SURMODICS INC
Form 10-K
December 11, 2009

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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, 2009

Commission file number 0-23837

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

Minnesota	**41-1356149**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
9924 West 74th Street **Eden Prairie, Minnesota** *(Address of Principal Executive Offices)*	**55344** *(Zip Code)*

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

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

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 o No þ

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

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

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

Large accelerated filer o	Accelerated filer þ
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

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, 2009 was approximately $197 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 7, 2009 was 17,471,760.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s definitive Proxy Statement for the Registrant s 2010 Annual Meeting of Shareholders are incorporated by reference into Part III.

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

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ITEM 1. *BUSINESS.*

Overview

SurModics, Inc. (referred to as SurModics, the Company, we, us, our and other like terms) is a leading provider 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 characteristics; 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 or balloon catheters) 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 minimally invasive devices (e.g., 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 believe that drug-eluting balloons may also show great promise, and 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 three-year follow-up during fiscal 2009. The clinical data suggest that the I-vation™ TA (triamcinolone acetonide) intravitreal implant is safe and well tolerated in patients with DME. In June 2007, we entered into a License and Research Collaboration Agreement and separate Supply Agreement with Merck & Co., Inc. (Merck) related to this technology. Under the terms of the Merck agreements, we received an up front license fee of $20 million and were eligible 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, as well as payment for our research and development activities. In September 2008, following a strategic review of its business and product portfolio, Merck terminated 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 became effective in December 2008. Merck s termination was not related to

safety or efficacy concerns with either the I-vation[tm] platform, generally, or the I-vation[tm] TA product, specifically. We continue to believe that if future clinical trials demonstrate longer term safety and efficacy of this product, I-vation[tm] TA could represent a viable commercial product.

On October 5, 2009, we entered into a License and Development Agreement with F. Hoffmann-La Roche, Ltd. (Roche) and Genentech, Inc., a wholly owned member of the Roche Group (Genentech). Under the terms of the

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License Agreement, Roche and Genentech has an exclusive license to develop and commercialize a sustained drug delivery formulation of Lucentis® (ranibizumab injection) utilizing SurModics proprietary biodegradable microparticles drug delivery system. Under the terms of the agreement, we received an up front licensing fee of $3.5 million, are eligible to receive potential payments of up to approximately $200 million in fees and milestone payments in the event of the successful development and commercialization of multiple products, and will be paid for development work done on these products. Roche and Genentech will have the right to obtain manufacturing services from SurModics. In the event a commercial product is developed, we will also receive royalties on sales of such products.

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., a leading provider of drug delivery technology primarily to the pharmaceutical industry. This acquisition created our SurModics Pharmaceuticals business unit (formerly known as our Brookwood 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. SurModics Pharmaceuticals customer projects target a number of key clinical indications in the diabetes, oncology, ophthalmology, cardiovascular, orthopedics, dermatology and central nervous system (CNS) markets, in addition to other fields. SurModics Pharmaceuticals generates revenue from research and development fees, polymer sales, and license fees.

In August 2007, we acquired 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 SurModics 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, pharmaceutical and biotechnology companies. 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™ 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.

Revenue from our licensing arrangements typically includes research and development revenue, license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees product sales. In addition to research and development services, we offer manufacturing services for clinical trial materials as well as for commercial products through the state-of-the-art Current Good Manufacturing Practice (cGMP) facility we are completing in Birmingham, Alabama. We have completed construction of the facility, and expect to fully complete cGMP qualification in the near future. 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 their products. We also sell a range of biodegradable polymers under our Lakeshore Biomaterials brand. Additionally, through our CodeLink® microarray slide product line, which we re-acquired from GE Healthcare in September 2008 along with the right to use the CodeLink® trademark, we manufacture and sell microarray slides to the diagnostic and biomedical research markets. Other immunoassay diagnostic products include a line of stabilization products used to extend the shelf life of immunoassay diagnostic

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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.

In November 2008, we changed our organizational structure from seven business units into four clinically and market focused business units. In addition, a new centralized research and development function was formed to serve the needs of our business units, other than the SurModics Pharmaceuticals business unit, which continues to maintain certain R&D operations. The following is a summary of our four business units: Cardiovascular, Ophthalmology, In Vitro Technologies, and SurModics Pharmaceuticals.

Cardiovascular, supporting the drug delivery and surface modification needs of our cardiovascular customers by providing drug delivery polymers and coating technologies including our advanced lubricity (slippery) coatings which ease placement and maneuverability of medical devices in the body.

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.

SurModics 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 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, and diagnostic format intellectual property.

We believe we have sufficient financial resources available to continue developing and growing our business. We intend to continue investing in research and development to advance our 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.

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

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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 existing drugs. 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 and improved patient convenience can result in improved patient compliance with a specified administration schedule, thereby further enabling the drug s effect to be optimized.

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. In addition, the ability to create sustained release formulations of drugs and biologics presents another opportunity for the Company.

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 at least three primary areas with strong future potential: (1) improving the function of a device which itself is necessary to treat the medical condition; (2) enabling drug delivery in cases where the device serves only as a vehicle to deliver a drug to a specific site in the body; and (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

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We offer customers several distinct polymer families for site specific drug delivery. Our Bravo™ Drug Delivery Polymer Matrix is utilized on the CYPHER® Sirolimus-eluting Coronary Stent from Cordis Corporation, a 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™ TA (triamcinolone acetonide) 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), when 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 a variety of methods including, but not limited to, 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.

Key differentiating characteristics of our coatings are their durability, 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 generally compatible with 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 SurModics Pharmaceuticals in July 2007, and certain proprietary technology from PR Pharmaceuticals, Inc. in November 2008, as well as internal development and other acquisition of biodegradable material technology, we offer customers drug delivery systems based on polymer-based microparticles and implants.

These systems enable the controlled delivery of a broad variety of drugs, ranging in size from small molecule drugs to larger molecule drugs such as peptides and proteins. Depending on the drug and application, our microparticles and implants can incorporate drugs for delivery over days, weeks or months.

