

SURMODICS INC  
Form 10-K  
December 15, 2008

**Table of Contents**

**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, 2008**

**Commission file number 0-23837**

**SURMODICS, INC.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Minnesota**

*(State or other jurisdiction of  
incorporation or organization)*

**41-1356149**

*(IRS Employer  
Identification No.)*

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

**55344**  
*(Zip Code)*

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

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

**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  No

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2008 was approximately \$438 million (based upon the closing sale price of the registrant's Common Stock on such date).

The number of shares of the registrant's Common Stock outstanding as of December 8, 2008 was 17,667,059.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement for the Registrant's 2009 Annual Meeting of Shareholders are incorporated by reference into Part III.

---

## Table of Contents

	<b>Page</b>
<b>PART I</b>	
<u>Item 1.</u> <u>Business</u>	3
<u>Item 1A.</u> <u>Risk Factors</u>	20
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	26
<u>Item 2.</u> <u>Properties</u>	27
<u>Item 3.</u> <u>Legal Proceedings</u>	27
<u>Item 4.</u> <u>Submission of Matters to a Vote of Security Holders</u>	27
<u>Executive Officers of the Registrant</u>	27
<b>PART II</b>	
<u>Item 5.</u> <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	30
<u>Item 6.</u> <u>Selected Financial Data</u>	32
<u>Item 7.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	32
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	43
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	43
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	43
<u>Item 9A.</u> <u>Controls and Procedures</u>	44
<u>Item 9B.</u> <u>Other Information</u>	46
<b>PART III</b>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance of the Registrant</u>	46
<u>Item 11.</u> <u>Executive Compensation</u>	46
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	46
<u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>	47
<u>Item 14.</u> <u>Principal Accountant Fees and Services</u>	47
<b>PART IV</b>	
<u>Item 15.</u> <u>Exhibits and Financial Statement Schedules</u>	47
<u>EX-10.18</u>	
<u>EX-21</u>	
<u>EX-23</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

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



**Table of Contents****ITEM 1. BUSINESS.****Overview**

SurModics, Inc. (referred to as SurModics, the Company, we, us, our and other like terms) is a leading provider of drug delivery and surface modification technologies to the healthcare industry. Our mission is to exceed our customers' expectations and enhance the well-being of patients by providing the world's foremost, innovative drug delivery and surface modification technologies and products. We partner with many of the world's leading 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 drug delivery and surface modification technologies and products, enabling us to strengthen our position as a leading edge product development partner to the healthcare industry.

Our drug delivery and surface modification technologies are utilized by our customers to enable drug delivery through our microparticle, polymer implant or device platforms, alter the characteristics of the surfaces of devices and biological materials (e.g., lubricity or hemocompatibility), or create new functions for the surfaces of the devices (e.g., drug delivery or promotion of healing). For example, our patented drug delivery technologies can create new device capabilities by enabling site specific, controlled release drug delivery in cases where devices (e.g., stents) are themselves 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). Microparticles can be used to provide sustained drug delivery, allowing patients to receive injections at less frequent intervals (e.g., monthly instead of daily). Similarly, our patented PhotoLink® technology enhances the maneuverability of dilatation catheters and guidewires within the body by improving the lubricity of the device surface.

We believe that site specific, localized 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. 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 two-year follow-up during fiscal 2008. The clinical data suggest that the I-vation™ TA (triamcinolone acetonide) intravitreal implant is safe and well tolerated in patients with DME. In September 2008, we announced that Merck & Co., Inc. (Merck), following a strategic review of its business and product portfolio, would terminate its collaborative research and license agreement with us covering the development and possible commercialization of products incorporating our I-vation™ platform, including the I-vation™ TA product. Merck's termination was not related to safety or efficacy concerns with either the I-vation™ platform, generally, or the I-vation™ TA product, specifically. We continue to believe that if future clinical trials demonstrate longer term safety and efficacy of this product, I-vation™ TA could represent a viable commercial product.

We plan to continue to invest in our technologies and products to expand our core capabilities for ophthalmic drug delivery platforms. 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.

In July 2007, we acquired Brookwood Pharmaceuticals, Inc. ( Brookwood ), a leading provider of drug delivery technology primarily to the pharmaceutical industry. This acquisition created our Brookwood

## **Table of Contents**

Pharmaceuticals business unit and greatly increased our drug delivery capabilities in the areas of proprietary injectable microparticles and implant technology, both of which are based on biodegradable polymers, to provide sustained drug delivery. Our Brookwood Pharmaceuticals customer projects target a number of key clinical indications in the diabetes, oncology, ophthalmology, cardiovascular, orthopedics, central nervous system (CNS) markets, in addition to other fields. Brookwood Pharmaceuticals generates revenue from research and development fees, polymer sales, and royalties and license fees.

In August 2007, we acquired all of the assets of BioFX Laboratories, Inc. ( BioFX ). Based in Owings Mills, Maryland, BioFX is a leading provider of innovative reagents and substrates for the biomedical research and medical diagnostic markets. BioFX offers both colorimetric and chemiluminescent substrates, as well as other products for use in *in vitro* diagnostic applications. This acquisition expanded our product offerings for customers developing diagnostic test kits.

In November 2008, we extended our technology offerings by acquiring a portfolio of intellectual property and collaborative drug delivery projects from PR Pharmaceuticals, Inc., a drug delivery company specializing in injectable, biodegradable sustained release microparticle formulations. We believe that this acquisition, together with our Brookwood Pharmaceuticals business unit, strengthens our portfolio of drug delivery technologies available to the pharmaceutical and biotechnology industries.

We continue to commercialize our drug delivery and surface modification technologies primarily through licensing and royalty arrangements with medical device manufacturers. Additionally, we continue to strengthen our ability to partner with pharmaceutical and biotechnology companies allowing for the integration of their proprietary drugs with our unique drug delivery platform technologies, such as our polymer-based microparticles and implants as well as our I-vation<sup>tm</sup> 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 to research and development services, through our Brookwood Pharmaceuticals business unit, we offer manufacturing services for clinical trial materials as well as for commercial products. In addition to licensing fees and research and development fees, we generate revenue from the manufacture and sale of a variety of products. We manufacture and sell the chemical reagents used by our customers in coating these products. Additionally, through our CodeLink<sup>®</sup> microarray slide product line, which we re-acquired from GE Healthcare in September 2008 along with the right to use the CodeLink<sup>®</sup> trademark, we manufacture and sell microarray slides to the diagnostic and biomedical research markets. 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.

For the fiscal year ending September 30, 2008, we managed 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).

## **Table of Contents**

*In Vitro Technologies*, specializing in *in vitro* diagnostic products and technologies for the biomedical research and medical diagnostic markets. 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.

*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.

*Brookwood Pharmaceuticals*, 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. This business also supplies biodegradable polymers to corporate and academic customers. In November 2008, we enhanced these offerings by acquiring a portfolio of intellectual property and collaborative drug delivery projects from PR Pharmaceuticals, Inc., a drug delivery company specializing in injectable, biodegradable sustained release formulations.

In November 2008, we announced that we were changing our organizational structure so that we will now be organized into four clinically and market focused business units: Cardiovascular, Ophthalmology, In Vitro Technologies, and Brookwood Pharmaceuticals. We believe that this structure will improve the visibility, marketing and adoption of our broad array of technologies within specific markets and help our customers in the medical device, pharmaceutical and life science industries solve unmet clinical needs. In addition, a new centralized research and development function has been formed to serve the needs of our clinically and market focused business units. Brookwood Pharmaceuticals' research and development operations will remain unchanged. Because this change occurred in fiscal 2009, and to provide comparability of our results, we will primarily describe our business herein as it was conducted in fiscal 2008.

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 drug delivery and surface modification 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.

## **Drug Delivery and Surface Modification 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 drug delivery and surface modification 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.

## **Table of Contents**

### ***Pharmaceutical and Biotechnology Industries***

The pharmaceutical and biotechnology industries have become increasingly competitive as a result of 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, for instance, be 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's effect 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.

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 drug delivery and surface modification 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 Drug Delivery and Surface Modification Technologies Overview**

We believe SurModics is uniquely positioned to exploit the continuing trend of incorporating drug delivery and surface modification 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—all key ingredients to bring innovation together for the benefit of patients, the Company, and the healthcare industry.

### ***Coatings for Drug Delivery and Surface Modification***

Our drug delivery coating technologies allow therapeutic drugs to be 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

## **Table of Contents**

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.

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 subsidiary of Johnson & Johnson. 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.

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 drug delivery and surface modification reagents. Additionally, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput and cost requirements of our customers.

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 competing 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 in July 2007, and certain proprietary technology from PR Pharmaceuticals, Inc. in November 2008, 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

## **Table of Contents**

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, proprietary know-how and patented capability in the field of microparticle drug delivery, working with a wide range of drug classes. Our microparticles incorporate a customer's 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 scientists and engineers can 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 prescribed 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 the 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.

### ***SurModics Drug Delivery and Surface Modification Technologies 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 is currently selling throughout the world a drug-eluting stent incorporating SurModics' technology. We have also developed the I-vation™ sustained drug delivery 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 are designed to improve and accelerate tissue healing of implantable medical devices through nature's own healing mechanisms. Certain ECM proteins, such as collagen and laminin, specifically stimulate the migration and proliferation of endothelial cells (cells that line blood vessels) to promote healing. By covalently attaching the appropriate ECM proteins to device surfaces utilizing the PhotoLink coating process, the biomimetic surface can signal endothelial cells in the blood and vascular wall

**Table of Contents**

to form a stable endothelial lining over the implant. 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.

*Wettability.* PhotoLink hydrophilic coatings have been shown in internal and customer tests to accelerate liquid flow rates on normally hydrophobic (water repelling) materials by up to 75%. For example, some rapid point-of-care diagnostic tests, such as home monitoring or physician monitoring of glucose levels in diabetics, are currently done by pricking a patient's finger and placing a drop of blood onto a polymer strip which is then inserted into a blood glucose reader. We believe that the time it takes for the blood to flow up the strip to provide a readout can be dramatically reduced and the consistency can be greatly improved with the use of PhotoLink technology.

*DNA and Protein Immobilization.* Both DNA and protein microarrays are useful tools for the pharmaceutical, diagnostic and research industries. During a DNA gene analysis, typically thousands of different probes need to be placed in a pattern on a surface, called a DNA microarray. These microarrays are used by the pharmaceutical industry to screen for new drugs, by genome mappers to sequence human, animal or plant genomes, or by diagnostic companies to search a patient sample for disease causing bacteria or viruses. However, DNA does not readily adhere to most surfaces. We have developed various surface chemistries for both DNA and protein immobilization. In September 2008, we re-acquired the rights to our microarray slide product line which had previously been marketed by GE Healthcare under the CodeLink® trademark. As part of this transaction, we obtained the right to use the CodeLink® trademark of GE Healthcare in the sale and marketing of the product lines we re-acquired. 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 Drug Delivery and Surface Modification Technologies Applications***

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

<b>Market Segment Served</b>	<b>Desired Surface Property and Examples of Applications</b>
<b>Interventional cardiology and vascular access</b>	<i>Lubricity</i> : catheters, guidewires <i>Hemocompatibility</i> : vascular stents, catheters, distal protection devices <i>Drug/biologics delivery</i> : vascular stents, catheters <i>Prohealing</i> : vascular stents, vascular grafts

**Table of Contents**

<b>Market Segment Served</b>	<b>Desired Surface Property and Examples of Applications</b>
<b>Cardiac rhythm management</b>	<i>Lubricity</i> : pacemaker and defibrillator leads, electrophysiology devices <i>Hemocompatibility</i> : electrophysiology devices <i>Prohealing</i> : pacemaker and defibrillator leads <i>Drug/biologics delivery</i> : pacemaker and defibrillator leads
<b>Cardiothoracic surgery</b>	<i>Prohealing</i> : heart valves, septal defect repair devices <i>Hemocompatibility</i> : minimally invasive bypass devices, vascular grafts, ventricular assist devices
<b>In Vitro Diagnostics</b>	<i>Lubricity</i> : microfluidic devices <i>Hemocompatibility</i> : blood/glucose monitoring devices, biosensors <i>Biomolecule immobilization</i> : DNA and protein arrays, protein attachment to synthetic nanofibrillar extracellular matrix for cell culture applications <i>Cell culture growth and tissue integration</i> : cell culture products, <i>in vitro</i> applications using synthetic nanofibrillar extracellular matrix to provide a more <i>in vivo</i> -like surface
<b>Interventional neurology and neurosurgery</b>	<i>Lubricity</i> : catheters, guidewires <i>Prohealing</i> : neuroembolic devices <i>Tissue engineering</i> : aneurysm repair devices
<b>Urology and gynecology</b>	<i>Lubricity</i> : urinary catheters, incontinence devices, ureteral stents, fertility devices <i>Drug/biologics delivery</i> : prostatic stents, microparticle injections <i>Tissue engineering</i> : female sterilization devices
<b>Ophthalmology</b>	<i>Drug/biologics delivery</i> : sustained drug delivery implants and microparticle injections
<b>Orthopedics</b>	<i>Cell growth and tissue integration</i> : bone and cartilage growth <i>Infection resistance</i> : orthopedic and trauma implants <i>Drug/biologics delivery</i> : orthopedic and trauma implants and microparticle injections
<b>Metabolic disease</b>	<i>Drug/biologics delivery</i> : microparticle injections <i>Tissue engineering</i> : cell encapsulation
<b>Central nervous system disorders</b>	<i>Drug/biologics delivery</i> : microparticle injections, polymer implants
<b>Dermatology</b>	<i>Drug/biologics delivery</i> : polymer implants <i>Tissue engineering</i> : tissue bulking, space filling materials

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 drug delivery and surface modification technologies primarily through licensing arrangements with medical device and drug manufacturers. We believe this approach allows us to focus our

## **Table of Contents**

resources on further developing new technologies and expanding our licensing activities. Many of 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. Other customers, particularly in the pharmaceutical and biotechnology industries, prefer to outsource the manufacturing of drug delivery formulations to partners. Accordingly, we are investing in our Brookwood Pharmaceuticals manufacturing facility in Alabama in order to meet the Current Good Manufacturing Practice (CGMP) manufacturing needs of our customers.

We generate the largest portion of our revenue primarily through licensing arrangements. Royalties and license fees represented 53.4%, 72.0% and 75.9% of our total revenue in fiscal 2008, 2007 and 2006, respectively. Revenue from these licensing arrangements typically includes license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensee's 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, antigens and microarray slides to diagnostics customers; and licensing our proprietary diagnostic formats for use in point-of-care testing. Product sales represented 20.7%, 18.5% and 16.0% of total revenue in fiscal 2008, 2007 and 2006, respectively. Research and development fees represented 26.0%, 9.5% and 8.2% of total revenue in fiscal 2008, 2007 and 2006, respectively. The increase in research and development revenue reflects the addition of our Brookwood Pharmaceuticals business unit.

