolerability of the implant in patients with diabetic macular edema, and is being conducted under an investigational new drug application with the U.S. Food and Drug Administration. The Phase I trial plans to enroll 30 patients who will be subject to follow-up monitoring for three years. The first human implant in the trials occurred in June 2005.

Our ability to commercialize the implant by 2010 will depend on the success of our Phase I testing efforts and the performance of the implant in patients that participate in the trial and the successful enrollment and results

from other clinical trials that will be required before we or a partner can seek approval for commercial sale of the implant. Although the preliminary results of the Phase I trial have not presented any material problems, we cannot be certain the implant will perform as expected in additional clinical tests. Problems in connection with our Phase I trials or in any subsequent phases of required clinical trials may prevent or delay us or a partner obtaining necessary regulatory approvals and threaten our ability to timely or cost-effectively commercialize the implant, if at all.

Our Phase I trial is being conducted on a statistically insignificant number of human patients and is not intended to evaluate aspects of the effectiveness of the implant. Because the initial number of tests performed in humans will be relatively small, there is no assurance that the Phase I trials will identify problems that may become evident from a larger base of tests or after a longer period of observation of the patients. We will be able to accurately evaluate the performance of the implant in humans only after extensive testing in large numbers of patients over a period of years.

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 customers resulting from our inability to produce products for them.

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.

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 disposal of certain chemical waste 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, development and manufacturing 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, 2005, the closing sale price for our common stock ranged from \$23.80 to \$46.13 per share. As of December 9, 2005, the last reported sale price of our stock was \$38.43 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 strategic investment and 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 strategic investments and the acquisition of complementary businesses or technologies. Our identification of suitable investment opportunities and acquisition candidates involves risks inherent in assessing the technology, value, strengths, weaknesses, overall risks

and profitability, if any, of investment and acquisition candidates. We may not be able to identify suitable investment and acquisition candidates. If we do not make suitable investment and 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. Strategic investments may result in impairment charges if the value of any such investment declines significantly. 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 complete successfully any investments or acquisitions or that we will realize any anticipated benefits from investments or acquisitions that we complete.

ITEM 2. PROPERTIES.

We conduct our operations in two facilities located in suburban Minneapolis-St. Paul, Minnesota. In May 1999, we purchased the land and building we currently occupy in Eden Prairie, Minnesota. The building has approximately 64,000 square feet of space. Most of our operations take place at the Eden Prairie location. In October 2001, we purchased a facility in Bloomington, Minnesota, situated on 27 acres of land. In fiscal year 2004, we announced that after careful examination of our redefined business goals, we believed that the Bloomington contract manufacturing facility was no longer necessary for the execution of our strategic plan. Accordingly, we recorded a non-cash asset impairment charge of \$16.5 million in the third quarter of fiscal year 2004 and an additional \$2.5 million charge in the fourth quarter of fiscal year 2005. In September 2005, we entered an agreement to sell the Bloomington property and facility. During our fiscal third quarter, we began construction to improve the research and development activities of our Eden Prairie facility. We intend to occupy portions of the Bloomington facility until modifications to our Eden Prairie facility are complete, at which time we will consolidate operations at our Eden Prairie headquarters. We expect to vacate the Bloomington facility by the end of the third quarter of fiscal year 2006. The purchases of these two properties were internally funded and remain unencumbered. We believe that projected capacity of our Eden Prairie facility is adequate to service the needs of our customers for the foreseeable future. In addition, we lease approximately 3,000 square feet of office space in Irvine, California for use by our ophthalmology division.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to nor is any of our 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 year 2005.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

<u>Name</u>	<u>Age</u>	<u>Position</u>
Bruce J Barclay	49	President and Chief Executive Officer
Aron B. Anderson, Ph.D	42	Vice President and Chief Scientific Officer
Philip D. Ankeny	42	Chief Financial Officer, and Vice President, Business Development
Douglas P. Astry	53	General Manager, Diagnostics and Drug Discovery
Lise W. Duran, Ph.D	50	Vice President and General Manager, Regenerative Technologies
Steven J. Keough	50	Vice President and Chief Intellectual Property Counsel and General Manager, Orthopedics
Paul A. Lopez	49	Vice President, and President, Ophthalmology Division
Loren R. Miller	40	Vice President and Controller
Dale R. Olseth	75	Executive Chairman
Charles W. Olson	41	Vice President U.S. Sales, and General Manager, Hydrophilic Technologies
David S. Wood	49	Vice President and General Manager, Drug Delivery
Gregory T. Yung	56	Vice President, Worldwide Marketing and International Sales

Bruce J Barclay joined the Company as its President and Chief Operating Officer in December 2003. He became a director of the Company in July 2004 and Chief Executive Officer of the Company in July 2005. Mr. Barclay has more than 25 years of experience in the health care industry. 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. 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 diagnostic and therapeutic cardiology products and services. 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.

Aron B. Anderson, Ph.D., joined the Company as an Associate Scientist in 1991. In 1994, he was named Director, Hemocompatibility R&D, in 2001, named Director, Drug Delivery, and in January 2005, Vice President and Chief Scientific Officer. Dr. Anderson serves on the Board of Directors of University Enterprise Laboratories, a partnership between the University of Minnesota and the city of St. Paul that functions as a technology company incubator. Dr. Anderson received a B.S. in Chemical Engineering from the University of Minnesota in 1985, and received an M.S. in 1987 and Ph.D. in 1991, both in Chemical Engineering, from Stanford University.

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 also serves on the Board of Directors of Innovex, Inc., which designs and manufactures flexible

circuit interconnect solutions to original equipment manufacturers in the electronics industry. 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 serves on the Board of Directors as Treasurer of the Surfaces in Biomaterials Foundation. 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 Senior Vice President and Chief Intellectual Property Counsel in January 2004 and added the duties of Vice President and General Manager of the New Ventures business unit in April of that year. The current Orthopedics business unit emerged in October 2005 from New Ventures, and is led by Mr. Keough. 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.

Paul A. Lopez joined SurModics in July 2005 as Vice President and President of the Company's Ophthalmology division. Before joining SurModics, Mr. Lopez was President and CEO of Valley Forge Pharmaceuticals, an early stage pharmaceutical company. Prior to Valley Forge, Mr. Lopez served in various senior level positions at Bausch & Lomb, including President, North America Surgical; Vice President, Commercial Operations, Americas and Asia Pacific Regions; and Vice President, Business Integration. Mr. Lopez has also held roles at Monsanto Company, Pharmacia and Upjohn, Inc. and Iolab Corporation. Mr. Lopez serves on the Boards of Directors of Alliance Medical Products and Valley Forge Pharmaceuticals, both private companies located in Irvine, California. Mr. Lopez received an M.B.A. from California State Polytechnic University and a B.S. in Business Administration from California State University.

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 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.

Dale R. Olseth joined the Company in 1986 as its President, Chief Executive Officer and a director of the Company. Mr. Olseth served as the Company's President and Chief Executive Officer until July 2005. Mr. Olseth continues to serve as the Company's Executive Chairman. Mr. Olseth has been 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.

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. In April 2005, the position of Vice President, U.S. Sales was added to his responsibilities. 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.

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. In April 2005, he was named Vice President, Worldwide Marketing and International Sales. 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.

<u>Fiscal Quarter ended:</u>	<u>High</u>	<u>Low</u>
September 30, 2005	45.50	35.40
June 30, 2005	46.13	31.85
March 31, 2005	34.75	28.08
December 31, 2004	32.90	23.80
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

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 10, 2005, there were 278 holders of record of our Common Stock and approximately 13,261 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, 2005.

In July 2005, we issued 60,002 additional shares of common stock to former shareholders of InnoRx pursuant to the terms of and as a result of our January 2005 acquisition of InnoRx and successful completion of a milestone established in the acquisition. (See Liquidity and Capital Resources for more information related to our InnoRx acquisition.) Such shares were issued only to the 15 stockholders of InnoRx, and exemption from registration therefore was claimed at the time of the acquisition under Section 4(2) of such Securities Act.

ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of and for the years ended September 30, 2005, 2004, and 2003 are derived from our audited financial statements included elsewhere in this report. The financial data as of and for the years ended September 30, 2002 and 2001 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 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.

(Dollars in thousands, except per share data)	Fiscal Year				
	2005	2004**	2003	2002	2001
Income Statement Data:					
Total revenue	\$ 62,381	\$ 49,738	\$43,232	\$29,488	\$22,693
Operating income	2,985	10,474	20,640	10,709	7,566
Net income (loss)	(8,246)	7,242	13,936	7,796	5,109
Diluted net income (loss) per share	(.45)	.41	.78	.44	.29
Pro forma amounts assuming the accounting change* was applied retroactively:					
Net income (loss)	(8,246)	7,242	13,936	7,796	6,814
Diluted net income (loss) per share	(.45)	.41	.78	.44	.38
Balance Sheet Data:					
Cash and short-term investments	\$ 24,445	\$ 19,215	\$ 6,647	\$13,149	\$14,840
Total assets	124,225	109,587	97,808	77,248	60,583
Retained earnings	27,915	36,161	28,918	14,982	7,186
Total stockholders' equity	115,581	94,310	86,114	69,995	55,700
Pro forma amounts assuming the accounting change* was applied retroactively:					
Retained earnings	27,915	36,161	28,918	14,982	7,186
Total stockholders' equity	115,581	94,310	86,114	69,995	55,700

* 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.