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SurModics 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. A variety of commercially viable, proprietary 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 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 SurModics 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, weeks or 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. For example, in collaboration with Genentech we are developing a sustained release formulation of Lucentis™ (ranibizumab injection) using our proprietary biodegradable microparticle technology. 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 surface being coated.

Prohealing. Biologically based extracellular matrix (ECM) protein coatings for use in various applications are designed to improve and accelerate the healing of the tissue at or near the implant site through nature s own

healing mechanisms following procedures involving implantable medical devices. 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

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cells in the blood and vascular wall 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.

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 from 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.

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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.

Market Segment Served	Desired Surface Property and Examples of Applications
Interventional cardiology and vascular access	*Lubricity*: catheters, guidewires, delivery systems *Hemocompatibility*: vascular stents, catheters, distal protection devices *Drug/biologics delivery*: vascular stents, catheters *Prohealing*: vascular stents, vascular grafts
Cardiac rhythm management	*Lubricity*: pacemaker and defibrillator leads, electrophysiology devices *Hemocompatibility*: electrophysiology devices *Prohealing*: pacemaker and defibrillator leads *Drug/biologics delivery*: pacemaker and defibrillator leads
Cardiothoracic surgery	*Prohealing*: heart valves, septal defect repair devices *Hemocompatibility*: minimally invasive bypass devices, vascular grafts, ventricular assist devices
***In Vitro* Diagnostics**	*Lubricity*: microfluidic devices *Hemocompatibility*: blood/glucose monitoring devices, biosensors *Biomolecule immobilization*: DNA and protein arrays, protein attachment to synthetic extracellular matrix for cell culture applications
Interventional neurology and Neurosurgery	*Lubricity*: catheters, guidewires *Prohealing*: neuroembolic devices *Tissue engineering*: aneurysm repair devices
Urology and gynecology	*Lubricity*: urinary catheters, incontinence devices, ureteral stents, fertility devices *Drug/biologics delivery*: prostatic stents, microparticle injections *Tissue engineering*: female sterilization devices
Ophthalmology	*Drug/biologics delivery*: sustained drug delivery implants and microparticle injections
Orthopedics	*Cell growth and tissue integration*: bone and cartilage growth *Infection resistance*: orthopedic and trauma implants *Drug/biologics delivery*: orthopedic and trauma implants and microparticle injections
Metabolic disease	*Drug/biologics delivery*: microparticle injections *Tissue engineering*: cell encapsulation
Central nervous system disorders	*Drug/biologics delivery*: microparticle injections, polymer implants

Dermatology	*Drug/biologics delivery*: polymer implants *Tissue engineering*: tissue bulking, space filling materials

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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 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 SurModics Pharmaceuticals manufacturing facility in Alabama in order to meet the Current Good Manufacturing Practice (cGMP) manufacturing needs of our customers. We have completed construction of the facility, and expect to fully complete cGMP qualification in the near future.

We generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 62.1%, 53.4% and 72.0% of our total revenue in fiscal 2009, 2008 and 2007, respectively. Revenue from these licensing arrangements typically includes license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees product sales. We also generate revenue from sales of chemical reagents to licensees for use in their coating processes, and from polymer sales under our Lakeshore Biomaterials brand. Our In Vitro Technologies business unit generates revenue from: sales of stabilization products, substrates, antigens and microarray slides to diagnostics customers; and licensing our proprietary diagnostic formats for use in point-of-care testing. Product sales represented 15.9%, 20.7% and 18.5% of total revenue in fiscal 2009, 2008 and 2007, respectively. Research and development fees represented 22.0%, 26.0% and 9.5% of total revenue in fiscal 2009, 2008 and 2007, respectively. The increase in research and development revenue since 2007 reflects the addition of our SurModics 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 SurModics Pharmaceuticals business unit also supports many of our drug delivery customers by manufacturing microparticles and implants incorporating customers drugs through preclinical and clinical trials and by providing an option to manufacture products upon commercialization as well.

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

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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. Royalties are generally paid one quarter after the customer s actual product sales occur because of the delay in reporting sales by our licensees.

As of September 30, 2009, we had 103 licensed product classes (customer products utilizing SurModics technology) already on the market generating royalties and 108 customer product classes incorporating our technology pending regulatory approval. These 211 product classes are being sold or developed by 106 licensed customers. We signed 22 new licenses in fiscal 2009, compared with 23 in fiscal 2008.

Under most of our licensing agreements, we are required to keep the identity of our customers confidential unless they approve of such disclosure. Some of our licensed customers who allow the use of their name are: Abbott Laboratories, Boston Scientific Corporation, CardioMind, Inc., Conor Medsystems, LLC (a wholly owned subsidiary of Johnson & Johnson), Cook Medical, Cordis Corporation (a subsidiary of Johnson & Johnson), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott Laboratories), Elixir Medical Corporation, ev3 Inc., F. Hoffmann-La Roche, Ltd. and its subsidiary Genentech, Inc., Medtronic, Inc., Nexeon MedSystems, Inc. (formerly Paragon Intellectual Properties, LLC), NuPathe, Inc., OrbusNeich Medical, Inc., Spectranetics Corporation, St. Jude Medical, Inc., and ThermopeutiX Inc.

In Vitro Products

Stabilization Products

SurModics offers a full line of stabilization products for the *in vitro* diagnostics market. These products increase sensitivity and extend the shelf life of diagnostic kits, 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 bacilovirus/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.

Diagnostic Royalties

In December 2008, the diagnostic patents we licensed to Abbott Laboratories expired. Because net sales are reported, and royalties paid, following the end of a calendar quarter, we also recognized revenue from these patents

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in fiscal 2009. In addition, we recognized additional royalty income of $1.3 million in 2009 in connection with the settlement of previously disclosed litigation involving Abbott Laboratories and Church & Dwight Co, Inc. We do not anticipate any further revenue from these patents.

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 corporate 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 to serve the needs of the Company s clinically and market focused business units, other than our SurModics Pharmaceuticals business unit, which continues to have its own R&D operations.