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's specific technical needs. At any time prior to commercialization, a license agreement may be executed granting the licensee rights to use our technology. We 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 customer's drugs through preclinical and clinical trials and by providing an option to manufacture products upon commercialization as well.

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, 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's device (i.e., the device could not perform as desired without our technology). The amount of the license fees, milestone payments, and the royalty rate are based on various factors, including the stage of development of the product or technology being licensed, whether the arrangement is exclusive or nonexclusive, the perceived value of our technology to the customer's product, size of the potential market, and customer preferences. Most of our agreements also incorporate a minimum royalty to be paid by the licensee. Due to the delay in reporting sales by our licensees, royalties are generally paid one quarter after the customer's actual product sales occur.

As of September 30, 2008, we had 103 licensed product classes (customer products utilizing SurModics technology) already on the market generating royalties and 105 customer product classes incorporating our technology pending regulatory approval. These 208 product classes are being sold or developed by 101 licensed customers. We signed 23 new licenses in fiscal 2008, compared with 27 in fiscal 2007.

Under most of our licensing agreements, we are required to keep the identity of our customers confidential unless they approve such disclosure. Licensed customers who allow the use of their name include AbbeyMoor

## **Table of Contents**

Medical, Inc., Abbott Laboratories, Ambrilia Biopharma Inc., Boston Scientific Corporation, CardioMind, Inc., Conor Medsystems, LLC (a wholly owned subsidiary of Johnson & Johnson), Cook Medical, Corning Incorporated, Cordis Corporation (a subsidiary of Johnson & Johnson), Devax, Inc., Edwards Lifesciences Corporation, elbion N.V., Elixir Medical Corporation, ev3 Inc., FoxHollow Technologies, Inc. (a subsidiary of ev3 Inc.), Medtronic, Inc., Novocell, Inc., Nexeon MedSystems, Inc. (formerly Paragon Intellectual Properties, LLC), Spectranetics Corporation, St. Jude Medical, Inc., TherapeutiX Inc., and Xtent, Inc., among others.

### ***In Vitro Products***

#### *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*

Since the acquisition of BioFX in August 2007, SurModics has provided colorimetric and chemiluminescent substrates to 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.

#### *Recombinant Human Antigens*

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

#### *Microarray Slide Products*

During fiscal 1999, we began offering microarray slide products for use in the diagnostic and biomedical research markets. Microarray slides are used by researchers for DNA analysis. In September 2008, we re-acquired the rights to market our microarray slide product line from GE Healthcare, including the right to use the CodeLink® trademark in connection with these products. Previously, these products had been marketed by GE Healthcare under the CodeLink® trademark.

#### *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

## **Table of Contents**

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. In December 2008, the U.S. patents underlying the royalty streams from Abbott Laboratories will expire. Because net sales are reported, and royalties paid, following the end of a calendar quarter, we anticipate that we will continue to recognize some royalty revenue through the end of our second quarter in fiscal 2009, however following this we will not receive any additional diagnostic royalty revenue.

## **Research and Development**

Our research and development (R&D) personnel work to enhance and expand our technology offerings in the area of drug delivery and surface modification through internal scientific investigation. These scientists and engineers also evaluate external technologies in support of our business development activities. All of these efforts are guided by 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 relevant technologies 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 drug delivery and surface modification 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 extensive 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. In order to better serve our customers, in November 2008 we announced the creation of a new centralized R&D function in order to serve the needs of the Company's clinically and market focused business units. Our Brookwood Pharmaceuticals business unit will continue to have its own R&D operations, which will remain unchanged.

As medical products become more sophisticated and complex and as competition increases, we believe the need for drug delivery and surface modification will continue to grow. We intend to continue our development efforts to expand our drug delivery and surface modification technologies to provide additional optimized properties to meet these needs across multiple medical markets. In addition, we are expanding our drug delivery and surface modification technology expertise to capture more of the final product value. We are doing this by, in selected cases, developing or acquiring technologies or devices to develop from feasibility stage up to and including animal and human clinical testing stage. 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 R&D projects currently in progress include additional polymer systems for site specific and systemic drug delivery, including microparticles and nanoparticles, 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 2008, 2007 and 2006, our R&D expense was \$40.5 million, \$28.5 million and \$20.4 million, respectively. Of the above amounts, \$7.9 million, \$9.2 million and \$8.5 million were spent on internal R&D in 2008, 2007 and 2006, respectively, and \$32.6 million, \$19.3 million and \$11.9 million were spent on customer-sponsored R&D for which we are paid by the customer, which includes technology optimization and other development work

## **Table of Contents**

on customer product applications. We intend to continue investing in R&D to advance our drug delivery and surface modification 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 R&D 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 United States 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 United States applications. In fiscal 2008, we filed 25 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, 2008, we had 136 pending United States patent applications, 8 of which were exclusively licensed from others, and 237 foreign patent applications, of which 29 were exclusively licensed from others. Likewise, as of September 30, 2008, we owned 77 issued United States patents, 14 of which were exclusively licensed from others, and 174 international patents, of which 42 were exclusively licensed from others.

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. We believe that our new organizational structure will allow us to better understand and meet the needs of our customers by organizing our business around patient needs. 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 enter into sales and marketing relationships with third-parties to distribute our diagnostic products around the world. See Note 8 to the Consolidated Financial Statements for information regarding domestic and foreign revenue.

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

To support our marketing and sales activities, we publish technical literature on our various surface modification, 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 troubleshooting, preparation of product for clinical studies, and assistance with regulatory submissions for product approval. Most of these services are billable to customers.

## **Table of Contents**

### **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. In fiscal 2007 SurModics acquired Brookwood and BioFX for \$42.3 million and \$11.6 million, respectively. There are contingent consideration features associated with each acquisition whereby SurModics may be required to pay up to an additional \$22 million in cash related to Brookwood and \$11.4 million in cash related to BioFX. In fiscal 2008 both entities achieved earnout targets resulting in additional cash consideration paid of \$2 million and \$1.1 million for Brookwood and BioFX, respectively. The additional cash consideration was recorded as an increase to goodwill.

Following the successful completion of a milestone in May 2008, we completed a \$2.5 million equity investment in Nexeon MedSystems, Inc. (formerly Paragon Intellectual Properties, LLC and its subsidiary Apollo Therapeutics, LLC, which combined in 2008). This investment followed our \$3.5 million equity investment in Nexeon in fiscal 2007. The investment was made in conjunction with our agreement with Nexeon to collaborate on the development of a coronary stent system incorporating our proprietary Finale™ prohealing coating technology. See Note 2 to the Consolidated Financial Statements for discussion of SurModics' accounting for this investment.

In September 2008, we re-acquired the rights to directly sell our genomics slide product line, which had previously been marketed by GE Healthcare under the CodeLink® trademark. Prior to the re-acquisition, we had manufactured the slides, which were then sold by GE Healthcare. Following the acquisition, we believe we will capture incremental value associated with distributing these products directly to customers. As part of this transaction, we also acquired the right to use the CodeLink® trademark in connection with these products.

In November 2008, we extended our technology offerings by acquiring a portfolio of intellectual property and collaborative drug delivery projects from PR Pharmaceuticals, Inc., a drug delivery company specializing in injectable, biodegradable sustained release formulations.

### **Significant Customers**

We have two customers that each provided more than 10% of our revenue in fiscal 2008. Revenue from Johnson & Johnson and Abbott Laboratories represented approximately 20% and 10%, respectively, of our total revenue for the year ended September 30, 2008. We have several products for each generating revenue for us. 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.

In September 2008, following a strategic review of its business and product portfolio, Merck notified the Company of its intent to terminate its collaborative research and license agreement with us covering the development and possible commercialization of products incorporating our I-vation™ platform, including the I-vation™ TA product. The termination is expected to be effective December 16, 2008. The accounting treatment required by Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, has resulted in a deferred revenue balance in connection with the Merck agreement totaling \$34.8 million as of September 30, 2008. We anticipate that this deferred revenue will be recognized in the first quarter of fiscal 2009. In addition, we anticipate recognizing in the first quarter of fiscal 2009 a \$9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program.

**Competition**

The ability for drug delivery and surface modification 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 drug delivery and surface modification technologies compete with technologies developed by Alkermes, Inc., AST Products, Inc., Biocompatibles International plc, BioSensors International Group, Ltd., DSM Biomedical Materials B.V., Durect

## **Table of Contents**

Corporation, Hydromer, Inc., MediVas, LLC, pSivida Limited, QLT Inc., Specialty Coating Systems, Inc., STS Biopolymers Inc., a subsidiary 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 drug delivery and surface modification. 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 drug delivery and surface modification 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, ability to manufacture clinical and commercial products (especially for Brookwood Pharmaceuticals customers), 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 or drug products, such as regulatory approval, marketing and sales efforts of our licensees or competitive pricing pressures within the particular 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.

Some of our customers, particularly in the pharmaceutical and biotechnology industries, prefer to outsource the manufacturing of drug delivery formulations to partners. Accordingly, in April 2008 we acquired, for \$12.2 million, a facility in Birmingham, Alabama with approximately 286,000 square feet of warehouse and office space in order to upgrade our manufacturing capabilities. We are in the process of upgrading this facility to allow us to provide additional manufacturing services to customers and remove risk from our customers' commercialization efforts using our technologies. We expect to incur approximately \$24.0 to \$26.0 million in fiscal 2009 in additional expense related to the completion of construction, which we expect to be completed by Fall 2009.



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 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

## **Table of Contents**

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, pharmaceutical companies and universities. Several of the products that incorporate the polymers that we produce have been commercialized.

We also manufacture our proprietary line of microarray slides for sale under the CodeLink® brand. We obtained the right to use the CodeLink® trademark in connection with these products when we re-acquired the rights to this product line from GE Healthcare in September 2008. Precision glass slides are cleaned and pretreated in a multiple-step process. We apply our proprietary PhotoLink coating in a clean room environment and test the slides to assure they meet quality standards. The slides are then packaged in specialized containers, sealed in moisture-proof packaging and are marketed and sold as either blank slides or pre-arrayed with up to 40,000 genes.

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.

We follow quality management procedures in accordance with applicable regulations and guidance for the development and manufacture of materials and pharmaceutical, device, biotechnology or combination products that support clinical trials and commercialization. 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 drug delivery and surface modification technologies themselves are not directly regulated by the FDA, the medical devices, pharmaceutical and biotechnology products incorporating our technologies are subject to FDA regulation. New medical devices utilizing our 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 substantially equivalent to a previously marketed device (510(k) marketing clearance process), or in the case of implantable devices, safe and effective (PMA process), rests with our customers as the medical device manufacturers. New pharmaceutical and biotechnology products utilizing our technologies can only be marketed in the United States after a New Drug Application (NDA) or Biologics License Application (BLA) has been approved by the FDA. The burden of obtaining FDA approval of the NDA or BLA rests with our customers.

In support of our customers' regulatory filings, we maintain various confidential Drug Master Files, Device Master Files and Veterinary Master Files with the FDA and with other regulatory agencies outside the U.S. 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 various regulatory submissions to these agencies. This approach allows regulatory agencies to understand in confidence the details of our technologies without us having to share this highly confidential information with our customers.

## **Table of Contents**

U.S. legislation allows companies, prior to obtaining FDA clearance or approval to market a medical product in the U.S., to manufacture medical products 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 products 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<sup>tm</sup> 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 are currently conducting follow-up monitoring of the patients for three years.

## **Employees**

As of December 1, 2008, we had 254 employees, of whom 189 were engaged in product development, quality, or manufacturing positions, with the remainder in sales, marketing, or administrative positions. Post-graduate degrees are held by 57 of our employees, 30 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 our future success will depend in part on our ability to attract and retain qualified technical, management and marketing personnel. Such experienced personnel are in high demand, and we must compete for their services with other firms that may be able to offer more favorable benefits.

## **Forward-Looking Statements**

Certain statements contained in this Form 10-K, in the Company's annual report to shareholders or in other reports of the Company and other written and oral statements made from time to time by the Company do not relate strictly to historical or current facts. As such, they are considered forward-looking statements that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as anticipate, believe, could, estimate, expect, forecast, intend, may, plan, possible, project, will, 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 prospects, 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's 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<sup>®</sup> stent program, including among others, the rate of market penetration by Cordis, the timing of market introduction of competing products, product safety or efficacy concerns and intellectual property litigation the outcome of which could adversely affect the royalty revenue we derive based on the sales of licensed products.

General economic conditions we are subject to which are beyond our control, including the impact of recession, business investment and changes in consumer confidence;

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;

**Table of Contents**

the Company's ability to attract new licensees and to enter into agreements for additional product applications with existing licensees, the willingness of potential licensees to sign license agreements under the terms offered by the Company, changes in the development and marketing priorities of our licensees and development partners and the Company's ability to maintain satisfactory relationships with its licensees;

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

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

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 or approvals, 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 successfully manage clinical trials and related foreign and domestic regulatory processes for the I-vation™ intravitreal implant or other products under development by the Company, whether delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances or approvals postpone or preclude product commercialization of the intravitreal implant or other products, and whether the intravitreal implant and any other products remain viable commercial prospects;

product liability claims not covered by insurance;

the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;

the trend of consolidation in the medical device industry, resulting in more significant, complex and long term contracts than in the past and potentially greater pricing pressures;

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

the Company's ability to successfully internally perform certain product development activities and governmental and regulatory compliance activities which the Company has not previously undertaken in any

significant manner;

acts of God or terrorism which impact the Company's personnel or facilities; and

other factors described below in Risk Factors.

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

**Table of Contents**

**ITEM 1A. RISK FACTORS.**

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

*We are subject to changes in general economic conditions that are beyond our control including recession and declining consumer confidence.*

During periods of economic slowdown or recession, such as the United States and world economies are currently experiencing, many of our customers are forced to delay or terminate some of their product development plans. Because we rely on licensing and commercialization of our technology by third parties, we may be severely impacted by the decreasing research and development budgets of our customers. In addition, in an environment of decreasing research and development spending, sales of our In Vitro Technologies products involved in research may similarly suffer as a result of the decreased research and development activity. Although we attempt to manage these risks, any sustained period of decreased research and development spending by our customers and potential customers could adversely affect our financial position, liquidity, and results of operations.

*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 10% or more of our revenue in fiscal 2008. Revenue from Johnson & Johnson and Abbott Laboratories represented approximately 20% and 10%, respectively, of our total revenue for the year ended September 30, 2008. 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. For example, on September 16, 2008, we were informed by Merck that they intended to terminate their collaboration with us on the development and commercialization of our I-vation<sup>™</sup> intravitreal implant in combination with triamcinolone acetonide and certain proprietary Merck compounds. 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 small number of customers for a significant portion 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.