** In connection with our InnoRx acquisition, we retroactively adjusted our previously reported results to show the impact of accounting for InnoRx under the equity method. The net impact was an approximate \$194,000 reduction in net income for fiscal year 2004.

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. Any discussion and analysis regarding trends in our future financial condition and results of operations are 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 healthcare industry. The Company is organized into three operating segments composed of six technology-centered and industry-focused business units. The "Drug Delivery" operating segment contains: (1) the Drug Delivery business

unit, which is responsible for technologies dedicated to site specific delivery of drugs, and (2) the Ophthalmology division, which is dedicated to the advancement of treatments for eye diseases, such as age-related macular degeneration (AMD) and diabetic macular edema (DME), two of the leading causes of blindness. The "Hydrophilic and Other" operating segment consists of three business units: (1) Hydrophilic Technologies business unit, which focuses on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) Regenerative Technologies business unit, which is developing platforms intended to augment or replace tissue/organ function (e.g., cell encapsulation applications), or to modify medical devices to facilitate tissue/organ recovery through natural repair mechanisms (e.g., hemo/biocompatible coatings); and (3) Orthopedics business unit, which is committed to innovative solutions for orthopedics patients using proven SurModics technologies, and creating new technology solutions to existing patient care gaps in the orthopedics field. The "Diagnostics" operating segment contains the Diagnostics and Drug Discovery business unit, which includes our genomics slide technologies, our stabilization products for immunoassay diagnostics tests, our in vitro diagnostic format technology and the work being performed to develop synthetic cell culture products.

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

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

On January 18, 2005, we acquired all of the assets of InnoRx, Inc. by paying cash and issuing shares of SurModics common stock to InnoRx stockholders. InnoRx was an early-stage company developing drug delivery implants and therapies for the ophthalmology market. The assets we acquired were folded into our newly-created Ophthalmology division. Prior to the acquisition, SurModics held an ownership interest in InnoRx of less than 20% and accounted for the investment under the cost method. Upon completion of the InnoRx acquisition, we retroactively adjusted our previously reported results to show the impact of accounting for InnoRx under the equity method. The net impact was an approximate \$194,000 reduction in net income for fiscal year 2004 from previously reported results.

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 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 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 charge. Results in the third quarter of fiscal year 2004 include a non-cash asset impairment charge of \$16.5 million against our Bloomington, Minnesota contract manufacturing facility. Management determined the fair value using this real estate market data. In September 2005, we entered into an agreement to sell the Bloomington facility. Results in the fourth quarter of fiscal year 2005 include an additional non-cash asset impairment charge of \$2.5 million to reflect the fair value based on the agreed selling price. We intend to consolidate operations at our Eden Prairie, Minnesota headquarters by the end of the third quarter of fiscal year 2006.

Investments. Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities. Our investment 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, 2005 and 2004

<u>(Dollars in thousands)</u>	<u>Fiscal Year 2005</u>	<u>Fiscal Year 2004</u>	<u>Increase</u>	<u>% Increase</u>
Revenue:				
Drug Delivery	\$29,678	\$25,690	\$ 3,988	16%
Hydrophilic and Other	19,065	15,527	3,538	23%
Diagnostics	<u>13,638</u>	<u>8,521</u>	<u>5,117</u>	<u>60%</u>
Total revenue	<u>\$62,381</u>	<u>\$49,738</u>	<u>\$12,643</u>	<u>25%</u>

Revenue. Fiscal year 2005 revenue was \$62.4 million, an increase of \$12.6 million or 25% from fiscal year 2004. We experienced double digit revenue growth in all three operating segments as detailed in the table above and further explained in the narrative in the paragraphs that follow.

Drug Delivery. Revenue in the Drug Delivery segment increased 16% to \$29.7 million from \$25.7 million in fiscal year 2004. Significant growth in royalties and license fees offset a decrease in sales of reagent chemical products (chemicals that we manufacture and sell to licensees for coating their medical devices). Drug Delivery derives a substantial majority of its revenue from royalties and license fees and product sales attributable to Cordis Corporation, a Johnson & Johnson company, on its Cypher Sirolimus-eluting Coronary Stent. The Cypher stent incorporates a proprietary SurModics coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions.

Revenue from sales of reagents to Cordis decreased in fiscal year 2005 because of lower unit prices resulting from a contractual reduction in reagent pricing. Unit volume was little changed from fiscal year 2004. There are no further contractual price reductions and management does not anticipate further reductions in reagent prices to Cordis. Management believes the sales volume of reagents sold to Cordis will be directly impacted by anticipated continued improvements in manufacturing efficiencies by Cordis in addition to relative market share positions of drug-eluting stent players.

Drug Delivery research and development revenue in fiscal year 2005 was about the same as the prior year, with increased revenue from customers other than Cordis offsetting lower revenue from Cordis. In addition, prior to our January 2005 acquisition of InnoRx, a portion of our research and development revenue was attributable to InnoRx as a customer. Following the acquisition, we no longer record revenue for research and development activities in connection with the InnoRx technology.

Future royalty revenue could decrease because of lower Cypher stent sales as a result of continuing competition from Boston Scientific Corporation's Taxus drug-eluting stent. Boston Scientific was granted approval by the FDA to begin marketing in the U.S. its Taxus drug-eluting stent in our second fiscal quarter of 2004. The Taxus stent competes directly with the Cypher stent. While the overall market for drug-eluting stents is expected to continue growing, we anticipate that quarterly royalty revenue from the Cypher stent will continue to be volatile as the various marketers of drug-eluting stents continue competing in the marketplace and as others enter the marketplace. Management expects royalties from the Cypher stent to constitute a significant portion of our revenue in fiscal year 2006. However, whether and the extent to which royalties from the Cypher stent continue to constitute a significant source of revenue is subject to a number of risks, including intellectual property litigation generally and specifically the damages, settlements and mutual agreements that may result from various infringement suits between Boston Scientific and Cordis in which each has reported to have recently been found to have violated certain intellectual property rights of the other.

Hydrophilic and Other. Hydrophilic and Other revenue increased 23% to \$19.1 million, because of increased royalties and license fees and research and development fees. Whereas a significant percentage of revenue in Drug Delivery is attributable to Cordis, in Hydrophilic and Other there are several dozen licensees and an even larger number of coated products generating royalties. The growth in royalties reflects both newly introduced licensed products and increased sales of coated products already on the market. While management anticipates continued revenue growth in fiscal year 2006, it likely will not be as strong as growth in fiscal year 2005.

Diagnostics. Diagnostics revenue increased 60% to \$13.6 million. A substantial majority of the growth resulted from increased royalty revenue under certain sublicenses, whose royalty streams we purchased from Abbott in September 2004. While revenue from these royalty streams from Abbott are anticipated to continue into the future, we anticipate the growth in Diagnostics revenue in fiscal year 2006 will not be as high in percentage terms as 2005 results. Diagnostics derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories.

Revenue from product sales increased resulting from higher sales of stabilization products used for immunoassay diagnostic tests. Effective February 2005, we terminated our stabilization product distribution agreement with SeraCare and began selling directly to the U.S. diagnostics industry. Management believes revenue from stabilization products will continue to increase when compared to prior year comparable periods because of the impact of selling directly to the U.S. diagnostics industry, rather than through a distributor.

Product costs. Product costs were \$2.9 million for the fiscal year, a 6% decrease from \$3.0 million in the prior year. Overall product margins averaged 70% compared with 71% for the comparable period last year. Management anticipates overall product margins will be about the same in fiscal year 2006.

Research and development expenses. Research and development expenses were \$16.1 million, an increase of 27% compared with fiscal year 2004. A majority of the increase reflects legal costs associated with intellectual property processing and applications. In addition, we incurred costs associated with the clinical trial of our I-vation intravitreal implant and increased personnel costs related to establishing our new Ophthalmology division. Management believes research and development expense will continue to increase in fiscal year 2006 as a result of anticipated expenses for development activities and clinical trials associated with the intravitreal implant.

Sales and marketing expenses. Sales and marketing expenses were \$1.2 million in fiscal year 2005, a 28% decrease from the prior year. A substantial portion of the decrease resulted from lower payroll costs related to a reduction in senior marketing personnel in connection with a company-wide reorganization in 2004. Management anticipates sales and marketing expense to increase modestly in fiscal year 2006.

General and administrative expenses. General and administrative expenses were \$6.5 million in fiscal year 2005, a 20% increase compared with fiscal year 2004, primarily reflecting increased compensation, legal and utility costs. Management anticipates general and administrative expense to increase modestly in fiscal year 2006.

Purchased in-process research and development. On January 18, 2005, we acquired all of the assets of InnoRx, Inc. by paying cash and issuing shares of SurModics common stock to InnoRx stockholders. Results in fiscal year 2005 included a non-cash in-process research and development charge of \$30.3 million. The fair value of the in-process research and development was determined by an outside valuation consultant.

Asset impairment charge. Results in fiscal year 2005 included a non-cash asset impairment charge of \$2.5 million against our Bloomington, Minnesota contract manufacturing facility. Results in the fiscal year 2004 included

a non-cash asset impairment charge of \$16.5 million against the facility. In September 2005, we entered into an agreement to sell the Bloomington facility and plan to consolidate operations at our Eden Prairie, Minnesota headquarters.