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, nanoparticles and biodegradable technologies, as well as technologies to improve healing around implantable devices, technologies to deliver nucleic acids, proteins and cell therapies, slide-based microarray technologies and drug delivery platforms for ophthalmic applications.

In fiscal 2009, 2008 and 2007, our R&D expenses were $34.4 million, $40.5 million and $28.5 million, respectively. Of the above amounts, $21.2 million, $21.3 million and $22.6 million were spent on internal R&D in fiscal 2009, 2008 and 2007, respectively, and $13.2 million, $19.2 million and $5.8 million in those years, respectively, were spent on customer-sponsored R&D, which includes technology optimization and other development work 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 platforms. In addition, we continue to pursue access to products and technologies developed outside the Company as appropriate to complement our internal R&D efforts.

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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 2009, we filed 38 United States patent applications, expanding the portfolio protection around our current technologies as well as enabling pursuit of new technology concepts, innovations, and directions.

In particular, we have licensed our patented Bravo™ Drug Delivery Polymer Matrix (Bravo) to Cordis Corporation, a subsidiary of Johnson & Johnson, for utilization with its Cypher® Sirolimus-eluting Coronary Stent. Bravo is protected by 6 issued U.S. patents and 26 issued international patents. The expiration dates for these patents range from 2019 to 2023. Additionally, we have 3 pending U.S. patent applications and 6 pending international patent applications protecting various aspects of Bravo, including methods of manufacturing and coating products.

The Company aggressively pursues patent protection covering the proprietary technologies that we consider important to our business. In addition to seeking patent protection in the U.S., we also generally file patent applications in European countries and additional foreign countries, including Australia, Canada and Japan, on a selective basis. Generally, the expiration dates of our issued patents are determined based on the filing date of the earliest filed patent application from which the patent claims priority. We strategically manage our patent portfolio so as to ensure that we have valid and enforceable patent rights protecting our technological innovations.

As of September 30, 2009, we had 164 pending United States patent applications, 6 of which were exclusively licensed from others, and 283 foreign patent applications, of which 39 were exclusively licensed from others. Likewise, as of September 30, 2009, we owned 124 issued United States patents, 13 of which were exclusively licensed from others, and 244 international patents, of which 50 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 allows 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 11 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, or on an exclusive basis, but limited to a specific field of use. 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 website, and conduct direct mailings to appropriate target markets.

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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.

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. See Note 2 to the consolidated financial statements for further information regarding our minority equity investments. 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 July 2007, we acquired Brookwood Pharmaceuticals, Inc. (now known as SurModics Pharmaceuticals, Inc.) for an up-front payment, including fees, of $42.3 million and potential additional payments of up to $22 million based upon achievement of certain milestones. Since the acquisition, we have paid the sellers additional consideration of $5 million related to achievement of milestones. The additional cash consideration was recorded as an increase to goodwill.

In August 2007, we acquired BioFX Laboratories, Inc. (BioFX) for consideration consisting of an up-front payment, including fees, of $11.6 million and potential additional payments of up to $11.4 million based upon achievement of certain milestones. Since the acquisition, we have paid the sellers additional consideration of $1.1 million related to achievement of a milestone, and the sellers are still eligible to receive up to $7.6 million in additional consideration.

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 for an up-front payment, including fees, of $3.2 million and potential payments of up to $6.0 million based upon achievement of certain milestones. Since the acquisition, we have paid the sellers additional consideration of $2.4 million related to achievement of milestones.

Significant Customers

We have two customers that each provided more than 10% of our revenue in fiscal 2009. Revenue from Merck and Johnson & Johnson represented approximately 37% and 11%, respectively, of our total revenue for the year ended September 30, 2009.

Our contract with Merck was terminated in December 2008. This termination resulted in deferred revenue in the amount of $35 million being recognized in the first quarter of fiscal 2009. In addition, in the first quarter of fiscal 2009 we recognized a $9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program. Additionally, as previously discussed, on October 5, 2009, we entered into a License and Development Agreement with F. Hoffmann-La Roche, Ltd. (Roche) and Genentech, Inc., a wholly- owned member of the Roche Group (Genentech). Under the terms of the agreement, we received an up front licensing fee of $3.5 million, are eligible to receive potential payments of up to approximately $200 million in fees and milestone payments in the event of the successful development and commercialization of multiple products, and will be paid for development work done on these products. Roche and Genentech will have the right to obtain manufacturing services

from SurModics. In the event a commercial product is developed, we will also receive royalties on sales of such products.

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.

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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. Some of our competitors offer drug delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target ophthalmology applications, while others target cardiovascular or other medical device applications. In addition, because of 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. Many of our existing and potential competitors 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 SurModics 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 depends 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.

Competition in the diagnostics market is highly fragmented. In the product lines in which we compete (protein stabilization reagents, substrates, recombinant autoimmune antigens and surface chemistry technologies), we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Many of our competitors have substantially more capital resources, marketing experience, research and development resources and production facilities than we do. We believe that our products compete on performance, stability (shelf life), sensitivity (lower levels detected, faster results), consistency and price. We believe that our continued competitive success will depend on our ability to develop or acquire new proprietary products, obtain patent or other protection for our products and successfully market our products directly or through partners.

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 a facility in Birmingham, Alabama with approximately 286,000 square feet of space in order to upgrade our manufacturing capabilities.

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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 and ISO 9001 certification in fiscal 2004 and has maintained and updated those certifications without interruption since.

Government Regulation

Although our drug delivery and surface modification technologies themselves are not directly regulated by the Food and Drug Administration (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 generally 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.

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.

Employees

As of December 1, 2009, we had 248 employees, of whom 206 were engaged in research, product development, quality, or manufacturing positions, with the remainder in sales, marketing, or administrative positions. Post-graduate degrees are held by 64 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 compensation packages or benefits.