*Drug delivery and surface modification 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 drug delivery and surface modification. Our drug delivery and surface modification technologies compete with technologies developed by Alkermes, Inc., AST Products, Inc., Biocompatibles



International plc, BioSensors International Group, Ltd., DSM Biomedical Materials B.V., Durect Corporation, Hydromer, Inc., MediVas, LLC, pSivida Limited, QLT Inc., Specialty Coating Systems, Inc., STS Biopolymers Inc., a subsidiary 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, drug delivery or surface modification technologies for use on their own devices. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own research and development efforts) have

## **Table of Contents**

greater financial and technical resources and production and marketing capabilities than us. Competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. Products incorporating our competitors' technologies may gain market acceptance more rapidly than products using ours. Developments by competitors may render our existing and potential products noncompetitive or obsolete. Furthermore, there can be no assurance that new products or technologies developed by others, or the emergence of new industry standards, will not render our products or technologies or licensees' products incorporating our technologies noncompetitive or obsolete. Any new technologies that make our drug delivery or surface modification 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.

### ***The acquisitions that we have made, or any future acquisitions that we undertake could be difficult to integrate, disrupt our business, dilute shareholder value, or harm our operating results.***

Since June 30, 2007, we have completed four acquisitions, including Brookwood Pharmaceuticals, Inc., the largest acquisition in our history. In addition, we may continue to make more strategic investments or acquire complementary businesses, technologies, or products if we identify suitable investment or acquisition candidates. The process of integrating acquired 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, including the need to manage several remote locations with a limited management team;

- 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 successfully complete any investments or acquisitions or that we will realize any anticipated benefits from investments or acquisitions that we complete.

### ***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.

**Table of Contents**

***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.

***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 titled, *Revenue Arrangements with Multiple Deliverables*. Our compliance with such accounting standards often involves management's judgment 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 Securities and Exchange Commission or the Financial Accounting Standards Board 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 revenue recognized, for one or more prior reporting periods, which 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, 2008, 2007 and 2006, we derived approximately 53%, 72% and 76% of our revenue, respectively, from royalties and license fees. Although we do market certain diagnostic products and reagents, we do not currently market, distribute or sell our own medical devices or pharmaceutical compounds, nor do we intend to do so in the foreseeable future. Thus, our prospects are greatly 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. For example, as discussed previously, on September 16, 2008, Merck informed us that they intend to terminate their collaboration with us on the development and commercialization of our I-vation<sup>™</sup> intravitreal implant in combination with triamcinolone acetonide and certain proprietary Merck compounds following a strategic review of its business and product development portfolio. 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 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 drug

**Table of Contents**

delivery or surface modification 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. In particular, because most of our customers use these reagents to create royalty-bearing products, failure by us to deliver products, including polymers and reagents, could result in decreased royalty revenue, as well as decreased revenue from the sale of products. 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 certain of our licensing agreements, we may elect to manufacture pharmaceutical or biotechnology products for existing or future licensees under appropriate circumstances. In addition, certain potential customers may require that we be responsible for the manufacture of pharmaceutical or biotechnology products in order to enter into licensing agreements with us. The manufacture of pharmaceutical or biotechnology products can be an expensive, time consuming, and complex process. Further, any manufacturer of pharmaceutical and biotechnology products is subject to applicable Current Good Manufacturing Practice (CGMP) regulations as prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities. In order to fulfill any manufacturing commitments we may have in the future, we will need to make investments in our operations to add CGMP manufacturing capacity. Although we have purchased a facility in Alabama and are in the process of upgrading it, there is no guarantee that the upgrades will be completed and validated according to our schedule, budget or at all. We may be unable to maintain our facilities in compliance with CGMP or other applicable regulatory standards. Such a failure to comply with CGMP could result in significant time delays or inability to obtain (and maintain) marketing approval for any future products that we may be required to manufacture, which may result in financial penalties under the terms of license agreements, as well as damage our relationships with our customers in the future. 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, the use or misuse of our products or the manufacture and supply of pharmaceutical 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 guarantee that we will not become involved in the manufacture and supply of commercial quantities of products to licensees, 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. Any product liability claims, with or without merit,

could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time, 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,

## **Table of Contents**

if at all. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any recall of products or devices incorporating our technologies because of alleged defects, whether such recall is instituted by us, a customer, or is 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 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 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 technology. This could result in lost royalties and product sales, which would harm our financial results. Adding suppliers to our approved vendor list may require significant time and resources since we typically thoroughly review a supplier's business and operations to become comfortable with the quality and integrity of the materials we purchase for use with our technology, including reviewing a supplier's manufacturing processes and evaluating the suitability of materials and packaging procedures the supplier uses. We routinely attempt to maintain multiple suppliers of each of our significant materials, so we have alternative suppliers if necessary. However, if the number of suppliers of a material is reduced, or if we are otherwise unable to obtain our material requirements on a timely basis and on favorable terms, our operations may be harmed.

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

Our success is dependent upon our ability to retain and attract highly qualified management and technical personnel. We face intense competition for such qualified personnel. We do not maintain key person insurance, nor do we have employment agreements with any of our employees, except for certain of our executive officers. Although we have non-compete agreements with most employees, there can be no assurance that such agreements will be enforceable or that they will serve to keep employees working for us. 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 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, 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

## **Table of Contents**

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.

***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 CLINICAL AND REGULATORY MATTERS**

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

Medical devices, biotechnology products 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 may be required. Clinical development, including preclinical testing, is a long, expensive and uncertain process. The burden of securing regulatory approval for these products typically rests with our licensees, the medical device or pharmaceutical

manufacturers. However, we have prepared Drug Master Files and 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's 510(k) marketing

## **Table of Contents**

approval process, which typically lasts from six to nine months. Supplemental or full PMA reviews require a significantly longer period, delaying commercialization. By contrast, pharmaceutical products incorporating our technologies are subject to the FDA's NDA process which typically takes a number of years to complete. Additionally, biotechnology products incorporating our technologies are subject to the FDA's BLA process, which also typically takes a number of years to complete. In addition, sales of medical devices and pharmaceutical or biotechnology 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.

***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 that 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.

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 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 *Forward-Looking Statements* and *Risk Factors*. The market value of your investment in our common stock may rise or fall sharply at any time because of this volatility, and also because of significant short positions taken by investors from time to time in our stock. In the fiscal year ended September 30, 2008, the closing sale price for our common stock ranged from \$28.05 to \$56.09 per share. As of December 8, 2008, the last reported sale price of our stock was \$23.54 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.

**Table of Contents****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. We also lease another facility in Eden Prairie which contains approximately 73,000 square feet. In November 2008, we announced the consolidation of all of our Eden Prairie personnel into our owned facility as part of our reorganization efforts. We estimate this consolidation will be substantially complete by the end of December 2008. We also own an undeveloped parcel of land adjacent to our principal facility, which we intend to use to accommodate our growth needs.

In addition to our Eden Prairie facilities, we also own and lease facilities in Birmingham, Alabama in connection with our Brookwood Pharmaceuticals operations. The facility which we acquired in the Brookwood acquisition consists of approximately 33,000 square feet. In April 2008, we acquired a second building in Birmingham, Alabama that has approximately 286,000 square feet of warehouse and office space in order to upgrade our manufacturing capabilities. We also lease an approximately 14,000 square foot facility in Birmingham which contains two cleanroom suites primarily used for the manufacture of drug products and a separate facility in Birmingham containing approximately 4,500 square feet of warehouse space. 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.***

See Note 6 to the Consolidated Financial Statements for information regarding commitments and contingencies.

**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 2008.

**EXECUTIVE OFFICERS OF THE REGISTRANT**

As of December 12, 2008, the names, ages and positions of the Company's executive officers are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Bruce J Barclay	52	President and Chief Executive Officer
Aron B. Anderson, Ph.D.	45	Vice President and Chief Scientific Officer
Philip D. Ankeny	45	Senior Vice President and Chief Financial Officer
Douglas P. Astry	56	General Manager, In Vitro Technologies
Lise W. Duran, Ph.D.	53	Vice President of Research
Paul A. Lopez	52	Vice President and President Ophthalmology Division
Charles W. Olson	44	Vice President and General Manager Cardiovascular
Bryan K. Phillips	37	Vice President, General Counsel and Secretary
Brian L. Robey	45	Vice President of Product Development and Operations
Michael J. Shoup	48	Vice President of Quality, Regulatory and Clinical Affairs
Arthur J. Tipton, Ph.D.	51	Vice President, and President of Brookwood Pharmaceuticals
Jan M. Webster	49	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 30 years of experience in the health care industry. Prior to joining SurModics, he served as President and Chief Executive Officer of Vascular Architects, Inc., a medical device company that developed, manufactured and sold products to treat peripheral vascular disease, from 2000 to 2003. Prior to Vascular Architects, he served at Guidant Corporation, most recently as an officer and Senior Vice President from 1998 to 2000. Previously, he was a Vice President of Guidant's Interventional Cardiology division with responsibility for

**Table of Contents**

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 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 (now known as In Vitro Technologies) in April 2004. Prior to joining SurModics, from 2002 to 2003, he was Vice President of Marketing and Business Development at HTS Biosystems, and from 1980 through 2001, he held various research and business management positions at 3M, most recently Business Development Manager of 3M's Bioanalytical Technologies Group. Mr. Astry received his B.A. degree in Biology from Williams College 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.*, 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. Dr. Duran became Vice President and General Manager of the Regenerative Technologies business unit in April 2004. In November 2008 following the change in our organizational structure, Dr. Duran was named Vice President Research. 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.

*Paul A. Lopez* joined the Company in July 2005 as Vice President and President of the Company's 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 a B.S. in Business Administration from California State University, Long Beach in 1979 and an M.B.A. from California State Polytechnic University in 1984.

*Charles W. Olson* joined the Company in July 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, Sales was added to his responsibilities. In November 2008 following the change in our organizational structure, Mr. Olson was named Vice President of our

**Table of Contents**

Cardiovascular business unit. 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 Deputy General Counsel in October 2007, and was promoted to his current role as Vice President, General Counsel and Corporate Secretary in September 2008. Prior to joining SurModics, from 2001 to 2005, Mr. Phillips served as patent counsel at Guidant Corporation's Cardiac Rhythm Management Group where he was responsible for developing and implementing intellectual property strategies and also for supporting the company's business 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 March 2005 as Senior Director, Commercial Development for Drug Delivery and was promoted to Vice President and General Manager, Drug Delivery in May 2006. In November 2008 following the change in our organizational structure, Mr. Robey was named Vice President of Product Development and Operations. 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 B.S. and M.S. degrees in biomedical engineering from Louisiana Tech University in 1985 and 1987, respectively, 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's Cardiac Surgery Division from 2005 to 2006 and held various positions at Acorn Cardiovascular from 1998 to 2005, most recently as Director of Operations. Mike's employment history also includes Integ (1994-1998), SciMed Life Systems, now part of Boston Scientific (1990-1994) and Minco Products (1983-1990). He teaches in the area of medical device design and manufacturing 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 B.S. in mechanical engineering from the University of Minnesota in 1982 and earned an M.B.A. with a manufacturing systems concentration from the University of St. Thomas in 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 as Vice President of Pharmaceutical Formulations and then became President and CEO of Brookwood Pharmaceuticals, when it was launched as a new company based on Southern Research Institute's pharmaceutical formulations business in January 2005. Prior to joining Southern Research Institute, Dr. Tipton served as Executive Vice President at Durect Corporation from 2001 to 2004. 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 B.S. in Chemistry from Spring Hill College in 1980 and a Ph.D. in Polymer Science and Engineering from the University of Massachusetts, Amherst in 1987.

*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's degree 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.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

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

<b>Fiscal Quarter Ended:</b>	<b>High</b>	<b>Low</b>
September 30, 2008	45.06	28.05
June 30, 2008	47.88	42.00
March 31, 2008	55.40	38.17
December 31, 2007	56.09	48.35
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

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 8, 2008, there were 284 holders of record of our Common Stock and approximately 13,826 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, 2008, 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.

(a)	(b)	(c)	(d)
	Average	Total Number of Shares Purchased as Part of Publicly Announced	Dollar Maximum Value of Shares That May Yet be Purchased Under the

<b>Period</b>	<b>Total Number of Shares</b>	<b>Price Paid per Share(1)</b>	<b>Plans or Programs</b>	<b>Plans or Programs(2)</b>
7/1/08 7/31/08	153,277	\$ 43.17	105,000	\$ 23,781,637
8/1/08 8/31/08	35,400	\$ 40.95	35,400	\$ 22,332,097
9/1/08 9/30/08	26,730	\$ 37.50	0	\$ 22,332,097
<b>Total</b>	<b>215,407</b>	<b>\$ 42.10</b>	<b>140,400</b>	<b>\$ 22,332,097</b>

- (1) The purchases in this column include (i) shares repurchased as part of our publicly announced program, (ii) 30,619 shares that 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 related to the vesting of employee stock options or restricted stock awards, and (iii) and 40,388 shares that had previously been issued to former stockholders of InnoRx, Inc.
- (2) On November 15, 2007, our Board of Directors announced the authorization of the repurchase of \$35 million of our outstanding common stock. As of September 30, 2008, we have repurchased 297,900 shares at an average price of \$42.52 per share. Under the current authorization, the Company has \$22.3 million available for authorized share repurchases as of September 30, 2008. The repurchase authorization does not have an expiration date.

**Table of Contents**

**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 30, 2003 and assumes reinvestment of dividends.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA.**

The data presented below as of and for the fiscal years ended September 30, 2008, 2007 and 2006 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, 2005 and 2004 are derived from our audited financial statements that are not included in this report. The information set forth below should be read in conjunction with the Company's consolidated financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 of this report and our consolidated financial statements and related notes beginning on page F-1 and other financial information included in this report.

	<b>Fiscal Year</b>				
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
	<b>(Dollars in thousand, except per share data)</b>				
<b>Statements of Operations Data:</b>					
Total revenue	\$ 97,051	\$ 73,164	\$ 69,884	\$ 62,381	\$ 49,738
Operating income	27,261	9,899	36,163	2,985	10,474
Net income (loss)	14,739	3,347	20,334	(8,246)	7,242
Diluted net income (loss) per share	0.80	0.18	1.09	(0.45)	0.41
<b>Balance Sheet Data:</b>					
Cash	\$ 15,376	\$ 13,812	\$ 3,751	\$ 3,921	\$ 2,709
Short-term and long-term investments	56,602	56,413	102,820	69,398	60,594
Total assets	191,028	171,331	157,402	124,225	109,587
Retained earnings	66,439	51,620	48,273	27,914	36,161
Total stockholders' equity	141,806	130,922	145,203	115,581	94,310

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

The following discussion and analysis of our financial condition, results of operations and trends for the future should be read together with Selected Financial Data and our audited 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 Forward-Looking Statements and Risk Factors. Our actual future financial condition and results of operations may differ materially from those anticipated in the forward-looking statements.