Other income, net. Other income was \$1.4 million in fiscal year 2005, an increase of 16% compared to the prior year. The increase reflects higher levels of investable cash and higher yields generated from our investment portfolio. Previously reported fiscal year 2004 results have been retroactively adjusted to show the impact of accounting for InnoRx under the equity method. Prior to completing the acquisition of InnoRx in January 2005, we accounted for our investment in InnoRx under the cost method.

Income tax provision. Our income tax provision was \$12.6 million in fiscal year 2005 compared with \$4.4 million in fiscal year 2004. Excluding the impact of the \$30.3 million in-process research and development charge, which is not tax deductible, the effective tax rate was 36.8% in fiscal year 2005, compared with 37.2% for the same period last year.

Years Ended September 30, 2004 and 2003

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

Revenue. Fiscal year 2004 revenue was \$49.7 million, an increase of 15% over fiscal year 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 year 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. Fiscal year 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 (the third quarter of fiscal year 2003). Accordingly, 2004 results reflect a full year of Cypher sales in the United States, whereas fiscal year 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. Although Cordis purchased a substantial majority of reagents sold in fiscal year 2004, reagent chemical sales to Cordis decreased in 2004 as both volume and unit prices decreased.

Hydrophilic and Other. In fiscal year 2004, 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 year 2003. Sales of reagent chemicals increased substantially compared with fiscal year 2003.

Diagnostics. Overall fiscal year 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 year 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.

Product costs. Product costs were \$3.0 million for fiscal year 2004, an increase of 15%, from the \$2.6 million recorded in fiscal year 2003. Overall product margins averaged 71%, a decrease from 78% in fiscal year 2003. Higher cost non-Cordis products made up a higher percentage of total product sales in fiscal year 2004.

Research and development expenses. Research and development expenses for fiscal year 2004 were \$12.6 million, an increase of \$633,000, or 5%, compared with the same period in fiscal year 2003.

Sales and marketing expenses. Sales and marketing expenses were \$1.7 million for fiscal year 2004, a decrease of \$331,000, or 16%, from fiscal year 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.

General and administrative expenses. General and administrative expenses were \$5.4 million for fiscal year 2004, a decrease of \$513,000, or 9%, compared with fiscal year 2003. The decrease reflects efficiencies gained in the reorganization as well as lower legal costs.

Asset impairment charge. Results in fiscal year 2004 included a non-cash asset impairment charge of \$16.5 million against our Bloomington, Minnesota contract manufacturing facility

Other income, net. Other income was \$1.2 million for fiscal year 2004, a decrease of 37%, from fiscal year 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 year 2003, our investment advisor sold and reinvested a portion of our bond portfolio generating gains of \$461,000. Results in fiscal year 2004 reflect approximately \$187,000 in gains from such sales. Previously reported fiscal year 2004 results have been retroactively adjusted to show the impact of accounting for InnoRx under the equity method. Prior to completing the acquisition of InnoRx in January 2005, we accounted for our investment in InnoRx under the cost method.

Income tax provision. Our income tax provision was \$4.4 million in fiscal year 2004 compared to \$8.6 million in fiscal year 2003. The effective tax rate was 37.2% in fiscal year 2004, a decrease from 38.0% in fiscal year 2003.

Liquidity and Capital Resources

As of September 30, 2005, we had working capital of \$36.5 million and cash, cash equivalents and investments totaling \$73.3 million. Our investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Our investment 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 our investment advisors to manage our investments primarily for the safety of principal for the foreseeable future. We had positive cash flows from operating activities of approximately \$26.0 million in fiscal year 2005, compared with \$23.2 million in fiscal year 2004.

We conduct a significant majority of our operations at our Eden Prairie, Minnesota headquarters. In addition, we own a facility in Bloomington, Minnesota. We believe we have adequate office space and manufacturing capacity in our Eden Prairie headquarters to support our business and strategic plan. As such, in September 2005, we entered into an agreement to sell the Bloomington facility and plan to consolidate operations in Eden Prairie. During our fiscal third quarter, construction began to improve the research and development capabilities at the Eden Prairie facility. Management estimates expending a total of approximately \$8 million. The capital improvements are expected to be completed during the second quarter of fiscal year 2006.

In February 2004, we invested \$2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing drug delivery devices and therapies for the ophthalmology market. We made an additional investment of approximately \$1.6 million in the first quarter of fiscal year 2005. On January 18, 2005, we entered into a merger agreement whereby SurModics acquired all of the assets of InnoRx, Inc. by paying approximately \$4.1 million in cash and issuing 600,064 shares of SurModics common stock to InnoRx stockholders. On July 1, 2005, we issued 60,002 shares of SurModics' common stock to the shareholders of InnoRx upon the successful completion of the first milestone involving the InnoRx technology acquired in the purchase of InnoRx. Upon the successful completion of the remaining development and commercial milestones involving InnoRx technology acquired in the transaction, we will be required to issue up to an aggregate 540,062 additional shares of our common stock to the stockholders of InnoRx. As the transaction was accounted for as a purchase of assets, SurModics was required to determine the fair value of the assets acquired and the total consideration given. The fair value was determined by an outside valuation consultant. The assets of InnoRx we acquired consisted almost exclusively of in-process research and development assets. In our second fiscal quarter of 2005, we

recorded a charge of \$30.3 million to write-off the value of these in-process research and development assets. In connection with the purchase, we recorded an \$8.1 million credit to additional paid-in capital to record the aggregate estimated value of the contingent payment obligations. Since the contingent payment obligations are recorded as additional paid-in capital, the obligations will not have any impact on future results of operations.

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

We have invested a total of \$5.2 million in Novocell, Inc., a privately-held Irvine, California-based biotech firm that is developing a unique treatment for diabetes. Working with Novocell, our 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 we anticipate that our investment in Novocell will help facilitate the commercialization of our technology and result in revenue for the Company in the future, there can be no assurance that this will occur. Novocell's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized. The \$5.2 million investment, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 5%.

In May 2005, we invested \$1.0 million in ThermopeutiX, an early stage company developing novel medical devices for the treatment of vascular and neurovascular diseases, including stroke. In addition to the investment, we have licensed our hydrophilic and hemocompatible coating technologies to ThermopeutiX for use with its devices. The \$1.0 million investment, which is accounted for under the cost method, represents an ownership interest of less than 20%.

Risks and uncertainties surrounding a development-stage company's ability to obtain on a timely and frequent basis financing needed to continue its development activities currently affect, and will continually affect, the prospects of our investments in Novocell, OctoPlus and ThermopeutiX and the revenue they may ultimately generate. There is no assurance that the development stage companies listed above will successfully meet their immediate or future financing needs or that their financing needs will be met when required. If adverse results occur in the development of their respective technology, or if their respective financing needs are not continually met, the viability of such companies, the value of our investment and their ability to be future sources of revenue for the Company will be in jeopardy, and our investment in such companies would likely be considered impaired and charged against 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. The remaining installments are reflected in other long-term liabilities.

As of September 30, 2005, we had no debt, nor did we have any credit agreements. We believe that our existing capital resources will be adequate to fund our operations into the foreseeable future.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at September 30, 2005 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 material operating leases. See Notes to Financial Statements for additional information regarding the below obligations and commitments.

<u>Contractual obligations</u>	<u>Maturity by Fiscal Year</u>						<u>Thereafter</u>
	<u>Total</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	
	(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 May 2005, FASB issued Statement of Financial Accounting Standards No. 154, Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3 (“SFAS 154”). This statement applies to all voluntary changes in accounting principle and changes required by an accounting pronouncement where no specific transition provisions are included. SFAS 154 requires retrospective application to prior periods’ financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The provisions of SFAS 154 are effective for the Company for accounting changes and correction of errors made in fiscal year 2007. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows.

In December 2004, the Financial Accounting Standards Board issued a revision to Statement of Financial Accounting Standards 123 (SFAS 123(R)), Share-Based Payment. The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. The statement eliminates the alternative method of accounting for employee share-based payments previously available under Accounting Principles Board (APB) Opinion No. 25. The Statement is effective for the Company beginning in the first quarter of fiscal year 2006.

In March 2005, the Securities and Exchange Commission (“SEC”) issued Staff Accounting Bulletin No. 107 (“SAB 107”), which provides guidance on the interaction between SFAS 123(R) and certain SEC rules and regulations. SAB 107 was issued to assist issuers in their initial implementation of SFAS 123(R) and enhance the information received by investors and other users of the financial statements. The Company will consider the guidance provided by SAB 107 as it implements SFAS 123(R) in the first quarter of fiscal year 2006.

In December 2004, the FASB staff issued FSP FASB 109-1 that provides guidance on the application of FASB Statement No. 109, Accounting for Income Taxes, to the provision within the American Jobs Creations Act of 2004 that provides a tax deduction on qualified production activities. This FSP is effective upon issuance. The adoption of this FSP did not have a material impact on our results of operations or financial position for fiscal year 2005. The Company has not determined the impact for fiscal year 2006.