Forward-Looking Statements

Certain statements contained in this Form 10-K, 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,

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could, estimate, expect, forecast, intend, may, plan, possible, project, will and similar words or ex 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 Genentech 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 reliance on a small number of significant customers, which causes our financial results and stock price to be subject to factors affecting those significant customers and their products, the timing of market introduction of their or 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 and pharmaceutical industries 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, including reduced reimbursement rates and new taxes on medical devices and pharmaceutical products that may adversely affect our customers ability to cost-effectively market and sell devices incorporating our technologies or affect the prices they receive for such products thereby affecting the Company s revenue;

- 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 decrease in available financing for the Company s customers and for new ventures which could potentially become customers can reduce the Company s potential opportunities;

- 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;

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the Company s ability to successfully manage clinical trials and related foreign and domestic regulatory processes for the I-vation[tm] 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 against which we are not indemnified or that are 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 and pharmaceutical industries, 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.

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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 may similarly suffer as a result of the decreased utilization of research-focused products. 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 decrease in available financing for our customers and for new ventures that could potentially become our customers can reduce our potential opportunities.

One of the consequences of the economic slowdown has been a decrease in the availability of financing for both start-up and other developing ventures, which can impact our business in several ways. For example, some customers have been unable to obtain additional financing and were forced to cease their operations. Because our financial results depend substantially on the success of our customers in commercializing their products, a reduced ability by companies to take their products to market can substantially adversely affect our results of operations. In addition, the decrease in available financing has resulted in fewer start-up medical device and biotechnology companies than in prior years. To the extent that fewer new companies are started, the number of potential customers for our technologies will be smaller, and we may be unable to meet our business goals, which could substantially affect our financial performance.

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 2009. Revenue from Merck and Johnson & Johnson represented approximately 37% and 11%, respectively, of our total revenue for the fiscal year ended September 30, 2009. In addition, as discussed earlier, we recently entered into a License Agreement with Roche and Genentech which provided for an up front licensing fee of $3.5 million, potential payments of up to approximately $200 million in fees and milestone payments in the event of the successful development and commercialization of multiple products, and payment for development work done on these products. 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, in December 2008, following a strategic review of its business and product portfolio, Merck terminated its collaboration with us relating to the development and potential commercialization of our I-vation^{tm} intravitreal implant and we do not expect to have any revenue from Merck in fiscal 2010. 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 commercialization opportunities 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

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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 a number of other companies. 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 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 uncompetitive 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 uncompetitive 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.

In recent years we have made several significant acquisitions, including SurModics Pharmaceuticals, Inc. (formerly Brookwood Pharmaceuticals, Inc.), the largest acquisition in our history. 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

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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.

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 Securities and Exchange Commission Staff Accounting Bulletin No. 104 (SAB 104), and accounting guidance associated with 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 SEC 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, 2009, 2008 and 2007, we derived approximately 62%, 53% and 72% 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. Additionally, our ability to generate positive operating

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results in connection with the achievement of development or commercialization milestones may also suffer. For example, as discussed previously, Merck terminated their collaboration with us relating to the development and potential commercialization of our I-vation[tm] intravitreal implant following a strategic review of its business and product development portfolio in 2008. 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 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 any of our existing production facilities becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our 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 be obligated 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 Food and Drug Administration or other rules and regulations prescribed by foreign regulatory authorities. Although we have purchased a facility in Alabama and have substantially completed upgrading the facility, 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,

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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 products, that parties indemnifying us will have the financial ability to honor their indemnification obligations 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 appropriate to our activities, however we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. 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, by 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 products incorporating 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 the majority 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.

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

Our commercial success also will depend, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property rights in the medical device and pharmaceutical industries, and intellectual property litigation may be used against us as a means of gaining a competitive advantage. Intellectual property litigation is complex, time consuming and expensive, and the outcome of such litigation is difficult to predict. If we were found to be infringing any third party patent or other intellectual property right, we could be required to pay significant damages, alter our products or processes, obtain licenses from others, which we may not be able to do on commercially reasonable terms, if at all, or cease commercialization of our products and processes. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

Patent litigation or U.S. Patent and Trademark Office interference proceedings may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. These activities could result in substantial cost to us, even if the eventual outcome is favorable to us. An adverse outcome of any such litigation or interference proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using our technology. Any action to defend or prosecute intellectual property would be costly and result in significant diversion of the efforts of our management and technical personnel, regardless of outcome, and could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may have a material adverse effect on us.

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators, and third-party payors to keep these costs down. Certain proposals, if implemented, would impose limitations on the prices our customers will be able to charge for their products, or the amounts of reimbursement available for their products from governmental agencies or third-party payors. Because a portion of our revenue is typically derived from royalties on products which constitute a percentage of the selling price, these limitations could have an adverse effect on our revenue.

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In addition, various members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. Various proposals have included reduced Medicare payments, reduced drug spending and increased taxes. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our customers products, reduce medical procedure volumes (thereby reducing the number of our customers products used), and adversely affect our business, our financial position and results of operations.

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 Food and Drug Administration (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 customer. 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 approval process, which typically lasts from six to nine months. Supplemental or full pre-market approval reviews require a significantly longer period, delaying commercialization. By contrast, pharmaceutical products incorporating our technologies are subject to the FDA s New Drug Application process which typically takes a number of years to complete. Additionally, biotechnology products incorporating our technologies are subject to the FDA s Biologics License Application 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, we could be held liable for any damages that might result from any such event. Any such liability could exceed our insurance and available resources and could have a material adverse effect on our business, financial condition and results of operations.

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Additionally, certain of our activities are regulated by federal and state agencies in addition to the FDA. For example, activities in connection with disposal of certain chemical waste are subject to regulation by the U.S. Environmental Protection Agency. We could be held liable in the event of improper disposal of such materials, even if these acts were done by third parties. 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 shares of 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, 2009, the sale price for our common stock ranged from $15.96 to $31.69 per share. The market prices for securities of medical technology, drug delivery and biotechnology companies historically have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS.***

None.

ITEM 2. ***PROPERTIES.***

Our principal operations are located in Eden Prairie, a suburb of Minneapolis, Minnesota, where we own a building that has approximately 64,000 square feet of space. 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 facility, we also own and lease facilities in Birmingham, Alabama in connection with our SurModics Pharmaceuticals operations. The facility which we acquired in the SurModics Pharmaceuticals 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 in order to upgrade our manufacturing capabilities. We also lease an approximately 14,000 square foot facility in Birmingham which contains three 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 9 to the Consolidated Financial Statements for information regarding commitments and contingencies.