**Overview**

SurModics is a leading provider of drug delivery and surface modification technologies to the healthcare industry. In November 2008, we announced that we were changing our organizational structure so that we will now be organized into four clinically and market focused business units: Cardiovascular, Ophthalmology, In Vitro Technologies, and Brookwood Pharmaceuticals. We believe that this structure will improve the visibility, marketing and adoption of the Company's broad array of technologies within specific markets and help its customers in the medical device, pharmaceutical and life science industries solve unmet clinical needs. In addition, a new centralized research and development function has been formed to serve the needs of the Company's clinically and market focused business units. Brookwood Pharmaceuticals' research and development operations will remain unchanged. Because this change occurred in fiscal 2009 and is not useful in explaining our fiscal 2008 results, we will primarily describe our business below as it operated in fiscal 2008.

Until November 2008, the Company was 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 was responsible for technologies dedicated to site-specific delivery of drugs; (2) the Ophthalmology business unit, which was 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



**Table of Contents**

technologies to companies developing improved pharmaceutical products. The Hydrophilic and Other operating segment consisted of three business units: (1) the Hydrophilic Technologies business unit, which focused on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) the Regenerative Technologies business unit, which developed 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 was 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 business unit, which includes our microarray slide products, our stabilization products, antigens and substrates for immunoassay diagnostic tests, our *in vitro* diagnostic format technology and our synthetic ECM cell culture products.

Revenue in each of our operating segments in fiscal 2008 is derived from three primary sources: (1) royalties and license fees from licensing our patented drug delivery and surface modification 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 polymers and reagent chemicals, stabilization products, antigens and substrates and microarray slides to the diagnostics and biomedical research industry; 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 have treated 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. We will be reviewing our segment reporting for fiscal 2009 as a result of the changes to our organizational structure in November 2008.

In June 2007, we signed a collaborative research and license agreement with Merck & Co., Inc. ( 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 had the potential to 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.

In September 2008, Merck gave notice that it was terminating the collaborative research and license agreement, as well as the supply agreement entered into in June 2007, following a strategic review of Merck's business and product development portfolio. The termination is expected to be effective December 16, 2008. We anticipate that the revenue deferred under the accounting treatment required by Emerging Issues Task Force Issue (EITF) No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, totaling \$34.8 million as of September 30, 2008, will be recognized in the first quarter of fiscal 2009. In addition, we anticipate recognizing a \$9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program. This program terminated 30 days following the notice given in September 2008.

In July 2007, we acquired Brookwood Pharmaceuticals, Inc. ( Brookwood ) 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. Our consolidated financial statements have included the operating results of Brookwood since the date of the acquisition.

## **Table of Contents**

In August 2007, we acquired all of the assets of BioFX Laboratories, Inc. ( BioFX ) by paying cash to BioFX stockholders. Based in Owings Mills, Maryland, BioFX is a leading provider of innovative reagents and substrates for the biomedical research and medical diagnostic markets. BioFX is a wholly owned subsidiary of SurModics and is reported as part of our In Vitro operating segment. Our consolidated financial statements have included the operating results of BioFX since the date of the acquisition.

In November 2008, we acquired a portfolio of intellectual property and collaborative drug delivery projects from PR Pharmaceuticals, Inc., a drug delivery company specializing in injectable, biodegradable sustained release formulations. The proprietary technologies we acquired complement and enhance the existing portfolio of drug delivery capabilities available from SurModics and Brookwood by providing a broader toolkit for protein delivery and the ability to use smaller gauge needles for microparticle injections. In addition, the multiple customer development programs we assumed complemented the diversified portfolio of customer projects at Brookwood and we believe will further leverage the investment we are making in cGMP manufacturing facilities.

## **Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations is based upon our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements is 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). Actual results may differ from these estimates under different assumptions or conditions and could materially impact our results of operations. We believe the following are critical areas in the application of our accounting policies that currently affect our financial condition and results of operations.

*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) collectability 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. Minimum royalty fees are recognized in the period earned. 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, collectability 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 30-45 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 EITF 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 except for services related to the Merck agreement, which are recognized as incurred. 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.

*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's acquisitions. Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment in accordance with Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets. Under certain situations, interim

**Table of Contents**

impairment tests may be required if events occur or circumstances change indicating that the carrying amount of goodwill may be impaired.

Evaluating goodwill for impairment involves the determination of the fair value of our reporting units in which we have recorded goodwill. A reporting unit is a component of an operating segment for which discrete financial information is available and reviewed by management on a regular basis. SurModics has determined that its reporting units are its Brookwood business unit, a component of the Drug Delivery operating segment, and the In Vitro operating segment.

We performed our annual impairment test of goodwill in the fourth quarter of fiscal 2008 and did not record an impairment charge. In evaluating whether goodwill was impaired, we compared the fair value of reporting units to which goodwill is assigned to their carrying value (step one of the impairment test). In calculating fair value, we used a valuation technique based on multiples of revenue and book value for comparable companies since the technique is consistent with the objective of measuring fair value. The comparison companies selected have operations comparable to each of the SurModics reporting units for which indefinite-lived assets were being evaluated.

*Investments.* Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities and are classified as available-for-sale or held-to-maturity at September 30, 2008. 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. 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 in accordance with Statement of Financial Accounting Standards No. 115,

Accounting for Certain Investments in Debt and Equity Securities. Our evaluation of the available-for-sale investments resulted in loss recognition of \$4.3 million related to our investment in OctoPlus N.V. (included in Other Assets in the Consolidated Balance Sheet) in fiscal 2008, as we determined the loss to be an other-than-temporary impairment based on a significant decline in the stock price. The impairment of the OctoPlus N.V. investment has resulted in a new cost basis. Investments which management has the intent and ability to hold to maturity are classified as held-to-maturity and reported at amortized cost. If there is an other-than-temporary impairment in the fair value of any individual security classified as held-to-maturity, the Company will write down the security to fair value with a corresponding adjustment to other income (loss). Interest on debt securities, including amortization of premiums and accretion of discounts, is included in other income (loss). Realized gains and losses from the sales of debt securities, which are included in other income (loss), are determined using the specific identification method.

*Income tax accruals and valuation allowances.* When preparing the Consolidated Financial Statements, we are required to estimate the income taxes in each of the jurisdictions in which we operate. This process involves estimating the actual current tax obligations based on expected income, statutory tax rates and tax planning opportunities in the various jurisdictions. In the event there is a significant unusual or one-time item recognized in the results of operations, the tax attributable to that item would be separately calculated and recorded in the period the unusual or one-time item occurred. Tax law requires certain items to be included in our tax return at different times than the items are reflected in our results of operations. As a result, the annual effective tax rate reflected in our results of operations is different than that reported on our tax return (i.e., our cash tax rate). Some of these differences are permanent, such as expenses that are not deductible in our tax return, and some are temporary differences that will reverse over time, such as depreciation expense on capital assets. These temporary differences result in deferred tax assets and liabilities, which are included in our Consolidated Balance Sheets. Deferred tax assets generally represent items that can be used as a tax deduction or credit in our tax return in future years for which we have already recorded the expense in our Consolidated Statements of Income. We must assess the likelihood that our deferred tax assets will be recovered from future taxable income, and to the extent we believe that recovery is not likely, we must establish a valuation allowance against those deferred tax assets. Deferred tax liabilities generally represent items for which we

have already taken a deduction in our tax return, but we have not yet recognized the items as expense in our results of operations. Significant judgment is required in evaluating our tax positions, and in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our deferred tax assets. We had total deferred tax assets in excess of total deferred tax liabilities of \$12.2 million as of September 30, 2008 and \$7.0 million as of September 30, 2007, including valuation allowances of \$3.4 million as of September 30, 2008 and \$1.8 million as

**Table of Contents**

of September 30, 2007. The valuation allowances related to impairment losses on investments and were recorded because the Company does not currently foresee future capital gains within the allowable carry-forward and carry-back periods to offset these capital losses when they are recognized. As such, no tax benefit has been recorded in the Consolidated Statements of Income.

The Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109, on October 1, 2007. The new standard defines the threshold for recognizing the benefits of tax return positions in the financial statements as more-likely-than-not to be sustained by the taxing authorities based solely on the technical merits of the position. If the recognition threshold is met, the tax benefit is measured and recognized as the largest amount of tax benefit that, in our judgment, is greater than 50 percent likely to be realized. The total gross amount of unrecognized tax benefits as of September 30, 2008 was \$1.5 million, excluding accrued interest and penalties. \$1.3 million of these tax benefits would affect our effective tax rate if recognized. Interest and penalties recorded for uncertain tax positions are included in our income tax provision. As of September 30, 2008, \$0.4 million of interest and penalties was accrued, excluding the tax benefits of deductible interest. Fiscal years 2005, 2006 and 2007 remain subject to examination by federal tax authorities. Tax returns for state and local jurisdictions for fiscal years 2003 through 2007 remain subject to examination by state and local tax authorities. In the event that we have determined not to file tax returns with a particular state or local jurisdiction, all years remain subject to examination by the tax authorities. The ultimate outcome of tax matters may differ from our estimates and assumptions. Unfavorable settlement of any particular issue would require the use of cash and could result in increased income tax expense. Favorable resolution could result in reduced income tax expense. Within the next 12 months, we do not expect that our unrecognized tax benefits will change significantly. See Note 5 to the Consolidated Financial Statements for further information regarding the impact of adopting this new standard as well as changes in unrecognized tax benefits during fiscal 2008.

**Results of Operations***Years Ended September 30, 2008 and 2007*

<i>(Dollars in thousands)</i>	<b>Fiscal 2008</b>	<b>Fiscal 2007</b>	<b>Increase</b>	<b>% Change</b>
Revenue:				
Drug Delivery	\$ 43,938	\$ 26,488	\$ 17,450	66%
Hydrophilic and Other	31,864	26,493	5,371	20%
<i>In Vitro</i>	21,249	20,183	1,066	5%
Total revenue	\$ 97,051	\$ 73,164	\$ 23,887	33%

*Revenue.* Fiscal 2008 revenue was \$97.1 million, an increase of \$23.9 million or 33% from fiscal 2007. 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 66% to \$43.9 million in fiscal 2008. The increase in total revenue reflects a significant increase in research and development fees, which was partially offset by an 8% decrease in royalties and license fees related to drug delivery and ophthalmology projects. Brookwood contributed \$20.6 million and \$2.4 million in revenue for fiscal 2008 and 2007, respectively. Fiscal 2007 results included Brookwood for only two months, as the acquisition closed on July 31, 2007.

Drug Delivery derives a substantial portion of its revenue from royalties and license fees and product sales attributable to Cordis Corporation, a subsidiary of Johnson & Johnson, on its CYPHER<sup>®</sup> Sirolimus-eluting Coronary Stent. The CYPHER<sup>®</sup> stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions.

The decrease in Drug Delivery royalties and license fees principally reflects a 19% decrease in royalty revenue from Cordis as a result of lower CYPHER<sup>®</sup> sales, partially offset by 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 \$11 million in license fees from Merck in association with the collaborative



**Table of Contents**

research and license agreement we signed in fiscal 2007. However, we recognized as revenue only a small portion of these fees, as well as the initial \$20 million license fee from Merck paid in fiscal 2007, as we are amortizing these amounts over the estimated economic life of the technology we licensed to Merck. Fiscal 2008 sales of reagent chemicals (chemicals that we manufacture and sell to licensees for coating their medical devices) to Cordis decreased significantly compared with the prior year.

The CYPHER<sup>®</sup> stent, from which we derive a substantial amount of our Drug Delivery revenue, faces continuing competition from drug-eluting stents manufactured by Boston Scientific, Medtronic and Abbott. These stents compete directly with the CYPHER<sup>®</sup> stent both domestically and internationally. The Company also receives a royalty on the Medtronic Endeavor<sup>®</sup> drug-eluting stent, but the associated royalty revenue is reflected in the Hydrophilic and Other segment. In addition to competition among the various players, the total size of the drug-eluting stent market has decreased significantly in the past two years 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 due to lower CYPHER<sup>®</sup> stent sales as a result of the overall market contraction and the ongoing and expected future competition. We anticipate that quarterly royalty revenue from the CYPHER<sup>®</sup> stent may be volatile throughout fiscal 2009 and beyond as the various marketers of drug-eluting stents continue competing in the marketplace and as others enter the marketplace.

The inclusion of Brookwood, which contributed to Drug Delivery revenue for only two months in fiscal 2007, impacted the overall revenue and revenue mix in fiscal 2008, as a substantial majority of Brookwood's revenue is comprised of research and development fees. Our research and development revenue increased 344% to \$22.0 million in fiscal 2008 and it constituted a majority of total Drug Delivery revenue.

In September 2008, following a strategic review of its business and product development portfolio, Merck gave notice that it was terminating the collaborative research and license agreement as well as the supply agreement entered into in June 2007. The termination is expected to be effective December 16, 2008. We anticipate that the revenue deferred under the accounting treatment required by Emerging Issues Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, totaling \$34.8 million as of September 30, 2008, will be recognized in the first quarter of fiscal 2009. In addition, we anticipate recognizing a \$9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program. This program terminated 30 days following the notice given in September 2008.

*Hydrophilic and Other.* Hydrophilic and Other revenue increased 20% to \$31.9 million, primarily as a result of 21% growth in royalties and license fees and 60% growth in research and development fees. 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 5% to \$21.2 million. The increase was mainly attributable to increased product sales, principally as a result of the addition of \$4.6 million of BioFX products sold during the year as compared with BioFX product sales of \$0.5 million in fiscal 2007. Operating results of BioFX have been included in the Company's consolidated financial statements since August 14, 2007. The product sales increase was substantially offset by a 27% decrease in royalties and license fees. Royalties and license fees likely will decrease in fiscal 2009. In Vitro derives a significant percentage of its revenue from GE Healthcare and Abbott Laboratories. Royalty revenue generated under our diagnostic format patent license agreement with Abbott Laboratories (the Abbott Agreement) is expected to cease following the expiration of the licensed patents in December 2008. Consistent with our revenue recognition practices, royalty revenue is recognized as licensees report it to us, which typically occurs one quarter following the sales of the licensee's products. Accordingly, we expect royalties generated under the Abbott

Agreement to extend into the second quarter of fiscal 2009. Royalty revenue from GE Healthcare decreased 76% in fiscal 2008 compared with fiscal 2007 as a result of the transition to a non-exclusive license in January 2008. We re-acquired the CodeLink® microarray slide product line from GE Healthcare in September 2008. This will eliminate future royalty revenue from this customer for these products.

