SURMODICS INC Form 10-K December 14, 2007

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON. DC 20549** 

# **FORM 10-K**

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended September 30, 2007

Commission file number 0-23837

# SURMODICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Minnesota 41-1356149

(State or other jurisdiction of incorporation or organization) (IRS Employer Identification No.)

9924 West 74<sup>th</sup> Street Eden Prairie, Minnesota

55344

(Address of Principal Executive Offices) (Zip Code)

(Registrant

S Telephone Number, Including Area Code)

(952) 829-2700

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

Title of Each Class

Name of Exchange on Which Registered

Common Stock, \$0.05 par value NASDAQ Global Select Market

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 x No x

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 o No x

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 x No o

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

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 o

Accelerated filer x

Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

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, 2007 was approximately \$356 million (based upon the closing sale price of the registrant scommon Stock on such date).

The number of shares of the registrant S Common Stock outstanding as of December 7, 2007 was 18,274,054.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant□s definitive Proxy Statement for the Registrant□s 2008 Annual Meeting of Shareholders are incorporated by reference into Part III.

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

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#### PART I

### ITEM 1. BUSINESS.

#### **Overview**

SurModics, Inc. (referred to as <code>SurModics, The Company, Twe, Tus, Tour</code> and other like terms) is a lead provider of surface modification and drug delivery technologies to the healthcare industry. Our mission is to exceed our customers expectations and enhance the well-being of patients by providing the world foremost, innovative surface modification and drug delivery technologies and products. We partner with many of the world sleading and emerging medical device, pharmaceutical and life science companies to develop and commercialize innovative products designed to improve patient outcomes. Our core offerings include: drug delivery technologies (coatings, microparticles, and implants); surface modification coating technologies that impart lubricity, prohealing, and biocompatibility capabilities; and components for *in vitro* diagnostic test kits and specialized surfaces for cell culture and microarrays. Our strategy is to build on our technical leadership in the field of surface modification and drug delivery technologies and products, enabling us to strengthen our position as a leading edge product development partner to the healthcare industry.

Our surface modification and drug delivery technologies are utilized by our customers to 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 enable drug delivery through our microparticle, polymer implant or device platforms. For example, our patented PhotoLink® technology enhances the maneuverability of dilatation catheters and guidewires within the body 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 (e.g., stents) necessary to treat a medical condition and in cases where devices serve only as a vehicle to deliver a drug (e.g., ophthalmology implants and drug delivery depots).

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.

In January 2005, we extended the application of 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 intravitreal

implant in patients with diabetic macular edema (DME) was initiated during fiscal 2005. The study was fully enrolled in fiscal 2006 and patients completed their twelve-month follow-up during fiscal 2007. The initial clinical data suggest that the I-vation intravitreal 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 TA (triamcinolone acetonide) may represent a viable commercial prospect.

These clinical trial results, in part, led to the collaborative research and license agreement with Merck & Co., Inc. that we signed in June 2007. Through this agreement, SurModics and Merck will pursue the development and commercialization of the I-vation Sustained Drug Delivery System in combination with triamcinolone acetonide and proprietary Merck compounds. Under the terms of our agreement with Merck, we received an up-front license fee of \$20 million and may receive up to an additional \$288 million in fees and development milestones associated with the successful product development and attainment of appropriate U.S. and EU regulatory approvals for these new combination products. We will also be paid for our activities in researching and developing these combination products. Additionally, under the terms of our agreement with Merck, we will be responsible for the exclusive manufacture and supply of clinical and commercial products. We will also receive royalties on sales of products developed under our collaboration.

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We plan to continue to invest in our technologies and products to expand our core capabilities for ophthalmic drug delivery implants. We anticipate entering into one or more additional strategic relationships to further advance these ophthalmic technologies and products, and eventually commercialize such technologies if they lead to viable, approved treatment solutions.

Since our acquisition of Brookwood Pharmaceuticals, Inc. in July 2007, we also have offered controlled release local or systemic drug delivery through the incorporation of our customers drugs into our proprietary injectable microparticles or implants, both of which are polymer-based. (For more information on the Brookwood Pharmaceuticals acquisition, see Liquidity and Capital Resources in Item 7 of this report.) We believe that this acquisition strengthens SurModics portfolio of drug delivery technologies for the pharmaceutical and biotechnology industries. Customer projects within our Brookwood Pharmaceuticals business unit target a number of key clinical indications in the diabetes, oncology, ophthalmology, cardiovascular, orthopedics, dermatology, central nervous system and alcoholism markets, in addition to other fields.

We continue to commercialize our surface modification and drug delivery technologies primarily through licensing and royalty arrangements with medical device manufacturers. Additionally, we now have the capability to partner with pharmaceutical and biotechnology companies to integrate their proprietary drugs with our unique drug delivery platform technologies, such as our polymer-based microparticles and implants as well as our I-vation intravitreal implant, through similar licensing and royalty arrangements. 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 revenues, 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. Furthermore, for immunoassay diagnostic tests, we offer: a line of stabilization products used to extend the shelf life of immunoassay diagnostic tests; substrates used to detect and signal a result in immunoassay diagnostic tests; and recombinant human antigens through our role as exclusive North American distributor for DIARECT AG. 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.

We manage our business through the following seven 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., 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, substrates, recombinant autoimmune antigens, surface chemistry technologies for nucleic acid and protein immobilization, synthetic extracellular matrix (ECM) cell culture products, and diagnostic format intellectual property.

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• Brookwood Pharmaceuticals (acquired in July 2007), specializing in proprietary injectable microparticles and implants to provide sustained delivery of drugs being developed by leading pharmaceutical, biotechnology and medical device clients as well as emerging companies. These microparticles and implants are based on biodegradable polymers. An important part of Brookwood

sustained business continues to be the supply of biodegradable polymers to corporate and academic customers.

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.

# **Surface Modification and Drug Delivery Markets**

Medical Device Industry

Advances in medical device technology have helped drive improved 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 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.

Pharmaceutical and Biotechnology Industries

The pharmaceutical and biotechnology industries have become increasingly competitive due to the launch of new products (many of which have limited differentiating characteristics), patent expirations, and reimbursement pressures. In response to these competitive pressures, companies in these industries are continually seeking to develop new products with improved efficacy, safety and convenience. Reducing dosing frequency through polymer-based sustained release systems has the opportunity to enable the development of new drug entities as well as to improve a broad range of drugs developed by the pharmaceutical and biotechnology industries. Converting a drug that must be, for instance, given daily as a pill or injection, to one that can be administered by injection or implant weekly, monthly or even less frequently, may have several patient benefits. Sustained, controlled drug release has the potential to eliminate undesirable peak and trough drug levels in the body, which can lead to both improved drug safety and efficacy. Additionally, fewer treatments can result in improved patient compliance with a specified administration schedule, thereby further enabling the drug seffect to be optimized. Similarly, less frequent administration is typically considered to be more convenient to the patient.

Drug delivery solutions such as those offered by SurModics also create opportunities for local delivery of medications to sites of disease in the body. In certain applications such as ocular, orthopedic and pain applications, it can be beneficial to provide a high local concentration of drug. Such local delivery may enhance efficacy and reduce side effects by focusing the drug\[ ]s effect where it is needed and limiting the amount of drug impacting other parts of the body.

Pharmaceutical and biotechnology companies have also found that sustained drug delivery solutions can enhance product sales by creating competitive advantage and extending patent protection through the issuance of patents on controlled delivery formulations of their drugs.

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We believe the benefits of polymer-based sustained release systems make them applicable to drugs targeting a wide range of therapeutic fields, including ophthalmology, orthopedics, dermatology, metabolic disease, alcoholism, central nervous system disorders, and cardiovascular disease, among others.

Convergence of the Medical Device, Pharmaceutical and Biotechnology Industries

The convergence of the pharmaceutical, biotechnology 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 drug and medical device industries. We believe the benefits of combining drugs and biologics with implantable devices are becoming increasingly valuable in applications in cardiology, ophthalmology, orthopedics, and other large markets.

### SurModics Surface Modification and Drug Delivery Technologies Surface Modification Surface Modifi

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

Coatings for Surface Modification and Drug Delivery

Our proprietary 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 coating 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 medical condition; (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.

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We offer customers several distinct polymer families for site specific drug delivery. Our Bravo Drug Delivery Polymer Matrix is utilized on the CYPHER® Sirolimus-eluting Coronary Stent from Cordis Corporation, a Johnson & Johnson company. CYPHER® is a trademark of Cordis Corporation. The Bravo polymer is a durable coating and is also used on our I-vation intravitreal implant within our Ophthalmology business unit. 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 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.

Two key differentiating characteristics of our coatings are their flexibility and ease of use. In terms of flexibility, coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents. This flexibility allows customers to be innovative in the design of their products without significantly changing the dimensions or other physical properties of the device. Additionally, 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.

In terms of ease of use, unlike competitive 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, our Photolink coatings are compatible with generally accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

Systemic and Local Drug Delivery Through Injectable Microparticles and Implants

Through our acquisition of Brookwood Pharmaceuticals, as well as internal development and acquisition of our biodegradable materials, we offer customers drug delivery systems based on polymer-based microparticles and implants. These systems enable the controlled delivery of a broad variety of drugs, ranging in size from small molecule drugs to larger molecule drugs such as peptides and proteins. Depending on the drug and application, our microparticles and implants can incorporate drugs for delivery over days to weeks to months.

Brookwood Pharmaceuticals scientists have developed an extensive body of experience, know-how and patented capability in the field of microparticle drug delivery, working with a very wide range of drug classes. Our microparticles incorporate a customer drug and our polymers into very small particles that are measured in microns (1,000 microns equals one millimeter). Using our extensive technology base, we can develop long-acting, injectable microparticles for systemic, local, and cellular delivery of active pharmaceutical ingredients and vaccines. A variety of commercially viable microencapsulation processes are used including: solvent extraction, solvent evaporation, phase separation, fluid bed coating, and spray drying. Based on the desired product specifications, our development team will select the appropriate microencapsulation process, as well as the formulation variables to achieve dose, duration and other product specifications.

Injectable solid implants are rod, coil or other-shaped devices with drug dispersed throughout a polymer matrix. They are designed to release the drug at a programmed rate for days, weeks, or months. This type of drug delivery dosage form is especially suitable when efficacy is dependent on delivering a relatively large dose of a drug over a long duration. The polymer matrix controls the rate of release of drug from the implant. We are developing long-acting implants with biodegradable and non-biodegradable polymers. One of our biodegradable drug delivery implant systems has shape memory properties. This capability allows the implant to be delivered in one shape so that it can be placed through a catheter or other delivery device, after which the implant returns to its original shape once delivered to the desired site in the body.

Through our Brookwood Pharmaceuticals business unit, we are also collaborating with Genzyme Pharmaceuticals, a business unit of Genzyme Corporation, to develop novel drug delivery solutions, with an initial focus on peptide delivery. The relationship offers customized solutions for parenteral formulations by combining expertise in design for peptide delivery, peptide synthesis, and drug delivery technologies.

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# $SurModics \square Surface Modification and Drug Delivery Technologies \square Clinical Benefits$

- Drug Delivery. We provide drug delivery polymer technology to enable controlled, site specific or systemic delivery of therapeutic agents. Our proprietary polymer reagents create coatings, microparticles and implants which serve as reservoirs for therapeutic drugs. The drugs can then be released on a controlled basis over days to weeks to months. Some of our systems can release drugs for over a year. For instance, 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 throughout the world a drug-eluting stent incorporating SurModics∏ technology. We are also collaborating with Merck to pursue the joint development and commercialization of the I-vation sustained drug delivery system with triamcinolone acetonide and other products that combine Merck proprietary drug compounds with the I-vation system for the treatment of serious retinal diseases. 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 believe that we are unique in our ability to offer our medical device, pharmaceutical and biotechnology industry customers and their patients delivery of such a broad range of drugs through coatings, microparticles and implants.
- *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.
- 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.

- 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□s immune system. Accordingly, we have licensed technology to and have made an investment in Novocell, Inc., which is pursuing a treatment for diabetes by implanting encapsulated islet cells.

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- 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 singer 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□ Surface Modification and Drug Delivery 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 and drugs.

Desired Surface Property and

	Desired Surface Property and
Market Segment Served	Examples of Applications
Interventional cardiology and	Lubricity: catheters, guidewires
vascular access	Hemocompatibility: vascular stents, catheters, distal
	protection
	devices

Eugai Filling.	SUNIVIDIOS INC - FUITI TU-K
	Drug/biologics delivery: vascular stents, catheters Prohealing: vascular stents, vascular grafts
Cardiac rhythm management	Lubricity: pacemaker and defibrillator leads, electrophysiology devices  Hemocompatibility: electrophysiology devices  Drug/biologics delivery: pacemaker and defibrillator leads
Cardiothoracic surgery	Prohealing: heart valves, septal defect repair devices Hemocompatibility: minimally invasive bypass devices, vascular grafts, ventricular assist devices
In Vitro Diagnostics	Lubricity: microfluidic devices  Hemocompatibility: blood/glucose monitoring devices, biosensors  Biomolecule immobilization: DNA and protein arrays, protein attachment to synthetic nanofibrillar extracellular matrix for cell culture applications  Cell culture growth and tissue integration: cell culture products, in vitro applications using synthetic nanofibrillar extracellular matrix to provide a more [in vivo-like] surface
Interventional neurology and neurosurgery	Lubricity: catheters, guidewires
Urology and gynecology	Lubricity: urinary catheters, incontinence devices, ureteral stents, fertility devices Drug/biologics delivery: prostatic stents, microparticle injections
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Ophthalmology	Drug/biologics delivery: sustained drug delivery implants and microparticle injections
Orthopedics	Cell growth and tissue integration: bone and cartilage growth Infection resistance: orthopedic and trauma implants Drug/biologics delivery: orthopedic and trauma implants and microparticle injections
Metabolic disease	Drug/biologics delivery: microparticle injections Tissue engineering: cell encapsulation
Central nervous system disorders	

Drug/biologics delivery: microparticle injections, polymer
implants

### Dermatology

Drug/biologics delivery: polymer 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. Beyond coatings, our drug delivery technologies have also been applied to a wide range of drugs currently in preclinical and clinical development.

### **Licensing Arrangements**

We commercialize our surface modification and drug delivery technologies primarily through licensing arrangements with medical device and drug manufacturers. We believe this approach allows us to focus our resources on further developing new technologies and expanding our licensing activities. 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 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 and drugs, primarily through licensing arrangements. Royalties and license fees represented 72.0%, 75.9% and 76.3% of our total revenue in fiscal 2007, 2006 and 2005, respectively. Revenue from these licensing arrangements typically includes research and development revenue, license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees product sales. We also generate revenue from sales of chemical reagents to licensees for use in their coating processes, and from polymer sales under our Lakeshore Biomaterials brand. Our In Vitro Technologies business unit generates revenue from: sales of stabilization products, substrates and antigens to diagnostics customers; sales of genomic products; and licensing our proprietary diagnostic formats for use in point-of-care testing. Product sales represented 18.5%, 16.0% and 15.1% of total revenue in fiscal 2007, 2006 and 2005, respectively.