In March 2004, the Emerging Issues Task Force (“EITF”) released Issue No. 03-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments” (“EITF 03-1”) regarding disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under the FASB Statements No. 115, “Accounting for Certain Investments in Debt and Equity Securities,” (“FAS 115”). The effective date for evaluating whether an investment is other-than-temporarily impaired was delayed by FASB Staff Position (FSP) EITF Issue 03-1-1. In November 2005, the FASB issued FSP FAS 115-1 to clarify these rules. Effectively, the FSP issued in November 2005 reverts to the other-than-temporary guidance that predated the original effective date of EITF 03-1; however, it maintains certain guidance in EITF 03-1 relative to testing of cost-method equity securities and the disclosure requirements which have been effective since 2003. The FSP issued in November 2005 is effective for reporting periods beginning after December 15, 2005. The adoption of the FSP issued in November 2005 is not anticipated to have a material effect on our balance sheet or results of operations. The additional disclosures required by EITF 03-1 and maintained by the FSP issued in November 2005 have been considered for inclusion in the notes to our audited fiscal 2005 financial statements

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 \$1.0 million decrease in the fair value of the Company's available-for-sale securities as of September 30, 2005, but no material impact on the results of operations or cash flows. Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The balance sheets as of September 30, 2005 and 2004 and the statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2005, 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.

1. 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.

2. Internal Control over Financial Reporting.

(a) **Management's Report on Internal Control Over Financial Reporting.** Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of September 30, 2005. Management's assessment of the effectiveness of the Company's internal control over financial reporting as of September 30, 2005 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report below.

(b) **Attestation Report of the Independent Registered Public Accounting Firm.**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Report, that SurModics, Inc. (the "Company") maintained effective internal control over financial reporting as of September 30, 2005, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of September 30, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2005, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended September 30, 2005 of the Company and our report dated December 8, 2005 expressed an unqualified opinion on those financial statements.

DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
December 8, 2005

3. 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 2006 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 2006 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 2006 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 2006 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:

	<u>Page (s)</u>
Report of Independent Registered Public Accounting Firm	F-1
Balance Sheets	F-2
Statements of Operations	F-3
Statements of Stockholders' Equity	F-4
Statements of Cash Flows	F-5
Notes to Financial Statements	F-6–F-15

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, 2005

By: /s/ Bruce J Barclay
Bruce J Barclay
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 BRUCE J BARCLAY 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Bruce J Barclay</u> Bruce J Barclay	President and Chief Executive Officer (principal executive officer)	December 14, 2005
<u>/s/ Philip D. Ankeny</u> Philip D. Ankeny	Chief Financial Officer (principal financial officer) and Vice President	December 14, 2005
<u>/s/ Loren R. Miller</u> Loren R. Miller	Vice President and Controller (principal accounting officer)	December 14, 2005
<u>/s/ Dale R. Olseth</u> Dale R. Olseth	Executive Chairman, Director	December 14, 2005
<u>/s/ Jose H. Bedoya</u> Jose H. Bedoya	Director	December 14, 2005
<u>/s/ John W. Benson</u> John W. Benson	Director	December 14, 2005
<u>/s/ Gerald B. Fischer</u> Gerald B. Fischer	Director	December 14, 2005
<u>/s/ Kenneth H. Keller</u> Kenneth H. Keller	Director	December 14, 2005
<u>/s/ David A. Koch</u> David A. Koch	Director	December 14, 2005
<u>/s/ Kendrick B. Melrose</u> Kendrick B. Melrose	Director	December 14, 2005
<u>/s/ John A. Meslow</u> John A. Meslow	Director	December 14, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of SurModics, Inc. (the "Company") as of September 30, 2005 and 2004, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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 financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of SurModics, Inc. as of September 30, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2005, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of September 30, 2005, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 8, 2005 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
December 8, 2005

SurModics, Inc.
 Balance Sheets
 As of September 30

(thousands, except share data)

	<u>2005</u>	<u>2004</u>
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 3,921	\$ 2,709
Short-term investments	20,524	16,506
Accounts receivable, net of allowance for doubtful accounts of \$40 as of September 30, 2005 and 2004	10,996	8,130
Income taxes receivable	3,640	—
Inventories	1,091	1,040
Deferred tax asset	353	379
Prepays and other	<u>1,079</u>	<u>805</u>
Total current assets	41,604	29,569
Property and Equipment, net	14,832	15,738
Long-Term Investments	48,874	44,088
Deferred Tax Asset	2,868	5,579
Other Assets, net	<u>16,047</u>	<u>14,613</u>
Total Assets	<u>\$124,225</u>	<u>\$109,587</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 1,163	\$ 683
Accrued liabilities —		
Compensation	1,629	894
Accrued income taxes payable	—	3,827
Accrued other	1,917	5,857
Deferred revenue	<u>414</u>	<u>528</u>
Total current liabilities	5,123	11,789
Deferred Revenue, less current portion	1,521	1,488
Other Long-Term Liabilities	<u>2,000</u>	<u>2,000</u>
Total liabilities	<u>8,644</u>	<u>15,277</u>
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 18,535,761 and 17,536,656 shares issued and outstanding	927	877
Additional paid-in capital	89,721	57,849
Unearned compensation	(2,621)	(632)
Accumulated other comprehensive income (loss)	(360)	56
Retained earnings	<u>27,914</u>	<u>36,160</u>
Total stockholders' equity	<u>115,581</u>	<u>94,310</u>
Total Liabilities and Stockholders' Equity	<u>\$124,225</u>	<u>\$109,587</u>

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

SurModics, Inc.
Statements of Operations
For the Years Ended September 30

<i>(thousands, except net income per share)</i>	<u>2005</u>	<u>2004</u>	<u>2003</u>
Revenue			
Royalties and license fees	\$ 47,582	\$34,836	\$25,833
Product sales	9,403	10,478	11,804
Research and development	5,396	4,424	5,595
Total revenue	<u>62,381</u>	<u>49,738</u>	<u>43,232</u>
Operating Costs and Expenses			
Product	2,855	3,035	2,649
Research and development	16,072	12,633	12,000
Sales and marketing	1,209	1,683	2,014
General and administrative	6,496	5,416	5,929
Asset impairment charge	2,487	16,497	—
Purchased in-process research & development	30,277	—	—
Total operating costs and expenses	<u>59,396</u>	<u>39,264</u>	<u>22,592</u>
Income from Operations	<u>2,985</u>	<u>10,474</u>	<u>20,640</u>
Other Income, net			
Investment income	1,967	1,185	1,398
Other income (loss)	(602)	(7)	461
Other income, net	<u>1,365</u>	<u>1,178</u>	<u>1,859</u>
Income Before Income Taxes	4,350	11,652	22,499
Income Tax Provision	<u>(12,596)</u>	<u>(4,410)</u>	<u>(8,563)</u>
Net income (loss)	<u>(\$ 8,246)</u>	<u>\$ 7,242</u>	<u>\$13,936</u>
Basic net income (loss) per share	(\$0.45)	\$0.41	\$0.80
Diluted net income (loss) per share	(\$0.45)	\$0.41	\$0.78
Weighted Average Shares Outstanding			
Basic	18,131	17,501	17,363
Dilutive effect of outstanding stock options	—	299	474
Diluted	<u>18,131</u>	<u>17,800</u>	<u>17,837</u>

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

SurModics, Inc.

Statements of Stockholders' Equity

For the Years Ended September 30, 2005, 2004 and 2003

<i>(in thousands)</i>	Common Stock		Additional Paid-In Capital	Unearned Compensation	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount					
Balance, September 30, 2002	17,272	\$864	\$53,936	\$ (460)	\$ 673	\$14,982	\$ 69,995
Components of comprehensive income, net of tax:							
Net income	—	—	—	—	—	13,936	13,936
Unrealized holding losses on available-for-sale securities arising during the period	—	—	—	—	(51)	—	(51)
Less reclassification for gains included in net income, net of tax	—	—	—	—	(285)	—	(285)
Comprehensive income							13,600
Issuance of common stock	17	1	404	—	—	—	405
Common stock options exercised, net	149	7	765	—	—	—	772
Tax benefit from exercise of stock options	—	—	1,186	—	—	—	1,186
Restricted stock activity	1	—	162	(162)	—	—	—
Amortization of unearned compensation	—	—	—	156	—	—	156
Balance, September 30, 2003	17,439	872	56,453	(466)	337	28,918	86,114
Components of comprehensive income, net of tax:							
Net income	—	—	—	—	—	7,242	7,242
Unrealized holding losses on available-for-sale securities arising during the period	—	—	—	—	(164)	—	(164)
Less reclassification for gains included in net income, net of tax	—	—	—	—	(117)	—	(117)
Comprehensive income							6,961
Issuance of common stock	19	1	344	—	—	—	345
Common stock options exercised, net	63	3	350	—	—	—	353
Tax benefit from exercise of stock options	—	—	325	—	—	—	325
Restricted stock activity	16	1	377	(378)	—	—	—
Amortization of unearned compensation	—	—	—	212	—	—	212
Balance, September 30, 2004	17,537	877	57,849	(632)	56	36,160	94,310
Components of comprehensive loss, net of tax:							
Net loss	—	—	—	—	—	(8,246)	(8,246)
Unrealized holding losses on available-for-sale securities arising during the period	—	—	—	—	(481)	—	(481)
Less reclassification for losses included in net income, net of tax	—	—	—	—	65	—	65
Comprehensive loss							(8,662)
Issuance of common stock	682	34	25,731	—	—	—	25,765
Common stock options exercised, net	244	12	2,310	—	—	—	2,322
Tax benefit from exercise of stock options	—	—	1,258	—	—	—	1,258
Restricted stock activity	73	4	2,573	(2,577)	—	—	—
Amortization of unearned compensation	—	—	—	588	—	—	588
Balance, September 30, 2005	<u>18,536</u>	<u>\$927</u>	<u>\$89,721</u>	<u>(\$ 2,621)</u>	<u>(\$ 360)</u>	<u>\$27,914</u>	<u>\$115,581</u>

