

SURMODICS INC  
Form 10-K  
December 14, 2006

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**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, DC 20549

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**FORM 10-K**

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**Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the fiscal year ended September 30, 2006**

**Commission file number 0-23837**

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**SURMODICS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Minnesota**

(State or other jurisdiction of  
incorporation or organization)

**41-1356149**

(IRS Employer  
Identification No.)

**9924 West 74<sup>th</sup> 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:

**Common Stock, \$.05 par value**

Securities registered pursuant to Section 12(g) of the Act:

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer 

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). 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, 2006 was approximately \$560 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 8, 2006 was 18,393,019.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the Registrant's 2007 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](http://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.

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## 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 include, among others, our PhotoLink® surface modification coatings, our drug delivery polymer matrices, and our ophthalmic drug delivery platforms and systems. These technologies are employed in the development of new medical devices and other biomedical products or in the improvement of existing ones. 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, ophthalmic drug delivery platforms and systems, in vitro diagnostic products, 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 and products, 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 customers to either alter the characteristics of the surfaces of devices and biological materials (e.g., lubricity or hemocompatibility), create new functions for the surfaces of the devices (e.g., drug delivery or promotion of healing) or to enable drug delivery from our device platforms. For example, our patented PhotoLink® technology enhances the maneuverability of dilatation 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 dramatically improve patient outcomes. 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 platform technologies (e.g., our I-vation<sup>®</sup> implant) and delivery systems. We believe this approach allows us to focus our resources on the further development of our core technologies and enables us to expand our licensing activities into new markets.

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, strep and flu tests.

In January 2005, we extended our drug delivery technologies beyond the cardiovascular market, where our drug delivery polymer expertise first gained prominence, into the ophthalmology market by acquiring all of the assets of InnoRx, Inc., including its innovative sustained drug delivery platform technologies used to treat a variety of serious eye diseases. (For more information on the InnoRx acquisition, see Liquidity and Capital Resources in Item 7 of this report.) A Phase I clinical trial to demonstrate safety of the I-vation<sup>®</sup> intravitreal implant in patients with diabetic macular edema was initiated during fiscal 2005. The study was fully enrolled and all patients completed their first six-month follow-up during fiscal 2006. The initial data suggest that the I-vation<sup>®</sup> intravitreal

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implant is safe and well tolerated in patients with DME. If this and other future clinical trials demonstrate longer term safety and efficacy of this product, I-vation<sup>®</sup> TA (triamcinolone acetonide) may represent a viable commercial prospect. Such positive results can also provide the Company with the ability to partner with pharmaceutical and ophthalmology companies to integrate their proprietary ophthalmic drugs with our unique sustained drug delivery platforms and systems. We plan to continue to invest in our technologies and products to expand our core capabilities for ophthalmic drug delivery implants. We also anticipate entering into one or more strategic relationships to further advance these ophthalmic technologies and products, 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, urology, oncology, 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 pharmaceutical and ophthalmology companies 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 and prohealing coatings).
- **Orthopedics**, developing innovative solutions for the treatment of structural defects in patients using proven SurModics technologies, and creating new technology solutions for existing patient care needs in the orthopedics field.

- ***In Vitro Technologies*** (formerly *Diagnostics and Drug Discovery*), specializing in surface modification products and technologies for healthcare applications focused in vitro (outside the body). These products and technologies include protein stabilization reagents, recombinant autoimmune antigens, surface chemistry technologies for nucleic acid and protein immobilization, synthetic extracellular matrix (ECM) cell culture products, and diagnostic format intellectual property.

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 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 and other similar 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

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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 the healthcare industry. The dramatic success of drug-eluting stents in interventional cardiology has captured the attention of the pharmaceutical and medical device industries. We believe the benefits of combining drugs and biologics with implantable devices are becoming increasingly valuable.

## **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 Company and the healthcare industry.

Our PhotoLink coating technology is a versatile, easily applied, 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 other physical properties of devices. Our PhotoLink technology utilizes proprietary, light activated (photochemical) reagents, which include 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 making the coating very durable and resilient.

Our proprietary PhotoLink reagents can be applied to a variety of substrates. Our reagents are easily applied to the 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, 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 environment. 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. 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 at least 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.

We offer customers several distinct polymer families for site specific drug delivery. Our Bravo<sup>®</sup> Drug Delivery Polymer Matrix is utilized on the CYPHER<sup>®</sup> Sirolimus-eluting Coronary Stent from Cordis Corporation, a Johnson & Johnson company. CYPHER<sup>®</sup> is a trademark of Cordis Corporation. The Bravo polymer is also used on our I-vation<sup>®</sup> Intravitreal Implant within our Ophthalmology division. Our Encore<sup>®</sup> Drug Delivery Polymer Matrix delivers a wider variety of therapeutic agents, including Rapamycin analogs, from more types of devices than previously possible. In addition, we offer several biodegradable polymer technologies that can be used for drug delivery applications. Because some biodegradable polymers can deliver proteins and other large molecule therapeutic

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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.

### **SurModics<sup>®</sup> Coating Technologies <sup>®</sup> 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 other 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 a variety of minimally invasive applications. Lubricity also reduces tissue irritation and damage caused by products such as catheters, guidewires and endoscopy devices. Based on internal and customer evaluation, when compared with uncoated surfaces, our PhotoLink coatings have reduced the friction on surfaces by more than 90%, depending on the substrate being coated.
- *Drug Delivery.* We provide drug delivery polymer 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 not based on PhotoLink), 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 around the world. In addition to our biodurable polymer technologies, we offer a number of biodegradable polymer technologies allowing us to deliver both large and small molecule drugs and address a wide variety of applications. We also believe that drug-eluting devices have significant potential in the ophthalmology market, where sustained drug delivery implants have the potential to provide a long-term therapy benefit for patients with serious eye diseases.
- *Prohealing.* We are developing biologically based extracellular matrix (ECM) protein coatings for use in various applications 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. We believe these prohealing coatings could help prevent late stent thrombosis.

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- *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.
- *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) 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 □ 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.

- **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.
- **DNA and Protein Immobilization.** Both DNA and protein microarrays are useful tools for the pharmaceutical, diagnostic and research industries. 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 various surface chemistries for both DNA and protein immobilization. GE Healthcare has licensed our technology in this area and sells genomics slides under the trade name CodeLink®. CodeLink® is a trademark of GE Healthcare. Protein microarrays are used as diagnostic and research tools to determine the presence and/or quantity of proteins in a biological sample. The most common type of protein microarray is the antibody microarray, where antibodies are spotted onto a surface and used as capture molecules for protein detection.

**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.

Market Segment Served	Desired Surface Property and Examples of Applications
<b>Interventional cardiology and vascular access</b>	<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
<b>Cardiac rhythm management</b>	<i>Lubricity:</i> pacemaker and defibrillator leads, electrophysiology devices <i>Hemocompatibility:</i> electrophysiology devices
<b>Cardiothoracic surgery</b>	<i>Prohealing:</i> heart valves, septal defect repair devices <i>Hemocompatibility:</i> minimally invasive bypass devices, vascular grafts, ventricular assist devices
<b>In Vitro Diagnostics</b>	<i>Lubricity:</i> microfluidic devices <i>Hemocompatibility:</i> blood/glucose monitoring devices, biosensors <i>Biomolecule Immobilization:</i> DNA and protein arrays, protein attachment to synthetic nanofibrillar extracellular matrix for cell culture applications <i>Cell culture growth and tissue integration:</i> cell culture products, <i>in vitro</i> applications using synthetic nanofibrillar extracellular matrix to provide a more <i>in vivo</i> -like surface
<b>Interventional neurology and</b>	<i>Lubricity:</i> catheters, guidewires



<b>neurosurgery</b>	
<b>Urology and gynecology</b>	<i>Lubricity:</i> urinary catheters, incontinence devices, ureteral stents, fertility devices <i>Site specific drug/biologics delivery:</i> prostatic stents
<b>Ophthalmology</b>	<i>Site specific drug/biologics delivery:</i> sustained drug delivery implants
<b>Orthopedics</b>	<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

Examples of applications for our coating technologies include 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, 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 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 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

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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 83 licensed products (customer products utilizing SurModics technology) already on the market generating royalties and 84 customer products incorporating our technology pending regulatory approval. These 167 products are being sold or developed by 83 licensed customers. We signed a record 21 new licenses in fiscal 2006.