The licensing process begins with the customer specifying a desired product feature to be created such as lubricity, drug delivery, etc. Because each device and drug is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating research and development revenue. Once the feasibility phase has been completed in a manner satisfactory to the customer, the customer funds a development project to optimize the formulation to meet the customer specific technical needs. At any time prior to commercialization, a license agreement may be executed granting the licensee rights to use our technology. 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. Our Brookwood Pharmaceuticals business unit also supports many of our drug delivery customers by manufacturing microparticles and implants incorporating customers drugs through preclinical and clinical trials and by providing an option to manufacture products upon commercialization as well.

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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. Moreover, as is the case with our agreement with Merck, even exclusive licenses may be limited to a specific field of use, allowing us the opportunity to further license technology to other 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 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 sactual sales of coated products in the prior quarter.

We currently have 100 licensed products (customer products utilizing SurModics technology) already on the market generating royalties and 94 customer products incorporating our technology pending regulatory approval. These 194 products are being sold or developed by 92 licensed customers. We signed a record 27 new licenses in fiscal 2007, up from 21 new licenses signed in fiscal 2006.

Licensed customers include AbbeyMoor Medical, Inc., Abbott Laboratories, Ambrilia Biopharma Inc., Bausch & Lomb Incorporated, Boston Scientific Corporation, CardioMind, Inc., Conor Medsystems, LLC (a wholly owned subsidiary of Johnson & Johnson), Cook Medical, Corning Incorporated, Cordis Corporation (a Johnson & Johnson company), Devax, Inc., Edwards Lifesciences Corporation, elbion NV, ev3 Inc., FoxHollow Technologies, Inc., GE Healthcare, Medtronic, Inc., Merck & Co., Inc., Novocell, Inc., Paragon Intellectual Properties, LLC, Spectranetics Corporation, St. Jude Medical, Inc., ThermopeutiX Inc., and Xtent, Inc., among others. Under most of our licensing agreements, we are required to keep the identity of our customers confidential 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, had an exclusive license to our coated glass slide technology that, in fiscal 2007, became a non-exclusive license. 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.

#### Substrates

Through the August 2007 acquisition of BioFX Laboratories, Inc. ( $\square$ BioFX $\square$ ), SurModics now offers colorimetric and chemiluminescent substrates for the *in vitro* diagnostics market. A substrate is the component of a diagnostic test kit that detects and signals that a reaction has taken place so that a result can be recorded. Colorimetric substrates signal a positive diagnostic result through a color change. Chemiluminescent substrates signal a positive diagnostic result by emitting light. We believe that our substrates offer a high level of stability, sensitivity and consistency.

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### Recombinant Human Antigens

SurModics is the exclusive North American distributor (and non-exclusive distributor in Japan) of DIARECT AG 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 bacilovirus/Sf9 expression system for autoimmune antigens as well as  $E.\ coli$  systems for particular expression tasks.

Ultra-Web∏ Synthetic Extracellular Matrix (ECM) Cell Culture Products

The Ultra-Web Synthetic ECM product line is the result of a collaboration between Donaldson Company, Inc. (providing the nanofiber technology) and SurModics (providing the surface modification technology). Ultra-Web is a trademark of Donaldson Company. 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, provides worldwide marketing and distribution of the nanofiber cell culture products for *in vitro* cell culture research and drug discovery applications. Corning Life Sciences launched the initial Ultra-Web nanofiber cell culture products in 96 well microplate and 100mm research dish formats in April 2007.

Ultra-Web 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 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\(\pred)s\) 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 products, 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 and optimization 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, microparticles and implants, to measure coating thickness and smoothness, and to map the distribution of chemicals throughout coatings, microparticles and implants. We believe our capabilities far exceed those of our direct competitors, and sometimes even exceed those of our large-company customers.

As medical products become more sophisticated and complex and as competition increases, 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 properties

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to meet these needs across multiple medical markets. In addition, we are expanding our drug delivery and surface modification technology expertise to capture more of the final product value. We are doing this by, in selected cases, developing or acquiring 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 formulation 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 in progress include additional polymer systems for site specific and systemic 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 2007, 2006 and 2005, our research and development expense was \$28.5 million, \$20.4 million and \$16.1 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 2007, 2006 and 2005, was \$6.9 million, \$5.7 million and \$5.4 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 coatings, drug delivery 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 2007, we filed 47 United States patent applications, expanding the portfolio protection around our current technologies as well as enabling pursuit of new technology concepts, innovations, and directions. As of September 30, 2007, we had 119 pending United States patent applications, 8 of which were exclusively licensed from others, and 272 foreign patent applications, of which 5 were exclusively licensed from others. We own 96 issued U.S. patents and 149 international patents. Additionally, we have exclusively licensed rights to 25 U.S. patents and 90 international patents.

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 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 further sales and marketing relationships in other geographies around the world. Information regarding domestic and foreign revenues in Note 8 [Operating Segments] under [Notes to Financial Statements] is incorporated herein by reference.

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, drug delivery, and *in vitro* technologies and products. In addition, we exhibit at major trade shows

and technical meetings, advertise in selected trade journals and through our web site, 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 may begin with a feasibility study, and also may include additional services such as assistance in the transfer of the technology to the licensee, further optimization, process control and trouble shooting, preparation of product for clinical studies, and assistance with regulatory submissions for product approval. Most of these services are billable to customers.

### **Acquisitions and Investments**

In order to further our strategic objectives and strengthen our existing businesses, we intend to continue to explore acquisitions, investments and strategic collaborations to diversify and grow our business. As a result, we expect to make future investments or acquisitions where we believe that we can broaden our technology offerings and expand our sources of revenue and the number of markets in which we participate. Mergers and acquisitions of medical technology companies are inherently risky and no assurance can be given that any of our previous or future acquisitions will be successful or will not materially adversely affect our consolidated results of operations, financial condition, or cash flows.

On July 10, 2007, we completed a \$3.5 million equity investment in Paragon Intellectual Properties, LLC, and its subsidiary, Apollo Therapeutics, LLC. SurModics has agreed to invest an additional \$2.5 million upon successful completion of specified development milestones, which we expect will occur no later than the second quarter of fiscal 2008. The investment was made in conjunction with our agreement with Apollo to collaborate on the development of a coronary stent system incorporating our proprietary Finale prohealing coating technology.

On August 1, 2007, we announced our acquisition of Brookwood Pharmaceuticals, Inc., a leading provider of drug delivery technology primarily to the pharmaceutical industry, from Southern Research Institute, for \$40 million in upfront cash at closing and up to an additional \$22 million in cash upon the successful achievement of specified milestones. We will account for our acquisition of Brookwood under the purchase method of accounting. Brookwood Pharmaceuticals is a drug delivery company that provides its proprietary polymer-based technologies to companies developing improved pharmaceutical products. The company has particular strength in proprietary injectable microparticles and implant technology, both of which are based on biodegradable polymers, to provide sustained drug delivery. This acquisition is expected to help us broaden our technology offerings to our customers, diversify the range of markets in which we participate, expand our customer base, and enhance our pipeline of potential revenue generating opportunities.

On August 13, 2007, we announced our acquisition of BioFX Laboratories, Inc., a provider of substrates to the *in vitro* diagnostics industry, for \$11.3 million in cash at closing and up to an additional \$11.4 million in cash upon the successful achievement of specified revenue targets. We will account for our acquisition of BioFX under the purchase method of accounting. BioFX Laboratories is a leading manufacturer of substrates, a critical component of diagnostic test kits used to detect and signal that a certain reaction has taken place. We expect our acquisition of BioFX to broaden our product portfolio in the *in vitro* diagnostics market and expand marketing opportunities for each company products by way of complementary customer bases.

### **Significant Customers**

We have two customers that each provided more than 10% of our revenue in fiscal 2007. Revenue from Johnson & Johnson and Abbott Laboratories represented approximately 33% and 16%, respectively, of our total revenue for the year ended September 30, 2007. We have several products from each generating revenue for us. Additionally, as previously discussed, during fiscal 2007, we announced the signing of a collaborative research and license agreement with Merck to pursue the development and commercialization of our I-vation intravitreal implant in combination with triamcinolone acetonide and certain proprietary Merck compounds. Under the terms of our agreement with Merck, we received an up-front license fee of \$20 million and may receive up to an additional \$288 million in fees and development milestones associated with the successful product development and attainment

of appropriate U.S. and EU regulatory approvals for these new combination products. We will also be paid for our activities in researching and developing these combination products. Additionally, under the terms of our agreement with Merck, we will be responsible for the exclusive manufacture and supply of clinical and commercial products. We will also receive royalties on sales of products developed under our collaboration. 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 drugs 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 Alkermes, Inc., AST Products, Inc., Biocompatibles International plc, BioSensors International Group, Ltd., Durect Corporation, Hydromer, Inc., MediVas, LLC, pSivida Limited, QLT Inc., Specialty Coating Systems, Inc., STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., and W.L. Gore & Associates, 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 customer changing the manufacturing process it uses once a device or drug has been approved for sale.

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

### **Manufacturing**

Historically, we have performed limited manufacturing activities for our customers. In general, we do not coat medical devices that are intended for commercial sale by our customers, though we often support our customers by coating products intended for pre-clinical and clinical development, including human clinical trials. However, during fiscal 2007, we agreed to become the exclusive manufacturer of all clinical and commercial I-vation products covered by our license agreement with Merck. Our manufacturing arrangements with Merck support our business strategy in a variety of ways, including allowing us to capture more of the final value of products being commercialized with our

technology. In order to fulfill our commitments to Merck, however, our facilities will need to be upgraded. In this regard, we expect to make investments in our operations to add capacity and to bring our facilities into compliance with GMP and other applicable regulatory standards. We may enter into similar arrangements with other of our customers where a clear, strategic rationale exists.

Currently, 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.

Our Brookwood Pharmaceuticals business unit supports many drug delivery customers by manufacturing microparticles and implants incorporating their drugs through preclinical and clinical trials. We also offer these customers commercial manufacturing capabilities for products that incorporate our drug delivery technologies, but none of our microparticle or polymer implant-based drug delivery products have yet reached the market. Additionally, our Brookwood Pharmaceuticals business unit manufactures polymers for more than 100 medical device companies, drug companies and universities. Several of the products that incorporate the polymers that we produce have been commercialized.

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.

Additionally, we 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. Through a somewhat different manufacturing process, our substrates are mixed in high purity water then sealed and labeled, all under controlled light conditions.

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 we are not currently regulated by Good Manufacturing Practices (GMP), we 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, our Eden Prairie, Minnesota facility received ISO 13485:2003 and ISO 9001:2000 certification in fiscal 2004 and has received updated certifications in each subsequent year.

### **Government Regulation**

Although our surface modification and drug delivery technologies themselves are not directly regulated by the U.S. Food and Drug Administration ([FDA]), the medical devices and drugs 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 ([PMA]) 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 (510(k) 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).

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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 our technologies without us having to share this highly confidential information with our customers.

U.S. legislation allows companies, 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, 2007, we had 244 employees, of whom 187 were engaged in product development, quality, or manufacturing positions, with the remainder in sales, marketing, or administrative positions. Post-graduate degrees are held by 79 of our employees, 32 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 sannual 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,[] []m []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 and Merck agreements, as well as 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 significant reliance on its relationship with Cordis, which causes our financial results and stock price to be subject to factors affecting Cordis and its CYPHER® stent program, including among others, the rate of market penetration by Cordis, the timing of market introduction of competing products, product safety or efficacy concerns and intellectual property litigation generally and specifically the litigation involving Boston Scientific Scimed, Inc. and Cordis in the U.S. District Court for the District of Delaware in which each was reported in June and July 2005 to have infringed the patent rights of the

other;

• the Company reliance on its relationship with Merck and the need to achieve development milestones, conduct clinical trials, obtain regulatory approvals, and market I-vation products covered by our license agreement with Merck;

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- 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 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 ability to maintain satisfactory relationships with its licensees:
- the Company 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 ability to facilitate through strategic investment and research and development support the creation of new medical device market segments and applications that incorporate its coating technologies;
- market acceptance of products sold by customers incorporating our technologies and the timing of new product introductions by licensees;
- market acceptance of products sold by customers competitors and the timing and pricing of new product introductions by customers competitors;
- the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances, which may result in lost market opportunities or postpone or preclude product commercialization by licensees;
- efficacy or safety concerns with respect to products marketed by us and our licensees, whether scientifically justified or not, that may lead to product recalls, withdrawals or declining sales;
- the ability to secure raw materials for reagents the Company sells;
- the Company[s ability to manage successfully clinical trials and related foreign and domestic regulatory processes for the I-vation[intravitreal implant or other acquired products from InnoRx under development by the Company[s Ophthalmology business unit, 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 sability 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 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;
- the Company ability to improve and qualify its facilities to accommodate its obligations to manufacture and supply clinical and commercial quantities of the I-vation intravitreal implant for Merck and other potential licensees of that technology;

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- 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\(\perp\)s personnel or facilities; and
- other factors described below in [Risk Factors.]

Many of these factors are outside the control and knowledge of the Company, and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon the Company $\square$ 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  $\square$ Risk Factors. $\square$ 

### ITEM 1A. RISK FACTORS.

### RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

The loss of, or significant reduction in business from, one or more of our major customers could significantly reduce our revenue, earnings or other operating results.

We have two customers that each provided more than 10% of our revenue in fiscal 2007. Revenue from Johnson & Johnson and Abbott Laboratories represented approximately 33% and 16%, respectively, of our total revenue for the year ended September 30, 2007. Additionally, as previously discussed, during fiscal 2007, we announced the signing of a collaborative research and license agreement with Merck to pursue the development and commercialization of our I-vation intravitreal implant in combination with triamcinolone acetonide and certain proprietary Merck compounds. The loss of one or more of our largest customers, or reductions in business from them, 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. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenue.

The long-term success of our business may suffer if we are unable 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 and drug manufacturers and other customers, thereby expanding the licensing base for our 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 customers 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 and drug delivery are competitive markets and carry 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 surface modification and drug delivery technologies compete with technologies developed by Alkermes, Inc., AST Products, Inc., Biocompatibles International plc, BioSensors International Group, Ltd., Durect Corporation, Hydromer, Inc., MediVas, LLC, pSivida Limited, QLT Inc., Specialty Coating Systems, Inc., STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., and W.L. Gore & Associates, 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

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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 surface modification or drug delivery technologies less competitive or obsolete would have a material adverse effect on our business, financial condition and results of operations.

### Failure to identify strategic investment and acquisition opportunities 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 investments and acquisitions, we may find it more difficult to realize our growth objectives.

# Any acquisitions that we undertake could be difficult to integrate, disrupt our business, dilute shareholder value, or harm our operating results.

We may make strategic investments or acquire complementary businesses, technologies, or products if we identify a suitable investment or acquisition candidate. 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 customers or other 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.

# Our acquisition of Brookwood Pharmaceuticals could be difficult to integrate and may disrupt our business, dilute shareholder value, or harm our operating results.