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 alleged 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 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. On September 17, 2009, the litigation between the Company, Abbott and Church & Dwight was settled. Under the terms of the settlement, we received a payment of $1.3 million, and on October 19, 2009, the U.S. District Court for the Northern District of Illinois entered an order dismissing all claims and counterclaims with prejudice.

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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 2009.

EXECUTIVE OFFICERS OF THE REGISTRANT

As of December 11, 2009, the names, ages and positions of the Company s executive officers are as follows:

Name	Age	Position
Bruce J Barclay	53	President and Chief Executive Officer
Aron B. Anderson, Ph.D.	46	Vice President and Chief Scientific Officer
Philip D. Ankeny	46	Senior Vice President and Chief Financial Officer
Douglas P. Astry	57	General Manager, In Vitro Technologies
Lise W. Duran, Ph.D.	54	Vice President of Research
Paul A. Lopez	53	Vice President, President Ophthalmology Division
Charles W. Olson	45	Vice President, General Manager Cardiovascular
Bryan K. Phillips	38	Vice President, General Counsel and Secretary
Brian L. Robey	46	Vice President of Product Development and Operations
Michael J. Shoup	49	Vice President of Quality, Regulatory and Clinical Affairs
Arthur J. Tipton, Ph.D.	52	Vice President, and President of SurModics Pharmaceuticals
Jan M. Webster	50	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. from 2000 to 2003. Prior to Vascular Architects, he served at Guidant Corporation, most recently as an officer and Senior Vice President from 1998 to 2000. Previously, he was a Vice President of Guidant s Interventional Cardiology division with responsibility for the law division, a new therapies technical development team and business development, charged with the acquisition of new products and technologies for the division. Mr. Barclay also has considerable experience in the pharmaceutical area serving in several positions at Eli Lilly and Company. Mr. Barclay received a B.S. in chemistry and a B.A. in biology from Purdue University in 1980 and a J.D. from the Indiana University School of Law in 1984. He is also a registered patent attorney.

Aron B. Anderson, *Ph.D.*, joined the Company as an Associate Scientist in 1991. In 1994, he was named Director, Hemocompatibility R&D, in 2001, named Director, Drug Delivery, and in January 2005, Vice President and Chief Scientific Officer. Dr. Anderson serves on the Board of Directors of University Enterprise Laboratories, a partnership between the University of Minnesota and the city of St. Paul, Minnesota 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.

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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 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. He 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 bar 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

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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. Mr. Shoup 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, SurModics Pharmaceuticals, coincident with the acquisition of SurModics Pharmaceuticals 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 SurModics 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 1988.

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.

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PART II

ITEM 5. *MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.*

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

Fiscal Quarter Ended:	High	Low
September 30, 2009	$ 25.14	$ 20.87
June 30, 2009	23.40	17.95
March 31, 2009	27.42	15.96
December 31, 2008	31.69	18.95
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

Our transfer agent is:

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

According to the records of our transfer agent, as of December 7, 2009, there were 264 holders of record of our Common Stock and approximately 10,825 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, 2009, 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) Total Number	(b) Average	(c) Total Number of Shares Purchased as Part of Publicly Announced	(d) Approximate Dollar Value of Shares That May Yet Be Purchased Under the

Period		of Shares Purchased(1)	Price Paid per Share(1)	Plans or Programs	Plans or Programs(2)
7/1/09	7/31/09	4,655	$ 22.93	0	$ 7,333,728
8/1/09	8/31/09	0	NA	0	$ 7,333,728
9/1/09	9/30/09	203	$ 24.02	0	$ 7,333,728
Total		4,858	$ 22.97	0	$ 7,333,728

(1) The purchases in this column 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 restricted stock or performance awards.

(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, 2009, we have repurchased 921,648 shares at an average price of $30.02 per share. Under the current authorization, the Company has $7.3 million available for authorized share repurchases as of September 30, 2009. The repurchase authorization does not have an expiration date.

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Stock Performance Chart

The following chart compares the cumulative total shareholder return on the Company s Common Stock with the cumulative total return on the Nasdaq Stock Market and the Nasdaq Medical Industry Index (Medical Devices, Instruments and Supplies). The comparison assumes $100 was invested on September 30, 2004 and assumes reinvestment of dividends.

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ITEM 6. ***SELECTED FINANCIAL DATA.***

The data presented below as of and for the fiscal years ended September 30, 2009, 2008 and 2007 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, 2006 and 2005 are derived from our audited financial statements which 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.

	Fiscal Year				
	2009	2008	2007	2006	2005
	(Dollars in thousands, except per share data)				
Statements of Operations Data:					
Total revenue	$ 121,534	$ 97,051	$ 73,164	$ 69,884	$ 62,381
Operating income	57,501	27,261	9,899	36,163	2,985
Net income (loss)	37,550	14,739	3,347	20,334	(8,246)
Diluted net income (loss) per share	2.15	0.80	0.18	1.09	(0.45)
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 47,868	$ 71,978	$ 70,225	$ 106,571	$ 73,319
Total assets	185,562	191,028	171,331	157,402	124,225
Retained earnings	103,989	66,439	51,620	48,273	27,914
Total stockholders equity	172,372	141,806	130,922	145,203	115,581

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 a change in our organizational structure into four clinically and market focused business units: Cardiovascular, Ophthalmology, SurModics Pharmaceuticals, and In Vitro Technologies. We believe that this structure improves the visibility, marketing and adoption of the Company s broad array of technologies within specific markets and helps our customers in the medical device, pharmaceutical and life science industries better 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, other than the SurModics Pharmaceuticals business unit, which continues to maintain certain R&D operations.