Licensed customers include AbbeyMoor Medical, Abbott Laboratories, Bausch & Lomb, Boston Scientific Corporation, CardioMind, Inc., Conor Medsystems, Cook, Corning Incorporated, Cordis Corporation (a Johnson & Johnson company), Devax, Edwards, ev3 Inc., FoxHollow Technologies, Inc., GE Healthcare, Medtronic, Inc., Novocell, Inc., Spectranetics Corporation, St. Jude Medical, Inc., ThermopeutiX, X-Cell Medical and Xtent, among others. Under most of our licensing agreements, we are required to keep confidential the identity of our customers unless they approve such disclosure.

### **In Vitro Products**

#### **Genomics Products**

During fiscal 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.

#### **Stabilization Products**

SurModics offers a full line of stabilization products for the in vitro diagnostics market. These products decrease the variability often associated with storage conditions, thereby producing more consistent assay results. SurModics' stabilization products are ready-to-use, eliminating the preparation time and cost of producing stabilization and blocking reagents in house.

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### **Recombinant Human Antigens**

SurModics is the exclusive North American distributor (and non-exclusive in Japan) of DIARECT AG's line of recombinant autoimmune antigens. Because of the lack of high-quality antigens from natural sources, DIARECT produces these proteins and other components using biotechnological methods. DIARECT has strong capabilities in the baculovirus/Sf9 expression system for autoimmune antigens as well as *E. coli* systems for particular expression tasks.

#### **Ultra-Web® Synthetic Extracellular Matrix (ECM)**

The Ultra-Web® Synthetic ECM product line, is the result of a collaboration between the Donaldson Company (providing the nanofiber technology) and SurModics (providing the surface modification technology). Ultra-Web® is a trademark of Donaldson Company, Inc. In May 2006, SurModics and Donaldson entered into a strategic marketing and distribution agreement with Corning Incorporated, through which Corning Life Sciences, a subsidiary of Corning Incorporated, will provide worldwide marketing and distribution of the nanofiber cell culture products for *in vitro* cell culture research and drug discovery applications.

Ultra-Web<sup>®</sup> Synthetic ECM is a nanofibrillar cell culture surface that provides a biomimetic environment for more consistent and reproducible *in vivo*-like cell phenotypes, leading to more biologically accurate results. The Ultra-Web<sup>®</sup> technology involves electrospinning various polymers to produce a nanofiber material that is a defined and reproducible cell culture surface. Modification of the nanofibers with specific surface chemistries and functional groups can further enhance the desired cell matrix interactions. Extensive laboratory testing of this cell culture surface has substantiated improved performance when compared to conventional plastic and glass surface technology, with observations of more *in vivo*-like cellular morphology, organization, and activity.

### **Diagnostic Royalties**

We have also licensed patent rights to Abbott Laboratories involving a format for *in vitro* diagnostic tests. This format has found broad application in the area of rapid point-of-care diagnostic testing, such as pregnancy, strep and flu tests. At the end of fiscal 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 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

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expertise to capture more of the final product value. We are doing this by, in selected cases, developing or acquiring technologies 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 technologies 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 2006, 2005, and 2004, our research and development expense was \$20.4 million, \$16.1 million, and \$12.6 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 2006, 2005, and 2004 was approximately \$5.7 million, \$5.4 million, and \$4.4 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 2006, we filed 56 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 101 pending United States patent applications, 16 of which were exclusively licensed from others, and 224 foreign patent applications, of which 61 were exclusively licensed from others. We own 79 issued United States patents, and are the exclusive licensee on 18 of those patents. Internationally, we own 147 patents and are exclusively licensed under 29 of those 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 dedicated sales professionals who focus on specific markets and companies. These sales professionals work in concert with business unit personnel to coordinate customer activities. Business unit general managers are also integrally involved in sales and marketing activities. The specialization of our sales professionals fosters an in-depth knowledge of the issues faced by our customers within these markets such as industry trends, technology changes, biomaterial changes and the regulatory environment. In 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.

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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 2006. Revenue from Cordis Corporation and Abbott Laboratories represented approximately 47% and 12%, respectively, of our total revenue for the year ended September 30, 2006. 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 Affinergy, AST, Biocompatibles International plc, BioSensors, Hydromer, MediVas, pSivida Limited, Specialty Coatings Systems, STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., TyRx, and W.L. Gore, 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, intellectual property protection, 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

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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. Precision 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 2004 and have received updated certifications in each subsequent year.

## **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 a pre-market approval application has been 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 of 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 or biologic, 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.

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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 our I-vation® implant. The study is being conducted at four clinical sites under an IND according to Good Clinical Practices. We completed enrollment of the Phase I trial in fiscal 2006, and we will conduct follow-up monitoring of the patients for three years.

## Employees

As of December 1, 2006, we had 146 employees, of whom 106 were engaged in product development, quality, and manufacturing positions, with the remainder in sales, marketing, or administrative positions. Post-graduate degrees are held by 32 of our employees, 16 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," "possible," "project," "will" and similar words or expressions. Any statement that is not a historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, are forward-looking statements. The Company's forward-looking statements generally relate to its growth strategy, financial results, product development programs, sales efforts, and the impact of the Cordis agreement and other significant customer agreements. You should carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. The Company undertakes no obligation to update any forward-looking statement.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from the Company's forward-looking statements, such factors include, among others:

- the Company's significant dependence upon Cordis, which causes our financial results and stock price to be subject to factors affecting Cordis and its CYPHER<sup>®</sup> 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<sup>®</sup> 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."

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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.

#### **ITEM 1A. 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 2006. Revenue from Cordis Corporation and Abbott Laboratories represented approximately 47% and 12%, respectively, of our total revenue for the year ended September 30, 2006. 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, 2006, 2005, and 2004, we derived approximately 76%, 76%, and 70% of our revenue, respectively, from royalties and license fees. We do not currently manufacture, market or sell our own medical devices nor do we intend to do so in the foreseeable future. Thus, our prospects are substantially dependent on the receipt of royalties from licensees of our technologies. The amount and timing of such royalties are, in turn, dependent on the ability of our licensees to 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<sup>□</sup> 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 Affinergy, AST, Biocompatibles International plc, BioSensors, Hydromer, MediVas, pSivida Limited, Specialty Coatings Systems, STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., TyRx, and W.L. Gore, 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<sup>®</sup> 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<sup>®</sup> intravitreal implant. Our Phase I trial is intended to help assess the safety and tolerability of the implant in patients with diabetic macular edema (DME), and is being conducted under an investigational new drug application with the U.S. Food and Drug Administration. A total of thirty subjects were enrolled in this Phase I trial, which enrollment was completed in March 2006, and will be subject to follow-up monitoring for three years. Our ability to commercialize this implant in a timely manner will depend upon the success of this Phase I safety trial, as well as future required clinical trials that will further evaluate and document the safety profile and therapeutic benefit in targeted patient populations. Although the early results of the Phase I trial have not presented any significant safety issues, 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 has been 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.

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**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, 2006, the closing sale price for our common stock ranged from \$31.92 to \$43.37 per share. As of December 8, 2006, the last reported sale price of our stock was \$33.21 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 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

We conduct our operations in two facilities. In May 1999, we purchased the land and building we currently occupy in Eden Prairie, a suburb of Minneapolis, Minnesota. The building has approximately 64,000 square feet of space. Throughout fiscal 2005 and 2006, we made \$6.1 million in capital improvements to enhance the research and development capabilities at the Eden Prairie facility. The purchase and subsequent upgrade of the property was internally funded and it remains unencumbered. We believe that projected capacity of our Eden Prairie facility is adequate to service the needs of our customers for the foreseeable future. Most of our operations take place at the Eden Prairie location, however, 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 2006.

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**EXECUTIVE OFFICERS OF THE REGISTRANT**

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

<b>Name</b>	<b>Age</b>	<b>Position</b>
Bruce J Barclay	50	President and Chief Executive Officer
Aron B. Anderson, Ph.D	43	Vice President and Chief Scientific Officer
Philip D. Ankeny	43	Senior Vice President and Chief Financial Officer
Douglas P. Astry	54	General Manager, In Vitro Technologies
Lise W. Duran, Ph.D	51	Vice President and General Manager, Regenerative Technologies
Peter L. Ginsberg	41	Vice President of Business Development and Strategic Planning
Steven J. Keough	51	Senior Vice President and General Manager, Orthopedics and Chief Intellectual Property Counsel
Paul A. Lopez	50	Vice President, and President, Ophthalmology Division
Loren R. Miller	41	Vice President and Controller
Charles W. Olson	42	Vice President, Sales, and General Manager, Hydrophilic Technologies
Brian L. Robey	43	Vice President and General Manager, Drug Delivery
Michael J. Shoup	46	Vice President of Quality, Regulatory and Clinical Affairs
Jan M. Webster	47	Vice President of Human Resources

*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 developed,

manufactured and sold 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 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. He was promoted to Senior Vice President and Chief Financial Officer in May 2006. 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

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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

*Peter L. Ginsberg* joined SurModics in May 2006 as Vice President of Business Development and Strategic Planning. Mr. Ginsberg has more than 15 years of healthcare and financial services experience. His previous positions were at Deephaven Capital Management, where he worked as an analyst responsible for equity investments in pharmaceutical, biotechnology and medical device firms from 2003 to 2006, at U.S. Bancorp Piper Jaffray as Senior Analyst from 1997 to 2003 (most recently as Managing Director), at Vector Securities International as a sell-side analyst from 1994 through 1997, and at USAA Investment Management as a buy-side analyst from 1991 to 1994. Additionally, Mr. Ginsberg serves on the faculty of the University of Minnesota's Carlson School of Management. Peter earned an A.B. in Economics from Princeton University in 1987 and an M.B.A. from the Amos Tuck School of Business at Dartmouth College in 1991.