Our acquisition of Brookwood Pharmaceuticals was the largest in our Company shistory. The process of integrating any acquired business, technology, or product into our business and operations may result in unforeseen operating difficulties and expenditures, including those described above. Our ability to realize the anticipated benefits of our acquisition of Brookwood will require the integration of our sales and marketing efforts to certain customers, integration of information technology and other administration systems. Additional operating difficulties may arise as a result of our having to manage a large, remote location with a limited management team. Failure to successfully integrate Brookwood into our operations may adversely affect our operating results.

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# Our failure to expand our management systems and controls to support anticipated growth or integrate acquisitions could seriously harm our operating results and business.

Our operations are expanding, and we expect this trend to continue as we execute our business strategy. Executing our business strategy has placed significant demands on management and our administrative, development, operational, information technology, manufacturing, financial and personnel resources. Accordingly, our future operating results will depend on the ability of our officers and other key employees to continue to implement and improve our operational, development, customer support and financial control systems, and effectively expand, train and manage our employee base. Otherwise, we may not be able to manage our growth successfully.

### Research and development of new technologies may adversely affect our operating results.

The success of our business depends on a number of factors, including our continued research and development of new technologies for future commercialization. In researching and developing such new technologies, we may incur significant expenses that may adversely affect our operating results, including our profitability. Additionally, these activities are subject to risks of failure that are inherent in the development of new medical technologies and as a result, may never result in commercially viable technologies.

# We recognize revenue in accordance with various complex accounting standards, and changes in circumstances or interpretations may lead to accounting adjustments.

Our revenue recognition policies involve application of various complex accounting standards, including SEC Staff Accounting Bulletin No. 104, or SAB 104, and Emerging Issues Task Force Issue No. 00-21 entitled, [Revenue Arrangements with Multiple Deliverables.] Our compliance with such accounting standards often involves management sjudgment regarding whether the criteria set forth in the standards have been met such that we can recognize as revenue the amounts that we receive as payment for our products or services. We base our judgments on assumptions that we believe to be reasonable under the circumstances. However, these judgments, or the assumptions underlying them, may change over time. In addition, the SEC, PCAOB or AICPA may issue new positions or revised guidance on the treatment of complex accounting matters. Changes in circumstances or third-party guidance could cause our judgments to change with respect to our interpretations of these complex standards, and transactions recorded, including revenues recognized, for one or more prior reporting periods could be adversely affected.

### RISKS RELATING TO OUR OPERATIONS AND RELIANCE ON THIRD PARTIES

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.

A principal element of our business strategy is to enter into licensing arrangements with medical device, pharmaceutical, and biotechnology companies that manufacture products incorporating our technologies. For the fiscal years ended September 30, 2007, 2006 and 2005, we derived approximately 72%, 76% and 76%, of our revenue, respectively, from royalties and license fees. We do not currently market, distribute or sell our own medical devices, pharmaceutical or biologic compounds, 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 market and sell (and most manufacture) the products incorporating our licensed technologies. If one or more of our licensees fail to pursue the development or marketing of these products as planned, our revenue and profits may not reach our expectations, or may decline. Additionally, our ability to generate positive operating results in connection with the achievement of development or commercialization milestones may also suffer. 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

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marketing efforts may be unsuccessful, resulting in delayed or discontinued products. Hence, the amount and timing of royalty payments received by us will fluctuate, and such fluctuations could have a material adverse effect on our business, financial condition and results of operations.

Under our standard license agreements, licensees can terminate the license for any reason upon 90 days prior written notice. Existing and potential licensees have no obligation to deal exclusively with us 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 have limited or no redundancy in our manufacturing facilities, 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, Birmingham, Alabama, and Owings Mills, Maryland facilities. If our existing production facilities become 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 customers, including certain of our licensees. Without our existing production facilities, we would have no other means of manufacturing products until we were able to restore the manufacturing capability at a particular 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.

# We have limited experience manufacturing pharmaceutical products for commercial sale and use, and we may be subject to adverse consequences if we fail to comply with applicable regulations.

Under the terms of our agreement with Merck, we will be responsible for the manufacture and supply of clinical and commercial quantities of the I-vation intravitreal implant for use with certain pharmaceutical compounds. In addition to our obligations to Merck, we may elect to manufacture other pharmaceutical products for other existing or future licensees under appropriate circumstances. The manufacture of pharmaceutical products can be an expensive, time consuming, and complex process. Further, any manufacturer of pharmaceutical products is subject to applicable Good Manufacturing Practices (GMP) as prescribed by the Food and Drug Administration or other rules and regulations prescribed by foreign regulatory authorities. Our current facilities do not meet these regulations. In order to fulfill our commitments to Merck, we will need to make

investments in our operations to add capacity and to bring our facilities into compliance with the applicable regulatory standards. We may be unable to maintain our facilities or implement procedures that comply with GMP or other applicable regulatory standards. Such a failure to comply with GMP could result in significant time delays or inability to obtain (and maintain) marketing approval for the I-vation products to be sold by Merck. Furthermore, we may be subject to sanctions, including temporary or permanent suspension of operations, product recalls and marketing restrictions, if we fail to comply with the laws and regulations pertaining to our business.

# 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

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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.

# Our manufacture and supply of pharmaceutical products may subject us to product liability claims directly against us that could result in costly litigation and significant liability

Our involvement in the manufacture and supply of clinical and commercial quantities of the I-vation intravitreal implant for Merck, and potentially other licensees, may expose us to significant risk of product liability claims filed directly against us. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management stime, attention and resources. We have obtained a level of liability insurance coverage that we believe is adequate in scope and coverage given our current stage of development. However, we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. If a product liability claim or series of claims are brought against us in excess of our insurance coverage, the payment of such liabilities could have a negative effect on our business and financial condition.

# 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 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 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, except for certain of our executive officers and other employees at Brookwood. 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.

### RISKS RELATING TO CLINICAL AND REGULATORY MATTERS

Products incorporating our technologies are subject to continuing regulations and an extensive approval process. If our licensees are unable to obtain or maintain the necessary regulatory approvals for such products, then our licensees will not be able to commercialize those products on a timely basis, if at all.

Although surface modification and drug delivery technologies themselves are not directly regulated, the medical devices or pharmaceutical products incorporating the technologies are subject to regulation by the FDA and other regulatory authorities. In order to obtain regulatory approval for products incorporating our technologies, extensive preclinical studies as well as clinical trials in humans will be required. Clinical development, including preclinical testing, is a long, expensive and uncertain process. The burden of securing regulatory approval for these

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products typically rests with our licensees (the medical device or pharmaceutical manufacturers). However, we have prepared Device Master Files which may be accessed by the FDA and other regulatory authorities to assist them in their review of the applications filed by our licensees.

The process of obtaining FDA and other required regulatory approvals is expensive and time-consuming. Historically, most medical devices incorporating our technologies have been subject to the FDA $\parallel$ s 510(k) marketing approval process, which typically lasts from six to nine months. Supplemental or full pre-market approval ( $\parallel$ PMA $\parallel$ ) reviews require a significantly longer period, delaying commercialization. By contrast, pharmaceutical products incorporating our technologies are subject to the FDA $\parallel$ s investigational new drug application process which typically takes a number of years to complete. Furthermore, sales of medical devices and pharmaceutical products 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 products 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.

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

We are currently collaborating with Merck in conducting a Phase I safety trial for our I-vation intravitreal implant. The 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. Merck sability 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 identified 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 our or our partner sobtaining 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 may face liability if we mishandle or improperly dispose of the hazardous materials used 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.

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Additionally, 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.

### RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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 proprietary 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.

We may become involved in expensive and unpredictable patent litigation or other intellectual property proceedings which could result in liability for damages, or impair our development and commercialization efforts.

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 and pharmaceutical industries, 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.

# If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through trade secret or confidentiality agreements with our employees, consultants, potential licensees, or other parties as well as through other security measures. There can be no assurance that these agreements or any security measure will provide meaningful protection for our unpatented proprietary information. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

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# If we or any of our licensees breach any of the agreements under which we have in-licensed intellectual property from others, we could be deprived of important intellectual property rights and future revenue.

We are a party to various agreements through which we have in-licensed or otherwise acquired from third parties rights to certain technologies that are important to our business. In exchange for the rights granted to us under these agreements, we agree to meet certain research, development, commercialization, sublicensing, royalty, indemnification, insurance, and other obligations. If we or one of our licensees fails to comply with these obligations set forth in the relevant agreement through which we have acquired rights, we may be unable to effectively use, license, or otherwise exploit the relevant intellectual property rights and may be deprived of current or future revenues that are associated with such intellectual property.

### RISKS RELATING TO OUR SECURITIES

### 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 <code>[Forward-Looking Statements[]]</code> and <code>[Risk Factors.[]]</code> 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 fiscal year ended September 30, 2007, the closing sale price for our common stock ranged from \$31.10 to \$52.68 per share. As of December 7, 2007, the last reported sale price of our stock was \$52.73 per share. The market prices for securities of medical technology, drug delivery and biotechnology companies historically have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

### ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

#### ITEM 2. PROPERTIES.

Our principal operations are located in Eden Prairie, a suburb of Minneapolis, Minnesota, where we own a building that has approximately 64,000 square feet of space. To accommodate the future growth needs of our business, in August 2007, we entered in a purchase agreement providing us with certain rights to acquire an

undeveloped parcel of land near our Eden Prairie facility, and we also entered into an agreement to lease a facility having approximately 73,000 square feet of space.

In addition to our Eden Prairie facilities, we also own and lease facilities in Birmingham, Alabama in connection with our Brookwood Pharmaceuticals operations. We also lease facilities in Owings Mills, Maryland in connection with our BioFX operations and lease office space in Irvine, California for use by our Ophthalmology business unit.

### ITEM 3. LEGAL PROCEEDINGS.

The information in Note 6 [Commitments and Contingencies] under [Notes to Financial Statements] is incorporated herein by reference.

### 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 2007.

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### **EXECUTIVE OFFICERS OF THE REGISTRANT**

The names, ages and positions of the Company\(\sigma\) s executive officers are as follows:

Name	Age	Position
Bruce J Barclay	51	President and Chief Executive Officer
Aron B. Anderson, Ph.D.	44	Vice President and Chief Scientific Officer
Philip D. Ankeny	44	Senior Vice President and Chief Financial Officer
Douglas P. Astry	55	General Manager, In Vitro Technologies
Lise W. Duran, Ph.D.	52	Vice President and General Manager, Regenerative Technologies
Peter L. Ginsberg	42	Vice President of Business Development and Strategic Planning
Steven J. Keough	52	Senior Vice President and General Manager, Orthopedics and Chief Intellectual Property Counsel
Paul A. Lopez	51	Vice President, and President, Ophthalmology Division
Charles W. Olson	43	Vice President, Sales, and General Manager, Hydrophilic  Technologies
Bryan K. Phillips	36	Deputy General Counsel and Corporate Secretary
Brian L. Robey	44	Vice President and General Manager, Drug Delivery
Michael J. Shoup	47	Vice President of Quality, Regulatory and Clinical Affairs
Arthur J. Tipton, Ph.D.	50	Vice President, and President of Brookwood Pharmaceuticals, Inc.
Jan M. Webster	48	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 Is 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 investment banking with Robertson Stephens and Morgan Stanley. In addition, his operating experience includes

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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 the Company 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\[Gamma]s Bioanalytical Technologies Group. Mr. Astry received his B.A. degree in Biology from Williams College in 1974, an M.S. in Physiology from the University of Connecticut in 1980, and an M.B.A. from the University of Minnesota in 1987.

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 a senior microbiologist and was promoted in 1992 to Director of Microbiology. She was promoted to Vice President of Product Development in 1998. From 1988 to 1990, Dr. Duran served as a Study Director for Microbiological Associates, Inc., in the Biotechnology Services Division. She also did a research fellowship in Immunology at the Mayo Clinic and was a postdoctoral associate in Laboratory Medicine and Pathology at the University of Minnesota. Dr. Duran received her B.S. in microbiology from the University of Maryland in 1977 and a Ph.D. in cellular immunology from the Uniformed Services University of the Health Sciences in 1984.

Peter L. Ginsberg joined the Company 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 Managing Director and Senior Analyst from 1997 to 2003, 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 Scarlson 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 the Company 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 in 1987, an M.A. from the Catholic University of America in 1982, and a Bachelor of Science degree from the United States Naval Academy in 1977.

Paul A. Lopez joined the Company in July 2005 as Vice President and President of the Company Ophthalmology business unit. 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, including President, North America Surgical; Vice President, Commercial Operations, Americas and Asia Pacific Regions; and Vice President, Business Integration from January 1999 to March 2001. 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 in 1984 and a B.S. in Business Administration from California State University, Long Beach in 1979.

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

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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 B.S. degree in Marketing from Winona State University in 1987.

Bryan K. Phillips joined the Company in July 2005 as Patent Counsel and Assistant General Counsel. In January 2006, Mr. Phillips was appointed Corporate Secretary, and he was promoted to his current role as Deputy General Counsel in October 2007. Prior to joining SurModics, Mr. Phillips served as patent counsel at Guidant Corporation Cardiac Rhythm Management Group where he was responsible for developing and implementing intellectual property strategies and also for supporting the company susiness development function. He also practiced law at the Minneapolis-based law firm of Merchant & Gould P.C. Mr. Phillips received a B.S. degree in Mechanical Engineering from the University of Kansas in 1993 and a law degree from the University of Minnesota Law School in 1999. He is admitted to the Minnesota State Bar association and is registered to practice before the United States Patent and Trademark Office.

Brian L. Robey joined the Company 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 sand master degrees in biomedical engineering from Louisiana Tech University in 1985 and 1987 and an M.B.A. from the University of Texas at San Antonio in 2000.

Michael J. Shoup joined the Company in March 2006 as Vice President of Quality, Regulatory and Clinical Affairs and assumed additional responsibilities for analytical and characterization sciences in January 2007. 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 Scardiac Surgery Division from 2005 to 2006 and held various positions at Acorn Cardiovascular from 1998 to 2005, most recently as Director of Operations. Mike 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 at the University of 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 an M.B.A. with a manufacturing systems concentration from the University of St. Thomas (1995).

Arthur J. Tipton, Ph.D., became Vice President, SurModics and President, Brookwood Pharmaceuticals, coincident with the acquisition of Brookwood by SurModics in July 2007. Dr. Tipton joined Southern Research Institute in 2004 and then became President and CEO of Brookwood Pharmaceuticals, when it was launched as a new company based on Southern Research Institute pharmaceutical formulations business in January 2005. Prior to joining Southern Research Institute, Dr. Tipton served as Executive Vice President at Durect Corporation. Dr. Tipton also held a variety of positions at Southern BioSystems (now part of Durect), including Vice President and Chief Scientific Officer, where he led all efforts on biodegradable technology from 1993 to 2001. Dr. Tipton was with Atrix Laboratories (now part of QLT Inc.) from 1988 to 1993. He currently serves on the Boards of the Biotechnology Association of Alabama and the Controlled Release Society. Dr. Tipton earned a Ph.D. in Polymer Science and Engineering from the University of Massachusetts, Amherst in 1987 and a B.S. in Chemistry from Spring Hill College in 1980.