*Product costs.* Product costs were \$8.5 million in fiscal 2008, a 52% increase from the prior year. Overall product margins averaged 58%, compared with 59% reported last year. The slight decrease in product margins

**Table of Contents**

reflects the mix of products sold in the period (in particular, some of our microarray slides and Brookwood polymer products carry lower margins than our reagent and stabilization products).

*Research and development expenses.* Research and development ( R&D ) expenses were \$40.5 million, an increase of 42% compared with fiscal 2007. The increase principally reflects the addition of Brookwood and BioFX to our operations, which together incurred total R&D expenses of \$13.9 million in fiscal 2008 compared with \$2.0 million for fiscal 2007. Fiscal 2007 amounts include Brookwood and BioFX from their respective acquisition dates through September 30, 2007. In addition compensation expenses have increased as we have added personnel to support customer and internal development projects. As of September 30, 2008, our R&D headcount has increased by 15 or 9%, growing from 159 employees to 174, compared with September 30, 2007. We have also incurred higher costs related to our internal development projects, and \$1.6 million of out-of-pocket expenses were incurred in connection with our Merck projects, for which we are reimbursed.

*Selling, general and administrative expenses.* Selling, general and administrative (SG&A) expenses were \$20.8 million, an increase of 53% compared with fiscal 2007. The increase principally reflects the addition of Brookwood and BioFX to our operations, which together incurred total SG&A expenses of \$4.9 million in fiscal 2008 compared with \$0.7 million in fiscal 2007. Fiscal 2007 amounts include Brookwood and BioFX from their respective acquisition dates through September 30, 2007. Our SG&A stock-based compensation costs were \$0.7 million higher in fiscal 2008 principally associated with second quarter transitions on our Board of Directors.

*Other income (loss), net.* Other loss was \$0.4 million in fiscal 2008, compared with income of \$4.8 million in fiscal 2007. The fiscal 2008 loss primarily reflects a \$4.3 million impairment loss on our investment in OctoPlus N.V., which we recorded in the fourth quarter of fiscal 2008, based on a significant decline in the stock price. Income from investments was \$3.3 million in fiscal 2008, compared with \$4.8 million in fiscal 2007. The decrease primarily reflects lower investment balances and lower yields generated from our investment portfolio as interest rates declined over the past twelve months, as well as the early repayment of a note receivable associated with the fiscal 2005 sale of our contract manufacturing facility located in Bloomington, Minnesota.

*Income tax expense.* The income tax provision was \$12.2 million in fiscal 2008, compared with \$11.3 million in fiscal 2007. The effective tax rate in fiscal 2008 was 45.2%. Excluding the impact of the \$4.3 million impairment loss in fiscal 2008 (since the Company does not currently foresee offsetting capital gains that could offset this capital loss, no tax benefit has been recorded), the effective tax rate was 38.9%. 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%. The increase in the effective tax rate, adjusted for the one-time items noted, reflects an increase in state tax contingency reserves in fiscal 2008 and a release of federal tax reserves in fiscal 2007.

**Years Ended September 30, 2007 and 2006**

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

*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.

**Table of Contents**

Drug Delivery derives a substantial portion of its revenue from royalties and license fees and product sales attributable to Cordis Corporation, a subsidiary of Johnson & Johnson, on its CYPHER<sup>®</sup> Sirolimus-eluting Coronary Stent. The decrease in drug delivery royalties and license fees principally reflects decreased royalty revenue from Cordis as a result of lower CYPHER<sup>®</sup> sales. Partially offsetting the decrease attributable to CYPHER<sup>®</sup> 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, and are amortizing the remaining amounts over the estimated economic life of the technology we licensed to Merck. As a result of Merck's September 2008 notice of termination, we anticipate recognizing these amounts in the first quarter of fiscal 2009. 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.

*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.

*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.

*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 in fiscal 2006. 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 manufacturing space at our Eden Prairie facility.

*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 and BioFX 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.

*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 and BioFX to our operations, higher compensation expenses, and increased incentive and stock-based compensation.

*Purchased in-process research and development.* In July 2007, we acquired all of the assets 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 management.

*Other income (loss), 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

**Table of Contents**

capital gains that could offset this capital loss, no tax benefit has been recorded), the effective tax rate was 38.2% in fiscal 2006.

**Liquidity and Capital Resources**

As of September 30, 2008, the Company had working capital of \$34.3 million, of which \$24.6 million consisted of cash, cash equivalents and short-term investments. Working capital increased \$6.2 million from the September 30, 2007 level driven principally by lower accrued income taxes payable. Our cash, cash equivalents and short-term and long-term investments totaled \$72.0 million at September 30, 2008, a slight increase from \$70.2 million at September 30, 2007. The Company's investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. The Company's policy requires that no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while meeting or exceeding a benchmark (Merrill Lynch 1-3 Year Government-Corporate Index) total rate of return. Management plans to continue to direct its investment advisors to manage the Company's investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments.

The Company had positive cash flows from operating activities of approximately \$39.8 million in fiscal 2008, compared with \$50.7 million in fiscal 2007. The following table depicts our cash flows from operations for each of fiscal 2008 and 2007:

	<b>For the Years Ended September 30, 2008                      2007 (Dollars in thousands)</b>	
Net income	\$ 14,739	\$ 3,347
Depreciation and amortization	6,071	4,214
Stock-based compensation	9,652	10,312
Purchased in-process research and development		15,573
Impairment loss on investment	4,314	
Net other operating activities	(3,938)	(11,004)
Net change in deferred revenue	11,452	19,166
Net change in other operating assets and liabilities	(2,468)	9,107
Net cash provided by operating activities	\$ 39,822	\$ 50,715

While net income in fiscal 2008 increased compared with fiscal 2007, there was a reduction of cash provided by operating activities. License fees and milestone payments received from Merck in fiscal 2008 totaled \$11 million while in fiscal 2007 we received a \$20 million up-front license fee from Merck. The decline in cash flow from Merck as well as lower CYPHER® stent royalties contributed significantly to the decline in cash provided by operating activities in fiscal 2008.

We conduct a significant majority of our operations at our Eden Prairie, Minnesota headquarters and at our Brookwood subsidiary located in Birmingham, Alabama. In addition to our Eden Prairie and Birmingham locations, 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, and approximately 73,000 square feet of office and warehouse space in Eden Prairie. In November 2008, we announced the consolidation of all of our Eden Prairie personnel into our owned facility as part of our reorganization efforts. We estimate this consolidation will be substantially complete by the end of December 2008. In April 2008 we purchased a building for \$12.2 million which has approximately 286,000 square feet of office and warehouse space and is located near our present location in Birmingham, Alabama. The warehouse portion of this building is being renovated to support the development and CGMP manufacturing needs of our customers.



**Table of Contents**

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 and the remaining \$1 million installment was paid in June 2008.

In January 2005, we made an equity investment of approximately \$3.9 million in OctoPlus N.V., 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. 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 N.V. 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 treats the investment in OctoPlus N.V. as an available-for-sale investment rather than a cost method investment. In fiscal 2008 we incurred an impairment loss of \$4.3 million on our investment in OctoPlus N.V. based on the decline in fair value of the common stock. Our new cost basis in the investment is \$1.7 million.

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, and agreeing to issue up to an additional 600,068 shares if certain development and commercial milestones are met. As of September 30, 2008, we issued 120,009 shares of SurModics common stock to the shareholders of InnoRx upon the successful completion of two milestones. 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 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. SurModics made an additional equity investment totaling \$2.5 million, based upon successful completion of specified development milestones, in the third 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 20%. We account for our investments in Paragon and Apollo under the equity method. In October 2008, Paragon announced that it had restructured, moving from a limited liability company with seven subsidiaries to a single C-corporation named Nexeon MedSystems, Inc. We will continue to account for our investment in Paragon and Apollo under the equity method in the first quarter of fiscal 2009, as both entities report results to us on a one-quarter lag. Commencing with the second quarter of fiscal 2009 we expect to account for our investment in Nexeon under the cost method as our ownership is less than 20%.

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. In the second quarter of fiscal 2008, a milestone was achieved and \$2 million of additional purchase price was recorded as an increase to goodwill. Based in Birmingham, Alabama, Brookwood specializes 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. This acquisition has helped 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. See Note 3 to the consolidated financial statements for further information.

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. In the first quarter of fiscal 2008, a milestone was achieved and \$1.1 million of additional purchase price was recorded as an increase to goodwill. Based in Owings Mills, Maryland, BioFX is a leading manufacturer of substrates, a critical component of diagnostic test kits used to

**Table of Contents**

detect and signal that a certain reaction has taken place. The acquisition of BioFX has broadened our product portfolio in the in vitro diagnostics market. See Note 3 to the consolidated financial statements for further information.

In August 2008, we purchased approximately five acres of undeveloped land adjacent to our headquarters in Eden Prairie, Minnesota for approximately \$3.6 million, including a \$100,000 non-refundable deposit paid to the seller in August 2007.

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 approximately \$977,000 in cash in October 2007 and a second payment, from an escrow account, of approximately \$36,000 in cash in April 2008, which have been recorded as other income in fiscal 2008. We received an additional payment of approximately \$36,000 in cash in October 2008 as proceeds were released from an escrow account. 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.

In November 2007, our Board of Directors authorized the repurchase of up to \$35 million of the Company's common stock in open-market transactions, private transactions, tender offers, or other transactions. The repurchase authorization does not have a fixed expiration date. During fiscal 2008, we purchased 297,900 shares of common stock for \$12.7 million at an average price of \$42.52 per share. Under the current authorization, the Company has \$22.3 million remaining available for authorized share repurchases as of September 30, 2008.

As of September 30, 2008, we had \$236,000 of short-term debt in connection with our Brookwood subsidiary, which was paid off in November 2008. We do not have any other credit agreements although we periodically review accessibility to credit facilities. We believe that our existing cash, cash equivalents and investments, together with cash flow from operations, will provide liquidity sufficient to meet the below stated needs and for our operations for the next twelve months. There can be no assurance, however, that the Company's business will continue to generate cash flows at current levels, and the current disruption in the global financial markets may negatively impact the Company's ability to access the capital markets under current and future sources of financing in a timely manner and on attractive terms. Our anticipated liquidity needs for fiscal 2009 include but are not limited to the following: capital expenditures related to the recently acquired Alabama facility in the range of \$24 million to \$26 million; general capital expenditures in the range of \$3 million to \$7 million; contingent consideration payments associated with our November 2008 acquisition of certain assets from PR Pharmaceuticals in the range of \$3 million to \$6 million; contingent consideration payments related to our acquisitions of Brookwood and BioFX; and any amounts associated with the repurchase of common stock under the authorization discussed above.

**Off-Balance Sheet Arrangements**

As of September 30, 2008, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

**Contractual Obligations**

Presented below is a summary of contractual obligations and other minimum commercial commitments. See Note 6 to the consolidated financial statements for additional information regarding the below obligations and commitments.

<b>Less than</b>	<b>More than</b>
------------------	------------------

	<b>Total</b>	<b>1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>5 Years</b>
Operating leases	\$ 3,116	\$ 1,260	\$ 1,567	\$ 256	\$ 33

Our only material lease commitment relates to a leased facility in Eden Prairie, Minnesota near our Minnesota headquarters.

**Table of Contents**

**New Accounting Pronouncements**

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 in fiscal 2009. The Company has not determined the impact that 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 has determined that the adoption of this statement will not have a material effect on the Company s consolidated financial statements as the Company has elected not to account for any additional financial assets or financial liabilities at fair value.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations ( SFAS No. 141(R) ), which establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in an acquiree, including the recognition and measurement of goodwill acquired in a business combination. SFAS No. 141(R) is effective for the Company in fiscal 2010. Earlier adoption is prohibited and once adopted SFAS No. 141(R) will impact recognition and measurement of future business combinations.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company s consolidated financial statements.

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

The Company s investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company s investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company s investment policies, the primary market risk associated with these investments is interest rate risk. SurModics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A one percentage point increase in interest rates would result in an approximate \$951,000 decrease in the fair value of the Company s available-for-sale and held-to-maturity securities as of September 30, 2008, but no material impact on the results of operations or cash flows. Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company s inventory exposure is not material.

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The consolidated balance sheets as of September 30, 2008 and 2007 and the consolidated statements of income, stockholders equity and cash flows for each of the three years in the period ended September 30, 2008, 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 DISCLOSURE.***

None.

**Table of Contents**

**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) Management's Report on Internal Control Over Financial Reporting.* Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of September 30, 2008. 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's internal control over financial reporting.

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

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the internal control over financial reporting of SurModics, Inc. and subsidiaries (the Company) as of September 30, 2008, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, 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's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2008, 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, 2008 of the Company and our report dated December 8, 2008 expressed an unqualified opinion on those financial statements.



As discussed in Note 5 to the consolidated financial statements, on October 1, 2007, the Company adopted Statement of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109.

DELOITTE & TOUCHE LLP

Minneapolis, Minnesota  
December 8, 2008

**Table of Contents**

**3. Changes in Internal Controls.**

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

**ITEM 9B. OTHER INFORMATION.**

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

**PART III**

**ITEM 10. DIRECTORS, 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, Section 16(a) Beneficial Ownership Reporting Compliance and Corporate Governance Code of Ethics and Business Conduct, which appear in the Company's definitive Proxy Statement for its 2009 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 2008, Compensation Committee Report and Corporate Governance Committee and Board Meetings, which appear in the Company's definitive Proxy Statement for its 2009 Annual Meeting of Shareholders.

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

The information required by Item 12 is incorporated herein by reference to the sections entitled Principal Shareholders and Management Shareholdings, which appear in the Company's definitive Proxy Statement for its 2009 Annual Meeting of Shareholders.

**Equity Compensation Plan Information**

The following table provides information related to the Company's equity compensation plans in effect as of September 30, 2008:

(a)	(b) Weighted-Average	(c) Number of Securities Remaining Available for
-----	-------------------------	---

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b>
Equity compensation plans approved by shareholders	1,908,067(1)	\$ 34.43(1)	315,486(2)
Equity compensation plans not approved by shareholders	0	N/A	0
<b>Total</b>	<b>1,908,067</b>	<b>\$ 34.43</b>	<b>315,486</b>

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

(2) Includes 238,564 shares available for future issuance under the amended and restated 2003 Equity Incentive Plan and 76,922 shares available under the 1999 Employee Stock Purchase Plan.

**Table of Contents**

**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 2009 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 Independent Registered Public Accounting Firm, which appears in the Company's definitive Proxy Statement for its 2009 Annual Meeting of Shareholders.