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

SurModics, Inc.
Statements of Cash Flows

<u>For the Years Ended September 30 (in thousands)</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>
Operating Activities			
Net income (loss)	(\$ 8,246)	\$ 7,242	\$ 13,936
Adjustments to reconcile net income (loss) to net cash provided by operating activities —			
Depreciation and amortization	3,733	3,125	2,583
Loss (gain) on InnoRx equity method and sales of investments	602	7	(461)
Asset impairment charge	2,487	16,497	—
Noncash compensation	588	212	156
Purchased in-process research & development	30,277	—	—
Deferred tax	5,143	(5,640)	839
Tax benefit from exercise of stock options	1,258	325	1,186
Loss (gain) on disposals of property and equipment	(65)	22	1
Change in operating assets and liabilities:			
Accounts receivable	(2,866)	1,015	(3,639)
Inventories	(51)	(177)	(117)
Accounts payable and accrued liabilities	912	(966)	447
Income taxes	(7,467)	2,269	2,043
Deferred revenue	(81)	(663)	202
Prepays and other	(274)	(78)	(124)
Net cash provided by operating activities	<u>25,950</u>	<u>23,190</u>	<u>17,052</u>
Investing Activities			
Purchases of property and equipment	(2,109)	(5,474)	(15,454)
Purchases of available-for-sale investments	(98,716)	(45,976)	(42,896)
Sales/maturities of available-for-sale investments	88,955	27,092	35,885
Purchase of equity in OctoPlus, Novocell and other	(5,133)	(302)	(925)
Purchase of licenses	(5,238)	(64)	(10)
Investment in and acquisition costs for InnoRx	(5,181)	(2,331)	—
Repayment of notes receivable	—	1,869	(30)
Net cash used in investing activities	<u>(27,422)</u>	<u>(25,186)</u>	<u>(23,430)</u>
Financing Activities			
Issuance of common stock	2,684	698	1,178
Net cash provided by financing activities	<u>2,684</u>	<u>698</u>	<u>1,178</u>
Net increase (decrease) in cash and cash equivalents	1,212	(1,298)	(5,200)
Cash and Cash Equivalents			
Beginning of year	<u>2,709</u>	<u>4,007</u>	<u>9,207</u>
End of year	<u>\$ 3,921</u>	<u>\$ 2,709</u>	<u>\$ 4,007</u>
Supplemental Information			
Cash paid for taxes	\$ 13,780	\$ 7,265	\$ 4,327
Noncash transaction-purchase Abbott Laboratories sublicense	—	\$ 7,020	—
Noncash transaction-acquisition of property, plant, and equipment on account	\$ 1,268	\$ 248	\$ 4,298

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

SurModics, Inc.Notes to Financial Statements
September 30, 2005 and 2004*1. Description*

SurModics, Inc. (the Company) develops, manufactures and markets innovative surface modification and drug delivery technologies for the healthcare industry. The Company's revenue is derived from three primary sources: (1) royalties and license fees from licensing its patented surface modification and drug delivery technologies and in vitro diagnostic formats 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 customers.

*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, 2005 and 2004. 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*):

	2005			
	<u>Original Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
U.S. government obligations	\$32,392	\$ 36	(\$256)	\$32,172
Mortgage-backed securities	15,782	37	(157)	15,662
Asset-backed securities	10,744	3	(81)	10,666
Municipal bonds	10,127	1	(154)	9,974
Corporate bonds	927	1	(4)	924
Total	<u>\$69,972</u>	<u>\$ 78</u>	<u>(\$652)</u>	<u>\$69,398</u>

	2004			
	<u>Original Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
Mortgage-backed securities	\$28,035	\$ 82	(\$ 56)	\$28,061
U.S. government obligations	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	<u>\$60,521</u>	<u>\$240</u>	<u>(\$167)</u>	<u>\$60,594</u>

The original cost and fair value of investments by contractual maturity at September 30, 2005, were as follows (in thousands):

	<u>Original Cost</u>	<u>Fair Value</u>
Debt securities due within:		
One year	\$20,504	\$20,524
One to five years	33,765	33,260
Five years or more	<u>15,703</u>	<u>15,614</u>
Total	<u>\$69,972</u>	<u>\$69,398</u>

The following table summarizes sales of available-for-sale securities for the years ended September 30, 2005, 2004, and 2003 (in thousands):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Proceeds from sales	\$88,955	\$27,092	\$35,885
Gross realized gains	\$17	\$187	\$506
Gross realized losses	(\$119)	\$0	(\$45)

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 as of September 30 (in thousands):

	<u>2005</u>	<u>2004</u>
Raw materials	\$ 512	\$ 634
Finished products	<u>579</u>	<u>406</u>
Total	<u>\$1,091</u>	<u>\$1,040</u>

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 Company recorded depreciation expense of approximately \$2.0 million in 2005, \$3.1 million in 2004, and \$2.6 million in 2003.

In September 2005, the Company entered an agreement to sell a building and 27 acres of land located in Bloomington, Minnesota. SurModics intends to occupy portions of the building until modifications to the Company's Eden Prairie, Minnesota facility are complete, at which time the Company will consolidate operations at its Eden Prairie headquarters. The Company will continue to record depreciation expense on the facility until completion of the sale. The Company expects to vacate the Bloomington facility by the end of the third quarter of fiscal 2006.

The 2005 and 2004 balances in construction-in-progress include the cost of enhancing the capabilities of our facilities. 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.

Property and equipment consisted of the following components as of September 30 (in thousands):

	<u>2005</u>	<u>2004</u>	<u>Useful life</u> <u>(in years)</u>
Laboratory fixtures and equipment	\$ 9,550	\$ 9,954	3 to 5
Building and improvements	7,306	7,411	5 to 30
Building subject to sale agreement	6,650	8,955	5 to 30
Office furniture and equipment	2,718	3,152	3 to 5
Construction-in-progress	2,456	127	
Less accumulated depreciation and amortization	<u>(13,848)</u>	<u>(13,861)</u>	
Property and equipment, net	<u>\$ 14,832</u>	<u>\$ 15,738</u>	

Other Assets

Other assets consist principally of investments, acquired patents, and licenses. The cost of patents is amortized over 4 to 19 years. The Company recorded amortization expense of \$1.7 million in 2005, \$22,000 in 2004, and \$23,000 in 2003.

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

In February 2004, the Company invested \$2.1 million in InnoRx, Inc., an Alabama-based, early-stage company developing drug delivery devices and therapies for the ophthalmology market. SurModics made an additional investment of approximately \$1.6 million in the first quarter of fiscal year 2005. On January 18, 2005, SurModics acquired via a merger all of InnoRx's assets by paying approximately \$4.1 million in cash, issuing 600,064 shares of SurModics common stock to InnoRx stockholders and agreeing to issue up to an additional 600,064 shares if certain development and commercial milestones are met. On July 1, 2005, the Company issued 60,002 shares of SurModics common stock to the shareholders of InnoRx upon the successful completion of the first milestone involving the InnoRx technology acquired in the purchase of InnoRx. Upon the successful completion of the remaining development and commercial milestones involving InnoRx technology acquired in the transaction, the Company will be required to issue up to an aggregate 540,062 additional shares of our common stock to the stockholders of InnoRx. As the transaction was accounted for as a purchase of assets, SurModics was required to determine the fair value of the assets acquired and the total consideration given. The assets of InnoRx we acquired consisted almost exclusively of in-process research and development assets. In the second fiscal quarter of 2005, we recorded a charge of \$30.3 million to write-off the value of these in-process research and development assets. In connection with the purchase, the Company recorded an \$8.1 million credit to additional paid-in capital to record the aggregate estimated value of the contingent payment obligations. Since the contingent payment obligations are recorded as additional paid-in capital, the obligations will not have any impact on future results of operations.

SurModics has invested a total of \$5.2 million in Novocell, Inc., a privately-held Irvine, California-based biotech firm that is developing a unique treatment for diabetes using coated islet cells, the cells that produce insulin in the human body. The \$5.2 million investment, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 5%. In January 2005, the Company made an equity investment of approximately \$3.9 million in OctoPlus, a privately owned company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers. The \$3.9 million investment, which is accounted for under the cost method, represents an ownership interest of less than 20%. In May 2005, the Company invested \$1.0 million in ThermopeutiX, an early stage company developing novel medical devices for the treatment of vascular and neurovascular diseases, including stroke. In addition to the investment, SurModics has licensed its hydrophilic and hemocompatible coating technologies to ThermopeutiX for use with its devices. The \$1.0 million investment, which is accounted for under the cost method, represents an ownership interest of less than 20%.

The Company expects to incur approximately \$1.7 million of amortization expense in fiscal 2006 through 2008, \$436,000 in fiscal 2009, and \$18,000 in fiscal 2010 related to all of its licenses and patents.