*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 from March 2001 to July 2005. Prior to Valley Forge, Mr. Lopez served in various senior level positions at Bausch & Lomb from 1998 to 2001, 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 Board of Directors of Alliance Medical Products, a private company 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

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addition he held various positions at Mesaba Aviation Inc. from 1988 until 1995, most recently as Controller. Mr. Miller is a CPA (inactive certificate) and received a B.S. degree in Business Administration & Finance and a B.S. degree in Accounting from Minnesota State University in 1988.

*Charles W. Olson* joined the Company in 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, 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.

*Brian L. Robey* joined SurModics in 2005 as Senior Director, Commercial Development for Drug Delivery and was promoted to Vice President and General Manager, Drug Delivery in May 2006. Mr. Robey has nearly 20 years of research and development and management experience in the medical device industry. Most recently, he was Manager, Product Development at Guidant Corporation in the Cardiac Rhythm Management Division from 2002 to 2005. Prior to Guidant, Mr. Robey was employed at Southwest Research Institute in San Antonio, Texas from 1987 to 2002, where he held engineering and project management positions of increasing responsibility with his last role as Manager of the Bioengineering Section. Mr. Robey received bachelor's and master's degrees in biomedical engineering from Louisiana Tech University in 1985 and 1987 and an MBA from the University of Texas at San Antonio in 2000.

*Michael J. Shoup* joined SurModics in March 2006 as Vice President of Quality, Regulatory and Clinical Affairs. Mr. Shoup has over 20 years of experience in quality assurance and manufacturing, including over 15 years in the medical device industry. Before joining SurModics, he was Director of Quality and Design Assurance for St. Jude Medical's Cardiac Surgery Division from 2005 to 2006 and held various positions at Acorn Cardiovascular from 1998 to 2005, most recently as Director of Operations. Mike's employment history also includes Integ (1994 - 1998), SciMed Life Systems, now part of Boston Scientific (1990 - 1994) and Minco Products (1983 - 1990). He teaches in the area of medical device design and manufacturing with St. Thomas as an adjunct professor in the School of Engineering and is a regular lecturer for the Center of Business Excellence. Mr. Shoup received a bachelor's degree in mechanical engineering from the University of Minnesota (1982) and earned his MBA with a manufacturing systems concentration from the University of St. Thomas (1995).



*Jan M. Webster* joined SurModics as Vice President of Human Resources in January of 2006. Ms. Webster came to SurModics with over 20 years of experience in the healthcare industry. From 1987 through 2005, she held various human resources and management positions at St. Jude Medical, Inc., most recently as Director of Human Resources for the Cardiac Surgery division. From 1984 to 1987, she served in several human resources roles for Fairview Health Services. Ms. Webster is a graduate of Minnesota State University, Mankato with a bachelor's degree in business administration and earned an M.A. in human resources and industrial relations from the University of Minnesota.

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

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**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 Global Select 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.

<b>Fiscal Quarter ended:</b>	<b>High</b>	<b>Low</b>
September 30, 2006	38.00	33.36
June 30, 2006	39.65	31.92
March 31, 2006	40.22	32.90
December 31, 2005	43.37	36.46
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

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 17, 2006, there were 273 holders of record of our Common Stock and approximately 15,516 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.

The following table presents information with respect to purchases of common stock of the Company made during the three months ended September 30, 2006, by the Company or on behalf of the Company or any "affiliated purchaser" of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

<b>Period</b>	<b>(a) Total Number of Shares</b>	<b>(b) Average Price Paid</b>	<b>(c) Total Number of Shares</b>	<b>(d) Maximum Number of Shares that</b>
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	Purchased(1)	Per Share(1)	Purchased as Part of Publicly Announced Plans or Programs(2)	May Yet Be Purchased Under the Plans or Programs(2)
7/1/06 - 7/31/06	0	0	NA	NA
8/1/06 - 8/31/06	886	\$35.43	NA	NA
9/1/06 - 9/30/06	1,401	\$34.97	0	1,000,000
Total	2,287	\$35.15	0	1,000,000

- (1) All of the shares were repurchased by the Company to pay the exercise price and/or to satisfy tax withholding obligations in connection with so-called "stock swap exercises" of employee stock options issued to seven employees.
- (2) In September 2006, we announced that our Board of Directors had authorized the repurchase of \$35 million and up to 1 million shares of the Company's common stock but no repurchases were made during fiscal 2006.

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In March 2006, we issued 60,007 shares of our common stock to former shareholders of InnoRx pursuant to the terms and as a result of our January 2005 acquisition of InnoRx and successful completion of the second milestone established in the acquisition. (See Liquidity and Capital Resources for more information related to our InnoRx acquisition.) Such shares were issued to 15 stockholders of InnoRx, and exemption from registration therefore was claimed at the time of the acquisition under Section 4(2) of the Securities Act.

## ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of and for the years ended September 30, 2006, 2005, and 2004 are derived from our audited financial statements included elsewhere in this report. The financial data as of and for the years ended September 30, 2003 and 2002 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.

<i>(Dollars in thousands, except per share data)</i>	Fiscal Year				
	2006	2005	2004	2003	2002
<b>Income Statement Data:</b>					
Total revenue	\$ 69,884	\$ 62,381	\$ 49,738	\$ 43,232	\$ 29,488
Operating income	36,163	2,985	10,474	20,640	10,709
Net income (loss)	20,334	(8,246)	7,242	13,936	7,796
Diluted net income (loss) per share	1.09	(.45)	.41	.78	.44
<b>Balance Sheet Data:</b>					
Cash and short-term investments	\$ 58,813	\$ 24,445	\$ 19,215	\$ 6,647	\$ 13,149
Total assets	157,402	124,225	109,587	97,808	77,248
Retained earnings	48,273	27,915	36,161	28,918	14,982
Total stockholders' equity	145,203	115,581	94,310	86,114	69,995

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

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 or prohealing 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 "In Vitro" operating

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segment contains the In Vitro Technologies (formerly Diagnostics and Drug Discovery) business unit, which includes our genomics slide technologies, our stabilization products for immunoassay diagnostic tests, our in vitro diagnostic format technology and our 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; the vast majority (typically in excess of 90%) of revenue in the "royalties and license fees" category is in the form of royalties; (2) the sale of reagent chemicals to licensees of our technologies, stabilization products to the diagnostics industry and coated glass slides to the genomics market; and (3) research and development fees generated on 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 activity level associated with customer development projects; 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.

In January 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 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 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 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.

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Results in the fourth quarter of fiscal 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 consolidated operations at our Eden Prairie, Minnesota headquarters at the beginning of April 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 Operation

#### Years Ended September 30, 2006 and 2005

<i>(Dollars in thousands)</i>	Fiscal year 2006	Fiscal year 2005	Increase	% Increase
Revenue:				
Drug Delivery	\$32,918	\$29,678	\$3,240	11%
Hydrophilic and Other	22,233	19,065	3,168	17%
In Vitro	14,733	13,638	1,095	8%
Total revenue	\$69,884	\$62,381	\$7,503	12%

**Revenue.** Fiscal 2006 revenue was \$69.9 million, an increase of \$7.5 million or 12% from fiscal 2005. We experienced growth in all three operating segments as detailed in the table above and further explained in the narrative below.

*Drug Delivery.* Revenue in the Drug Delivery segment increased 11% to \$32.9 million in fiscal 2006. The growth in total revenue reflects increases in royalties and license fees, and research and development revenue related to drug delivery and ophthalmology projects.