Jan M. Webster joined the Company 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 received a bachelor segree in business administration from Minnesota State University, Mankato in 1981 and earned an M.A. in human resources and industrial relations from the University of Minnesota in 2006.

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  $\square SRDX$ . The table below sets forth the range of high and low closing sale prices, by quarter, for our Common Stock, as reported by Nasdaq, in each of the last two fiscal years.

Fiscal Quarter Ended:	High	Low
September 30, 2007	52.68	44.72
June 30, 2007	50.00	35.30
March 31, 2007	38.49	31.11
December 31, 2006	35.38	31.10
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

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 December 7, 2007, there were 295 holders of record of our Common Stock and approximately 5,784 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, 2007, 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>(c)</b>	(d)
			Total	
			Number	Maximum
			of Shares	Number of
			Purchased	Shares that
			as Part	
			of	May Yet Be
	(a)	<b>(b)</b>	Publicly	Purchased
	<b>Total Number</b>	Average	Announced	<b>Under the</b>
	of Shares	<b>Price Paid</b>	Plans or	Plans or
		Per		
Period	Purchased(1)	Share(1)	Programs	Programs
7/1/07 - 7/31/07	6,390	\$ 50.87	N/A	N/A
8/1/07 - 8/31/07	33,400	\$ 49.48	N/A	N/A
9/1/07 - 9/30/07	7,810	\$ 48.00	N/A	N/A
Total	47,600	\$ 49.42	N/A	N/A

(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.

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### **Stock Performance Chart**

The following chart compares the cumulative total shareholder return on the Company□s Common Stock with the cumulative total return on the Nasdaq Stock Market and the Nasdaq Medical Industry Index (Medical Devices, Instruments and Supplies). The comparison assumes \$100 was invested on September 28, 2002 and assumes reinvestment of dividends.

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### ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of and for the fiscal years ended September 30, 2007, 2006, and 2005 are derived from our audited consolidated financial statements included elsewhere in this report. The financial data as of and for the fiscal years ended September 30, 2004 and 2003 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 financial statements and Management 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 on page F-1 and other financial information included in this report.

			Fiscal Year		
(Dollars in Thousands)	2007	2006	2005	2004	2003
Statements of Operations Data:					
Total revenue	\$ 73,164	\$ 69,884	\$ 62,381	\$ 49,738	\$ 43,232
Operating income	9,899	36,163	2,985	10,474	20,640

Net income (loss)	3,347	20,334	(8,246)	7,242	13,936
Diluted net income (loss) per share	0.18	1.09	(.45)	.41	.78
Balance Sheet Data:					
Cash and investments	\$ 26,308	\$ 58,813	\$ 24,445	\$ 19,215	\$ 6,647
Total assets	171,331	157,402	124,225	109,587	97,808
Retained earnings	51,620	48,273	27,914	36,161	28,918
Total stockholders∏ equity	130,922	145,203	115,581	94,310	86,114

# 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 <code>Selected Financial Data</code> and our audited consolidated 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 <code>Forward-Looking Statements</code> and <code>Risk Factors</code>. 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 seven 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; (2) the Ophthalmology business unit, 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; and (3) the Brookwood Pharmaceuticals unit, which provides proprietary polymer-based technologies to companies developing improved pharmaceutical products. The ∏Hydrophilic and Other∏ operating segment consists of three business units: (1) the Hydrophilic Technologies business unit, which focuses on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) the 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) the 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, antigens and substrates for immunoassay diagnostic tests, our in vitro diagnostic format technology and our synthetic ECM cell culture products.

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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, antigens and substrates 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 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 business unit. 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.

In June 2007, we signed a collaborative research and license agreement with Merck to pursue the joint development and commercialization of the I-vation sustained drug delivery system with triamcinolone acetonide and other products that combine Merck proprietary drug compounds with the I-vation system for the treatment of serious retinal diseases. Under the terms of our agreement with Merck, we received an up-front license fee of \$20 million and may receive up to an additional \$288 million in fees and development milestones associated with the successful product development and attainment of appropriate U.S. and EU regulatory approvals for these new combination products. We will also be paid for our activities in researching and developing these combination products. Additionally, under the terms of our agreement with Merck, we will be responsible for the exclusive manufacture and supply of clinical and commercial products. Once products licensed under the agreement are commercialized, we will also receive royalties on sales of such products.

In July 2007, we acquired all of the assets of Brookwood Pharmaceuticals, Inc. by paying cash to Southern Research Institute, which owned the capital stock of Brookwood. Brookwood is a drug delivery company based in Birmingham, Alabama that provides its proprietary polymer-based technologies to companies developing improved pharmaceutical products. Brookwood is a wholly owned subsidiary of SurModics and is reported as part of our Drug Delivery operating segment.

In August 2007, we acquired all of the assets of BioFX Laboratories, Inc. by paying cash to BioFX stockholders. Based in Owings Mills, Maryland, BioFX Laboratories is a leading manufacturer of substrates, a critical component of diagnostic test kits used to detect and signal that a certain reaction has taken place. BioFX is a wholly owned subsidiary of SurModics and is reported as part of our In Vitro operating segment.

# **Critical Accounting Policies**

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

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Revenue recognition. In accordance with SEC Staff Accounting Bulletin (SAB) No. 104, [Revenue Recognition,] revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) shipment has occurred or delivery has occurred if the terms specify destination; (3) the sales price is fixed or determinable; and (4) collectibility is reasonably assured. However, when there are additional performance requirements, revenue is recognized when such requirements have been satisfied. 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 a quarterly report. Revenue related to a performance milestone is recognized upon achievement of the milestone and meeting specific revenue recognition criteria. We recognize initial license fees over the term of the related agreement. Product Sales to third parties are recognized at the time of shipment, provided that an order has been received, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured and returns can be reasonably estimated. Our sales terms provide no right of return outside of our standard warranty policy. Payment terms are generally set at 30 days. Generally, revenue for research and development is

recorded as performance progresses under the applicable contract. When we have revenue arrangements with multiple deliverables, we comply with Emerging Issues Task Force Issue No. 00-21, [Accounting for Revenue Arrangements with Multiple Deliverables, and recognize each element as it is earned.

Costs related to products delivered are recognized in the period revenue is recognized. Customer advances are accounted for as a liability until all criteria for revenue recognition have been met.

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 were less than the carrying amount of the assets, we would recognize an impairment charge. In September 2005, we signed an agreement to sell our Bloomington facility and based on the selling price recorded a \$2.5 million impairment charge.

**Goodwill.** Goodwill represents the excess of the cost of the acquired entities over the fair value assigned to the assets purchased and liabilities assumed in connection with the Company acquisitions. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that the carrying amount of goodwill may be impaired.

Investments. Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities. Our investment policy calls for no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. Investments are classified as available-for-sale, that is, investments are reported at fair value with unrealized gains and losses excluded from operations and reported as a separate component of stockholders equity, except for other-than-temporary impairments, which are reported as a charge to current operations and result in a new cost basis for the investment.

### **Results of Operations**

### Years Ended September 30, 2007 and 2006

(Dollars in thousands) Revenue:	Fiscal 2007	Fiscal 2006	Increase (Decrease)	% Change
Drug Delivery	\$26,488	\$32,918	\$(6,430)	(20)%
Hydrophilic and				
Other	26,493	22,233	4,260	19%
In Vitro	20,183	14,733	5,450	37%
Total revenue	\$73,164	\$69,884	\$ 3,280	5%

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**Revenue.** Fiscal 2007 revenue was \$73.2 million, an increase of \$3.3 million or 5% from fiscal 2006. A decrease in Drug Delivery operating segment revenue was more than offset by growth in the Hydrophilic and Other and In Vitro operating segments, as detailed in the table above and further explained in the narrative below.

*Drug Delivery*. Revenue in the Drug Delivery segment decreased 20% to \$26.5 million in fiscal 2007. The decrease in total revenue reflects a significant decrease in royalties and license fees, which was partially offset by an increase in research and development revenue related to drug delivery and ophthalmology projects and the addition of \$2.4 million in revenue from Brookwood Pharmaceuticals.

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 polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions.

The decrease in drug delivery royalties and license fees principally reflects decreased royalty revenue from Cordis as a result of lower CYPHER® sales. Partially offsetting the decrease attributable to CYPHER® was an increase in royalties and license fees from ophthalmology customers, as well as an increase in research and development fees from drug delivery and ophthalmology customers. We received a \$20 million license fee from Merck in association with the collaborative research and license agreement that we signed in fiscal 2007. However we recognized as revenue only a small portion of this fee as we will be amortizing these payments over the estimated economic life of the technology we licensed to Merck. Fiscal 2007 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 the proportion of stenting procedures that utilize drug eluting stents, in addition to relative market share positions of drug eluting stent players.

The CYPHER® 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, Abbott Vascular and others sold outside the U.S. In addition, drug eluting stents from Medtronic and Abbott are expected to be approved in the U.S. within the next year. These stents compete or will compete directly with the CYPHER® stent. In addition to competition among the various players, the total size of the drug eluting stent market has decreased significantly in the past eighteen months as a result of concerns about product safety, mostly related to potential clotting associated with stents. Therefore, future royalty and reagent sales revenue could decrease because of lower CYPHER® stent sales as a result of the market contraction and the ongoing and expected future competition. We anticipate that guarterly royalty revenue from the CYPHER® stent may be volatile throughout fiscal 2008 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® stent to continue to constitute a significant portion of our revenue in fiscal 2008. However, whether and the extent to which royalties from the CYPHER® stent continue to constitute a significant source of revenue is subject to a number of risks, including intellectual property litigation generally, and specifically the damages, settlements and mutual agreements that may result from various infringement suits between Boston Scientific and Cordis in which each has been found to have violated certain intellectual property rights of the other.

The inclusion of Brookwood Pharmaceuticals, which contributed to Drug Delivery revenue for only two months in fiscal 2007, will also impact the overall revenue and mix in fiscal 2008. A substantial majority of Brookwood□s revenue is comprised of research and development fees.

Hydrophilic and Other. Hydrophilic and Other revenue increased 19% to \$26.5 million, primarily as a result of 27% growth in royalties and license fees and 13% growth in reagent sales, partially offset by a 19% decrease 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 that revenue will likely continue to increase in fiscal 2008; however, the rate of growth will depend upon the timing and market success of newly released products.

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In Vitro. Revenue in the In Vitro segment increased 37% to \$20.2 million. Over 60% of the increase was attributable to increased royalties and license fees. The balance of the growth resulted from growth in sales of our stabilization products, antigens and substrates used by diagnostic kit manufacturers in immunoassay diagnostic tests. We began selling recombinant autoimmune antigens in the first quarter of fiscal 2007, and sales of BioFX products following the acquisition of BioFX in August 2007 contributed \$0.5 million of product sales to our results. We anticipate continued growth in our In Vitro segment revenue in fiscal 2008, but the rate of growth will likely not be as high as fiscal 2007. We anticipate continued growth in product sales reflecting particularly the addition of BioFX products for a full year of operations, but the rate of growth will depend on the success of certain product launches. Royalties and license fees likely will not increase. In Vitro derives a significant

percentage of its revenue from GE Healthcare and Abbott Laboratories.

**Product costs.** Product costs were \$5.6 million in fiscal 2007, a 64% increase from the prior year. Overall product margins averaged 59%, compared with 70% reported last year. The decrease in product margins reflects the mix of products sold in the period (in particular, some of our stabilization and antigen products, genomics slides and Brookwood polymer products carry lower margins than our reagent products) and higher depreciation costs on the recently-constructed manufacturing space at our Eden Prairie facility. We anticipate that product margins will continue to be lower on a year-over-year basis throughout fiscal 2008 when compared to prior year results, principally as a result of product mix.

Research and development expenses. Research and development expenses were \$28.5 million, an increase of 40% compared with fiscal 2006. The increase principally reflects the addition of Brookwood Pharmaceuticals and BioFX Laboratories to our operations, higher compensation expenses as we have added personnel to support customer projects and internal development projects, increased incentive and stock-based compensation, and higher costs related to our internal development projects. Research and development expenses are expected to continue to increase in fiscal 2008 reflecting the addition of Brookwood Pharmaceuticals and BioFX Laboratories to our operations, and as we expand our research and development organization. Brookwood research and development expenses, in particular, are a higher percentage of that unit stotal revenues than for our other business units.

**Selling, general and administrative expenses.** Selling, general and administrative expenses were \$13.6 million, an increase of 37% compared with fiscal 2006. The increase principally reflects the addition of Brookwood Pharmaceuticals and BioFX Laboratories to our operations, higher compensation expenses, and increased incentive and stock-based compensation. We expect selling, general and administrative expenses to continue to increase reflecting the addition of Brookwood Pharmaceuticals and BioFX Laboratories to our operations, and as we expand our organization to support our anticipated growth.

**Purchased in-process research and development.** In July 2007, we acquired all of the assets of Brookwood Pharmaceuticals, Inc. by paying cash to Southern Research Institute, which owned the capital stock of Brookwood. Results in the fourth quarter of fiscal 2007 include an in-process research and development charge of \$15.6 million related to the Brookwood acquisition. The fair value of the in-process research and development was determined by an independent valuation consultant.

**Other income, net.** Other income was \$4.8 million in fiscal 2007, compared with a loss of \$0.6 million in fiscal 2006. The fiscal 2006 loss primarily reflects a \$4.7 million impairment loss on our investment in Novocell, which we recorded in the second quarter of fiscal 2006. Income from investments was \$4.8 million in fiscal 2007, compared with \$4.1 million in fiscal 2006. The increase reflects higher yields generated from our investment portfolio.

**Income tax expense.** The income tax provision was \$11.3 million in fiscal 2007 compared with \$15.2 million in fiscal 2006. The effective tax rate in fiscal 2007 was 77.2%. Excluding the impact of the non-tax deductible purchased in-process research and development charges, the fiscal 2007 effective rate was 37.4%. Excluding the impact of the \$4.7 million impairment loss in fiscal 2006 (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.

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# Years Ended September 30, 2006 and 2005

	Fiscal	Fiscal		%
(Dollars in thousands)	2006	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	1095	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® Sirolimus-eluting Coronary Stent. The CYPHER® 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® 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.

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.

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. 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 in 2005.

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 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.

**Selling, general and administrative expenses.** Selling, general and administrative expenses were \$9.9 million, an increase of 29% compared with fiscal 2005. We recorded approximately \$2.9 million in non-cash stock-based compensation charges compared with \$588,000 in fiscal 2005. Excluding the impact of stock-based compensation,

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selling, general and administrative expenses decreased approximately 1% 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 selling, general and administrative expenses.

**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 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 independent 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 the bulk of the increase in the effective tax rate from fiscal 2006.

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

As of September 30, 2007, the Company had working capital of \$28.0 million and cash, cash equivalents and investments totaling \$70.2 million. The Company 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 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 investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments.