**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:

	<b>Page (s)</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets</u>	F-2
<u>Consolidated Statements of Income</u>	F-3
<u>Consolidated Statements of Stockholders' Equity</u>	F-4
<u>Consolidated Statements of Cash Flows</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6-F-23

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.

**Table of Contents****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 )

By: /s/ Bruce J Barclay

Bruce J Barclay  
Chief Executive Officer

Dated: December 12, 2008

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 or her true and lawful attorneys-in-fact and agents, each acting alone, with full power of substitution and resubstitution, for him or her and in his or her 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 or she might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Bruce J Barclay Bruce J Barclay	President and Chief Executive Officer (principal executive officer)	December 12, 2008
/s/ Philip D. Ankeny Philip D. Ankeny	Senior Vice President and Chief Financial Officer (principal financial officer)	December 12, 2008
/s/ Mark A. Lehman Mark A. Lehman	Corporate Controller (principal accounting officer)	December 12, 2008
/s/ José H. Bedoya José H. Bedoya	Director	December 12, 2008

Edgar Filing: SURMODICS INC - Form 10-K

/s/ John W. Benson

Director

December 12, 2008

John W. Benson

/s/ Robert C. Buhrmaster

Director

December 12, 2008

Robert C. Buhrmaster

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gerald B. Fischer Gerald B. Fischer	Director	December 12, 2008
/s/ Kenneth H. Keller Kenneth H. Keller	Director	December 12, 2008
/s/ Susan E. Knight Susan E. Knight	Director	December 12, 2008
/s/ Kendrick B. Melrose Kendrick B. Melrose	Director	December 12, 2008
/s/ John A. Meslow John A. Meslow	Director	December 12, 2008

**Table of Contents**

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

**EXHIBIT INDEX TO FORM 10-K**

**For the Fiscal Year Ended September 30, 2008**

**SURMODICS, INC.**

**Exhibit**

- 2.1 Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 18, 2005, SEC File No. 0-23837.
- 2.2 Stock Purchase Agreement, dated July 31, 2007, between SurModics, Inc. and Southern Research Institute. incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated July 31, 2007, SEC File No. 0-23837.
- 3.1 Restated Articles of Incorporation, as amended incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarter ended December 31, 1999, SEC File No. 0-23837.
- 3.2 Restated Bylaws incorporated by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2007, SEC File No. 0-23837.
- 4 Rights Agreement, dated as of April 5, 1999, between the Company and Firstar Bank Milwaukee, NA., as Rights Agent, including as: Exhibit A Statement of Designation of Series A Preferred Stock of the Company; Exhibit B Summary of Rights to Purchase Shares of Series A Preferred Stock; and Exhibit C Form of Right Certificate incorporated by reference to Exhibit 1 to the Company's Registration of Securities on Form 8-A, SEC File No. 0-23837.
- 10.1\* Company's Incentive 1997 Stock Option Plan, including specimen of Incentive Stock Option Agreement incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
- 10.2\* Form of Restricted Stock Agreement under 1997 Plan incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
- 10.3\* Form of Non-qualified Stock Option Agreement under 1997 Plan incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
- 10.4 Adjusted License Agreement by and between the Company and Cordis Corporation effective as of January 1, 2003 incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2002, SEC File No. 0-23837.
- 10.5 Reagent Supply Agreement by and between the Company and Cordis Corporation effective as of January 1, 2003 incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2002, SEC File No. 0-23837.
- 10.6\* Form of officer acceptance regarding employment/compensation incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005, SEC File No. 0-23837.
- 10.7\* 2003 Equity Incentive Plan (as amended and restated December 13, 2005) (adopted December 13, 2005 by the board of directors and approved by the shareholders on January 30, 2006) incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed February 3, 2006, SEC File No. 0-23837.
- 10.8\*



Edgar Filing: SURMODICS INC - Form 10-K

Form of SurModics, Inc. 2003 Equity Incentive Plan Nonqualified Stock Option Agreement incorporated by reference to Exhibit 99.1 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.

- 10.9\* Form of SurModics, Inc. 2003 Equity Incentive Plan Incentive Stock Option Agreement incorporated by reference to Exhibit 99.2 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.10\* Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Agreement incorporated by reference to Exhibit 99.3 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.11\* Form of SurModics, Inc. 2003 Equity Incentive Plan Performance Share Award Agreement incorporated by reference to Exhibit 99.4 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.

**Table of Contents****Exhibit**

- 10.12\* Form of SurModics, Inc. 2003 Equity Incentive Plan Performance Unit Award (cash settled) Agreement incorporated by reference to Exhibit 99.5 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.13\* Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Unit Agreement incorporated by reference to Exhibit 99.6 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.14\* Form of SurModics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (cash settled) Agreement incorporated by reference to Exhibit 99.7 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.15\* Form of SurModics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (stock settled) Agreement incorporated by reference to Exhibit 99.8 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.16\* Change in Control Agreement with Bruce J Barclay, dated April 19, 2006 incorporated by reference to Exhibit 99.1 to the Company's Form 8-K filed April 25, 2006, SEC File No. 0-23837.
- 10.17\* Change in Control Agreement with Philip D. Ankeny, dated April 19, 2006 incorporated by reference to Exhibit 99.2 to the Company's Form 8-K filed April 25, 2006, SEC File No. 0-23837.
- 10.18 The Company's Board Compensation Policy, Amended and Restated in its entirety as of May 19, 2008.\*\*
- 10.19\* Change in Control Agreement with Paul A. Lopez, dated November 15, 2006 incorporated 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.
- 10.20\* Description of certain retirement benefits for Dale R. Olseth incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2006, SEC File No. 0-23837.
- 10.21+ Exclusive License and Research Collaboration Agreement with Merck & Co., Inc. dated June 26, 2007 incorporated 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.
- 10.22+ Supply Agreement with Merck & Co., Inc. dated June 26, 2007 incorporated 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.
- 10.23\* Employment Agreement of Arthur J. Tipton, Ph.D., dated July 31, 2007 incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2007.
- 10.24 Purchase Agreement with Vest Mykyng LLC, dated August 24, 2007 incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2007.
- 10.25 Real Estate Purchase and Sale Agreement dated March 11, 2008 by and between Belk, Inc. and Brookwood Pharmaceuticals, Inc. incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, SEC File No. 0-23837.
- 21 Subsidiaries of the Registrant.\*\*
- 23 Consent of Deloitte & Touche LLP.\*\*
- 24 Power of Attorney (included on signature page of this Form 10-K).\*\*
- 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.\*\*
- 31.2 Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.\*\*
- 32.1 Certification of Chief Executive Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.\*\*
- 32.2 Certification of Chief Financial Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.\*\*

\* Management contract or compensatory plan or arrangement

\*\* Filed herewith

+ Confidential treatment requested as to portions of the exhibit. Confidential portions omitted and provided separately to the Securities and Exchange Commission.

**Table of Contents**

**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, Inc. and subsidiaries (the Company) as of September 30, 2008 and 2007, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2008. These financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedules 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, Inc. and subsidiaries as of September 30, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2008, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 30, 2008, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 8, 2008 expressed an unqualified opinion on the Company's internal control over financial reporting.

As discussed in Note 5 to the consolidated financial statements, on October 1, 2007, the Company adopted Statement of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*.

DELOITTE & TOUCHE LLP

Minneapolis, Minnesota  
December 8, 2008

F-1

---

**Table of Contents****SurModics, Inc. and Subsidiaries****Consolidated Balance Sheets  
As of September 30**

	<b>2008</b>	<b>2007</b>
	<b>(In thousands, except share data)</b>	
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 15,376	\$ 13,812
Short-term investments	9,251	12,496
Accounts receivable, net of allowance for doubtful accounts of \$135 and \$40 as of September 30, 2008 and 2007, respectively	14,589	16,138
Inventories	2,651	2,497
Deferred tax asset	1,058	1,116
Prepays and other	3,584	1,836
Total Current Assets	46,509	47,895
Property and equipment, net	41,897	19,738
Long-term investments	47,351	43,917
Deferred tax asset	11,099	5,908
Intangible assets, net	16,870	18,399
Goodwill	18,001	15,686
Other assets, net	9,301	19,788
Total Assets	\$ 191,028	\$ 171,331
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 3,466	\$ 2,541
Accrued liabilities:		
Compensation	3,015	3,137
Accrued income taxes payable		6,227
Accrued other	1,407	1,050
Deferred revenue	4,335	5,586
Other current liabilities	303	1,311
Total Current Liabilities	12,526	19,852
Deferred revenue, less current portion	33,243	20,305
Other long-term liabilities	3,453	252
Total Liabilities	49,222	40,409

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; 18,030,270 and 18,164,980 shares issued and outstanding	901	909
Additional paid-in capital	74,573	76,670
Accumulated other comprehensive income (loss)	(107)	1,723
Retained earnings	66,439	51,620
Total Stockholders' Equity	141,806	130,922
Total Liabilities and Stockholders' Equity	\$ 191,028	\$ 171,331

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

**Table of Contents****SurModics, Inc. and Subsidiaries****Consolidated Statements of Income  
For the Years Ended September 30**

	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except net income per share)</b>		
Revenue			
Royalties and license fees	\$ 51,788	\$ 52,679	\$ 53,008
Product sales	20,052	13,543	11,172
Research and development	25,211	6,942	5,704
Total revenue	97,051	73,164	69,884
Operating Costs and Expenses			
Product	8,476	5,584	3,399
Research and development	40,498	28,465	20,391
Selling, general and administrative	20,816	13,643	9,931
Purchased in-process research and development		15,573	
Total operating costs and expenses	69,790	63,265	33,721
Income from Operations	27,261	9,899	36,163
Other Income (Loss)			
Investment income, net	3,329	4,844	4,210
Impairment loss on investment	(4,314)		(4,651)
Other income (loss), net	616	(75)	(157)
Other income (loss), net	(369)	4,769	(598)
Income Before Income Taxes	26,892	14,668	35,565
Income Tax Provision	(12,153)	(11,321)	(15,231)
Net Income	\$ 14,739	\$ 3,347	\$ 20,334
Basic net income per share	\$ 0.82	\$ 0.19	\$ 1.10
Diluted net income per share	\$ 0.80	\$ 0.18	\$ 1.09
Weighted Average Shares Outstanding			
Basic	18,026	18,033	18,527
Dilutive effect of outstanding stock options	304	184	192
Diluted	18,330	18,217	18,719

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

F-3

---



**Table of Contents****SurModics, Inc. and Subsidiaries****Consolidated Statements of Stockholders Equity  
For the Years Ended September 30, 2008, 2007 and 2006**

	Common Stock		Additional Paid-in Capital	Unearned Compensation	Accumulated Other Comprehensive Income		Retained Earnings	Total Stockholders Equity
	Shares	Amount			(Loss)			
Balance September 30, 2005	18,536	\$ 927	\$ 89,721	\$ (2,621)	\$ (360)	\$ 27,914	\$ 115,581	
Components of comprehensive income, net of tax:								
Net income						20,334	20,334	
Unrealized holding losses on available-for- sale securities arising during the period					(31)		(31)	
Add reclassification for losses included in net income, net of tax benefit of \$59					98		98	
Comprehensive income							20,401	
Issuance of common stock	75	4	395				399	
Common stock options exercised, net	169	8	2,854				2,862	
Purchase of common stock to pay employee taxes	50	3	(3)					
Tax benefit from exercise of stock options			249				249	
Stock-based compensation			5,526				5,526	
Accounting change due to adoption of SFAS 123R			(2,461)	2,621		25	185	
Balance September 30, 2006	18,830	942	96,281		(293)	48,273	145,203	
Components of comprehensive income, net of tax:								
Net income						3,347	3,347	
Unrealized holding gains on available-for-sale securities arising during the period					1,999		1,999	

Add reclassification for losses included in net income, net of tax benefit of \$10				17		17
Comprehensive income						5,363
Issuance of common stock	14	1	457			458
Common stock repurchased	(1,008)	(50)	(34,980)			(35,030)
Common stock options exercised, net	217	11	4,778			4,789
Purchase of common stock to pay employee taxes	112	5	(379)			(374)
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	1,723	51,620	130,922
Components of comprehensive income, net of tax:						
Net income					14,739	14,739
Unrealized holding losses on available-for-sale securities arising during the period				(5,882)		(5,882)
Add reclassification for losses included in net income, net of tax provision of \$167				4,052		4,052
Comprehensive income						12,909
Issuance of common stock	16	1	516			517
Common stock repurchased	(342)	(17)	(13,954)			(13,971)
Common stock options exercised, net	114	4	2,514			2,518
Purchase of common stock to pay employee taxes	77	4	(1,678)			(1,674)
Tax benefit from exercise of stock options			1,081			1,081
Stock-based compensation			9,652			9,652
Other			(228)			(228)
Accounting change due to adoption of FIN 48					80	80
Balance September 30, 2008	18,030	\$ 901	\$ 74,573	\$ (107)	\$ 66,439	\$ 141,806

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



**Table of Contents****SurModics, Inc. and Subsidiaries****Consolidated Statements of Cash Flows  
For the Years Ended September 30**

	<b>2008</b>	<b>2007</b>	<b>2006</b>
		<b>(In thousands)</b>	
<b>Operating Activities</b>			
Net income	\$ 14,739	\$ 3,347	\$ 20,334
Adjustments to reconcile net income to net cash provided by operating activities			
Depreciation and amortization	6,071	4,214	3,710
Loss on equity method investments and sales of investments	415	75	157
Amortization of (discount) premium on investments	70	(1,388)	(1,534)
Impairment loss on investment	4,314		4,651
Stock-based compensation	9,652	10,312	5,711
Purchased in-process research and development		15,573	
Deferred tax	(3,428)	(9,434)	(2,134)
Tax benefit from exercise of stock options	(1,081)	(466)	(249)
Loss (gain) on disposals of property and equipment	78	379	(169)
Change in operating assets and liabilities:			
Accounts receivable	1,548	1,940	(3,497)
Inventories	(154)	(850)	139
Accounts payable and accrued liabilities	(264)	2,594	(532)
Income taxes	(5,003)	5,501	5,799
Deferred revenue	11,452	19,166	2,489
Prepays and other	1,413	(248)	404
Net cash provided by operating activities	39,822	50,715	35,279
<b>Investing Activities</b>			
Purchases of property and equipment	(23,866)	(3,626)	(5,857)
Sales of property and equipment	32	37	238
Purchases of available-for-sale investments	(22,857)	(136,498)	(193,966)
Sales/maturities of available-for-sale investments	29,258	185,075	161,778
Purchases of held-to-maturity investments	(6,485)		
Investment in other strategic assets	(2,562)	(5,749)	(160)
Purchase of licenses and patents	(2,452)	(1,355)	(1,592)
Acquisitions, net of cash acquired	(3,219)	(49,112)	
Repayment of notes receivable	5,870	530	600
Other investing activities	(228)	(265)	
Net cash used in investing activities	(26,509)	(10,963)	(38,959)
<b>Financing Activities</b>			

Edgar Filing: SURMODICS INC - Form 10-K

Tax benefit from exercise of stock options	1,081	466	249
Issuance of common stock	3,037	5,247	3,261
Repurchase of common stock	(13,971)	(35,030)	
Issuance of common stock to pay employee taxes	(1,674)	(374)	
Repayment of notes payable	(222)		
Net cash (used in) provided by financing activities	(11,749)	(29,691)	3,510
Net change in cash and cash equivalents	1,564	10,061	(170)
Cash and Cash Equivalents			
Beginning of year	13,812	3,751	3,921
End of year	\$ 15,376	\$ 13,812	\$ 3,751
Supplemental Information			
Cash paid for income taxes	\$ 21,058	\$ 14,930	\$ 11,338
Noncash proceeds from sale of property	\$	\$	\$ 6,655
Noncash transaction acquisition of property, plant, and equipment on account	\$ 1,745	\$ 252	\$ 989

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

F-5

---

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

**Notes to Consolidated Financial Statements  
September 30, 2008 and 2007**

**1. Description**

SurModics, Inc. (the Company) develops, manufactures and markets innovative drug delivery and surface modification technologies for the healthcare industry. The Company's revenue is derived from three primary sources: (1) royalties and license fees from licensing its patented drug delivery and surface modification technologies and *in vitro* diagnostic formats to customers; (2) the sale of polymers and reagent chemicals to licensees; substrates, antigens and stabilization products to the diagnostics industry; microarray slides to the diagnostic and biomedical research markets; and synthetic ECM products to the cell culture market; and (3) research and development fees generated on projects for customers.