The reorganization change resulted in the Company being comprised of new market focused business units. Therapeutic contains: (1) the Cardiovascular business unit, which provides drug delivery and surface modification

technologies to customers in the cardiovascular market; (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 SurModics Pharmaceuticals business unit, which provides proprietary polymer-based drug delivery technologies to companies developing improved pharmaceutical products. Revenue results in Therapeutic are presented by the clinical market areas in which our customers participate (Cardiovascular, Ophthalmology and Other Markets). Diagnostic contains the In Vitro Technologies business unit, which includes our microarray slide technologies, our stabilization products, antigens and substrates for immunoassay diagnostic tests, and our *in vitro* diagnostic format technology.

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Our revenue is derived from three primary sources: (1) royalties and license fees from licensing our proprietary 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, substrates and microarray slides to the diagnostics and biomedical research industry; and (3) research and development fees generated on customer projects. Revenue fluctuates from quarter to quarter depending on, among other factors: our customers success in selling products incorporating our technologies; the timing of introductions of licensed 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 customers; and the timing of future acquisitions we complete, if any.

For financial accounting and reporting purposes, we report our results in one reportable segment. We made this determination because each business unit has similar economic characteristics; a significant percentage of our employees provide support services (including research and development) to each business unit; technology and products from each business unit are marketed to the same or similar customers; each business unit uses the same sales and marketing resources; and each business unit operates in the same regulatory environment.

In June 2007, we entered into a License and Research Collaboration Agreement and separate Supply Agreement with Merck & Co., Inc. (Merck) related to our I-vation TA (triamcinolone acetonide) intravitreal implant. Under the terms of the Merck agreements, we received an up front license fee of $20 million and were eligible 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, as well as payment for our research and development activities. 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. This decision was not based on any concerns about the safety or efficacy of the I-vation system. The termination was effective in December 2008, and we have recognized revenue related to the termination of approximately $45 million in fiscal 2009, principally from amounts that previously had been deferred and amortized under the accounting treatment required by accounting guidance for revenue arrangements with multiple deliverables. The $45 million includes a $9 million milestone payment associated with the termination of the triamcinolone acetonide development program.

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. Total consideration paid through September 30, 2009 was $5.6 million and PR Pharmaceuticals, Inc. is eligible to receive up to an additional $3.6 million in cash upon successful achievement of specified milestones. The proprietary technologies we acquired complement and enhance our existing portfolio of drug delivery capabilities 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 complement the diversified portfolio of customer projects at SurModics Pharmaceuticals, and we believe will further leverage the investment we are making in cGMP manufacturing.

On October 5, 2009, we entered into a License and Development Agreement with F. Hoffmann-La Roche, Ltd. (Roche) and Genentech, Inc., a wholly-owned member of the Roche Group (Genentech). Under the terms of the License Agreement, Roche and Genentech will have an exclusive license to develop and commercialize a sustained drug delivery formulation of Lucentis® (ranibizumab injection) utilizing SurModics proprietary biodegradable microparticles drug delivery system. Under the terms of the agreement, we received an up front licensing fee of $3.5 million and are eligible to receive potential payments of up to approximately $200 million in fees and milestone payments in the event of the successful development and commercialization of multiple products, as well as payment for development work done on these products. Roche and Genentech will have the right to obtain manufacturing

services from SurModics. In the event a commercial product is developed, we will also receive royalties on sales of such products.

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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 accounting guidance, 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 current accounting guidance 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 have been 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 accounting guidance. Under certain situations, interim 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 our results for which discrete financial information is available and reviewed by management on a regular basis. SurModics has determined that its reporting units are its SurModics Pharmaceuticals business unit, a component within Therapeutics, and the In Vitro Technologies business unit.

We performed our annual impairment test of goodwill in the fourth quarter of fiscal 2009 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, 2009. 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, net of tax. Available-for-sale investments are reported at fair value with unrealized gains and losses excluded from operations and reported as a separate component of stockholders equity, except for other-than-temporary impairments, which are reported as a charge to current operations and result in a new cost basis for the investment in accordance with accounting guidance. Our evaluation of the available-for-sale investments resulted in no loss recognition in fiscal 2009 and loss recognition of $4.3 million related to our investment in OctoPlus N.V. (included in Other Assets in the consolidated balance sheets) in fiscal 2008, as we determined the loss to be an other-than-temporary impairment based on a significant decline in the stock price as of September 30, 2008. The impairment of the OctoPlus N.V. investment 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 $2.9 million as of September 30, 2009 and $12.2 million as of September 30, 2008, including valuation allowances of $3.3 million as of September 30, 2009 and $3.4 million as of September 30, 2008. 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 accounting provisions on October 1, 2007 which defined new standards 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, 2009 and 2008 was $2.0 million and $1.5 million, respectively, excluding accrued interest and penalties. $2.0 million of these tax benefits would affect our effective tax rate, if recognized. Interest and penalties recorded for uncertain tax positions

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are included in our income tax provision. As of September 30, 2009 and 2008, $0.6 million and $0.4 million, respectively, of interest and penalties were accrued, excluding the tax benefits of deductible interest. Fiscal years 2006, 2007 and 2008 remain subject to examination by federal tax authorities. Tax returns for state and local jurisdictions for fiscal years 2003 through 2008 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 8 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 2009 and 2008.

Results of Operations

Years Ended September 30, 2009 and 2008

(Dollars in thousands)	**Fiscal 2009**	**Fiscal 2008**	**Increase/ (Decrease)**	**% Change**
Revenue:				
Therapeutic				
Cardiovascular	$ 39,841	$ 47,675	$ (7,834)	(16)%
Ophthalmology	52,102	10,252	41,850	408%
Other Markets	13,114	17,875	(4,761)	(27)%
Total Therapeutic	105,057	75,802	29,255	39%
Diagnostic	16,477	21,249	(4,772)	(22)%
Total revenue	$ 121,534	$ 97,051	$ 24,483	25%

Revenue. Fiscal 2009 revenue was $121.5 million, an increase of $24.5 million, or 25%, from fiscal 2008. The increase in Therapeutic and decrease in Diagnostic revenue, as detailed in the table above, are further explained in the narrative below.