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<sup>®</sup> Sirolimus-eluting Coronary Stent. The CYPHER<sup>®</sup> stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions.

Over three-fourths of the overall increase in drug delivery revenue reflects increased royalty revenue from Cordis as a result of higher CYPHER<sup>®</sup> sales. The balance of the fiscal 2006 increase was a result of increased research and development fees from drug delivery and ophthalmology customers. Fiscal 2006 sales of reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices) to Cordis decreased slightly when compared with the prior year. The unit volume of reagents sold to Cordis will likely be directly impacted by anticipated continued improvements in manufacturing efficiencies by Cordis in addition to relative market share positions of drug-eluting stent players.

The CYPHER<sup>®</sup> stent, from which we derive a substantial majority of our Drug Delivery revenue, faces continuing competition from Boston Scientific Corporation's Taxus drug-eluting stent, which is sold within and outside the U.S., and stents from Medtronic, Conor Medsystems, Abbott Vascular, and others sold outside the U.S. In addition, several drug-eluting stents from others are expected to be approved in the U.S. within the next two years. These stents compete or will compete directly with the CYPHER<sup>®</sup> stent. Therefore future royalty and reagent sales revenue could decrease because of lower CYPHER<sup>®</sup> stent sales as a result of this ongoing and expected future competition. We anticipate that quarterly royalty revenue from the CYPHER<sup>®</sup> stent may be volatile throughout fiscal 2007 and beyond 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<sup>®</sup> stent to continue to constitute a significant portion of our revenue in fiscal 2007. However, whether and the extent to which royalties from the CYPHER<sup>®</sup> stent continue to constitute a significant source of revenue is subject to a number of risks, including intellectual property

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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 been found to have violated certain intellectual property rights of the other.

*Hydrophilic and Other.* Hydrophilic and Other revenue increased 17% to \$22.2 million, primarily as a result of 19% growth in royalties and license fees and 35% growth in reagent sales, partially offset by a 15% decline in research and development revenue. In contrast to our Drug Delivery segment, where a significant percentage of revenue is attributable to Cordis, there are several dozen licensees and an even larger number of coated products generating royalties in our Hydrophilic and Other segment. The growth in royalties principally reflects increased sales of coated products already on the market, and to a lesser extent newly introduced licensed products. We believe growth in fiscal 2007 will be more significantly influenced by royalty revenue earned on newly released products. We believe that revenue will likely continue to increase in fiscal 2007, however the rate of growth will depend upon the timing and market success of newly released products.

*In Vitro.* Revenue in the In Vitro segment increased 8% to \$14.7 million. Roughly 60% of the increase was attributable to growth in sales of our stabilization products used by diagnostic kit manufacturers in immunoassay diagnostic tests. The balance of the growth resulted from increased royalty revenue from our diagnostic format patents. We anticipate that growth in our In Vitro segment revenue in fiscal 2007 will likely be on par with fiscal 2006 on the continued strength of product sales. In Vitro derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories.

**Product costs.** Product costs were \$3.4 million in fiscal 2006, a 19% increase from the prior year. Overall product margins averaged 70%, on par with the 70% reported for the comparable period last year. We anticipate the impact of higher depreciation costs on our recently-constructed manufacturing space at our Eden Prairie facility combined with non-cash stock-based compensation charges will decrease margins in fiscal 2007.

**Research and development expenses.** Research and development expenses were \$20.4 million, an increase of 27% compared with fiscal 2005. Approximately \$2.5 million of the \$4.3 million increase was related to non-cash stock-based compensation charges following the adoption of SFAS No. 123(R). Research and development expenses included no such charge in fiscal 2005. Excluding stock-based compensation, research and development expenses increased 11% in fiscal 2006. The balance of the increase reflects higher costs associated with the clinical trial on our I-vation<sup>®</sup> intravitreal implant, increased costs of operating the recently-constructed clean rooms and drug coating suites at our Eden Prairie headquarters, and increased personnel costs. These increased costs were partially offset by reduced legal costs. Research and development expenses are expected to continue to increase in fiscal 2007 as we expand our research and development organization. Note, in April 2006, we ceased operations at our Bloomington, Minnesota contract manufacturing facility and consolidated our operations at Eden Prairie. Therefore, facilities costs associated with research and development will increase reflecting increased depreciation on our Eden Prairie facility. However, the cost of operating the Bloomington facility (reported in general and administrative expenses) has been eliminated.

**Sales and marketing expenses.** Sales and marketing expenses were \$1.4 million in fiscal 2006, an 18% increase from the prior year. Approximately \$205,000 of the \$215,000 increase was related to stock-based compensation. Sales and marketing expenses included no such costs in fiscal 2005. Excluding stock-based compensation, sales and marketing expenses increased 1%. We expect sales and marketing expenses to increase modestly in fiscal 2007.

**General and administrative expenses.** General and administrative expenses were \$8.5 million, an increase of 31% compared with fiscal 2005. We recorded approximately \$2.7 million in non-cash stock-based compensation charges compared with \$588,000 in fiscal 2005. Excluding the impact of stock-based compensation, general and administrative expenses decreased approximately 2% as a result of the cost savings realized since we exited our contract manufacturing facility in Bloomington in April 2006. The majority of the operating costs of the Bloomington facility were reported in general and administrative expenses. We expect general and administrative expenses to be lower when compared with prior year results for the next couple of quarters reflecting lower facility operating costs.

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**Asset impairment charge.** Results in fiscal 2005 included a non-cash asset impairment charge of \$2.5 million against our Bloomington, Minnesota, contract manufacturing facility. Results in the fiscal 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 consolidated operations at our Eden Prairie, Minnesota, headquarters in April 2006.

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

**Other income, net.** Other income resulted in a loss of \$598,000 in fiscal 2006 compared with income of \$1.4 million in fiscal 2005, primarily as a result of the \$4.7 million impairment loss on our investment in Novocell we recorded in the second quarter of fiscal 2006. Income from investments was \$4.2 million in fiscal 2006, an increase of \$2.2 million, compared with \$2.0 million in fiscal 2005. The increase reflects higher levels of investable cash and higher yields generated from our investment portfolio. Prior year other income results also include a \$500,000 loss related to the impact of accounting for the InnoRx acquisition under the equity method. We recorded no such comparable transaction in fiscal 2006.

**Income tax expense.** The income tax provision was \$15.2 million in fiscal 2006 compared with \$12.6 million in fiscal 2005. Excluding the impact of the \$4.7 million impairment loss, (since the Company does not currently

foresee offsetting capital gains to offset this capital loss, no tax benefit has been recorded), the effective tax rate was 38.2% in fiscal 2006, compared with 36.8% for fiscal 2005 when the impact of non-tax deductible purchased in-process research and development is excluded. The impact of adopting SFAS No. 123(R) accounts for bulk of the increase in the effective tax rate from fiscal 2006.

**Years Ended September 30, 2005 and 2004**

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

**Revenue.** Fiscal 2005 revenue was \$62.4 million, an increase of \$12.6 million or 25% from fiscal 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 2004. A 33% growth in royalties and license fees more than offset a 52% 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 2005 because of lower unit prices resulting from a contractual reduction in reagent pricing. Unit volume was little changed from fiscal 2004. There are no further contractual price reductions and management does not anticipate further reductions in reagent prices to Cordis.

Drug Delivery research and development revenue in fiscal 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.

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*Hydrophilic and Other.* Hydrophilic and Other segment revenue increased 23% to \$19.1 million, reflecting a 20% increase in royalties and license fees and a 77% increase in research and development fees. The growth in royalties reflects principally newly introduced licensed products and, to a lesser extent, increased sales of coated products already on the market.

*In Vitro.* In Vitro segment revenue increased 60% to \$13.6 million. 84% of the growth resulted from increased royalty revenue under certain sublicenses, whose royalty streams we purchased from Abbott in September 2004. The In Vitro segment derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories. The increase in product sales reflects a 28% increase in sales of stabilization products used for immunoassay diagnostic tests and a 49% increase in sales of genomics slides. Effective February 2005, we terminated our stabilization product distribution agreement with SeraCare and began selling directly to the U.S. diagnostics industry.

**Product costs.** Product costs were \$2.9 million for fiscal 2005, a 6% decrease from \$3.0 million in the prior year. Overall product margins averaged 70% compared with 71% for the prior year period.

**Research and development expenses.** Research and development expenses were \$16.1 million, an increase of 27% compared with fiscal 2004. Approximately 27% of the increase reflects legal costs associated with intellectual property processing and applications. The balance of the increase reflects costs associated with the clinical trial of our I-vation<sup>®</sup> intravitreal implant and increased personnel costs related to establishing our new Ophthalmology division.