Other assets consisted of the following as of September 30 (*in thousands*):

	<u>2005</u>	<u>2004</u>
Abbott license	\$ 7,037	\$ 7,020
Investment in Novocell	5,210	5,210
Investment in InnoRx	—	1,968
Investment in OctoPlus	3,935	—
Investment in ThermopeutiX	1,000	—
Patents and other	732	599
Less accumulated amortization	<u>(1,867)</u>	<u>(184)</u>
Other assets, net	<u>\$16,047</u>	<u>\$14,613</u>

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 Statements of Financial Accounting Standards (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 (loss) 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):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net income (loss)			
As reported	(\$ 8,246)	\$ 7,242	\$13,936
Fair value compensation expense, net of tax	<u>(2,746)</u>	<u>(1,742)</u>	<u>(1,574)</u>
Pro forma	<u>(\$10,992)</u>	<u>\$ 5,500</u>	<u>\$12,362</u>
Basic net income (loss) per share:			
As reported	(\$ 0.45)	\$ 0.41	\$0.80
Fair value compensation expense, net of tax	<u>(0.16)</u>	<u>(0.10)</u>	<u>(0.09)</u>
Pro forma	<u>(\$ 0.61)</u>	<u>\$ 0.31</u>	<u>\$0.71</u>
Diluted net income (loss) per share:			
As reported	(\$ 0.45)	\$ 0.41	\$0.78
Fair value compensation expense, net of tax	<u>(0.16)</u>	<u>(0.10)</u>	<u>(0.09)</u>
Pro forma	<u>(\$ 0.61)</u>	<u>\$ 0.31</u>	<u>\$0.69</u>

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 2005, 2004, and 2003 respectively: risk-free interest rates of 3.77%, 3.56%, and 3.05%; expected lives of 7.0, 7.4, and 7.4; and expected volatility of 63%, 66%, and 69%. 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 and investments. 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. In fiscal 2004, the Company announced that after careful examination of its redefined business goals, the Company believed its Bloomington contract manufacturing facility was no longer necessary for the execution of its strategic plan. Accordingly, results in the third quarter of fiscal year 2004 included a non-cash asset impairment charge of \$16.5 million. In September 2005, the Company signed an agreement to sell the Bloomington property and facility and based on the selling price recorded an additional \$2.5 million impairment charge in the fourth quarter of fiscal year 2005.

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 the Company's product is shipped. Revenue for research and development is recorded as performance progresses under the applicable contract.

Use of Estimates

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

Reclassifications and Retroactive Adjustments

Certain reclassifications have been made to the prior year's financial statements in order to conform to the 2005 presentation. Fiscal year 2004 results have been retroactively adjusted to show the impact of accounting for InnoRx under the equity method. The net impact reduced net income an approximate \$194,000 from previously reported results.

New Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board (FASB) issued SFAS No. 154, Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3 (“SFAS 154”). This statement applies to all voluntary changes in accounting principle and changes required by an accounting pronouncement where no specific transition provisions are included. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The provisions of SFAS 154 are effective for the Company for accounting changes and correction of errors made in fiscal year 2007. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS 123(R), Share-Based Payment. The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. The statement eliminates the alternative method of accounting for employee share-based payments previously available under APB Opinion No. 25. The Statement is effective for the Company beginning in the first quarter of fiscal year 2006.

In March 2005, the Securities and Exchange Commission (“SEC”) issued Staff Accounting Bulletin No. 107 (“SAB 107”), which provides guidance on the interaction between SFAS 123(R) and certain SEC rules and regulations. SAB 107 was issued to assist issuers in their initial implementation of SFAS 123(R) and enhance the information received by investors and other users of the financial statements. The Company will consider the guidance provided by SAB 107 as it implements SFAS 123(R) in the first quarter of fiscal year 2006.

In March 2004, the Emerging Issues Task Force (“EITF”) released Issue No. 03-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments” (“EITF 03-1”) regarding disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under the FASB Statements No. 115, “Accounting for Certain Investments in Debt and Equity Securities,” (“FAS 115”). The effective date for evaluating whether an investment is other-than-temporarily impaired was delayed by FASB Staff Position (FSP) EITF Issue 03-1-1. In November 2005, the FASB issued FSP FAS 115-1 to clarify these rules. Effectively, the FSP issued in November 2005 reverts to the other-than-temporary guidance that predated the original effective date of EITF 03-1; however, it maintains certain guidance in EITF 03-1 relative to testing of cost-method equity securities and the disclosure requirements which have been effective since 2003. The FSP issued in November 2005 is effective for reporting periods beginning after December 15, 2005. The adoption of the FSP issued in November 2005 is not anticipated to have a material effect on our balance sheet or results of operations. The additional disclosures required by EITF 03-1 and maintained by the FSP issued in November 2005 have been considered for inclusion in the notes to our audited fiscal year 2005 financial statements.

In December 2004, the FASB staff issued FSP FASB 109-1 that provides guidance on the application of SFAS No. 109, Accounting for Income Taxes, to the provision within the American Jobs Creations Act of 2004 that provides a tax deduction on qualified production activities. This FSP is effective upon issuance. The adoption of this FSP did not have a material impact on our results of operations or financial position for fiscal year 2005.

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 21,556, 19,169, and 17,179 shares under the Stock Purchase Plan during fiscal 2005, 2004, and 2003, respectively. As of September 30, 2005 and 2004, there was approximately \$233,000 and \$255,000, 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 the vesting 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 vesting term.

Transactions in restricted stock were as follows:

Outstanding at September 30, 2002	55,000
Granted	5,000
Canceled	(4,000)
Vested	<u>(8,000)</u>
Outstanding at September 30, 2003	48,000
Granted	20,000
Canceled	(4,000)
Vested	<u>(22,500)</u>
Outstanding at September 30, 2004	41,500
Granted	73,500
Canceled	—
Vested	<u>(7,000)</u>
Outstanding at September 30, 2005	<u>108,000</u>

4. Stock-Based Compensation Plan

In fiscal year 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 had 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 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. In January 2005, shareholders approved an amendment to increase the shares reserved under the 2003 Plan by 1,800,000 shares to 2,400,000 shares.

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, 2005, there were 1,216,450 additional shares available for grant under the 2003 Plan. Information regarding stock options under all plans is summarized as follows:

<u>Exercise Price Range</u>	<u>Shares Outstanding at September 30, 2005</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Shares Exercisable at September 30, 2005</u>	<u>Weighted Average Exercise Price</u>
\$ 2.50-\$ 8.44	151,575	\$ 7.00	1.68	151,575	\$ 7.00
\$10.25-\$21.82	311,240	21.19	5.69	81,400	20.26
\$22.46-\$25.09	117,000	24.95	2.58	103,368	25.07
\$27.00-\$29.89	669,950	29.38	6.03	60,020	29.32
\$30.13-\$53.00	<u>280,170</u>	37.24	5.42	<u>72,260</u>	36.02
	1,529,935	\$26.60	5.16	468,623	\$20.62

<u>Options</u>	<u>2005</u>		<u>2004</u>		<u>2003</u>	
	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding, beginning of year	1,147,563	\$20.12	982,965	\$19.57	964,215	\$14.86
Granted	698,100	31.38	352,700	21.54	241,100	30.01
Exercised	(244,418)	9.58	(62,052)	5.69	(155,418)	6.30
Canceled	(71,310)	27.54	(126,050)	26.90	(66,932)	20.26
Outstanding, end of year	<u>1,529,935</u>	<u>\$26.60</u>	<u>1,147,563</u>	<u>\$20.12</u>	<u>982,965</u>	<u>\$19.57</u>
Exercisable, end of year	<u>468,623</u>	<u>\$20.62</u>	<u>568,367</u>	<u>\$14.52</u>	<u>505,025</u>	<u>\$11.61</u>
Weighted average fair value of options granted	<u>\$20.26</u>		<u>\$14.57</u>		<u>\$20.69</u>	

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 operations for the years ended September 30 were as follows (*in thousands*):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Current provision:			
Federal	\$ 7,059	\$ 8,697	\$6,524
State and foreign	<u>371</u>	<u>1,179</u>	<u>1,032</u>
Total current provision	7,430	9,876	7,556
Deferred provision (benefit):			
Federal	4,592	(4,827)	981
State	<u>574</u>	<u>(639)</u>	<u>26</u>
Total deferred provision (benefit)	<u>5,166</u>	<u>(5,466)</u>	<u>1,007</u>
Total provision	<u>\$12,596</u>	<u>\$ 4,410</u>	<u>\$8,563</u>

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*):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Amount at statutory federal income tax rate	\$ 1,513	\$ 4,146	\$7,870
Change due to:			
State taxes	496	351	676
Other	(10)	(87)	17
Write-off of in-process R&D	<u>10,597</u>	<u>—</u>	<u>—</u>
Income tax provision	<u>\$12,596</u>	<u>\$ 4,410</u>	<u>\$8,563</u>

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*):

	<u>2005</u>	<u>2004</u>
Depreciable assets	\$1,584	\$4,851
Deferred revenue	611	625
Accruals and reserves	362	379
Restricted stock amortization	273	149
Equity items	(33)	(33)
Other	—	(13)
Net operating loss	<u>424</u>	<u>—</u>
Total deferred tax asset	<u>3,221</u>	<u>5,958</u>
Current deferred tax asset	<u>353</u>	<u>379</u>
Noncurrent deferred tax asset	<u>\$2,868</u>	<u>\$5,579</u>

6. Commitments and Contingencies

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 will not 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 \$223,000, \$210,000, and \$204,000 have been charged to income for the years ended September 30, 2005, 2004, and 2003.

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.