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The Company had positive cash flows from operating activities of approximately \$50.7 million in fiscal 2007, compared with \$35.3 million in fiscal 2006. The following table depicts our cash flows from operations for each of fiscal 2006 and 2007:

	For the Years Ended	
	September 30,	
(Dollars in thousands)	2007	2006
Net income	\$ 3,347	\$ 20,334
Depreciation and amortization	4,214	3,710
Stock-based compensation	10,312	5,711
Purchased in-process research & development	15,573	
Asset impairment charge		4,651
Net other operating activities	(11,004)	(3,929)
Net change in deferred revenue	19,166	2,489

Net change in other operating assets and liabilities	9,107	2,313
Net cash provided by operating activities	\$ 50,715	\$ 35,279

While net income in fiscal 2007 decreased compared with fiscal 2006, certain non-cash charges contributed substantially to the decrease in net income. Specifically, we recorded a \$15.6 million in-process research and development charge in connection with the acquisition of Brookwood Pharmaceuticals and \$10.3 million of stock-based compensation. Additionally, we received a \$20 million up-front license fee from Merck in fiscal 2007, of which \$19.7 million remains in deferred revenue.

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 business unit conducts a portion of its operations. In September 2007, we leased 73,000 square feet of office and warehouse space in Eden Prairie, Minnesota to accommodate planned growth and to construct manufacturing capabilities in support of our ophthalmology business.

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. We made an additional \$1 million installment payment in June 2007. The remaining \$1 million installment is reflected in other current liabilities at September 30, 2007.

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 480,059 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, we made an additional investment of \$1.9 million, bringing our total investment to \$6.0 million, representing an ownership interest of less than 10%. Also in October 2006, OctoPlus common

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stock began trading on an international exchange following an initial public offering of its common stock. With a readily determinable fair market value, the Company now treats the investment in OctoPlus as an available-for-sale investment rather than a cost method investment.

In September 2006, our Board of Directors authorized the repurchase of up to \$35 million of the Company□s common stock. During fiscal 2007, the Company repurchased 1,007,752 shares of its common stock for \$35.0 million at an average price of \$34.76 per share.

In July 2007, we made equity investments in Paragon Intellectual Properties, LLC ([Paragon[]) and Apollo Therapeutics, LLC ([Apollo[]), a Paragon subsidiary. The Paragon and Apollo investments totaled \$3.5 million. The arrangement calls for SurModics to invest additional equity totaling \$2.5 million upon successful completion of specified development milestones, which we expect to occur no later than the second quarter of fiscal 2008. Our investment in Paragon represents an ownership interest of approximately 5% and the investment in Apollo

represents an ownership interest of less than 10%. Following the additional investment, our investment in Apollo will represent an ownership interest of 20%. We account for our investments in Paragon and Apollo under the equity method.

In July 2007, we entered into a stock purchase agreement with Southern Research Institute whereby we acquired 100% of the capital stock of Brookwood Pharmaceuticals, Inc. ([Brookwood[]) for \$40 million in cash on the closing date, and up to an additional \$22 million in cash upon the successful achievement of specified milestones. Brookwood is a drug delivery company based in Birmingham, Alabama that provides proprietary polymer-based technologies to companies developing pharmaceutical products. See Note 3 to the consolidated financial statements.

In August 2007, we entered into a stock purchase agreement to acquire 100% of the capital stock of BioFX Laboratories, Inc. ([BioFX[]) for \$11.3 million in cash on the closing date, and up to an additional \$11.4 million in cash upon the successful achievement of specified milestones. Based in Owings Mills, Maryland, BioFX Laboratories is a leading manufacturer of substrates, a critical component of diagnostic test kits used to detect and signal that a certain reaction has taken place. See Note 3 to the consolidated financial statements.

In August 2007, we entered into an agreement to purchase an undeveloped parcel of land in Eden Prairie, Minnesota for approximately \$3.6 million (including a non-refundable deposit of \$100,000 paid to the seller at the time we signed the agreement). The agreement requires that we complete the purchase on or before August 24, 2008. While it is the Company□s intention to complete the purchase on or before that date, if we fail to do so, we will be required to pay the seller \$1.6 million and will have no further rights to acquire the land.

We have a current income tax liability of \$6.2 million, which will be paid in December 2007. This payment will include taxes payable on the \$20 million up-front license fee received from Merck. Because this license fee will be amortized over 16 years under the EITF 00-21 accounting treatment, the related tax expense has been deferred and will be recognized over the same period. Accordingly, going forward, we will carry a deferred tax asset even though the cash taxes will have been paid.

In October 2007, QLT Inc. acquired ForSight Newco II ([ForSight[]), a company with drug delivery technology for ophthalmology. SurModics held a small equity stake in ForSight, for which we received an initial payment of over \$900,000 in cash, which will be recorded as other income in fiscal 2008. Additionally, we may receive future payments associated with the successful attainment of certain clinical development, and commercialization milestones for products developed by QLT that incorporate the technology acquired from ForSight. The amount of any such payments will be prorated according to the level of our equity ownership in ForSight prior to the acquisition.

In November 2007, our Board of Directors authorized the repurchase of up to \$35 million of the Company□s stock. No purchases have been made to date under this authorization.

As of September 30, 2007, we had \$252,000 of long-term debt in connection with our Brookwood Pharmaceuticals and BioFX subsidiaries. We do not have any other credit agreements. We believe that our existing cash, cash equivalents and investments will be adequate to fund our operations and material commitments into the foreseeable future.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2007, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

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# **Contractual Obligations**

Presented below is a summary of contractual obligations and other minimum commercial commitments. See the Notes to the consolidated financial statements for additional information regarding the below obligations and commitments.

		Less than			More than
	Total	1 Year	1-3 Years	3-5 Years	5 Years
Operating leases	\$ 2,344	\$ 684	\$ 1,660	<b>\$</b> [	\$□
Other liabilities reflected on the					
balance sheet under GAAP Total	1,000 \$ 3,344	1,000 \$ 1,684	\$ 1,660	<b>\$</b> □	\$□

Our only material lease commitment relates to a recently leased facility in Eden Prairie, Minnesota near our Minnesota headquarters. Additionally, in August 2007, we entered into an agreement to purchase an undeveloped parcel of land in Eden Prairie, Minnesota for approximately \$3.6 million (including a non-refundable deposit of \$100,000 paid to the seller at the time we signed the agreement). The agreement requires that we complete the purchase on or before August 24, 2008. While it is the Company intention to complete the purchase on or before that date, if we fail to do so, we will be required to pay the seller \$1.6 million and will have no further rights to acquire the land.

#### **New Accounting Pronouncements**

On July 13, 2006, the Financial Accounting Standards Board ([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 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 interpretation 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 in 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 Statement of Financial Accounting Standard ([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, that the adoption of this statement will have on its financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS No. 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. SFAS No. 159 is effective for the Company in fiscal 2009. The Company is currently evaluating the impact, if any, the adoption of SFAS No. 159 will have on the consolidated financial position and results of operations.

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

The Company is investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company 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 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 \$931,000 decrease in the fair value of the Company available-for-sale securities as of September 30, 2007, 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 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 consolidated balance sheets as of September 30, 2007 and 2006 and the statements of operations, stockholders equity and cash flows for each of the three years in the period ended September 30, 2007, together with Report of Independent Registered Public Accounting Firm 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 DISC

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 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)

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**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*  $\square$  *Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As discussed in Note 3 to the Consolidated Financial Statements, in July 2007 the Company acquired Brookwood Pharmaceuticals, Inc. and in August 2007 the Company acquired BioFX Laboratories, Inc. In accordance with guidance published by the Securities and Exchange Commission, the Company\\\ assessment of internal control over financial reporting excluded the acquisitions of Brookwood and BioFX, which together represented approximately 4% of total revenue for the fiscal year ended September 30, 2007, and approximately 20% of total assets (excluding goodwill of Brookwood and BioFX) as of September 30, 2007. Based on this evaluation, management concluded that the Company\( \sigma\) s internal control over financial reporting was effective as of September 30, 2007. Deloitte & Touche LLP, the registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, has issued the

attestation report below regarding the Company $\square$ s internal control over financial reporting.

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

**(b)** 

We have audited the internal control over financial reporting of SurModics, Inc. and subsidiaries (the <code>\[Company\]\]</code>) as of September 30, 2007, based on criteria established <code>imternal Control</code> <code>\[Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management\[Tomathtile{\text{Report on Internal Control Over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Brookwood Pharmaceuticals Inc. and BioFX Laboratories LLC, which were acquired in August 2007 and whose financial statements constitute 29% and 27% of net and total assets, respectively, 4% of revenues, and 0% of net income of the consolidated financial statement amounts as of and for the year ended September 30, 2007. Accordingly, our audit did not include the internal control over financial reporting at Brookwood Pharmaceuticals Inc. and BioFX Laboratories LLC. The Company\[Tomathtile{\text{Smanagement}} is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management\[Tomathtile{\text{Smanagement}} is Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company\[Tomathtile{\text{Smanagement}} internal control over financial reporting based on our audit.}</code>

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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company sinternal control over financial reporting is a process designed by, or under the supervision of, the company principal executive and principal financial officers, or persons performing similar functions, and effected by the company 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 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 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, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2007, 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 consolidated financial statements as of and for the year ended September 30, 2007 of the Company and our report dated December 13, 2007 expressed an unqualified opinion on those financial statements.

**DELOITTE & TOUCHE LLP** 

Minneapolis, Minnesota December 13, 2007

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#### 3. Changes in Internal Controls.

There were no changes in the Company 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 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, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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, [Election 16(a) Beneficial Ownership Reporting Compliance and [Election Governance - Code of Ethics and Business Conduct, which appear in the Company sefinitive Proxy Statement for its 2008 Annual Meeting of Shareholders. The information required by Item 10 relating to executive officers appears in Part I of this Form 10-K.

#### ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 is incorporated herein by reference to the sections entitled [Executive Compensation and Other Information, [Compensation Discussion and Analysis, Director Compensation for Fiscal 2007, Compensation Committee Report and Corporate Governance Committee and Board Meetings, which appear in the Company selfinitive Proxy Statement for its 2008 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  $\square$ Principal Shareholders $\square$  and  $\square$ Management Shareholdings, $\square$  which appear in the Company $\square$ s definitive Proxy Statement for its 2008 Annual Meeting of Shareholders.

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#### **Equity Compensation Plan Information**

The following table provides information related to the Company

s equity compensation plans in effect as of September 30, 2007:

	(a)  Number of securities to be issued upon exercise of outstanding options, warrants and	(b) Weighted-average exercise price of outstanding options, warrants and	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in
Plan Category	rights	rights	column(a))
Equity compensation plans			
approved by shareholders	1,607,611 (1)	\$27.28 (1)	730,491 (2)
Equity compensation plans not			
approved by shareholders	0	N/A	0
Total	1,607,611	\$27.28	730,491

(1) Excludes shares that may be issued under the Company s 1999 Employee Stock Purchase Plan.

(2) Includes 637,528 shares available for future issuance under the amended and restated 2003 Equity Incentive Plan and 92,963 shares available under the 1999 Employee Stock Purchase Plan.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by Item 13 is incorporated herein by reference to the sections entitled □Corporate Governance - Related Person Transaction Approval Policy□ and □Corporate Governance - Majority of Independent Directors; Committees of Independent Directors,□ which appear in the Company□s definitive Proxy Statement for its 2008 Annual Meeting of Shareholders.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by Item 14 is incorporated herein by reference to the section entitled  $\square$ Independent Registered Public Accounting Firm, $\square$  which appears in the Company $\square$ s definitive Proxy Statement for its 2008 Annual Meeting of Shareholders.

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#### **PART IV**

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

#### (a) 1. Financial Statements

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

	Page (s)
Report of Independent Registered Public Accounting	
Firm	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Stockholders□ Equity	F-4
Consolidated Statements of Cash Flows	F-5
Notes to Consolidated Financial Statements.	F-6 □ F-20

- 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, 2007 By: <u>/s/ Bruce J Barclay</u>

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.

Signature	Title	Date
/s/ Bruce J Barclay Bruce J Barclay	President and Chief Executive Officer (principal executive officer)	December 14, 2007
/s/ Philip D. Ankeny Philip D. Ankeny	Senior Vice President and Chief Financial Officer (principal financial officer and acting principal accounting officer)	December 14, 2007
José H. Bedoya	Director	
/s/ John W. Benson	Director	December 14, 2007

John W. Benson		
<u>/s/ Gerald B. Fischer</u>	Director	December 14, 2007
Gerald B. Fischer	Director	December 14, 2007
<u>/s/ Kenneth H. Keller</u>	Director	Dagambar 14, 2007
Kenneth H. Keller	Director	December 14, 2007
/s/ David A. Koch	Director	December 14, 2007
David A. Koch		
<u>/s/ Kendrick B.</u> <u>Melrose</u>	Director	December 14, 2007
Kendrick B. Melrose		
/s/ John A. Meslow	Director	December 14, 2007
John A. Meslow		

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Director

/s/ Dale R. Olseth

Dale R. Olseth

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

# **EXHIBIT INDEX TO FORM 10-K**

# For the Fiscal Year Ended September 30, 2007

# SURMODICS, INC.

Exhibit	
2.1	Agreement of Merger, dated January 18, 2005, with InnoRx, Incincorporated 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.
2.2	Stock Purchase Agreement, dated July 31, 2007, between SurModics, Inc. and Southern Research Instituteincorporated by reference to Exhibit 2.1 to the Company Current Report on Form 8-K dated July 31, 2007, SEC File No. 0-23837.
3.1	Restated Articles of Incorporation, as amendedincorporated 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. **
4	Rights Agreement, dated as of April 5, 1999, between the Company and Firstar Bank Milwaukee, NA., as Rights Agent, including as:

December 14, 2007

	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 Certificateincorporated by reference to Exhibit 1 to the Company□s Registration of Securities on Form 8-A, SEC File No. 0-23837.
10.1*	Company Incentive 1987 Stock Option Plan, including specimen of Incentive Stock Option Agreementincorporated by reference to Exhibit 10.2 to the Company Registration Statement on form SB-2, Reg. No. 333-43217.
10.2*	Company Incentive 1997 Stock Option Plan, including specimen of Incentive Stock Option Agreementincorporated by reference to Exhibit 10.3 to the Company Registration Statement on form SB-2, Reg. No. 333-43217.
10.3*	Form of Restricted Stock Agreement under 1997 Planincorporated 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 Planincorporated by reference to Exhibit 10.5 to the Company Registration Statement on form SB-2, Reg. No. 333-43217.
10.5	Form of License Agreementincorporated 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 Planincorporated by reference to Exhibit 10 to the Company 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, 2003incorporated 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, 2003incorporated 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.
Exhibit	
10.9* Form of officer acceptance reg	arding employment/compensationincorporated by reference to Exhibit Report on Form 10-K for the fiscal year ended September 30, 2005, SEC
2005 by the board of directors	s amended and restated December 13, 2005) (adopted December 13, and approved by the shareholders on January 30, 2006)incorporated the Company Form 8-K filed February 3, 2006, SEC File No. 0-23837.
	. 2003 Equity Incentive Plan Nonqualified Stock Option eference to Exhibit 99.1 to the Company 8 8-K filed March 20, 2006, SEC
	Equity Incentive Plan Incentive Stock Option Agreementincorporated the Company∏s 8-K filed March 20, 2006, SEC File No. 0-23837.