**Sales and marketing expenses.** Sales and marketing expenses were \$1.2 million in fiscal 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 fiscal 2004.

**General and administrative expenses.** General and administrative expenses were \$6.5 million in fiscal 2005, a 20% increase compared with fiscal 2004. Approximately 70% of the increase was related to compensation costs with the balance of the increase due to legal and utility costs.

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

**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 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.

**Other income, net.** Other income was \$1.4 million in fiscal 2005, an increase of 16% compared with the prior year. The increase reflects higher levels of investable cash and higher yields generated from our investment portfolio. Previously reported fiscal 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 2005 compared with \$4.4 million in fiscal 2004. Excluding the impact of the \$30.3 million in-process research and development charge, which is not tax deductible, the effective tax rate was 36.8% in fiscal 2005, compared with 37.2% in the prior year period.

Certain information in this Annual Report on Form 10-K pertaining to the effects of stock-based compensation may be considered non-GAAP financial information as contemplated by SEC Regulation G. Management believes the presentation of financial measures that identify the magnitude of the impact of stock-based compensation charges on its results of operations provide useful information to investors as the information allows investors to better evaluate ongoing business performance and factors that influenced performance during the period under report, including when comparing against prior periods. Management also uses such financial measures internally to monitor performance of the business. These potential non-GAAP financial measures should be considered in addition to, and not a substitute for, financial measures prepared in accordance with GAAP.

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## Liquidity and Capital Resources

As of September 30, 2006, the Company had working capital of \$67.1 million and cash, cash equivalents and investments totaling \$106.6 million. The Company's investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. The Company's policy requires that no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while meeting or exceeding a benchmark (Merrill Lynch 1-3 Year Government-Corporate Index) total rate of return. Management plans to continue to direct its investment advisors to manage the Company's investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments. The Company had positive cash flows from operating activities of approximately \$35.3 million in fiscal 2006, compared with \$26.0 million in fiscal 2005.



We conduct a significant majority of our operations at our Eden Prairie, Minnesota, headquarters. Throughout fiscal 2005 and 2006, we constructed capital improvements to enhance the research and development capabilities at the Eden Prairie facility. The \$6.1 million in capital improvements were sufficiently complete by the end of second quarter of fiscal 2006, allowing us to vacate our contract manufacturing facility in Bloomington, Minnesota, and consolidate our Minnesota operations at our Eden Prairie headquarters. In addition to our Eden Prairie location, we lease approximately 3,000 square feet of commercial office space in Irvine, California, where our Ophthalmology division conducts a portion of its operations.

In January 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. In July 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. In March 2006, we issued an additional 60,007 shares as a result of completion of the second milestone. 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 approximately 480,060 additional shares of our common stock to the stockholders of InnoRx.

In January 2005, we made an equity investment of approximately \$3.9 million in OctoPlus, a company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers. In May 2006, we made an additional investment of approximately \$160,000. As of September 30, 2006 the \$4.1 million investment, which is accounted for under the cost method, represented an ownership interest of less than 20%. In October 2006, our fiscal 2007, we made an additional investment of \$1.9 million, bringing our total investment to slightly more than \$6.0 million, representing an ownership interest of approximately 9%.

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. During the second quarter of fiscal 2006, we recorded an impairment loss of approximately \$4.7 million. The balance of our investment, \$559,000, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 5%. Novocell's primary technology is in its development stage, and we anticipate that it will be years before commercialization may be realized, if ever.

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%.

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. 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

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in Novocell, OctoPlus and ThermopeutiX and the revenue they may ultimately generate. 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 two remaining \$1 million installments are reflected in other current and long-term liabilities.

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In September 2006, we announced that our Board of Directors had authorized the repurchase of \$35 million and up to 1 million shares of the Company's stock. In November 2006, the Company entered into a Rule 10b5-1 agreement and purchased \$17.5 million of the \$35 million authorized at an average price of \$32.87 per share.

As of September 30, 2006, 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

As of September 30, 2006, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

### Contractual Obligations

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

Contractual obligations	Maturity by Fiscal Year						
	Total	2007	2008	2009	2010	2011	Thereafter
Other long-term liabilities reflected on balance sheet under GAAP	\$2.0	\$1.0	\$1.0	□	□	□	□
Total	\$2.0	\$1.0	\$1.0	□	□	□	□

(in millions)

### New Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board (FASB) issued statement 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 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.

On July 13, 2006, FASB Interpretation (FIN) No. 48, Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109, was issued. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The new FASB standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The provisions of FIN 48 are effective for the Company beginning fiscal 2008. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial condition.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. This statement establishes a consistent framework for measuring fair value and expands disclosures on fair value measurements. SFAS No. 157 is effective for the Company starting in fiscal 2008. The Company has not determined the impact, if any, the adoption of this statement will have on its 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 \$1.5 million decrease in the fair value of the Company's available-for-sale securities as of September 30, 2006, 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, 2006 and 2005 and the statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2006, 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, 2006.

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Management's assessment of the effectiveness of the Company's internal control over financial reporting as of September 30, 2006 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.**

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**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, 2006, 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, 2006, 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, 2006, 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, 2006, of the Company and our report dated December 12, 2006, expressed an unqualified opinion on those financial statements.

DELOITTE & TOUCHE LLP

Minneapolis, Minnesota  
December 12, 2006

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### **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.

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## **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 2007 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 2007 Annual Meeting of Shareholders.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

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 2007 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 2007 Annual Meeting of Shareholders.

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## **PART IV**

### **ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.**

- (a) 1. *Financial statements*

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

	<b>Page (s)</b>
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.

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**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, 2006

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Bruce J Barclay</u> Bruce J Barclay	President and Chief Executive Officer (principal executive officer)	December 14, 2006

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<u>/s/ Philip D. Ankeny</u> Philip D. Ankeny	Senior Vice President and Chief Financial Officer, (principal financial officer)	December 14, 2006
<u>/s/ Loren R. Miller</u> Loren R. Miller	Vice President and Controller (principal accounting officer)	December 14, 2006
<u>/s/ Jose H. Bedoya</u> Jose H. Bedoya	Director	December 14, 2006
<u>/s/ John W. Benson</u> John W. Benson	Director	December 14, 2006
<u>/s/ Gerald B. Fischer</u> Gerald B. Fischer	Director	December 14, 2006
<u>/s/ Kenneth H. Keller</u> Kenneth H. Keller	Director	December 14, 2006
<u>/s/ David A. Koch</u> David A. Koch	Director	December 14, 2006
<u>/s/ Kendrick B. Melrose</u> Kendrick B. Melrose	Director	December 14, 2006
<u>/s/ Dale R. Olseth</u> Dale R. Olseth	Director	December 14, 2006
<u>/s/ John A. Meslow</u> John A. Meslow	Director	December 14, 2006

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

**EXHIBIT INDEX TO FORM 10-K**

**For the Fiscal Year Ended September 30, 2006**

**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.



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- 10.9\* Form of officer acceptance regarding employment/compensation [] incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005, SEC File No. 0-23837.
- 10.10\* 2003 Equity Incentive Plan (as amended and restated December 13, 2005) (adopted December 13, 2005 by the board of directors and approved by the shareholders on January 30, 2006) [] incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed February 3, 2006, SEC File No. 0-23837.
- 10.11\* Form of SurModics, Inc. 2003 Equity Incentive Plan Nonqualified Stock Option Agreement[] incorporated by reference to Exhibit 99.1 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.

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**Exhibit**

- 10.12\* Form of SurModics, Inc. 2003 Equity Incentive Plan Incentive Stock Option Agreement[] incorporated by reference to Exhibit 99.2 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.13\* Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Agreement[] incorporated by reference to Exhibit 99.3 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.14\* Form of SurModics, Inc. 2003 Equity Incentive Plan Performance Share Award Agreement[] incorporated by reference to Exhibit 99.4 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.15\* Form of SurModics, Inc. 2003 Equity Incentive Plan Performance Unit Award (cash settled) Agreement[] incorporated by reference to Exhibit 99.5 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.16\* Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Unit Agreement[] incorporated by reference to Exhibit 99.6 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.17\* Form of SurModics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (cash settled) Agreement[] incorporated by reference to Exhibit 99.7 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.18\* Form of SurModics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (stock settled) Agreement[] incorporated by reference to Exhibit 99.8 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.19\* 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.
- 10.20\* The Company's FY 2006 Bonus Plan, as adopted by the Compensation Committee of the Board of Directors on September 30, 2005 -- incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005, SEC File No. 0-23837.
- 10.21\* The Company's FY 2007 Bonus Plan, as adopted by the Compensation Committee of the Board of Directors of the Company on September 15, 2006.\*\*
- 10.22\* The Company's Board Compensation Policy, Amended and Restated in its entirety as of July 31, 2006.\*\*
- 10.23\* FY 06 Summary of Compensation Arrangements for Named Executive Officers of the Company -- -- incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005, SEC File No. 0-23837.