***Basis of Presentation***

The consolidated financial statements include all accounts and wholly-owned subsidiaries, and have been prepared in accordance with accounting principles generally accepted in the United States of America. All significant inter-company transactions have been eliminated.

**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 or held-to-maturity at September 30, 2008. There were no investments classified as held-to-maturity at September 30, 2007. 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. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other income (loss). This adjustment results in a new cost basis for the investment. Investments which management has the intent and ability to hold to maturity are classified as held-to-maturity and reported at amortized cost. If there is an other-than-temporary impairment in the fair value of any individual security classified as held-to-maturity, the Company will write down the security to fair value with a corresponding adjustment to other income (loss). Interest on debt securities, including amortization of premiums and accretion of discounts, is included in other income (loss). Realized gains and losses from the sales of debt securities, which are included in other income (loss), are determined using the specific identification method.



**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

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

	<b>2008</b>			
	<b>Original Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>
U.S. government obligations	\$ 18,440	\$ 91	\$ (87)	\$ 18,444
Mortgage-backed securities	10,147	46	(179)	10,014
Municipal bonds	11,022	153	(3)	11,172
Asset-backed securities	6,193	2	(171)	6,024
Corporate bonds	4,582	8	(33)	4,557
<b>Total</b>	<b>\$ 50,384</b>	<b>\$ 300</b>	<b>\$ (473)</b>	<b>\$ 50,211</b>

	<b>2007</b>			
	<b>Original Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>
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
<b>Total</b>	<b>\$ 56,357</b>	<b>\$ 252</b>	<b>\$ (196)</b>	<b>\$ 56,413</b>

The original cost and fair value of investments by contractual maturity at September 30, 2008 were as follows (*in thousands*):

	<b>Original Cost</b>	<b>Fair Value</b>
Debt securities due within:		
One year	\$ 9,261	\$ 9,250
One to five years	31,909	31,865
Five years or more	9,214	9,096
<b>Total</b>	<b>\$ 50,384</b>	<b>\$ 50,211</b>



The following table summarizes sales of available-for-sale securities for the years ended September 30, 2008, 2007 and 2006 (*in thousands*):

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Proceeds from sales	\$ 29,258	\$ 185,075	\$ 161,778
Gross realized gains	\$ 454	\$ 7	\$ 24
Gross realized losses	\$ (26)	\$ (34)	\$ (181)

At September 30, 2008, the amortized cost and fair market value of held-to-maturity debt securities was \$6.4 million and \$6.3 million, respectively. Investments in securities designated as held-to-maturity consist of tax-exempt municipal bonds and have maturity dates ranging between one and five years from September 30, 2008.

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)*****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*):

	<b>2008</b>	<b>2007</b>
Raw materials	\$ 1,308	\$ 1,241
Finished products	1,343	1,256
Total	\$ 2,651	\$ 2,497

***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 \$3.1 million, \$2.2 million and \$2.0 million for the years ended September 30, 2008, 2007 and 2006, respectively.

The September 30, 2008 and 2007 balances in construction-in-progress include the cost of enhancing the capabilities of the Company's Eden Prairie, Minnesota and Birmingham, Alabama facilities. 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.

In April 2008, the Company acquired a 286,000 square foot facility situated on 42 acres located in Birmingham, Alabama for \$12.2 million. The Company plans to remodel the existing facility to accommodate research and development, clinical manufacturing and commercial manufacturing of drug delivery products for pharmaceutical and biotechnology customers. The building is currently classified in construction-in-progress until renovation and remodeling is completed. The value of the land associated with the purchase is classified as part of the total land carrying value.

In August 2008, the Company also acquired approximately five acres of undeveloped land adjacent to its headquarters in Eden Prairie, Minnesota for approximately \$3.6 million. The value of the land purchase is classified as part of the total land carrying value.

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

	<b>Useful Life (In years)</b>	<b>2008</b>	<b>2007</b>
Land		\$ 7,409	\$ 1,699
Laboratory fixtures and equipment	3 to 10	15,767	13,673

Edgar Filing: SURMODICS INC - Form 10-K

Building and improvements	3 to 32	15,025	14,920
Office furniture and equipment	3 to 10	4,156	3,940
Construction-in-progress		16,931	1,244
Less accumulated depreciation		(17,391)	(15,738)
Property and equipment, net		\$ 41,897	\$ 19,738

***Other Assets***

Other assets consist principally of strategic investments and a note receivable. In fiscal 2008, the balance in other assets decreased primarily as a result of repayment of the note receivable and a write-down in the value of the Company's investment in OctoPlus N.V., offset by an increase in the Company's investment in Nexeon MedSystems, Inc., formerly Paragon Intellectual Properties, LLC.

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

In January 2005, the Company made an equity investment of approximately \$3.9 million in OctoPlus N.V., 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 N.V.. Also in October 2006, OctoPlus N.V. 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 N.V. 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, recorded in the other income (loss) section of the Consolidated Statements of Income, and result in a new cost basis for the investment. As of September 30, 2008, the investment in OctoPlus N.V. represents an ownership interest of less than 10%. The Company recognized in fiscal 2008 an impairment loss on the investment totaling \$4.3 million based on a significant decline in the stock price of OctoPlus N.V. as a result of current market conditions. The new cost basis in OctoPlus N.V. is \$1.7 million which is also the fair value of the investment. The Company recorded no realized gain or loss related to this investment 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's 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 was collateralized by the property. The terms of the note called for monthly installment payments of principal and interest at 6% with the remaining amount due and payable in September 2010. On January 14, 2008, the outstanding balance (including principal and accrued interest) of \$5.8 million was repaid to the Company in its entirety.

The Company 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, represents less than a 5% ownership interest.

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. SurModics made an additional equity investment totaling \$2.5 million, based upon successful completion of specified development milestones, in the third quarter of fiscal 2008. The investment in Paragon represents an ownership interest of approximately 5% and the investment in Apollo represents an ownership interest of 20%. In addition to the investments, the Company has licensed its Finale<sup>tm</sup> prohealing coating technology and provides development services on a time and materials basis to Apollo. The Company accounts for the investments in Paragon and Apollo under the

equity method. In October 2008, Paragon announced that it had restructured, moving from a limited liability company with seven subsidiaries to a single C-corporation named Nexeon MedSystems, Inc. SurModics will continue to account for the investments in Paragon and Apollo under the equity method in the first quarter of fiscal 2009, as both entities report results to us on a one-quarter lag. Commencing with the second quarter of fiscal 2009, SurModics expects to account for the investment in Nexeon under the cost method as the Company's ownership level is less than 20%.

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

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

	<b>2008</b>	<b>2007</b>
Investment in OctoPlus N.V.	\$ 1,714	\$ 8,762
Long-term portion of note receivable		5,158
Investment in Paragon and subsidiary	5,388	3,632
Investment in ThermopeutiX	1,185	1,185
Investment in Novocell	559	559
Other	455	492
Other assets, net	\$ 9,301	\$ 19,788

In the years ended September 30, 2008, 2007 and 2006, the Company recognized revenue of \$4,118,000, \$909,000 and \$399,000, respectively, from activity with companies in which it had a strategic investment.

***Intangible Assets***

Intangible assets consist principally of acquired patents and core technology, customer relationships, licenses, and trademarks. The Company recorded amortization expense of \$3.0 million, \$2.0 million, and \$1.7 million for the years ended September 30, 2008, 2007 and 2006, 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, an additional \$1 million installment was paid in fiscal 2007 and the remaining \$1 million installment was paid in fiscal 2008.

In fiscal 2007, the Company acquired Brookwood Pharmaceuticals, Inc. and BioFX Laboratories, Inc., which resulted in an increase to intangible assets. See Note 3 for further information regarding the acquisitions.

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

	<b>Useful Life (In years)</b>	<b>2008</b>	<b>2007</b>
Customer list	9-11	\$ 7,340	\$ 7,340
Abbott license	4	7,037	7,037
Core technology	8-18	6,930	6,933
Patents and other	7-20	3,398	1,988

Trademarks	580	580
Less accumulated amortization	(8,415)	(5,479)
Intangible assets, net	\$ 16,870	\$ 18,399

Based on the intangible assets in service as of September 30, 2008, estimated amortization expense for the next five fiscal years is as follows (*in thousands*):

2009	\$ 1,796
2010	1,378
2011	1,378
2012	1,378
2013	1,378

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

**Notes to Consolidated Financial Statements (Continued)**

***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's 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.

***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) collectability 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, Accounting for Revenue Arrangements with Multiple Deliverables, (EITF 00-21) and recognizes each separable deliverable as it is earned.

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

Taxes collected from customers and remitted to governmental authorities are excluded from revenue and amounted to \$309,000, \$170,000 and \$81,000 for the years ended September 30, 2008, 2007 and 2006, respectively.

***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's 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. Minimum royalty fees are recognized in the period earned.

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.

F-11

---

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

**Notes to Consolidated Financial Statements (Continued)**

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, collectability of the resulting receivable is reasonably assured and returns can be reasonably estimated. The Company's 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.

*Arrangements with multiple deliverables.* 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 can be determined, such 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. Revenue associated with arrangements with multiple deliverables totaled \$4.2 million and \$0.3 million in fiscal 2008 and 2007, respectively.

*Merck Agreement.* On June 27, 2007 the Company announced a license and research collaboration agreement with Merck & Co., Inc. ( 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's 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 in fiscal 2007 and additional license fees totaling \$11 million in fiscal 2008. In addition, the Company is paid for its activities in researching and developing the combination products. Research and development fees totaling \$5.8 million were billed in fiscal 2008. The Company has recognized out-of-pocket reimbursements, totaling \$1.6 million in fiscal 2008, as revenue in the period as the related costs are incurred as commensurate value is transferred to Merck in exchange for the reimbursement received.

The Company is recognizing revenue from the up-front license fee, additional license fees and research and development fees over the economic life of the technology licensed to Merck, which is 16 years. As of September 30, 2008 and 2007, \$34.8 million and \$20.6 million, respectively, of license fees and research and development fees remained in deferred revenue.

In September 2008, following a strategic review of Merck's business and product development portfolio, Merck gave notice to SurModics of its intent to terminate the collaborative research and license agreement as well as the supply agreement entered into in June 2007. The termination is expected to be effective December 16, 2008. The Company anticipates that the revenue deferred under the accounting treatment required by EITF 00-21 totaling \$34.8 million as of September 30, 2008, will be recognized in the first quarter of fiscal 2009; however, there is no certainty that the contract will terminate at that time. In addition, the Company anticipates recognizing a \$9 million

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

**Notes to Consolidated Financial Statements (Continued)**

milestone payment from Merck associated with the termination of the triamcinolone acetonide development program. This program terminated 30 days following the notice given in September 2008 and this revenue also is expected to be recognized in the first quarter of fiscal 2009 following effectiveness of Merck's termination.

***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, 2008 and 2007, the Company recorded deferred revenue of \$37.6 million and \$25.9 million, respectively.

Costs related to products and services delivered are recognized in the period revenue is recognized except for services related to the Merck agreement, which are recognized as incurred. 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.

***New Accounting Pronouncements***

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 in fiscal 2009. FASB Staff Position No. FAS 157-2 provides a deferral of SFAS No. 157 provisions for non-financial assets and liabilities until fiscal 2010. The Company is currently evaluating the impact 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 has determined that the adoption of this statement will not have a material effect on the Company's consolidated financial statements as the Company has elected not to account for any additional financial assets or financial liabilities at fair value.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations ( SFAS No. 141(R) ), which establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in an acquiree, including the recognition and measurement of goodwill acquired in a business combination. SFAS No. 141(R) is effective for the Company in fiscal 2010. Earlier adoption is prohibited and, once adopted, SFAS No. 141(R) will impact recognition and measurement of future business combinations.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company s consolidated financial statements.

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****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. In the second quarter of fiscal 2008, a milestone was achieved and \$2 million of additional purchase price was recorded as an increase to goodwill. 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, operates 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 of Brookwood have been included in the Company's consolidated financial statements since August 1, 2007.

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 as of July 31, 2007 (*in thousands*):

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

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.

As part of the acquisition, the Company recognized in-process research and development (IPR&D) of \$15.7 million. The IPR&D was expensed on the date of acquisition and relates to polymer-based drug delivery systems. The value assigned to IPR&D is related to projects for which the related products have not received commercial feasibility and have no future alternative use. The amount of purchase price allocated to IPR&D was based on estimating the future cash flows of each project and discounting the net cash flows back to their present values. The discount rate used was determined at the time of acquisition in accordance with accepted valuation methods. These methodologies include consideration of the risk of the project not achieving commercial feasibility. The research efforts ranged from 5% to 50% complete at the date of acquisition. The Company used a combination of the Relief from Royalty and Excess Earnings valuation methods to assess the fair value of the projects with a risk adjusted discount rate of 18%. The Company determined a combination of the two methods was appropriate based on the nature of the projects and future

cash flow streams. The research and development work performed is billed to customers, in most cases, using standard commercial billing rates which include a reasonable markup. Accordingly, the Company has no fixed cost obligations to carry projects forward. There have been no significant changes to the development plans for the acquired incomplete projects. Significant net cash inflows would commence with the launches of the projects or products.