10.13*	Earns of ComModice Inc. 2002 Equity Inconting Plan Destricted Cheels Agreement in compared by
10.13*	Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Agreementincorporated 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 Agreementincorporated 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) Agreementincorporated 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 Agreementincorporated 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) Agreementincorporated 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) Agreementincorporated by reference to Exhibit 99.8 to the Company□s 8-K filed March 20, 2006, SEC File No. 0-23837.
10.19*	Change in Control Agreement with Bruce J Barclay, dated April 19, 2006incorporated by reference to Exhibit 99.1 to the Company S Form 8-K filed April 25, 2006, SEC File No. 0-23837.
10.20*	Change in Control Agreement with Philip D. Ankeny, dated April 19, 2006incorporated by reference to Exhibit 99.2 to the Company□s Form 8-K filed April 25, 2006, SEC File No. 0-23837.
10.21*	The Company Board Compensation Policy, Amended and Restated in its entirety as of July 31, 2006incorporated by reference to Exhibit 10.22 to the Company S Annual Report on Form 10-K for the fiscal year ended September 30, 2006, SEC File No. 0-23837.
10.22*	Fiscal Year 2007 Summary of Compensation Arrangements for Named Executive Officers of the Companyincorporated by reference to Exhibit 10.24 to the Company□s Annual Report on Form 10-K for the fiscal year ended September 30, 2006, SEC File No. 0-23837.
10.23*	Change in Control Agreement with Paul A. Lopez, dated November 15, 2006incorporated by reference to Exhibit 10.27 to the Company□s Annual Report on Form 10-K for the fiscal year ended September 30, 2006, SEC File No. 0-23837.
10.24*	Description of certain retirement benefits for Dale R. Olsethincorporated by reference to Exhibit 10.28 to the Company  SEC File No. 0-23837.
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<b>Exhibit</b> 10.25+	Exclusive License and Research Collaboration Agreement with Merck & Co., Inc. dated June 26, 2007incorporated by reference to Exhibit 10.1 to the Company∏s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, SEC File No. 0-23837.
10.26+	Supply Agreement with Merck & Co., Inc. dated June 26, 2007incorporated by reference to Exhibit 10.2 to the Company∏s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, SEC File No. 0-23837.
10.27*	Employment Agreement of Arthur J. Tipton, Ph.D., dated July 31, 2007.**

10.28	Purchase Agreement with Vest Mykyng LLC, dated August 24, 2007.**
21	Subsidiaries of the Registrant.**
	Substitution of the region and
23	Consent of Deloitte & Touche LLP.**
24	Power of Attorney (included on signature page of this Form 10-K).**
21	Tower of Autorney (morated on signature page of this form to 10).
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.**
01.2	of mindules of other financial efficient abdume to be strong the 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.**
02.2	of miletion of other random officer random to decide 300 of durbunes oxicy flet of 2002.

- \* Management contract or compensatory plan or arrangement
- \*\* Filed herewith
- + Confidential treatment requested as to portions of the exhibit. Confidential portions omitted and provided separately to the Securities and Exchange Commission.

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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 consolidated balance sheets of SurModics and subsidiaries (the [Company]) as of September 30, 2007 and 2006, and the related consolidated statements of operations, stockholders[ equity, and cash flows for each of the three years in the period ended September 30, 2007. 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 consolidated financial statements present fairly, in all material respects, the financial position of SurModics and subsidiaries as of September 30, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2007, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company\(\sigma\) internal control over financial reporting as of September 30, 2007, based on the criteria established in *Internal Control\(\sigma\) Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 13, 2007 expressed an unqualified opinion on the Company\(\sigma\) internal control over financial reporting.

# DELOITTE & TOUCHE LLP

Minneapolis, Minnesota December 13, 2007

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# SurModics, Inc. and Subsidiaries

Consolidated Balance Sheets As of September 30

(thousands, except share data) ASSETS	2007	2006
Current Assets		
Cash and cash equivalents	\$ 13,812	\$ 3,751
Short-term investments	12,496	55,062
Accounts receivable, net of allowance for doubtful accounts of \$40 as	,	,
of		
September 30, 2007 and 2006	16,138	14,493
Inventories	2,497	952
Deferred tax asset	1,116	435
Prepaids and other	1,836	1,403
Total Current Assets	47,895	76,096
Property and equipment, net	19,738	11,686
Long-term investments	43,917	47,758
Deferred tax asset	5,908	4,883
Intangible assets, net	18,399	5,530
Goodwill	15,686	
Other assets, net	19,788	11,449
Total Assets	\$171,331	\$157,402
LIABILITIES AND STOCKHOLDERS∏ EQUITY		
Current Liabilities		
Accounts payable	\$ 2,541	\$ 963
Accrued liabilities:		
Compensation	3,137	1,275
Accrued income taxes payable	6,227	1,910
Accrued other	1,050	1,605
Deferred revenue	5,586	2,236
Other current liabilities	1,311	1,000
Total Current Liabilities	19,852	8,989
Deferred revenue, less current portion	20,305	2,210
Other long-term liabilities	252	1,000
Total Liabilities	40,409	12,199
Commitments and Contingencies (Note 6)		
Stockholders∏ Equity		
Series A preferred stock - \$.05 par value, 450,000 shares authorized;		
no shares issued and outstanding		
Common stock - \$.05 par value, 45,000,000 shares authorized;	_	_
18,164,980		
and 18,830,455 shares issued and outstanding	909	942
Additional paid-in capital	76,670	96,281
Accumulated other comprehensive income (loss)	1,723	(293)
Retained earnings	51,620	48,273
Total Stockholders Equity	130,922	145,203
Total Liabilities and Stockholders Equity	\$171,331	\$157,402
1 out Business and occamonation Equity	ψ1/1,001	Ψ107,402

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

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# SurModics, Inc. and Subsidiaries

Consolidated Statements of Operations For the Years Ended September 30

Revenue       \$ 52,679       \$ 53,008       \$ 47,582         Product sales       13,543       11,172       9,403         Research and development       6,942       5,704       5,396         Total revenue       73,164       69,884       62,381         Operating Costs and Expenses         Product       5,584       3,399       2,855         Research and development       28,465       20,391       16,072         Selling, general and administrative       13,643       9,931       7,705         Asset impairment charge       □       2,487         Purchased in-process research & development       15,573       □       30,277         Total operating costs and expenses       63,265       33,721       59,396
Product sales       13,543       11,172       9,403         Research and development       6,942       5,704       5,396         Total revenue       73,164       69,884       62,381         Operating Costs and Expenses         Product       5,584       3,399       2,855         Research and development       28,465       20,391       16,072         Selling, general and administrative       13,643       9,931       7,705         Asset impairment charge       □       □       2,487         Purchased in-process research & development       15,573       □       30,277
Research and development       6,942       5,704       5,396         Total revenue       73,164       69,884       62,381         Operating Costs and Expenses       8         Product       5,584       3,399       2,855         Research and development       28,465       20,391       16,072         Selling, general and administrative       13,643       9,931       7,705         Asset impairment charge       1       2,487         Purchased in-process research & development       15,573       30,277
Total revenue         73,164         69,884         62,381           Operating Costs and Expenses         8         3,399         2,855           Product         5,584         3,399         2,855           Research and development         28,465         20,391         16,072           Selling, general and administrative         13,643         9,931         7,705           Asset impairment charge         0         0         2,487           Purchased in-process research & development         15,573         0         30,277
Operating Costs and Expenses         5,584         3,399         2,855           Product         5,584         3,399         2,855           Research and development         28,465         20,391         16,072           Selling, general and administrative         13,643         9,931         7,705           Asset impairment charge         □         □         2,487           Purchased in-process research & development         15,573         □         30,277
Product         5,584         3,399         2,855           Research and development         28,465         20,391         16,072           Selling, general and administrative         13,643         9,931         7,705           Asset impairment charge         □         □         2,487           Purchased in-process research & development         15,573         □         30,277
Research and development 28,465 20,391 16,072 Selling, general and administrative 13,643 9,931 7,705 Asset impairment charge $\Box$ $\Box$ 2,487 Purchased in-process research & development 15,573 $\Box$ 30,277
Selling, general and administrative13,6439,9317,705Asset impairment charge[]2,487Purchased in-process research & development15,573[]30,277
Asset impairment charge
Purchased in-process research & development 15,573   30,277
Total operating costs and expenses 63 265 33 721 59 306
Total operating costs and expenses 05,205 55,721 55,550
Income from Operations 9,899 36,163 2,985
Other Income (Loss)
Investment income, net 4,844 4,210 1,967
Impairment loss on investment
Other loss, net (75) (157)
Other income (loss), net 4,769 (598) 1,365
Income Before Income Taxes 14,668 35,565 4,350
Income Tax Provision (11,321) (15,231) (12,596)
Net Income (Loss) \$ 3,347 \$ 20,334 \$ (8,246)
Basic net income (loss) per share $$0.19$ $$1.10$ $$(0.45)$
Diluted net income (loss) per share \$ 0.18 \$ 1.09 \$ (0.45)
Weighted Average Shares Outstanding
Basic 18,033 18,527 18,131
Dilutive effect of outstanding stock options 184 192
Diluted 18,217 18,719 18,131

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

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# SurModics, Inc. and Subsidiaries

Consolidated Statements of Stockholders Equity For the Years Ended September 30, 2007, 2006 and 2005

				A	ccumulate	d	
			Additional		Other		Total
	Commo	n Stock	Paid-In	UnearneCo	mprehensi Income	ve Retained	Stockholders
(in thousands)	<b>Shares</b>	Amount	Capital	Compensation	(Loss)	<b>Earnings</b>	Equity
Balance September 30, 2004	17,537	\$877	\$ 57,849	\$ (632)	\$ 56	\$36,160	\$ 94,310

Components of comprehensive loss,

net of tax:						_	
Net loss						(8,246)	(8,246)
Unrealized holding losses on available-							
for-sale securities arising							
during the							
period					(481)		(481)
Add reclassification for losses			- 11			- 1	
included in		_	_		_		_
net income (loss) net of tax	П	П	П	П	65	П	65
Comprehensive loss							(8,662)
Issuance of common stock	682	34	25,731				25,765
Common stock options	0.4.4	4.0	0.040				0.000
exercised, net  Tax benefit from exercise of	244	12	2,310		L		2,322
stock options	П	П	1,258	П	П	П	1,258
Restricted stock activity	73	4	2,573	(2,577)			
Amortization of unearned							
compensation				588			588
Balance September 30, 2005 Components of comprehensive	18,536	927	89,721	(2,621)	(360)	27,914	115,581
income, net of							
tax:							
Net income						20,334	20,334
Unrealized holding losses on			- 11			- 1	
available- for-sale securities arising							
during the			- 11				
period	П	П	П	П	(31)	П	(31)
Add reclassification for losses							, ,
included in							
net income, net of tax					98		98
Comprehensive	П	П	П	П	П	П	20,401
Issuance of common stock	125	7	392	П	П	П	399
Common stock options				_	_		
exercised, net	169	8	2,854				2,862
Tax benefit from exercise of stock options	П	П	249	п	п	П	249
Stock-based compensation	П		5,526	П			5,526
Accounting change due to			0,020	Ц			0,020
adoption of SFAS 123R			(2,461)	2,621		25	185
Balance September 30, 2006	18,830	942	96,281		(293)	48,273	145,203
Components of comprehensive							
income, net of							
tax: Net income	П	П	П	П	П	3,347	3,347
Unrealized holding gains on				L		3,347	3,347
available-							
for-sale securities arising							
during							
the period					1,999		1,999

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Add reclassification for losses included in							
net income, net of tax					48		17
Comprehensive							
income							5,363
Issuance of common stock	126	6	78				84
Common stock repurchased	(1,008)	(50)	(34,980)				(35,030)
Common stock options exercised, net	217	11	4,778				4,789
Tax benefit from exercise of							
stock options			466				466
Stock-based compensation			10,312				10,312
Other			(265)				(265)
Balance September 30, 2007	18,165	\$909	\$ 76,670	\$ □	\$1,754	\$51,620	\$ 130,922

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

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# SurModics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows For the Years Ended September 30

(in thousands)	2007	2006	2005
Operating Activities			
Net income (loss)	\$ 3,347_	\$ 20,334_	\$ (8,246)
Adjustments to reconcile net			
income (loss) to net cash provided			
by			
operating activities			
Depreciation and amortization	4,214	3,710	3,733
Loss on equity method	4,414	3,710	3,733
investments and sales of			
investments	75	157	602
Amortization of discount on			
investments	(1,388)	(1,534)	
Asset impairment charge		4,651	2,487
Stock-based compensation	10,312	5,711	
Purchased in-process			
research & development	15,573		30,277
Deferred tax	(9,434)	(2,134)	5,143
Tax benefit from exercise of			
stock options	(466)	(249)	1,258
Loss (gain) on disposals of			
property and equipment	379	(169)	(65)
Change in operating assets			
and liabilities:			
Accounts receivable	1,940	(3,497)	(2,866)
Inventories	(850)	139	(51)
Accounts payable and	2.504	(522)	010
accrued liabilities	2,594	(532)	912
Income taxes	5,501	5,799	(7,467)
Deferred revenue	19,166	2,489	(81)

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Prepaids and other	(248)	404		(274)
Net cash provided by operating activities Investing Activities	50,715	35,279		25,950
Purchases of property and equipment  Sales of property and equipment	(3,626) 37	(5,857) 238		(2,109)
Purchases of available-for-sale investments Sales/maturities of	(136,498)	(193,966)		(98,716)
available-for-sale investments Investment in other strategic	185,075	161,778		88,955
assets Purchase of licenses	(5,749) (1,355)	(160) (1,592)		(5,133) (5,238)
Acquisitions, net of cash acquired Repayment of notes receivable	(49,112) 530	600		(5,181)
Other investing activities  Net cash used in	(265)			
investing activities Financing Activities	(10,963)	(38,959)		(27,422)
Tax benefit from exercise of stock options	466	249		
Issuance of common stock Repurchase of common stock	4,873 (35,030)	3,261		2,684
Net cash (used in) provided by financing activities Net change in cash and cash equivalents	(29,691) 10,061	3,510	ī	2,684
Cash and Cash Equivalents				
Beginning of year End of year	\$ 3,751 13,812	3,921 \$ 3,751	\$	2,709 3,921
Supplemental Information				
Cash paid for income taxes Noncash proceeds from sale of	\$ 14,930	\$ 11,338	\$	13,780
property Noncash transaction□acquisition of property,	\$	\$ 6,655	\$	
plant, and equipment on account	\$ 252	\$ 989	\$	1,268

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

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#### SurModics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements September 30, 2007 and 2006

# 1. Description

SurModics, Inc. (the Company) develops, manufactures and markets innovative surface modification and drug delivery technologies for the healthcare industry. The Company\(\sigma\) 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; substrates, antigens and stabilization products to the diagnostics industry; coated slides to the genomics market; and synthetic ECM products to the cell culture 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, 2007 and 2006. Available-for-sale investments are reported at fair value with unrealized gains and losses net of tax 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):

		2007			
	Original Cost	Unrealized Gains	Unrealized Losses	Fair Value	
U.S. government obligations	\$19,744	\$101	\$ (65)	\$ 19,780	
Mortgage-backed securities	14,814	83	(56)	14,841	
Municipal bonds	11,985	49	(36)	11,998	
Asset-backed securities	8,899	14	(39)	8,874	
Corporate bonds	915	5	0	920	
Total	\$56.357	\$252	\$(196)	\$ 56.413	

	2006			
	Original Cost	Unrealized Gains	Unrealized Losses	Fair Value
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

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The original cost and fair value of investments by contractual maturity at September 30, 2007 were as follows (in thousands):

	Original	
	Cost	Fair Value
Debt securities due within:		
One year	\$12,542	\$12,496
One to five years	27,855	27,949
Five years or more	15,960	15,968
Total	\$56,357	\$56,413

The following table summarizes sales of available-for-sale securities for the years ended September 30, 2007, 2006, and 2005 (in thousands):

	2007	2006	2005
Proceeds from sales	\$185,075	\$161,778	\$88,955
Gross realized gains	\$7	\$24	\$17
Gross realized losses	\$(34)	\$(181)	\$(119)

#### *Inventories*

Inventories are principally 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):

	2007	2006
Raw materials	\$1,241	\$512
Finished products	1,256	440
Total	\$2,497	\$952

#### Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over 3 to 32 years, the estimated useful lives of the assets. The Company recorded depreciation expense of \$2.2 million, \$2.0 million and \$2.0 million for the years ended September 30 2007, 2006 and 2005, respectively.