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- 10.24\* FY 07 Summary of Compensation Arrangements for Named Executive Officers of the Company.\*\*
- 10.25\* Change of Control Agreement with Bruce J Barclay, dated April 19, 2006[]incorporated by reference to Exhibit 99.1 to the Company[]s Form 8-K filed April 25, 2006, SEC File No. 0-23837.
- 10.26\* Change of Control Agreement with Philip D. Ankeny, dated April 19, 2006[]incorporated by reference to Exhibit 99.2 to the Company[]s Form 8-K filed April 25, 2006, SEC File No. 0-23837.
- 10.27\* Change of Control Agreement with Paul A. Lopez, dated November 15, 2006.\*\*
- 10.28\* Description of certain retirement benefits for Dale R. Olseth.\*\*
- 23.1 Consent of Deloitte & Touche LLP.\*\*
- 24 Power of Attorney (included on signature page of this Form 10-K).\*\*
- 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.\*\*
- 31.2 Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.\*\*
- 32.1 Certification of Chief Executive Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.\*\*
- 32.2 Certification of Chief Financial Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.\*\*

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\* Management contract or compensatory plan or arrangement

\*\* Filed herewith

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**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, 2006 and 2005, and the related statements of income, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2006. 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 as of September 30, 2006 and 2005, and the results of its operations and cash flows for each of the three years in the period ended September 30, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 to the financial statements, in 2006 the Company adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payment, which relates to the method of accounting for

stock-based compensation.

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, 2006, 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 12, 2006, 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 12, 2006

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### SurModics, Inc.

Balance Sheets

As of September 30

<i>(thousands, except share data)</i>	<b>2006</b>	<b>2005</b>
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 3,751	\$ 3,921
Short-term investments	55,062	20,524
Accounts receivable, net of allowance for doubtful accounts of \$40 as of September 30, 2006 and 2005	14,493	10,996
Income taxes receivable	□	3,640
Inventories	952	1,091
Deferred tax asset	435	353
Prepays and other	1,403	1,079
Total current assets	76,096	41,604
Property and Equipment, net	11,686	14,832
Long-Term Investments	47,758	48,874
Deferred Tax Asset	4,883	2,868
Other Assets, net	16,979	16,047
Total Assets	\$ 157,402	\$ 124,225
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 963	\$ 1,163
Accrued liabilities-		
Compensation	1,275	1,629
Accrued income taxes payable	1,910	□
Accrued other	1,605	1,917
Deferred revenue	2,236	414
Other current liabilities	1,000	□
Total current liabilities	8,989	5,123
Deferred revenue, less current portion	2,210	1,521

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Other long-term liabilities	1,000	2,000
Total liabilities	12,199	8,644
<b>Commitments and Contingencies (Note 5)</b>		
<b>Stockholders' Equity</b>		
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 18,830,455 and 18,535,761 shares issued and outstanding	942	927
Additional paid-in capital	96,281	89,721
Unearned compensation	□	(2,621)
Accumulated other comprehensive income (loss)	(293)	(360)
Retained earnings	48,273	27,914
Total stockholders' equity	145,203	115,581
Total Liabilities and Stockholders Equity	\$ 157,402	\$ 124,225

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

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**SurModics, Inc.**

Statements of Operations

For the Years Ended September 30

<i>(thousands, except net income per share)</i>	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>Revenue</b>			
Royalties and license fees	\$ 53,008	\$ 47,582	\$ 34,836
Product sales	11,172	9,403	10,478
Research and development	5,704	5,396	4,424
Total revenue	69,884	62,381	49,738
<b>Operating Costs and Expenses</b>			
Product	3,399	2,855	3,035
Research and development	20,391	16,072	12,633
Sales and marketing	1,424	1,209	1,683
General and administrative	8,507	6,496	5,416
Asset impairment charge	□	2,487	16,497
Purchased in-process research & development	□	30,277	□
Total operating costs and expenses	33,721	59,396	39,264
Income from Operations	36,163	2,985	10,474
<b>Other Income (Loss), net</b>			
Investment income	4,210	1,967	1,185
Impairment loss on investment	(4,651)	□	□
Other loss	(157)	(602)	(7)
Other income (loss), net	(598)	1,365	1,178
Income Before Income Taxes	35,565	4,350	11,652
Income Tax Provision	(15,231)	(12,596)	(4,410)

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Net income (loss)	\$ 20,334	(\$ 8,246)	\$ 7,242
Basic net income (loss) per share	\$1.10	(\$0.45)	\$ 0.41
Diluted net income (loss) per share	\$1.09	(\$0.45)	\$ 0.41
Weighted Average Shares Outstanding			
Basic	18,527	18,131	17,501
Dilutive effect of outstanding stock options	192	□	299
Diluted	18,719	18,131	17,800

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

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**SurModics, Inc.**

Statements of  
Stockholders' Equity  
For the Years Ended September 30, 2006,  
2005 and 2004

<i>(in thousands)</i>	Common Stock		Additional	Unearned	Accumulated	Retained	Total
	Shares	Amount	Paid-In Capital	Compensation	Other Comprehensive Income (Loss)	Earnings	Stockholders Equity
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

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Restricted stock activity	16	1	377	(378)	0	0	0
Amortization of unearned compensation	0	0	0	212	0	0	212
Balance, September 30, 2004	17,537	877	57,849	(632)	56	36,160	94,310
Components of comprehensive income, net of tax:							
Net loss	0	0	0	0	0	(8,246)	(8,246)
Unrealized holding losses on available-for-sale securities arising during the period	0	0	0	0	(481)	0	(481)
Add reclassification for losses included in net income, net of tax	0	0	0	0	65	0	65
Comprehensive loss	0	0	0	0	65	0	(8,662)
Issuance of common stock	682	34	25,731	0	0	0	25,765
Common stock options exercised, net	244	12	2,310	0	0	0	2,322
Tax benefit from exercise of stock options	0	0	1,258	0	0	0	1,258
Restricted stock activity	73	4	2,573	(2,577)	0	0	0
Amortization of unearned compensation	0	0	0	588	0	0	588
Balance, September 30, 2005	18,536	927	89,721	(2,621)	(360)	27,914	115,581
Components of comprehensive loss, net of tax:							
Net income	0	0	0	0	0	20,334	20,334
Unrealized holding losses on available-for-sale securities arising during the period	0	0	0	0	(31)	0	(31)
Add reclassification for losses included	0	0	0	0	98	0	98

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in net income, net of tax							
Comprehensive income	□	□	□	□	□	□	20,401
Issuance of common stock	125	7	392	□	□	□	399
Common stock options exercised, net	169	8	2,854	□	□	□	2,862
Tax benefit from exercise of stock options	□	□	249	□	□	□	249
Stock based compensation	□	□	5,526	□	□	□	5,526
Accounting change due to adoption of SFAS 123R	□	□	(2,461)	2,621	□	25	185
Balance, September 30, 2006	18,830	\$ 942	\$ 96,281	\$ □	(\$ 293)	\$ 48,273	\$ 145,203

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

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**SurModics, Inc.**

Statements of Cash Flows

For the Years Ended September 30 (in thousands)	2006	2005	2004
<b>Operating Activities</b>			
Net income (loss)	\$ 20,334	(\$ 8,246)	\$ 7,242
Adjustments to reconcile net income (loss) to net cash provided by operating activities-			
Depreciation and amortization	3,710	3,733	3,125
Loss on sales of investments and equity method loss on InnoRx	157	602	7
Amortization of discount on investments	(1,534)	□	□
Asset impairment charge	4,651	2,487	16,497
Noncash compensation	5,711	588	212
Purchased in-process research & development	□	30,277	□
Deferred tax	(2,134)	5,143	(5,640)
Tax benefit from exercise of stock options	(249)	1,258	325
Loss (gain) on disposals of property and equipment	(169)	(65)	22
Change in operating assets and liabilities:			
Accounts receivable	(3,497)	(2,866)	1,015
Inventories	139	(51)	(177)
Accounts payable and accrued liabilities	(532)	912	(966)