SurModics manages its business on the basis of the operating segments noted in the table below, which are comprised of the Company's six business units. The three operating segments are aggregated into one reportable segment. The "Drug Delivery" operating segment contains the Drug Delivery business unit, which is responsible for technologies dedicated to site specific delivery of drugs, and the Ophthalmology division, which is dedicated to the advancement of treatments for eye diseases, such as age-related macular degeneration (AMD) and diabetic macular edema (DME), two of the leading causes of blindness. The "Hydrophilic and Other" operating segment consists of three business units: (1) Hydrophilic Technologies business unit, which focuses on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) Regenerative Technologies business unit, which is developing platforms intended to augment or replace tissue/organ function (e.g., cell encapsulation applications), or to modify medical devices to facilitate tissue/organ recovery through natural repair mechanisms (e.g., hemo/biocompatible coatings); and (3) Orthopedics business unit, which is committed to innovative solutions for orthopedics patients using proven SurModics technologies, and creating new technology solutions to existing patient care gaps in the orthopedics field. The "Diagnostics" operating segment contains the Diagnostics and Drug Discovery business unit, which includes our genomics slide technologies, our stabilization products for immunoassay diagnostics tests, our in vitro diagnostic format technology and the work being performed to develop synthetic cell culture products.

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. Revenue for each operating segment for the years ended September 30 was as follows (*in thousands*):

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Operating segment:			
Drug Delivery	\$29,678	\$25,690	\$20,168
Hydrophilic and Other	19,065	15,527	12,380
Diagnostics	<u>13,638</u>	<u>8,521</u>	<u>10,684</u>
Total Revenue	<u>\$62,381</u>	<u>\$49,738</u>	<u>\$43,232</u>

Major Customers

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cordis Corporation	46%	52%	48%
Abbott Laboratories	14%	8%	10%
GE Healthcare (formerly Amersham plc)	6%	7%	13%

The revenues from each of the customers are derived from all three primary sources: licensing, product sales, and research and development.

Geographic Revenue

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

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Domestic	85%	79%	66%
Foreign	15%	21%	34%

9. Quarterly Financial Data

The following is a summary of the unaudited quarterly results for the years ended September 30, 2005, 2004 and 2003 (in thousands, except per share data).

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<u>Fiscal Year 2005</u>				
Revenue	\$14,069	\$ 15,705	\$ 16,518	\$16,090
Income (loss) from operations	8,638	(21,148)	9,148	6,346
Net income (loss)	5,682	(24,371)	6,095	4,793
Net income (loss) per share:				
Basic	0.32	(1.34)	0.33	0.26
Diluted	0.32	(1.34)	0.32	0.25
<u>Fiscal Year 2004</u>				
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	4,305	(6,551)	5,378
Net income (loss) per share:				
Basic	0.24	0.25	(0.37)	0.31
Diluted	0.23	0.24	(0.37)	0.30
<u>Fiscal Year 2003</u>				
Revenue	\$ 8,048	\$ 9,742	\$ 12,819	\$12,623
Income from operations	2,856	3,992	6,958	6,834
Net income	2,171	2,750	4,572	4,443
Net income per share:				
Basic	0.13	0.16	0.26	0.25
Diluted	0.12	0.15	0.26	0.25

In the second quarter of fiscal year 2005, we recorded a charge of \$30.3 million to write-off the value of in-process research and development assets acquired in the purchase of InnoRx. In addition, fiscal year 2005 fourth quarter results include a \$2.5 million impairment charge recorded against our Bloomington, Minnesota contract manufacturing facility.

Fiscal year 2004 results have been retroactively adjusted to show the impact of accounting for InnoRx under the equity method. The net impact reduced net income an approximate \$67,000 in the second quarter, \$61,000 in the third quarter and \$66,000 in the fourth quarter from previously reported results. Fiscal year 2004 third quarter results include an impairment charge recorded against our Bloomington 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, 2005

SURMODICS, INC.

Exhibit

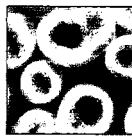
- 2.1 Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 18, 2005, SEC File No. 0-23837.
- 3.1 Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 to 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.
- 4.1 Rights Agreement, dated as of April 5, 1999, between the Company and Firststar Bank Milwaukee, NA., as Rights Agent, including as: Exhibit A Statement of Designation of Series A Preferred Stock of the Company; Exhibit B Summary of Rights to Purchase Shares of Series A Preferred Stock; and Exhibit C Form of Right Certificate — incorporated by reference to Exhibit 1 to the Company's Registration of Securities on Form 8-A, 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 under 1997 Plan — 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 under 1997 Plan — 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 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.
- 10.8 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.
- 10.9* Form of officer acceptance regarding employment/compensation.**
- 10.10* The Company's 2003 Equity Incentive Plan, including forms of incentive stock option, non-qualified stock option and restricted stock agreements.**

Exhibit

- 10.11* Amendment (adopted November 15, 2005 by the board of directors and approved January 31, 2005, by shareholders) to the Company's 2003 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, SEC File No. 0-23837.
- 10.12* The Company's 2005 Bonus Plan — incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2004, SEC File No. 0-23837.
- 10.13* The Company's Board Compensation Policy effective January 31, 2005, as modified November 14, 2005.**
- 10.14* Summary of Compensation Arrangements for Named Executive Officers of the Company.**
- 10.15* The Company's 2006 Bonus Plan — Executive Officers**
- 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.**

* Management contract or compensatory plan or arrangement

** Filed herewith



2005 Annual Report and Shareholder Letter

To Our Shareholders:

I am pleased to report another impressive year of financial and operational achievements for fiscal year 2005.

In last year's letter to you we reflected on the significant strategic and operational changes made through our business reorganization earlier in fiscal year 2004. These changes were designed to both improve our operating results by instilling a greater sense of urgency and more accountability through the newly formed business units, and accelerate our technology leadership by focusing on the creation and acquisition of value added technology. I am pleased to report that in fiscal year 2005 our organization made significant progress in both of these important areas aided by our new strategic direction and our entrepreneurial, customer focused and technology centered business units.

Delivering Operating Results That Matter Most

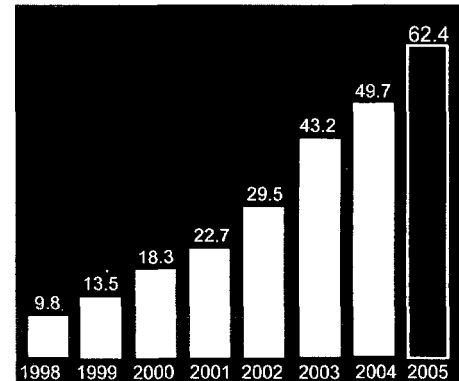
Strong Financial Results

Since our IPO, we have delivered record revenue for eight consecutive years and have demonstrated our proven leadership in surface modification and site specific drug delivery. We also produced many other highly successful fiscal year 2005 results including records for number of licenses signed with our customers, number of patent applications filed, and earnings before non-cash charges. Total revenue increased 25% to \$62.4 million, and excluding certain non-cash charges*, operating income increased 33% and net income was \$23.6 million, or \$1.27 per diluted share, up 34% from \$17.6 million, or \$0.99 per diluted share, in fiscal year 2004. Our operating margin increased to 57.3%.

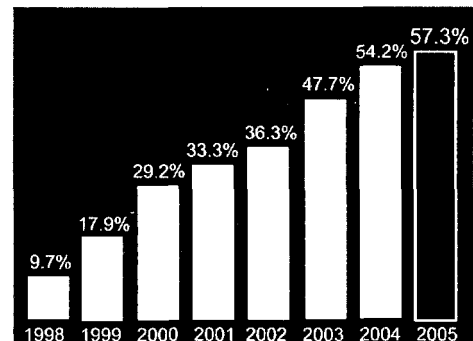
Strong CYPHER® Stent Results . . . But Our Diversification Strategy is Working

The CYPHER® Sirolimus-eluting Coronary Stent from Cordis Corporation, a Johnson & Johnson company, continues to benefit from a growing body of clinical data published in prestigious cardiology journals suggesting superior safety and efficacy. J&J reported the CYPHER stent's share of the U.S. market has grown to 46% for the quarter ended September 30, 2005, up from 35% in the year earlier period. We are pleased to be associated with the success of the CYPHER stent.

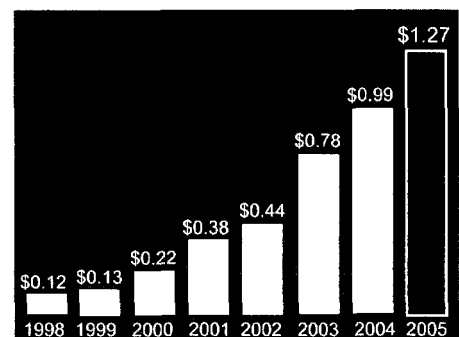
TOTAL REVENUE
(dollars in millions)

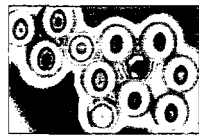


OPERATING MARGIN
(excluding certain charges)



DILUTED EPS
(excluding certain charges)





We are also aggressively diversifying our business. One measure of the progress we have made toward our diversification goals is the increasing percentage of non-Cordis related revenue. In fiscal year 2004, non-Cordis represented 48% of total revenue, but despite year-over-year growth in Cordis revenue, the non-Cordis contribution increased to 54% in 2005. Looking at it in another way, total revenue from Cordis grew 11% from fiscal year 2004 to fiscal year 2005, while non-Cordis revenue grew 41% during the same period.