The September 30, 2007 and 2006 balances in construction-in-progress include the cost of enhancing the capabilities of the Company□s Eden Prairie facility. As assets are 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):

	Useful Life		
	(in Years)	2007	2006
Laboratory fixtures and equipment	3 to 10	\$ 13,673	\$ 10,531
Building and improvements	3 to 32	16,619	12,083
Office furniture and equipment	3 to 10	3,940	3,022
Capital work-in-progress		1,244	94
Less accumulated depreciation		(15,738)	(14,044)
Property and equipment, net		\$ 19.738	\$ 11.686

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#### Other Assets

Other assets consist principally of strategic investments, a note receivable, and acquired patents. In fiscal 2007, the balance in other assets increased primarily as a result of an investment in Paragon Intellectual Properties, LLC and its subsidiary, Apollo Therapeutics, LLC; and an additional investment in OctoPlus N.V., and the increased market value of OctoPlus during the year. In addition to the investments, the Company has licensed its Finale prohealing coating technology and provides development services on a time and materials basis to Apollo. The Company investments in Paragon and Apollo are accounted for under the equity method.

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, the Company made an additional investment of \$160,000. As of September 30, 2006 the \$4.1 million investment, which was accounted for under the cost method, represented an ownership interest of less than 20%. In October 2006, the Company made an additional investment of \$1.9 million in OctoPlus. Also in October 2006, OctoPlus common stock began trading on an international exchange following an initial public offering of its common stock. With a readily determinable fair market value, the Company now treats the investment in OctoPlus as an available-for-sale investment rather than a cost method investment. Available-for-sale investments are reported at fair value with unrealized gains and losses 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. As of September 30, 2007, the investment in OctoPlus represents an ownership interest of less than 10%. As of September 30, 2007 the total cost basis in OctoPlus was \$6.0 million and the fair value was \$8.7 million, resulting in an unrealized gain of \$2.7 million. The Company had no realized gain or loss related to the investment in OctoPlus in fiscal 2007.

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. In fiscal 2007, the Company invested an additional \$185,000 in ThermopeutiX. The Company investment in ThermopeutiX, which is accounted for under the cost method, represents an ownership interest of less than 20%.

In September 2005, the Company entered into an agreement to sell a 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 property. 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 \$5.2 million balance in other assets represents the long-term portion due on the note.

SurModics has invested a total of \$5.2 million in Novocell, Inc., a privately-held Irvine, California-based biotechnology firm that is developing a unique treatment for diabetes using coated islet cells, the cells that produce insulin in the human body. In fiscal 2006, the Company determined its investment in Novocell was impaired and that the impairment was other-than-temporary. Accordingly, the Company recorded an impairment loss of \$4.7 million. The balance of the investment, \$559,000, which is accounted for under the cost method, is included in other assets and represents less than a 5% ownership interest.

In January 2005, the Company entered into a merger agreement whereby SurModics acquired all of the assets of InnoRx, Inc., an early stage company developing drug delivery devices and therapies for the ophthalmology market, 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 600,073 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 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, SurModics will be required to issue up to approximately 480,059 additional shares of its 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 the Company acquired consisted almost exclusively of in-process research and development assets. In the second quarter of fiscal 2005, the Company recorded a charge of \$30.3 million

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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.

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

	2007	2006
Investment in OctoPlus	\$ 8,762	\$ 4,095
Long-term portion of note receivable	5,158	5,635
Investment in Paragon and subsidiary	3,632	
Investment in ThermopeutiX	1,185	1,000
Investment in Novocell	559	559
Other	492	160
Other assets, net	\$ 19,788	\$ 11,449

In the fiscal years ended September 30, 2007, 2006 and 2005, the Company recognized revenue of \$909,000, \$399,000 and \$710,000, respectively, from activity with companies in which it had a strategic investment.

#### Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer relationships, licenses, and trademarks. The Company recorded amortization expense of \$2.0 million, \$1.7 million, and \$1.7 million for the years ended September 30, 2007, 2006 and 2005, respectively.

In September 2004, the Company 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 the Company\( \) s diagnostic format patent license with Abbott Laboratories. Prior to such amendment, the Company was receiving only a portion of the royalties under such sublicenses. The first \$5 million installment was paid in fiscal 2005, and an additional \$1 million installment was paid in fiscal 2007. The remaining \$1 million installment is reflected in other current liabilities.

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

	Useful Life		
	(in Years)	2007	2006
Customer list	9 - 11	\$ 7,340	\$
Abbott license	4	7,037	7,037
Core technology	8 - 18	6,933	
Patents and other	3 - 20	1,988	2,102
Trademarks	12	580	
Less accumulated amortization		(5,479)	(3,609)
Intangible assets, net		\$18,399	\$ 5,530

Based on the intangible assets in service as of September 30, 2007, estimated amortization expense for the next five fiscal years is as follows (*in thousands*):

2008	\$3,009
2009	1,761
2010	1,343
2011	1,343
2012	1,343

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Goodwill

Goodwill represents the excess of the cost of the acquired entities over the fair value assigned to the assets purchased and liabilities assumed in connection with the Company acquisitions (described in Note 3). The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that the carrying amount of goodwill may be impaired.

#### 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 were less than the carrying amount of the assets, the Company would recognize an impairment loss reducing the carrying value to fair market value. In September 2005, the Company signed an agreement to sell its Bloomington property and facility and based on the selling price recorded a \$2.5 million impairment charge.

#### Revenue Recognition

In accordance with SEC Staff Accounting Bulletin ( $\Box$ SAB $\Box$ ) No. 104,  $\Box$ Revenue Recognition, $\Box$  revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) shipment has occurred or delivery has occurred if the terms specify destination; (3) the sales price is fixed or determinable; and (4) collectibility is reasonably assured. However, when there are additional performance requirements, revenue is recognized when all such requirements have been satisfied. Under revenue arrangements with multiple deliverables, the Company utilizes Emerging Issues Task Force Issue No. 00-21,  $\Box$ Accounting for Revenue Arrangements with Multiple Deliverables, $\Box$  ( $\Box$ EITF 00-21 $\Box$ ) and recognizes each separable element as it is earned.

Revenue is derived from three primary sources: (1) royalties and license fees from licensing patented surface modification and drug delivery technologies and *in vitro* diagnostic formats to customers; (2) the sale of reagent chemicals to licensees, stabilization products, antigens and substrates to the diagnostics industry, and coated glass slides to the genomics market; and (3) research and development fees generated on customer projects.

Royalties & License Fees. The Company licenses technology to third parties and collects royalties. Royalty revenue is generated when a customer sells products incorporating the Company licensed technologies. Royalty revenue is recognized as licensees report it to the Company, and payment is typically submitted concurrently with the report. Generally, license fees are recognized as revenue when the Company receives payment and the contract price is fixed or determinable. For stand-alone license agreements, up-front license fees are recognized 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 and provided the following conditions have been met:

- The milestone payment is non-refundable.
- The milestone is achieved, involves a significant degree of risk, and was not reasonably assured at the inception of the arrangement.
- Accomplishment of the milestone involves substantial effort.
- The amount of the milestone payment is commensurate with the related effort and risk.
- A reasonable amount of time passes between the initial license payment and the first and subsequent milestone payments.

If these conditions have not been met, the milestone payment is deferred and recognized over the term of the agreement.

*Product Sales.* Product sales to third parties are recognized at the time of shipment, provided that an order has been received, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured and returns can be reasonably estimated. The Company sales terms provide no right of return outside of the standard warranty policy. Payment terms are generally set at 30-45 days.

*Research and Development.* The Company performs third party research and development activities, which are typically provided on a time and materials basis. Generally, revenue for research and development is recorded as performance progresses under the applicable contract.

Multiple element arrangements. Arrangements such as license and development agreements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and development, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. The Company recognizes up-front license payments under these agreements as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations would then be accounted for separately. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting, and the license payments and payments for performance obligations would be recognized as revenue over the estimated period of when the performance obligations are performed, or the economic life of the technology licensed to the customer. When the Company determines that an arrangement should be accounted for as a single unit of accounting, it recognizes the related revenue based on a time-based accounting model.

Merck Agreement. On June 27, 2007 the Company announced a license and research collaboration agreement with Merck. The agreement calls for SurModics and Merck to pursue the joint development and commercialization of SurModics I-vation sustained drug delivery system with TA (triamcinolone acetonide), and other products combining certain of Merck proprietary drug compounds and the I-vation system for the treatment of serious retinal diseases. Under the terms of the agreement, Merck will lead and fund development and commercialization activities. SurModics received an up-front license fee of \$20 million and will be eligible to receive up to an additional \$288 million in fees and development milestones. In addition, the Company will be paid for its activities in researching and developing the combination products, and will be responsible for the manufacture and supply of the jointly developed products. The Company will also receive royalties on product sales.

The Company will recognize revenue from the up-front license fee over the economic life of the technology licensed to Merck, which is 16 years. As of September 30, 2007, \$19.7 million of the up-front license fee remains in deferred revenue.

# Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets, with deferred revenue to be recognized beyond one year being classified as non-current deferred revenue. As of September 30, 2007 and 2006, the Company recorded deferred revenue of \$25.9 million and \$4.4 million, respectively.

Costs related to products and services delivered are recognized in the period revenue is recognized. Customer advances are accounted for as a liability until all criteria for revenue recognition have been met.

# Research and Development

Research and development costs are expensed as incurred. Some research and development costs are related to third party contracts, and the related revenue is recognized as described in [Revenue Recognition] above.

#### 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.

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#### Reclassifications

The fiscal 2007 and 2006 consolidated balance sheets present intangible assets and other assets on separate lines; in previous financial statements these items were presented as one line, <code>[Other Assets.[]]</code> Additionally, the consolidated statements of operations present <code>[Selling, general and administrative.]</code> expenses as one line; in previous statements these items were reflected on two lines, <code>[Sales and marketing.]</code> and <code>[General and administrative...]</code>

#### New Accounting Pronouncements

On July 13, 2006, the Financial Accounting Standards Board, ([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 interpretation 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 in 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 Statement of Financial Accounting Standards ([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.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS No. 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. SFAS No. 159 is effective for the Company in fiscal 2009. The Company is currently evaluating the impact, if any, the adoption of SFAS No. 159 will have on the consolidated financial position and results of operations.

#### 3. Acquisitions

Brookwood Pharmaceuticals, Inc. On July 31, 2007, the Company entered into a stock purchase agreement with Southern Research Institute (SRI) whereby it acquired 100% of the capital stock of Brookwood Pharmaceuticals, Inc. (□Brookwood□) held by SRI for \$42.3 million consisting of \$40 million in cash on the closing date and \$2.3 million in transaction costs. SRI could receive up to an additional \$22 million in cash upon the successful achievement of specified milestones. Brookwood is a drug delivery company based in Birmingham, Alabama that provides proprietary polymer-based technologies to companies developing pharmaceutical products. Brookwood, a wholly owned subsidiary of SurModics, will operate as a separate business unit within the Drug Delivery operating segment. Management believes this acquisition strengthens SurModics□ portfolio of drug delivery technologies for the pharmaceutical and biotechnology industries in particular. Operating results for the period from August 1, 2007 to September 30, 2007 have been included in the Company□s consolidated financial statements.

The purchase price was allocated to the fair value of the net tangible and intangible assets acquired and liabilities assumed, with the excess purchase price over fair value allocated to goodwill. The purchase price was allocated as follows (in thousands):

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Net working capital	\$ 5,348
Property and equipment	7,300
Core technology	6,400
Customer relationships	2,900
Other assets and liabilities, net	(4,182)
In-process research and	
development	15,706
Goodwill	8,839
Total purchase price	\$ 42,311

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The acquired developed technology is amortized on a straight-line basis over 18 years, and customer relationships are amortized over 11 years. The weighted average life of the developed technology and customer relationships is 15.8 years. Goodwill resulting from this transaction is not deductible for tax purposes.

*BioFX Laboratories, Inc.* On August 13, 2007, the Company acquired 100% of the capital stock of BioFX Laboratories, Inc., a provider of substrates to the *in vitro* diagnostics industry, for \$11.6 million, \$11.3 million of which was in cash to the sellers and \$300,000 in transaction costs. The Company is also required to pay up to an additional \$11.4 million in cash upon the successful achievement of specified revenue targets. BioFX is a wholly owned subsidiary of SurModics, and will operate within the In Vitro Technologies business unit within the In Vitro operating segment. Management believes the acquisition will enhance the Company□s technological position in the *in vitro* diagnostics market. Operating results for the period from August 14, 2007 to September 30, 2007 have been included in the Company□s consolidated financial statements.

The purchase price was allocated to the fair value of the net tangible and intangible assets acquired and liabilities assumed, with the excess purchase price over fair value allocated to goodwill. The purchase price was allocated as follows (in thousands):

Net working capital	\$	1,182
Property and equipment		155
Trademarks and trade name	Ц	580
Core technology		530
Customer relationships	Ц	4,440
Other assets and liabilities, net		(2,134)
Goodwill		6,847
Total purchase price	\$	11,600

The acquired core technology is amortized on a straight-line basis over 8 years, customer relationships are amortized over 9 years and trademarks and trade name are amortized over 12 years. The weighted average life of the core technology and customer relationships is 10.3 years. Goodwill resulting from this transaction is not deductible for tax purposes.