Therapeutic. Revenue in Therapeutic was $105.1 million in fiscal 2009, a 39% increase compared with $75.8 million in the prior-year period. The increase in total revenue reflects the recognition of revenue of approximately $45 million associated with the terminated Merck collaborative research and license agreement. Excluding these significant event-specific items, Therapeutic revenue decreased $15.7 million, or 21%.

Cardiovascular derives a substantial amount of revenue from royalties and license fees and product sales attributable to Cordis Corporation, a Johnson & Johnson company, on its CYPHER® Sirolimus-eluting Coronary Stent. The CYPHER® stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. The CYPHER® stent faces continuing competition from Boston Scientific, Medtronic, and Abbott Laboratories. Stents from these companies compete directly with the CYPHER® stent both domestically and internationally. Future royalty and reagent sales revenue could decrease as a result of lower CYPHER® stent sales as a result of the ongoing and expected future competition. We anticipate that royalty revenue from the CYPHER® stent may be volatile throughout fiscal 2010 and beyond as the various marketers

of drug-eluting stents compete in the marketplace and as others enter the marketplace. We also receive a royalty on sales of the Medtronic Endeavor® drug-eluting stent delivery system incorporating our hydrophilic technology, which is sold in the United States and internationally and commenced sales in Japan in May 2009.

Cardiovascular revenue decreased $7.8 million, or 16%, in fiscal 2009, compared with the prior-year period principally as a result of lower royalties and license fees and research and development revenue. Our royalty revenue from Cordis decreased approximately 35% as a result of the decrease in CYPHER® stent sales.

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Ophthalmology revenue increased $41.9 million, or 408%, in fiscal 2009, compared with the prior-year period. The significant increase principally reflects the recognition of approximately $45 million of previously deferred revenue associated with the terminated collaborative research and license agreement with Merck and a milestone payment associated with the termination of the triamcinolone acetonide development program.

Ophthalmology revenue, excluding the Merck event-specific items of fiscal 2009 and amortization of revenue in fiscal 2008, was unchanged at $7.1 million in both fiscal years.

Other Markets revenue decreased $4.8 million, or 27%, in fiscal 2009, compared with the prior-year period. Lower research and development revenue was the primary reason for the decrease. Selected customers have delayed, slowed or cancelled development projects in fiscal 2009 as a result of various factors including current economic conditions. Other Markets revenue is derived from more than 50 customers.

Diagnostic. Revenue in Diagnostic was $16.5 million in fiscal 2009, a decrease of 22% compared with $21.2 million in the prior-year period. This decrease was attributable to lower royalties and license fees in fiscal 2009. In past years, Diagnostic derived a significant percentage of revenue from Abbott Laboratories. Fiscal 2009 was the last year in which we received royalty revenue from our diagnostic format patent license agreement with Abbott Laboratories. Royalty revenue from Abbott was $4.9 million in fiscal 2009, compared with $8.7 million in fiscal 2008. Product sales in Diagnostic decreased 4% compared with fiscal 2008 as customers slowed purchasing activity in early fiscal 2009.

Product costs. Product costs were $7.5 million in fiscal 2009, an 11% decrease from the prior year. Overall product margins averaged 61%, compared with 58% in the prior year. The increase in product margins reflected the mix of products sold in fiscal 2009 as we had a decrease in sales of our SurModics Pharmaceuticals polymer products, which carry lower margins than our reagent and diagnostic products.

Customer research and development expenses. Customer research and development (Customer R&D) expenses were $13.2 million, a decrease of 31% compared with fiscal 2008. The decrease principally reflects the impact of lower research and development revenue, adjusted for Merck. Customer R&D margins were 51%, compared with 24% in fiscal 2008. The margins were 32% and 21% for fiscal 2009 and 2008, respectively, after adjusting for Merck deferred revenue recognition in both periods. The increase in fiscal 2009 margins reflects lower labor and material costs incurred on projects, as well as lower overhead costs allocated to Customer R&D.

Other research and development expenses. Other research and development (Other R&D) expenses were $21.2 million, essentially unchanged compared with $21.3 million in fiscal 2008. Our research and development headcount decreased in fiscal 2009 as a result of our November 2008 reorganization, resulting in lower labor costs, which were offset by higher overhead costs being allocated to Other R&D.

Selling, general and administrative expenses. Selling, general and administrative expenses were $17.2 million, a decrease of 17% compared with fiscal 2008. The decrease principally reflects lower employee compensation costs related to our annual incentive compensation program and lower stock-based compensation expense, as fiscal 2008 included costs related to transitions on our Board of Directors.

Purchased in-process research and development. In November 2008, we acquired certain assets comprised of intellectual property and collaborative programs from PR Pharmaceuticals, Inc. The fair value of $3.2 million associated with the in-process research and development intangible asset was determined by management and recognized as an expense.

Restructuring charges. In November 2008, we announced a functional reorganization to better serve our customers and improve our operating performance. As a result of the reorganization, we eliminated 15 positions, or approximately 5% of our workforce. These employee terminations occurred across various functions, and the reorganization plan was completed by the end of the first quarter of fiscal 2009. The reorganization also resulted in SurModics vacating a leased office facility in Eden Prairie, Minnesota, and consolidating into our owned office and research facility also in Eden Prairie.

We recorded total restructuring charges of $1.8 million in connection with the reorganization. These pre-tax charges consisted of $0.5 million of severance pay and benefits expenses and $1.3 million of facility-related costs.

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Costs totaling $0.8 million have been paid, and we anticipate paying the remaining $1.0 million within the next fifteen months.

Other income (loss), net. Other income was $2.0 million in fiscal 2009, compared with a loss of $0.4 million in fiscal 2008. Income from investments was $1.8 million in fiscal 2009, compared with $3.3 million in fiscal 2008. The decrease primarily reflects lower investment balances in fiscal 2009. The fiscal 2008 loss primarily reflects a $4.3 million impairment loss on our investment in OctoPlus N.V., based on a significant decline in the stock price as of September 30, 2008.