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Income taxes	5,799	(7,467)	2,269
Deferred revenue	2,489	(81)	(663)
Prepays and other	404	(274)	(78)
Net cash provided by operating activities	35,279	25,950	23,190
<b>Investing Activities</b>			
Purchases of property and equipment	(5,857)	(2,109)	(5,474)
Sales of property and equipment	238		
Purchases of available-for-sale investments	(193,966)	(98,716)	(45,976)
Sales/maturities of available-for-sale investments	161,778	88,955	27,092
Purchase of equity in OctoPlus, Novocell and other	(160)	(5,133)	(302)
Purchase of licenses	(1,592)	(5,238)	(64)
Investment in and acquisition costs for InnoRx	□	(5,181)	(2,331)
Repayment of notes receivable	600	□	1,869
Net cash used in investing activities	(38,959)	(27,422)	(25,186)
<b>Financing Activities</b>			
Tax benefit from exercise of stock options	249	□	□
Issuance of common stock	3,261	2,684	698
Net cash provided by financing activities	3,510	2,684	698
Net increase (decrease) in cash and cash equivalents	(170)	1,212	(1,298)
<b>Cash and Cash Equivalents</b>			
Beginning of year	3,921	2,709	4,007
End of year	\$ 3,751	\$ 3,921	\$ 2,709
<b>Supplemental Information</b>			
Cash paid for taxes	\$ 11,338	\$ 13,780	\$ 7,265
Noncash transaction-purchase Abbott Laboratories sublicense	□	□	\$ 7,020
Noncash proceeds from sale of property	\$ 6,655	□	□
Noncash transaction-acquisition of property, plant, and equipment on account	\$ 989	\$ 1,268	\$ 248

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

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**SurModics, Inc.**

Notes to Financial Statements September 30, 2006 and 2005

*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 its 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, 2006 and 2005. 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*):

	<b>2006</b>			
	<b>Original Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>
U.S. government obligations	\$ 70,085	\$ 18	(\$227)	\$ 69,876
Mortgage-backed securities	12,312	42	(123)	12,231
Municipal bonds	10,595	20	(124)	10,491
Asset backed securities	8,658	3	(76)	8,585
Corporate bonds	1,639	□	(2)	1,637
Total	\$ 103,289	\$ 83	(\$552)	\$ 102,820

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

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The original cost and fair value of investments by contractual maturity at September 30, 2006, were as follows (*in thousands*):

	<b>Original Cost</b>	<b>Fair Value</b>
Debt securities due within:		
One year	\$ 55,091	\$ 55,062
One to five years	32,208	31,875
Five years or more	15,990	15,883
Total	\$ 103,289	\$ 102,820

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The following table summarizes sales of available-for-sale securities for the years ended September 30, 2006, 2005, and 2004 (*in thousands*):

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Proceeds from sales	\$ 161,778	\$ 88,955	\$ 27,092
Gross realized gains	\$ 24	\$ 17	\$ 187
Gross realized losses	(\$ 181)	(\$ 119)	\$ 0

*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*):

	<b>2006</b>	<b>2005</b>
Raw materials	\$ 512	\$ 512
Finished products	440	579
Total	\$ 952	\$ 1,091

*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 2006, \$2.0 million in 2005, and \$3.1 million in 2004. The balance in property and equipment as of September 30, 2005 included \$6.7 million in real property located in Bloomington, Minnesota. The Company entered into an agreement to sell the Bloomington property in September 2005; we completed the sale and consolidated operations at our Eden Prairie location at the end of March 2006. The 2006 and 2005 balances in construction-in-progress include the cost of enhancing the capabilities of our Eden Prairie facility. 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*):

	<b>2006</b>	<b>2005</b>	<b>Useful life (in years)</b>
Laboratory fixtures and equipment	\$ 10,531	\$ 9,550	3 to 10
Building and improvements	12,083	7,306	5 to 20
Building subject to sale agreement	□	6,650	5 to 30
Office furniture and equipment	3,022	2,718	3 to 10
Construction-in-progress	94	2,456	
Less accumulated depreciation	(14,044)	(13,848)	
Property and equipment, net	\$ 11,686	\$ 14,832	

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*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 2006, \$1.7 million in 2005, and \$22,000 in 2004.

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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 current liabilities and other long-term liabilities.

In September 2005, the Company entered an agreement to sell its contract manufacturing facility and 27 acres of land located in Bloomington, Minnesota. The terms of the sale agreement included a \$100,000 cash down payment and a note receivable of \$6.9 million, which is collateralized by the assets. The terms of the note call for monthly installment payments of principal and interest at 6% with the remaining amount due and payable in September 2010. The \$5.6 million balance in other assets represents the long-term portion due on the note.

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. In May 2006, we made an additional investment of approximately \$160,000. As of September 30, 2006 our \$4.1 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%.

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. After reviewing updated guidance provided by FASB Staff Position 115-1 (FSP 115-1), The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments, combined with Novocell valuation information gathered in conjunction with a prospective round of financing, the Company determined its investment in Novocell was impaired and that the impairment was other-than-temporary. During the second quarter of fiscal 2006, we recorded an impairment loss of approximately \$4.7 million. The balance of our investment, \$559,000, which is accounted for under the cost method, is included in other assets and represents an ownership interest of less than 5%.

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. In January 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. In July 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. In March 2006, the Company issued an additional 60,007 shares a result of completion of the second milestone. 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 approximately 480,060 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.

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The Company expects to incur approximately \$1.8 million of amortization expense in fiscal 2007 and 2008, \$532,000 in fiscal 2009, and \$113,000 in fiscal 2010 and 2011 related to all of its licenses and patents. Other assets consisted of the following as of September 30 (*in thousands*):

2006	2005
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Abbott license	\$ 7,037	\$ 7,037
Long-term portion of note receivable	5,635	□
Investment in OctoPlus	4,095	3,935
Investment in ThermopeutiX	1,000	1,000
Patents and other	2,262	732
Investment in Novocell	559	5,210
Less accumulated amortization of intangible assets	(3,609)	(1,867)
Other assets, net	\$ 16,979	\$ 16,047

*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 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 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 licensing 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*

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.

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In May 2005, the Financial Accounting Standards Board (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 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.

On July 13, 2006, FASB Interpretation (FIN) No. 48, Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109, was issued. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The new FASB standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The provisions of FIN 48 are effective for the Company beginning fiscal year 2008. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial condition.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements. This statement establishes a consistent framework for measuring fair value and expands disclosures on fair value measurements. SFAS No. 157 is effective for the Company starting in fiscal 2008. The Company has not determined the impact, if any, the adoption of this statement will have on its consolidated financial statements.

### 3. Stock-Based Compensation

Commencing October 1, 2005, the Company adopted Statement of Financial Accounting Standards No. 123(R), Share Based Payment (SFAS 123(R)), which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on their fair values, over the requisite service period. The Company recorded \$5.5 million of related compensation expense, before taxes, for the year ended September 30, 2006. The \$3.4 million compensation expense, net of related tax effects, reduced basic earnings per share by \$.19 and diluted earnings per share by \$.18 the year ended September 30, 2006. We additionally reclassified our unearned compensation on non-vested share awards (restricted stock) of \$2.6 million to additional paid in capital. The cumulative effect adjustment for forfeitures related to non-vested share awards was immaterial.

As of September 30, 2006, approximately \$18.7 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 3.4 years.

Prior to adopting SFAS 123(R), the Company accounted for stock-based compensation under the intrinsic value method pursuant to Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees. The Company has applied the modified prospective method in adopting SFAS 123(R). Accordingly, periods prior to adoption have not been restated. The Company did not amend or alter outstanding stock-based awards in anticipation of adopting SFAS 123(R). The following table illustrates the effect on net income and earnings per share if the fair value based method had been applied to the years ended September 30 (in thousands, except per share data):

	2005	2004
Reported net income (loss)	(\$ 8,246)	\$ 7,242
Restricted stock expense previously recorded, net of tax	374	134
Stock-based compensation determined under fair value based method, net of related tax effects	(3,120)	(1,876)
Pro forma net income (loss)	(\$10,992)	\$ 5,500
Income (loss) per common equivalent share:		
Basic - as reported	(\$0.45)	\$0.41
Diluted - as reported	(\$0.45)	\$0.41

Basic - pro forma	(\$0.61)	\$0.31
Diluted - pro forma	(\$0.61)	\$0.31

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The Company uses the Black-Scholes option pricing model to determine the weighted average fair value of options. The weighted average fair value of options granted during fiscal 2006, 2005 and 2004 was \$16.58, \$20.26, and \$14.57, respectively. The fair market value of each option is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for grants in 2006, 2005, and 2004, respectively: risk-free interest rates of 4.70%, 3.77% and 3.56%; expected lives of 4.8 years, 7.0 years, and 7.4 years; and expected volatility of 46%, 63% and 66%.