The following unaudited *pro forma* consolidated condensed financial results of operations for the fiscal years 2007, and 2006 are presented as if the acquisitions had been completed at the beginning of each period presented (*in thousands*).

	Years Ended	
	Septem	ber 30,
	2007	2006
Pro forma revenues	\$89,708	\$84,738
Pro forma income from operations	\$ 28,034	\$ 37,393
Pro forma net income	\$ 17,735	\$ 18,377

Pro forma basic earnings per share	\$ .98	\$ .99
Pro forma diluted earnings per shares	\$ .98	\$ .98

#### 4. Stockholders ☐ Equity

#### Stock Option Plans

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 as an operating expense, based on their fair values, over the requisite service period.

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,  $\square$ Accounting for Stock Issued to Employees.  $\square$  The Company has applied the modified prospective method in adopting SFAS 123(R). Accordingly, periods prior to

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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 loss and loss per share if the fair value based method had been applied to the year ended September 30, 2005 (in thousands, except per share data):

	2005
Reported net loss	\$ (8,246)
Restricted stock expense previously recorded, net of tax	374_
Stock-based compensation determined under fair value based method,	
net of related tax effects	(3,120)
Pro forma net loss	\$ (10,992)
Loss per common equivalent share:	
Basic - as reported	\$ (0.45)
Diluted - as reported	\$ (0.45)
Basic - pro forma	\$ (0.61)
Diluted - pro forma	\$ (0.61)

As a result of the adoption of SFAS 123(R), the Company has allocated stock-based compensation expense for the years ended September 30 as follows (in thousands):

	2007	2006
Product	\$ 96	\$ 91
Research and development	5,188	2,620
Selling, general and administrative	5,028	3,000
Total	\$ 10,312	\$5,711

As of September 30, 2007, approximately \$15.4 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.7 years.

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 2007, 2006, and 2005 was \$17.42, \$16.58, and \$20.26, respectively. The assumptions used as inputs in the model for the years ended September 30 were as follows:

	2007	2006	2005
Risk-free interest rates	4.50%	4.70%	3.77%
Expected life	5.4 years	4.8 years	7.0 years
Expected volatility	45%	46%	63%
Dividend yield	0%	0%	0%

The risk-free interest rate assumption was based on the U.S. Treasury srates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award. The expected life of options granted is determined based on the Company sexperience. Expected volatility is based on the Company stock price movement. Based on management sjudgment, dividend rates are expected to be zero for the expected life of the options. The Company also estimates forfeitures of options granted, which is based on historical experience.

The Company Incentive Stock Options ( $\square$ ISO $\square$ ) 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  $\square$ 2003 Plan $\square$ ), of which 638,000 remain available for future awards. As of September 30, 2007, the aggregate intrinsic value of the option shares

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outstanding and the option shares exercisable was \$24.8 million and \$9.6 million, respectively with an average remaining contractual life of 4.7 and 4.1 years, respectively. The intrinsic value of options exercised during fiscal 2007, 2006, and 2005 was \$4.4 million, \$3.6 million and \$6.5 million, respectively.

	Number of Shares	Weighted Average Exercise Price
Outstanding at September 30, 2006	1,510,780	\$ 29.69
Granted	166,400	37.85
Exercised	(253,060)	25.82
Forfeited	(22,700)	33.71
Outstanding at September 30, 2007	1,401,420	31.29
Exercisable at September 30, 2007	574,666	28.54

#### 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 206,191 common shares and is being charged to income over the vesting term. Stock compensation expense recognized related to these awards totaled \$1.2 million, \$879,000 and \$588,000 during fiscal 2007, 2006 and 2005, respectively.

		A
		Weighted
	Number of	Average
	Shares	<b>Grant Price</b>
Balance at September 30, 2006	153,000	\$ 32.14

Granted	83,027	42.07
Vested	(24,836)	37.87
Forfeited	(5,000)	34.56
Balance at September 30, 2007	206,191	35.89

#### 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 vest upon the achievement of all or a portion of certain performance objectives, which must be achieved during the performance period. Compensation is recognized in each period based on management[]s best estimate of the achievement level of the specified performance objectives and the resulting vesting amounts. Compensation has been recognized for the estimated fair value of the 132,375 shares awarded in September 2006 that were estimated to vest during fiscal 2007. Fiscal 2007 stock compensation expense related to the Performance Share awards expected to vest totaled \$4.8 million. The Company recorded \$764,000 in fiscal 2006 related to 21,000 Performance Shares. No such expense was recorded in fiscal 2005.

#### 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, 2007 and 2006, there was \$311,000 and \$283,000 of employee contributions, respectively, included in accrued liabilities in the accompanying consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan totaled \$156,000 and \$162,000 during fiscal 2007 and 2006, respectively. No such expense was recorded in fiscal 2005.

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#### 5. Income Taxes

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

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

	2007	2006	2005
Current provision:			
Federal	\$19,069	\$14,701	\$ 7,059
State and foreign	1,732	1,501	371
Total current provision	20,801_	16,202_	7,430
Deferred provision (benefit):			
Federal	(8,573)	(774)	4,592
State	(907)	(197)	574
Total deferred provision (benefit)	(9,480)	(971)	5,166
Total provision	\$11,321	\$15,231	\$12,596

The reconciliation of the difference between amounts calculated at the statutory federal tax rate and the Company\[ \] s effective tax rate was as follow\( \) in thousands\( ):

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	2007	2006	2005
Amount at statutory federal income tax rate	\$ 5,067	\$12,440	\$ 1,513
Change due to:			
State taxes	736	720	496
Other	(241)	(102)	(10)
Stock-based compensation	262	365	
Valuation allowance		1,808	
Write-off of in-process R&D	5,497		10,597
Income tax provision	\$11,321	\$15,231	\$12,596

In fiscal 2006, the Company recorded a \$1.8 million valuation allowance against the capital loss created by the impairment of the Novocell investment (see Note 2). The valuation allowance was recorded because the Company does not currently foresee future capital gains to offset this capital loss. As such, no tax benefit has been recorded in the consolidated statements 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):

	2007	2006
Depreciable assets	\$ (4,279)	\$ 2,192
Deferred revenue	8,163	552
Accruals and reserves	296	354
Restricted stock amortization		616
Stock options	3,938	1,302
Impaired asset	1,733	1,733
Unrealized gains (losses) on investments	(1,067)	176
Other	48	201
Valuation allowance	(1,808)	(1,808)
Total deferred tax asset	7,024	5,318
Less current deferred tax asset	(1,116)	(435)
Noncurrent deferred tax asset	\$ 5.908	\$ 4.883

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# 6. Commitments and Contingencies

Litigation. From time to time, the Company may become involved in various legal actions involving its products and technologies, including intellectual property disputes. The outcomes of these legal actions are not within the Company complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, which, if granted, could require significant expenditures or result in lost revenues. In accordance with SFAS No. 5, [Accounting for Contingencies,] the Company records a liability in the consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued. If a loss is possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. While it is not possible to predict the outcome for most of the actions discussed below and the Company believes that it has meritorious defenses against these matters, it is possible that costs associated with them could have a material adverse impact on the Company consolidated earnings, financial condition or cash flows.

On May 22, 2007, the former stockholders of InnoRx (the  $\square$ Plaintiffs $\square$ ) filed a declaratory judgment action in the U.S. District Court for the Southern District of Alabama (the  $\square$ Alabama Case $\square$ ) against Michael Cooney, M.D. ( $\square$ Dr. Cooney $\square$ ) of New York, New York. In the litigation, the Plaintiffs are seeking a determination that Dr. Cooney was not a co-founder of InnoRx, and further that he was not an inventor of certain patent rights covering technology for delivering drugs to the eye, including certain patent rights exclusively licensed by the Johns Hopkins University ( $\square$ JHU $\square$ ) to InnoRx (collectively, the  $\square$ Patent Rights $\square$ ), and now controlled by the Company as successor-in-interest to InnoRx pursuant to an agreement of merger between the Company and InnoRx made effective on January 18, 2005 (the  $\square$ Merger Agreement $\square$ ). The Company is not a party to the litigation.

On June 8, 2007, the Company was named as a defendant in litigation filed in the U.S. District Court for the District of Minnesota by Dr. Cooney (the ∏Minnesota Case∏). JHU and certain former shareholders of InnoRx, among others, were also named as defendants. The complaint alleges that Dr. Cooney was a co-founder of InnoRx and an inventor of subject matter claimed in the Patent Rights. The complaint seeks an order correcting inventorship, and certain unspecified damages (including punitive damages) based on claims of unjust enrichment, fraud, and breach of fiduciary duties. On October 5, 2007, the Minnesota Case was transferred to the U.S. District Court for the Southern District of Alabama, On October 22, 2007, Dr. Cooney amended his complaint to include a claim against the Company for tortious interference with prospective economic advantage. The Company is awaiting a ruling from the district court on its motion to dismiss Dr. Cooney∏s tortious interference claim. The transferred Minnesota Case was consolidated with the Alabama Case on November 2, 2007. The parties have requested a trial in February 2009, but the district court has not yet set the schedule in the case. As of September 30, 2007, the Company has incurred approximately \$365,000 in legal fees in connection with both the Alabama and Minnesota Cases. Pursuant to the Merger Agreement, the Company has submitted a demand to the former shareholder on InnoRX for indemnification of losses (including without limitation, damages, expenses, reasonably attorneys∏ fees, and costs) incurred as a result of the litigation involving Dr. Cooney, including both the Alabama and the Minnesota cases described above. The Company consolidated financial statements do not include any expenses or liabilities related to the above actions as the probability of the outcome is currently not determinable and any potential loss is not estimable. We believe that we have meritorious defenses to Dr. Cooney\\( \)s claims and will vigorously defend and prosecute this matter.

On June 18, 2007, the Company was named as an involuntary plaintiff in patent litigation between Abbott Laboratories ([Abbott]) and Church & Dwight, Inc. ([Church & Dwight]). In the litigation, Abbott is alleging that certain of Church & Dwight[s products utilizing lateral flow technology for diagnostic purposes infringe upon certain of the Company patents that have been exclusively licensed to Abbott under the terms of a license agreement between the Company and Abbott dated May 30, 1989, as amended and restated (the [License Agreement]). The suit was filed in the U.S. District Court for the Northern District of Illinois seeking a finding of infringement, monetary damages and injunctive relief. Pursuant to the terms of the License Agreement, Abbott is responsible for reimbursing the Company for at least a portion of its costs and fees incurred in connection with the suit. A trial has not yet been scheduled.

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Investment Obligation. In July 2007, the Company made equity investments in Paragon Intellectual Properties, LLC ([Paragon]) and Apollo Therapeutics, LLC ([Apollo]), a Paragon subsidiary. The Paragon and Apollo investments totaled \$3.5 million. The arrangement calls for SurModics to invest additional equity totaling \$2.5 million upon successful completion of specified development milestones, which it expects will occur no later than the second quarter of fiscal 2008.

Operating Leases. The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the years ended September 30, 2007, 2006 and 2005 was \$140,000, \$77,000 and \$19,000, respectively. Annual commitments pursuant to operating lease agreements are as follows:

Voor	Ending	September	30
rear	Ename	September	Sυ,

2008	\$ 684,000
2009	783,000
2010	746,000
2011	130,000
2012	

Total Minimum Lease Payments \$ 2,343,000

Land Purchase Commitment. In August 2007, the Company entered into an agreement to purchase an undeveloped parcel of land in Eden Prairie, Minnesota for approximately \$3.6 million (including a non-refundable deposit of \$100,000 paid to the seller at the time the purchase agreement was signed). The agreement requires that the Company complete the purchase on or before August 24, 2008 (the  $\square$ Closing Date $\square$ ). While it is the Company $\square$ s intention to complete the purchase on or before the Closing Date, the Company will be required to pay the seller \$1.6 million if it fails to do so and will have no further rights to acquire the land.

#### 7. Defined Contribution Plan

The Company has a 401(k) retirement and savings plan for the benefit of qualifying employees. The Company matches 50% of each dollar of the first 6% of the tax deferral elected by each employee. Company contributions totaling \$356,000, \$263,000 and \$223,000 have been charged to income for the years ended September 30, 2007, 2006 and 2005, respectively.

#### 8. Operating Segments

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

SurModics manages its business on the basis of the operating segments noted in the table below, which are comprised of the Company\(\pi\)s seven business units. The three operating segments are aggregated into one reportable segment. The ∏Drug Delivery∏ operating segment contains: (1) the Drug Delivery business unit, which is responsible for technologies dedicated to site specific delivery of drugs; (2) the Ophthalmology business unit, 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; and (3) the Brookwood Pharmaceuticals unit, which provides proprietary polymer-based technologies to companies developing improved pharmaceutical products. The ∏Hydrophilic and Other∏ operating segment consists of three business units: (1) the Hydrophilic Technologies business unit, which focuses on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) the 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) the 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 the Company□s genomics slide technologies, stabilization products, antigens and substrates for immunoassay diagnostics tests, its in vitro diagnostic format technology and its synthetic ECM cell culture products.

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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. 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 ):

	2007	2006	2005
Operating segment:			
Drug Delivery	\$26,488	\$32,918	\$29,678
Hydrophilic and Other	26,493	22,233	19,065
In Vitro	20,183	14,733	13,638
Total revenue	\$73,164	\$69,884	\$62,381

#### Major Customers

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

	2007	2006	2005
Johnson & Johnson	33%	47%	46%
Abbott Laboratories	16%	12%	14%

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

### Geographic Revenue

Geographic revenue was as follows for the years ended September 30:

	2007	2006	<b>2005</b>
Domestic	81%	84%	85%
Foreign	19%	16%	15%

# 9. Subsequent Events

In November 2007, the Company□s Board of Directors authorized the repurchase of \$35 million of the Company□s common stock. The repurchase authorization does not have a fixed expiration date.

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#### 10. Quarterly Financial Data (Unaudited)

The following is a summary of the unaudited quarterly results for the years ended September 30, 2007, 2006 and 2005 (in thousands, except per share data).

	First Quarter	Second Quarter	Third Ouarter	Fourth Quarter
Fiscal 2007	Quarter	Quarter	Quarter	Quarter
Revenue	\$ 16,740	\$ 17,362	\$ 17,762	\$ 21,300
Income (loss) from operations	8,109	8,085	7,518	(13,813)
Net income (loss)	5,992	5,675	5,587	(13,907)
Net income (loss) per share:				
Basic	0.32	0.31	0.31	(0.78)
Diluted	0.32	0.31	0.31	(0.78)
Fiscal 2006				
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
Fiscal 2005				

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

In the fourth quarter of fiscal 2007, the Company recorded a \$15.6 million charge for in-process research and development acquired in connection with the purchase of Brookwood Pharmaceuticals.

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

In the second quarter of fiscal 2005, the Company recorded a \$30.3 million charge for in-process research and development acquired in connection with the purchase of InnoRx. In addition, fiscal 2005 fourth quarter results include a \$2.5 million impairment charge recorded against the Company scontract manufacturing facility.