*BioFX Laboratories, Inc.* On August 13, 2007, the Company acquired 100% of the capital stock of BioFX Laboratories, Inc. ( BioFX ), 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. In the

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

first quarter of fiscal 2008, a milestone was achieved and \$1.1 million of additional purchase price was recorded as an increase to goodwill. BioFX is a wholly owned subsidiary of SurModics, and operates within the In Vitro Technologies business unit within the In Vitro operating segment. Management believes the acquisition enhances the Company's technological position in the *in vitro* diagnostics market. Operating results of BioFX have been included in the Company's consolidated financial statements since August 14, 2007.

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 as of August 13, 2007 (*in thousands*):

Net working capital	\$ 1,182
Property and equipment	155
Trademarks and trade name	580
Core technology	530
Customer relationships	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 indefinite-lived assets and are not amortized. 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*).

	<b>Years Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Pro forma revenue	\$ 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	\$ 0.98	\$ 0.99
Pro forma diluted earnings per shares	\$ 0.98	\$ 0.98

*InnoRx, Inc.*



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 600,068 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.

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****4. Stockholders Equity**

Effective 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 to be recognized as an operating expense, based on their fair values, over the requisite service period. The Company's stock-based compensation expenses for the years ended September 30 were allocated as follows (*in thousands*):

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Product	\$ 161	\$ 96	\$ 91
Research and development	3,793	5,188	2,620
Selling, general and administrative	5,698	5,028	3,000
Total	\$ 9,652	\$ 10,312	\$ 5,711

As of September 30, 2008, approximately \$17.4 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.0 years.

***Stock Option Plans***

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 2008, 2007 and 2006 was \$14.85, \$17.42, and \$16.58, respectively. The assumptions used as inputs in the model for the years ended September 30 were as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Risk-free interest rates	2.80%	4.50%	4.70%
Expected life	4.6 years	5.4 years	4.8 years
Expected volatility	37%	45%	46%
Dividend yield	0%	0%	0%

The risk-free interest rate assumption was based on the U.S. Treasury's rates 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's experience. Expected volatility is based on the Company's stock price movement. Based on management's judgment, dividend rates are expected to be zero for the expected life of the options. The Company also estimates forfeitures of options granted, which are based on historical experience.

The Company's Incentive Stock Options ( ISO ) are granted at a price of at least 100% of the fair market value of the Common Stock on the date of the grant or 110% with respect to optionees who own more than 10% of the total combined voting power of all classes of stock. Options expire in seven years or upon termination of employment and are exercisable at a rate of 20% per year commencing one year after the date of grant. Nonqualified stock options are

granted at fair market value on the date of grant. Options expire in 7 to 10 years or upon termination of employment or service as a Board member. Board member options are 20% immediately vested with the remainder exercisable at rates of 20% per year commencing one year after date of grant. Employee options are exercisable at rates of 20% per year from date of grant, or ranging from 20% to 33% per year commencing one year after the date of grant depending on the particular award granted. The Company has authorized 2,400,000 shares for grant under the 2003 Equity Incentive Plan (the 2003 Plan ), of which 239,000 remain available for future awards. As of September 30, 2008, the aggregate intrinsic value of the option shares outstanding and option shares exercisable was \$3.1 million and \$2.5 million, respectively. At September 30, 2008, the average remaining contractual life of options outstanding and options exercisable was 4.5 and 3.5 years, respectively. The intrinsic value of options exercised during fiscal 2008, 2007 and 2006 was \$2.9 million, \$4.4 million and \$3.6 million, respectively.

F-16

---

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
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
Granted	392,917	41.86
Exercised	(163,297)	27.45
Forfeited	(108,250)	33.59
Outstanding at September 30, 2008	1,522,790	\$ 34.26
Exercisable at September 30, 2008	681,063	\$ 30.23

***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 157,129 common shares and is being charged to income over the vesting term. Stock compensation expense recognized related to these awards totaled \$2.2 million, \$1.2 million and \$879,000 during fiscal 2008, 2007 and 2006, respectively.

	<b>Number of Shares</b>	<b>Weighted Average 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
Granted	12,383	42.18
Vested	(40,336)	38.76
Forfeited	(21,109)	32.83
Balance at September 30, 2008	157,129	\$ 36.06

***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 expense of \$1.9 million has been recognized in fiscal 2008 associated with the fair value of 30,552 one-year Performance Shares and with the estimated fair value of 30,552 three-year Performance Shares awarded in May 2008 and 7,600 Performance Shares that vested for certain individuals that met various performance objectives. The Company recorded compensation expense of \$4.8 million in fiscal 2007 related to 132,375 Performance Shares and the Company recorded compensation expense of \$764,000 in fiscal 2006 related to 21,000 Performance Shares.

F-17

---

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)*****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, 2008 and 2007, there was \$355,000 and \$311,000 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 \$199,000, \$156,000 and \$162,000 during fiscal 2008, 2007 and 2006, respectively.

**5. Income Taxes**

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes ( SFAS 109 ). Under the asset and liability method prescribed in SFAS 109, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in this assessment. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date of such change.

Income taxes in the accompanying consolidated statements of income for the years ended September 30 are as follows (in thousands):

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Current provision:			
Federal	\$ 13,534	\$ 19,069	\$ 14,701
State and foreign	1,516	1,732	1,501
Total current provision	15,050	20,801	16,202
Deferred benefit:			
Federal	(2,832)	(8,573)	(774)
State	(65)	(907)	(197)
Total deferred benefit	(2,897)	(9,480)	(971)
Total provision	\$ 12,153	\$ 11,321	\$ 15,231



**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

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

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Amount at statutory federal income tax rate	\$ 9,387	\$ 5,067	\$ 12,440
Change due to:			
State taxes	715	736	720
Other	223	(241)	(102)
Stock-based compensation	239	262	365
Valuation allowance	1,589		1,808
Write-off of in-process research and development		5,497	
Income tax provision	\$ 12,153	\$ 11,321	\$ 15,231

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*):

	<b>2008</b>	<b>2007</b>
Depreciable assets	\$ (4,325)	\$ (4,279)
Deferred revenue	11,005	8,163
Accruals and reserves	523	296
Stock options	4,397	3,938
Impaired asset	3,318	1,733
Unrealized gains (losses) on investments	66	(1,067)
Other	571	48
Valuation allowance	(3,398)	(1,808)
Total deferred tax asset	12,157	7,024
Less current deferred tax asset	(1,058)	(1,116)
Noncurrent deferred tax asset	\$ 11,099	\$ 5,908

In fiscal 2008, the Company recorded a \$1.6 million valuation allowance against the potential capital loss created by the impairment of the Company's investment in OctoPlus N.V. (see Note 2). In fiscal 2006, the Company recorded a \$1.8 million valuation allowance against the potential capital loss created by the impairment of the Company's investment in Novocell (see Note 2). The valuation allowances were recorded because the Company does not currently foresee future capital gains within the allowable carry forward and carry back periods to offset these capital



losses when they were recognized. As such, no tax benefit has been recorded in the consolidated statements of operations.

The Company adopted the provisions of FASB Interpretation No. 48 ( FIN 48 ) Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109, on October 1, 2007. Upon adoption of FIN 48, the Company recorded a net \$80,000 benefit related to taxes, which was recorded as an increase to the October 1, 2007 beginning retained earnings balance. Unrecognized tax benefits are the differences between a tax position taken, or expected to be taken in a tax return, and the benefit recognized for accounting purposes pursuant to FIN 48. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (*in thousands*):

	<b>Amount</b>
Balance at October 1, 2007	\$ 1,120
Additions for tax positions for prior years	194
Additions for tax positions for current year	237
Settlements with taxing authorities	
Lapse of the statute of limitations	(11)
Balance at September 30, 2008	\$ 1,540

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

The total amount of unrecognized tax benefits including interest and penalties that, if recognized, would affect the effective tax rate as of October 1, 2007 and September 30, 2008, respectively, are \$1.1 million and \$1.3 million. Currently, the Company does not expect the liability for unrecognized tax benefits to change significantly in the next twelve months with the above balances classified in long-term liabilities. Interest and penalties related to unrecognized tax benefits are recorded in income tax expense. As of October 1, 2007, and September 30, 2008, respectively, a gross balance of \$436,000 and \$397,000 for interest and penalties has been accrued related to the unrecognized tax benefits balance.

The Company files tax returns, including returns for its subsidiaries, in the United States ( U.S. ) federal jurisdiction and in various state jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. As of the date of the adoption of FIN 48, U.S. tax returns for fiscal years ended September 30, 2005, 2006, and 2007 remained subject to examination by federal tax authorities. Tax returns for state and local jurisdictions for fiscal years ended September 30, 2003 through 2007 remain subject to examination by state and local tax authorities.

**6. Commitments and Contingencies**

*Litigation.* From time to time, the Company has been, and may become, involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. The outcomes of these legal actions are not within the Company's 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's consolidated earnings, financial condition or cash flows.

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's 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.

*Alabama Jobs Commitment.* In April 2008, the Company purchased a 286,000 square foot office and warehouse facility to support CGMP (Current Good Manufacturing Practice) manufacturing needs of customers and the anticipated growth of the Brookwood business. At the same time, Brookwood entered into an agreement with various governmental authorities to obtain financial incentives associated with creation of jobs in Alabama. Some of the

governmental agencies have recapture rights in connection with the financial incentives if the number of full-time employees are not generated by June 2012, with an extension to June 2013 if circumstances or events occur that are beyond the control of Brookwood or could not have been reasonably anticipated by Brookwood. As of September 30, 2008 Brookwood has received \$1.5 million in connection with the agreement, and the Company has recorded the payment in other long-term liabilities.

F-20

---

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

*Operating Leases.* The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the years ended September 30, 2008, 2007 and 2006 was \$773,000, \$140,000 and \$77,000, respectively. Annual commitments pursuant to operating lease agreements are as follows:

**Year Ending September 30,**

2009	\$ 1,260,000
2010	1,252,000
2011	315,000
2012	125,000
2013	131,000
Thereafter	33,000
Total Minimum Lease Payments	\$ 3,116,000

**7. Defined Contribution Plans**

The Company has 401(k) retirement and savings plans 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 \$539,000, \$356,000 and \$263,000 have been charged to income for the years ended September 30, 2008, 2007 and 2006, respectively. The expense increase in fiscal 2008 reflects the addition of employees eligible for this benefit as a result of the Brookwood acquisition.

**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. In November 2008, the Company announced it was changing its operational structure so that the Company will now be organized into four clinically and market focused business units: Cardiovascular, Ophthalmology, In Vitro Technologies, and Brookwood Pharmaceuticals. The Company believes that this structure will improve the visibility, marketing and adoption of the Company's broad array of technologies within specific markets and help its customers in the medical device, pharmaceutical and life science industries solve unmet clinical needs. In addition, a new centralized research and development function has been formed to serve the needs of the Company's clinically and market focused business units. Brookwood Pharmaceuticals research and development operations will remain unchanged.

Prior to November 2008, SurModics managed its business on the basis of the operating segments noted in the table below, which were comprised of the Company's seven business units. For the periods ending September 30, 2008, 2007 and 2006, 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

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

business unit, which includes the Company's microarray slide technologies, stabilization products, antigens and substrates for immunoassay diagnostics tests, its *in vitro* diagnostic format technology and its synthetic ECM cell culture products. See Note 9 for discussion about changes to the Company's operating segments in fiscal 2009.

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*):

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Operating segment:			
Drug Delivery	\$ 43,939	\$ 26,488	\$ 32,918
Hydrophilic and Other	31,864	26,493	22,233
<i>In Vitro</i>	21,248	20,183	14,733
Total revenue	\$ 97,051	\$ 73,164	\$ 69,884

***Major Customers***

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

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Johnson & Johnson	20%	33%	47%
Abbott Laboratories	10%	16%	12%

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:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Domestic	79%	81%	84%

Foreign	21%	19%	16%
---------	-----	-----	-----

## 9. Subsequent Events

In November 2008, Brookwood acquired a portfolio of intellectual property and collaborative drug delivery projects of PR Pharmaceuticals, Inc. for approximately \$3 million in cash. The agreement also provides for contingent payments of up to an additional \$6 million based on achievement of certain future events.

In November 2008, the Company announced changes to its organizational structure to improve the Company's ability to meet the growing needs of its customers while more effectively managing its operations and cost structure. In connection with the changes, the Company reduced its workforce by approximately five percent or approximately 15 employees. The Company expects to record a charge in the range of approximately \$1.5 million to \$2.3 million for severance and other costs related to the workforce reduction as well as costs associated with facilities consolidation. The Company estimates annual cost savings of approximately \$2 million once the reorganization is fully implemented.

The changes to the Company's business unit structure could have potential impact on operating segment data effective with the first quarter of fiscal 2009. Any changes in operating segments would include restatement of prior period data to conform with the current reporting structure.

Table of Contents**SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)**

In November and December 2008 (through December 8, 2008), the Company repurchased 396,348 shares of common stock for \$9.2 million at an average price of \$23.23.

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

The following is a summary of the unaudited quarterly results for the years ended September 30, 2008, 2007 and 2006 (in thousands, except per share data).

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
<b>Fiscal 2008</b>				
Revenue	\$ 23,829	\$ 25,707	\$ 24,276	\$ 23,239
Income from operations	7,571	7,181	7,184	5,325
Net income (loss)	5,646	5,107	4,800	(814)
Net income (loss) per share(1):				
Basic	0.31	0.28	0.27	(0.05)
Diluted	0.31	0.28	0.26	(0.05)
<b>Fiscal 2007</b>				
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(1):				
Basic	0.32	0.31	0.31	(0.78)
Diluted	0.32	0.31	0.31	(0.78)
<b>Fiscal 2006</b>				
Revenue	\$ 16,465	\$ 17,707	\$ 18,139	\$ 17,573
Income from operations	8,580	8,953	9,463	9,167
Net income	6,218	1,465	6,358	6,293
Net income per share(1):				
Basic	0.34	0.08	0.34	0.34
Diluted	0.33	0.08	0.34	0.34

(1) The sum of the quarterly earnings per share may not equal the annual earnings per share due to changes in the average shares outstanding.

In the fourth quarter of fiscal 2008, the Company recorded a \$4.3 million non-cash impairment loss on its investment in OctoPlus, N.V.

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, Inc.



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

F-23