The Company's Incentive Stock Options ("ISO") are granted at a price of 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 commencing one year after the date of grant. Nonqualified stock options are granted at fair market value on the date of grant. Options expire in 7 to 10 years and are exercisable at rates of 20% per year from the date of grant or 20% to 33% per year commencing one year after the date of grant. The Company has authorized 2,400,000 shares for grant under the 2003 Equity Incentive Plan (the "2003 Plan"), of which approximately 992,000 remain available for future awards. As of September 30, 2006, the aggregate intrinsic value of the option shares outstanding and the option shares exercisable was \$11.5 million and \$6.1 million, respectively with an average remaining contractual life of 4.71 and 3.7 years, respectively. The intrinsic value of options exercised during fiscal years 2006, 2005, and 2004 was \$3.6 million, \$6.5 million and \$1.1 million, respectively. The fair value of options shares vested during fiscal years 2006, 2005, and 2004 was approximately \$5.1 million, \$4.6 million and \$2.5 million, respectively. Option transactions under the prior plans and the 2003 Plan during the fiscal year ended September 30, 2006 are summarized as follows:

	Number of shares	Weighted Average Exercise Price
Outstanding at September 30, 2005	1,529,935	\$ 26.60
Granted	317,900	36.87
Exercised	(176,735)	16.52
Forfeited	(160,320)	28.95
Outstanding at September 30, 2006	1,510,780	\$ 29.69
Exercisable at September 30, 2006	546,920	\$ 25.99

Exercise Price Range	Shares		Weighted Average		Weighted Average Exercise Price
	Outstanding at September 30, 2006	Weighted Average Exercise Price	Remaining Contractual Life (in years)	Exercisable at September 30, 2006	
\$ 2.50-\$14.06	64,600	\$ 6.57	2.20	64,600	\$ 6.57
\$ 20.64-\$24.27	261,270	21.57	4.91	113,510	21.54
\$ 25.09-\$29.89	617,330	28.77	4.58	249,890	27.90
\$ 30.13-\$ 35.75	230,240	34.85	5.13	74,620	34.92
\$ 36.37-\$48.85	337,340	38.55	6.27	44,300	39.88
	1,510,780	\$ 29.69	5.00	546,920	\$ 25.99

*Restricted Stock Awards*

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of Common Stock ("Restricted Stock"). Under SFAS 123(R), these shares are considered to be non-vested shares. The Restricted Stock will be released to the key employees if they are employed by the Company at the end of the vesting period. Compensation has been recognized for the estimated fair value of the 153,000 common shares and is being charged to income over the vesting term. Stock compensation expense recognized related to these awards totaled \$879,000, \$588,000 and \$212,000 during fiscal 2006, 2005 and 2004, respectively.

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	<b>Number of Shares</b>	<b>Weighted Average Grant Price</b>
Balance at September 30, 2005	108,000	\$ 30.15
Granted	65,000	36.07
Vested	(5,500)	35.10
Forfeited	(14,500)	33.24
Balance at September 30, 2006	153,000	\$ 32.14

*Performance Share Awards*

The Company has entered into Performance Share agreements with certain key employees, covering the issuance of Common Stock ("Performance Shares"). The Performance Shares will vest upon the achievement of all or a portion of certain performance objectives which must be achieved during the performance period. Compensation has been recognized for the estimated fair value of the 42,000 shares awarded in March 2006 that are estimated to vest during fiscal 2006. Fiscal 2006 stock compensation expense related to the Performance Share awards expected to vest totaled \$764,000. No such expense was recorded in fiscal 2005 or 2004.

*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. As of September 30, 2006, there was approximately \$283,000 of employee contributions included in accrued liabilities in the accompanying balance sheets. Stock compensation expense recognized related to Stock Purchase Plan totaled \$162,000 during fiscal 2006. No such expense was recorded in fiscal 2005 or 2004.

*4. 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*):

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Current provision:	[Bar]	[Bar]	[Bar]

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Federal	\$ 14,701	\$ 7,059	\$ 8,697
State and foreign	1,501	371	1,179
Total current provision	16,202	7,430	9,876
Deferred provision (benefit):			
Federal	(774)	4,592	(4,827)
State	(197)	574	(639)
Total deferred provision (benefit)	(971)	5,166	(5,466)
Total provision	\$ 15,231	\$ 12,596	\$ 4,410

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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*):

	2006	2005	2004
Amount at statutory federal income tax rate	\$ 12,440	\$ 1,513	\$ 4,146
Change due to:			
State taxes	720	496	351
Other	(102)	(10)	(87)
Stock Option Compensation	365	□	□
Valuation Allowance	1,808	□	□
Write-off of in-process R&D	□	10,597	□
Income tax provision	\$ 15,231	\$ 12,596	\$ 4,410

In fiscal 2006, the Company recorded a valuation allowance against the capital loss created by our impairment of the Novocell investment (see Note 2). The valuation allowance was recorded as the Company does not currently foresee future offsetting capital gains to offset this capital loss. As such, no tax benefit has been recorded in our statement of operations.

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*):

	2006	2005
Depreciable assets	\$ 2,192	\$ 1,584
Deferred revenue	552	611
Accruals and reserves	354	362
Restricted stock amortization	616	273
Stock Options	1,302	□
Impaired Asset	1,733	□
Equity items	176	(33)
Other	201	424
Valuation Allowance	(1,808)	□
Total deferred tax asset	5,318	3,221
Less current deferred tax asset	(435)	(353)
Noncurrent deferred tax asset	\$ 4,883	\$ 2,868

5. Commitments and Contingencies



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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.

### 6. 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 \$263,000, \$223,000, and \$210,000 have been charged to income for the years ended September 30, 2006, 2005, and 2004, respectively.

### 7. 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.

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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 "In Vitro" operating segment contains the In Vitro Technologies (formerly 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 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*):

	<b>2006</b>	<b>2005</b>	<b>2004</b>
Operating segment:			
Drug Delivery	\$ 32,918	\$ 29,678	\$ 25,690
Hydrophilic and Other	22,233	19,065	15,527
In Vitro	14,733	13,638	8,521
<b>Total Revenue</b>	<b>\$ 69,884</b>	<b>\$ 62,381</b>	<b>\$ 49,738</b>

### Major Customers

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

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	2006	2005	2004
Cordis Corporation	47%	46%	52%
Abbott Laboratories	12%	14%	8%

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:

	2006	2005	2004
Domestic	84%	85%	79%
Foreign	16%	15%	21%

*8. Subsequent Events*

In September 2006, the Board of Directors authorized the repurchase of \$35 million and up to 1 million shares of the Company's stock. In November 2006, the Company entered into a Rule 10b5-1 agreement and purchased \$17.5 million of the \$35 million in shares authorized at an average price of \$32.87 per share.

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In October 2006, our fiscal 2007, we made an additional investment of \$1.9 million in OctoPlus, a company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers, bringing our total investment to slightly more than \$6.0 million, representing an ownership interest of approximately 9%.

*9. Quarterly Financial Data (Unaudited)*

The following is a summary of the unaudited quarterly results for the years ended September 30, 2006, 2005 and 2004 (in thousands, except per share data).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
<b>Fiscal 2006</b>				
Revenue	\$ 16,465	\$ 17,707	\$ 18,139	\$ 17,573
Income from operations	8,580	8,953	9,463	9,167
Net income	6,218	1,465	6,358	6,293
Net income per share:				
Basic	0.34	0.08	0.34	0.34
Diluted	0.33	0.08	0.34	0.34
<b>Fiscal 2005</b>				
Revenue	\$ 14,069	\$ 15,705	\$ 16,518	\$ 16,090
Income (loss) from operations	8,638	(21,148)	9,148	6,346
Net income (loss)	5,237	(24,371)	6,095	4,793
Net income (loss) per share:				
Basic	0.30	(1.34)	0.33	0.26
Diluted	0.29	(1.34)	0.32	0.25
<b>Fiscal 2004</b>				
Revenue	\$ 12,087	\$ 12,738	\$ 11,444	\$ 13,469

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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

In the second quarter of fiscal 2006, we recorded a \$4.7 million non-cash impairment loss on our investment in Novocell, Inc.

In the second quarter of fiscal 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 2005 fourth quarter results include a \$2.5 million impairment charge recorded against our contract manufacturing facility.

Fiscal 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 2004 third quarter results include an impairment charge recorded against our contract manufacturing facility. The \$16.5 million impairment charge was included in loss from operations.