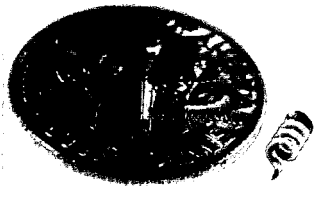
We are focused on maintaining a balanced revenue stream by growing our customer base and portfolio of products and technologies. The breadth and depth of our pipeline is increasing, and products are expected from each of our distinct business units. At fiscal year end, 80 products utilizing SurModics technology were on the market generating royalty revenue, with 72 licensed products awaiting launch, and an additional 64 non-licensed opportunities in the pipeline. Our efforts to optimize the portfolio have made us even more confident in the revenue potential and partnering promise of the projects employing SurModics technology under development today.

Enhancing the Business Model

Throughout fiscal year 2005, we focused on execution and implementation of our seven point revenue growth strategy designed to maintain long-term sustainable growth by: (1) exploiting the convergence of drugs and devices, (2) capturing more elements of the value chain, (3) expanding the portfolio of technology offerings, (4) leveraging our technology in new markets, (5) efficiently managing our product portfolio, (6) expanding our distribution capabilities, and (7) putting the balance sheet to work. For example:

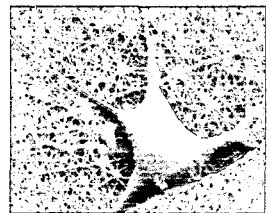
- The January acquisition of InnoRx, Inc. provided us with a platform technology that, in combination with our drug delivery polymers, provides the foundation for our new ophthalmology division. The InnoRx technology platform

By delivering both the coating and device platform along with relevant clinical data to potential partners, we expect to capture more components of the value chain.

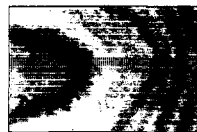


addresses two of the leading causes of blindness: age-related macular degeneration (AMD) and diabetic macular edema (DME). Industry experts anticipate this market will reach \$2.5 billion to \$7.0 billion within six years. Our **STRIDE** (Sustained Triamcinolone Release for Inhibition of Diabetic Macular Edema) Phase I clinical trial of the I-vation™ Intravitreal Implant was initiated in June, and we expect to have six-month follow-up data available in 2006. By delivering both the coating and device platform, along with relevant clinical data to potential partners, we expect to capture more components of the value chain. We believe that doing so gives us the potential to dramatically increase the royalty rates we can earn.

- In May, we entered into a joint development agreement with the Donaldson Company to improve cell culture performance by combining their nanofibers with our surface modification technology. Some industry experts estimate the targeted cell culture research market to be as large as \$100 million and the drug discovery high throughput screening market to total \$500 million. Because no FDA approval process is necessary for these products, we expect to be able to launch a new offering soon.



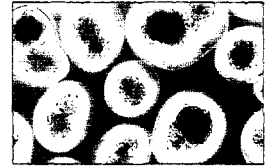
- We are leveraging multiple avenues to participate in the dynamic drug eluting stent (DES) market. Currently, we have three business units serving the cardiology field: Drug Delivery, Regenerative Technologies, and Hydrophilic Technologies. Our Drug Delivery unit offers eight polymers to provide site-specific controlled release drug delivery. Regenerative Technologies is introducing antithrombotic and pro-healing technologies into the market, which could play a significant role in future generations of





DES products. Hydrophilic Technologies offers advanced lubricity, hydrophilic coatings on DES delivery catheters. The experience gained during the development of our coating for the CYPHER stent, our strong track record and reputation, and our broad portfolio of technologies uniquely position us to exploit the convergence of drugs and devices.

- Lastly, we are encouraged by the positive steps taken by Novocell to develop a potential treatment for diabetes. Novocell has received FDA approval of its IND application and expects to commence its first-in-man Phase I/II trial soon. Our equity investment in Novocell and the role our technology plays in their offering positions us to greatly benefit from a technology with the potential to revolutionize the treatment of diabetes.

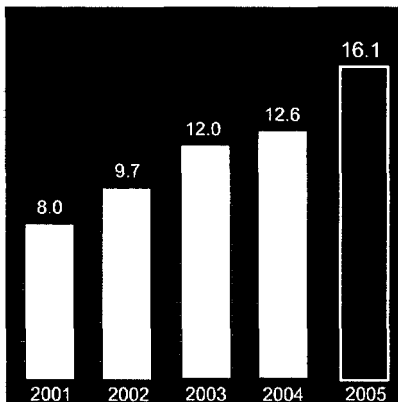


Accelerating Our Technology Leadership

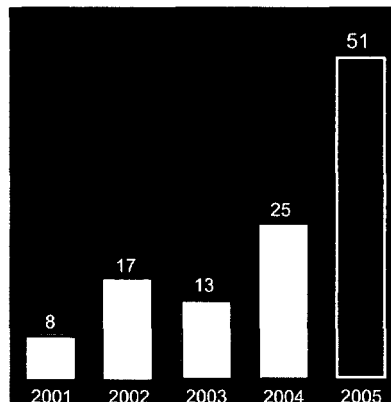
Increasing Our Investment in Research and Development

To keep our pipeline brimming with new technologies, we must remain deeply committed to R&D investment. We made significant investments in research and development to ensure that we stay on the cutting edge of science and technology. In fiscal year 2005, we dedicated \$16.1 million to R&D, a record amount representing 26% of revenue, and a 27% increase from the prior year period. As a result of this increased investment and to protect our innovations, we filed 51 new U.S. patent applications in fiscal year 2005, a record number for SurModics. As evidenced by our record number of customer licenses, we continue to develop technologies that are valued in the marketplace today.

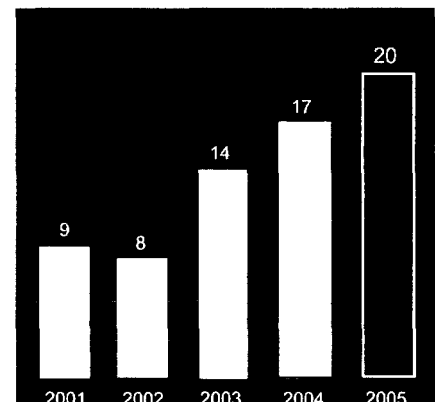
R&D SPENDING
(dollars in millions)



U.S. PATENT APPLICATIONS FILED

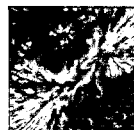


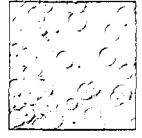
NEW CUSTOMER LICENSES EXECUTED



Acquiring External Technologies

We also put our balance sheet to work to expand our pipeline and increase the value we bring to our partners and customers. I have already mentioned our acquisition of InnoRx – one that we believe has the potential to create value for years to come. In addition, we gained rights to several other exciting technologies, including our licensing of the Rutgers biodegradable polymers and our equity investments in OctoPlus and ThermopeutiX. We are also very excited about our relationship with the University of Arizona and Dr. Stuart Williams to develop a promising approach to address the problem of stent thrombosis through novel prohealing technology.





Delivering Sustainable, Long-Term Shareholder Value

As much as we are pleased with our results to date, SurModics remains committed to continually enhancing our market position. Innovation will continue to thrive at SurModics as our product development capabilities grow ever stronger – both in developing proprietary technology and working in collaboration with our customers. We believe our future at the forefront of the convergence of drugs and devices looks bright, and we will continue to make good use of the wealth of opportunities that are afforded to us as a result of our unique position in the market. The core tenets of innovation and integrity that have been part of our company for over a quarter century remain steadfast as our business continues to evolve and improve. We will continue to be a results-driven company that follows ethical business practices.

We believe our future at the forefront of the convergence of drugs and devices looks bright . . .

Our employees have worked hard to create our leadership position in the surface modification and drug delivery area, and I thank them for their dedication and commitment. I would also like to thank our customers and shareholders for their loyalty and support. I look forward to reporting additional achievements from SurModics throughout the year.

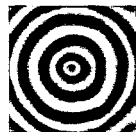
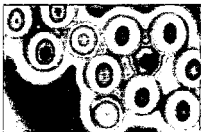
Bruce J Barclay
President and CEO



SurModics Corporate Officers: Standing (left to right): Charlie Olson, Paul Lopez, Greg Yung, Steve Keough, Phil Ankeny, Loren Miller, Doug Astry, Dave Wood. Seated: Aron Anderson, Bruce Barclay, Lise Duran.

* Non-cash charges included a \$30.5 million charge to write-off in-process research and development in connection with the acquisition of InnoRx in January 2005, and a \$2.5 million asset impairment charge related to the sale of our Bloomington, Minnesota facility in September 2005. Including these non-cash charges, operating income was \$3.0 million and our net loss was \$(8.2) million, or \$(0.45) per diluted share. Fiscal year 2004 results included a non-cash asset impairment charge of \$16.5 million against the Bloomington facility. Including the charge, operating income was \$10.5 million, and net income was \$7.2 million, or \$0.41 per diluted share.

Forward-Looking Statements. Certain statements contained in this communication may be deemed to be forward-looking statements under federal securities laws, and SurModics intends that such forward looking statements be subject to the safe harbor created thereby.



SurModics
Bringing Innovation Together™

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