Income tax expense. The income tax provision was $22.0 million in fiscal 2009, compared with $12.2 million in fiscal 2008. The effective tax rate in fiscal 2009 was 36.9% compared with 45.2% in fiscal 2008. 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 decrease in the effective tax rate, adjusted for the one-time item noted, is primarily a result of lower state taxes and the tax reserve associated with uncertain tax positions.

Years Ended September 30, 2008 and 2007

(Dollars in thousands)	**Fiscal 2008**	**Fiscal 2007**	**Increase**	**% Change**
Revenue:				
Therapeutic				
Cardiovascular	$ 47,675	$ 46,487	$ 1,188	3%
Ophthalmology	10,252	2,453	7,799	318%
Other Markets	17,875	4,041	13,834	342%
Total Therapeutic	75,802	52,981	22,821	43%
Diagnostic	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 both Therapeutic and Diagnostic, as detailed in the table above and further explained in the narrative below.

Therapeutic. Revenue in Therapeutic was $75.8 million in fiscal 2008, a 43% increase compared with $53.0 million in the prior-year period. The increase in total revenue reflects a significant increase in research and development revenue associated with the SurModics Pharmaceuticals acquisition in July 2007. SurModics Pharmaceuticals contributed $20.6 million and $2.4 million in revenue for fiscal 2008 and 2007, respectively. Fiscal 2007 results included SurModics Pharmaceuticals for only two months, as the acquisition closed on July 31, 2007.

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

Cardiovascular revenue increased $1.2 million, or 3%, in fiscal 2008, compared with the prior-year period principally as a result of higher research and development revenue from customers. Overall royalties and license fees revenue increased despite an approximately 22% decrease in our royalty revenue from Cordis, which reflects the decrease in CYPHER® stent sales.

Ophthalmology revenue increased $7.8 million, or 318%, in fiscal 2008, compared with the prior-year period. The significant increase principally reflects increased research and development revenue from various ophthalmology customers. Ophthalmology revenue, excluding the amortization of Merck revenue in fiscal 2008 and 2007, was $7.1 million and $2.1 million, respectively.

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Other Markets revenue increased $13.8 million, or 342%, in fiscal 2008, compared with the prior-year period. Higher research and development revenue and product sales were the main contributors to the increase. Other Markets revenue is derived from more than 50 customers.

Diagnostic. Revenue in Diagnostic was $21.2 million in fiscal 2008, an increase of 5% compared with $20.2 million in the prior-year period. 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. In Vitro Technologies 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 decreased 13% in fiscal 2008 compared with the prior year. 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.

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 in fiscal 2007. The slight decrease in product margins reflects the mix of products sold in the period (in particular, some of our microarray slides and SurModics Pharmaceuticals polymer products carry lower margins than our reagent and stabilization products).

Customer research and development expenses. Customer research and development (Customer R&D) expenses were $19.2 million, an increase of $13.3 million, or 229%, compared with fiscal 2007. The increase principally reflects the addition of SurModics Pharmaceuticals. Fiscal 2007 amounts include SurModics Pharmaceuticals for two months of operations following the acquisition. Customer R&D margins were 24% in fiscal 2008, compared with 16% in fiscal 2007. The increase in margins principally reflects the significant increase in research and development revenue as a result of the acquisition of SurModics Pharmaceuticals.

Other research and development expenses. Other research and development expenses (Other R&D) were $21.3 million, a decrease of $1.3 million, or 6%, compared with fiscal 2007. The decrease was driven principally by lower labor and benefit costs in fiscal 2008 compared with the prior year period, partially offset by higher Other R&D expenses from SurModics Pharmaceuticals and BioFX.

Selling, general and administrative expenses. Selling, general and administrative expenses were $20.8 million, an increase of 53% compared with fiscal 2007. The increase principally reflects the addition of SurModics Pharmaceuticals and BioFX to our operations and higher stock-based compensation expenses associated with second quarter fiscal 2008 Board of Directors transitions.

Purchased in-process research and development. In July 2007, we acquired all of the assets of SurModics Pharmaceuticals. Results in the fourth quarter of fiscal 2007 include an in-process research and development charge of $15.6 million related to the SurModics Pharmaceuticals acquisition. The fair value of the in-process research and development was determined by management.

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., 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 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.

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Liquidity and Capital Resources

As of September 30, 2009, the Company had working capital of $29.0 million, of which $20.6 million consisted of cash, cash equivalents and short-term investments. Working capital decreased $5.0 million from the September 30, 2008 level driven principally by lower cash, accounts receivable and income taxes receivable balances, offset by lower accrued compensation and deferred revenue balances. Deferred revenue balances have decreased as a result of the termination of the Merck arrangement in fiscal 2009. In addition, accrued annual incentive compensation decreased because fiscal 2009 objectives were not achieved. Our cash, cash equivalents and short-term and long-term investments totaled $47.9 million at September 30, 2009, a decrease of $24.1 million from $72.0 million at September 30, 2008. The decrease was principally driven by redemptions which were used to finance investment in our new manufacturing facility in Alabama, which totaled $24.4 million and for our stock repurchase program, which totaled $15.0 million. The Company s investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. The Company s policy requires that no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while meeting or exceeding a benchmark (Merrill Lynch 1-3 Year Government-Corporate Index) total rate of return. Management plans to continue to direct its investment advisors to manage the Company s investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments.

The Company had positive cash flows from operating activities of approximately $31.3 million in fiscal 2009, compared with $39.8 million in fiscal 2008. The following table depicts our cash flows from operations for each of fiscal 2009 and 2008:

	For the Years Ended September 30,	
	2009	2008
	(Dollars in thousands)	
Net income	$ 37,550	$ 14,739
Depreciation and amortization	5,912	6,071
Stock-based compensation	6,853	9,652
Purchased in-process research and development	3,200	
Impairment loss on investment		4,314
Deferred taxes and other net operating activities	10,433	(3,938)
Net change in deferred revenue	(36,050)	11,452
Net change in other operating assets and liabilities	3,423	(2,468)
Net cash provided by operating activities	$ 31,321	$ 39,822