

SURMODICS INC  
Form 10-K  
December 14, 2010

**Table of Contents**

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

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended September 30, 2010**

**Commission file number 0-23837**

**SURMODICS, INC.**

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

**Minnesota**

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

**41-1356149**

*(IRS Employer  
Identification No.)*

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

**Eden Prairie, Minnesota**

*(Address of Principal Executive Offices)*

**55344**

*(Zip Code)*

**(Registrant's Telephone Number, Including Area Code)**

**(952) 829-2700**

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

<b>Title of Each Class</b>	<b>Name of Exchange on Which Registered</b>
<b>Common Stock, \$0.05 par value</b>	<b>NASDAQ Global Select Market</b>

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

**None**

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

Edgar Filing: SURMODICS INC - Form 10-K

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

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

Indicate by check mark 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  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2010 was approximately \$207 million (based upon the closing sale price of the registrant's Common Stock on such date).

The number of shares of the registrant's Common Stock outstanding as of December 9, 2010 was 17,467,101.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement for the Registrant's 2011 Annual Meeting of Shareholders are incorporated by reference into Part III.

## Table of Contents

		<b>Page</b>
	<u>Forward Looking Statements</u>	2
	<b>Part I</b>	
<u>Item 1.</u>	<u>Business</u>	3
	<u>Executive Officers of the Registrant</u>	16
<u>Item 1A.</u>	<u>Risk Factors</u>	19
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	27
<u>Item 2.</u>	<u>Properties</u>	27
<u>Item 3.</u>	<u>Legal Proceedings</u>	27
<u>Item 4.</u>	<u>(Removed and Reserved)</u>	27
	<b>Part II</b>	
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	28
<u>Item 6.</u>	<u>Selected Financial Data</u>	30
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	30
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	44
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	45
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	45
<u>Item 9A.</u>	<u>Controls and Procedures</u>	45
<u>Item 9B.</u>	<u>Other Information</u>	47
	<b>Part III</b>	
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	47
<u>Item 11.</u>	<u>Executive Compensation</u>	47
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	47
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	48
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	48
	<b>Part IV</b>	
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	49
<u>EX-10.17</u>		
<u>EX-21</u>		
<u>EX-23</u>		
<u>EX-31.1</u>		
<u>EX-32.1</u>		

### 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, could, estimate, expect, forecast, intend, may, plan, possible, project, will and similar words or expressions 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. 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. Factors that could cause our actual results to differ from those discussed in the forward-looking statements include, but are not limited to, those described in Item 1A Risk Factors Below.

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

SurModics, Inc. (referred to as SurModics, the Company, we, us, our and other like terms) is a leading provider of drug delivery and surface modification technologies to the healthcare industry. Our mission is to exceed our customers' expectations and enhance the well-being of patients by providing the world's foremost, innovative drug delivery and surface modification technologies and products. We partner with many of the world's leading and emerging medical device, pharmaceutical and life science companies to develop and commercialize innovative products designed to improve patient outcomes. Our core offerings include: drug delivery technologies (coatings, microparticles, and implants); surface modification coating technologies that impart lubricity, prohealing, and biocompatibility characteristics; and components for *in vitro* diagnostic test kits 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, extended 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 coated 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.

On October 5, 2009, we entered into a License and Development Agreement with F. Hoffmann-La Roche, Ltd. (Roche) and Genentech, Inc., a member of the Roche Group (Genentech). Under the terms of the License Agreement, Roche and Genentech have an exclusive license to develop and commercialize a sustained drug delivery formulation of Lucentis® (ranibizumab injection) utilizing SurModics' proprietary biodegradable microparticle drug delivery system. Under the terms of the agreement, we received an upfront 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 product. During fiscal 2010, the focus of our development activities have changed, primarily as a result of technical issues experienced in the Lucentis® microparticle product development program. Such technical issues reflect the inherent challenges often experienced in the development of new or reformulated pharmaceutical

## **Table of Contents**

products. We are continuing to collaborate with Genentech under our agreement on sustained drug delivery products utilizing our proprietary biodegradable microparticle drug delivery system. However, the program remains subject to a number of risks and uncertainties, including those detailed under the heading **Risk Factors** in Item 1A of this Form 10-K.

In July 2007, we acquired Brookwood Pharmaceuticals, Inc., a leading provider of drug delivery technology primarily to the pharmaceutical industry. This acquisition 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. 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 constructed and qualified in Birmingham, Alabama. 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, license fees and manufacturing services.

In August 2007, we acquired BioFX Laboratories, Inc. ( **BioFX** ). 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.

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. We believe this approach allows us to focus our resources on the further development of our core technologies and enables us to expand our licensing activities into new markets.

Revenues from our licensing arrangements typically include research and development revenues, license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensee's product sales. 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<sup>®</sup> microarray slide product line. 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 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.

The Company was organized as a Minnesota corporation in June 1979. We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act on our web site, [www.surmodics.com](http://www.surmodics.com), as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our web site as a part of, or incorporating it by reference into our Form 10-K.

**Subsequent Events.** In October 2010, we announced initiatives intended to reduce our cost structure. As part of these initiatives, the Company implemented a change in its organizational structure to reflect our three complementary, but distinct business units: Medical Device, Pharmaceuticals, and In Vitro Diagnostics.

*Medical Device*, comprised of surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices, as well as drug delivery coating technologies to provide site-specific drug delivery from the surface of a medical device. End markets include coronary, peripheral,



neuro-vascular, and urology, among others.

*Pharmaceuticals*, incorporates a broad range of drug delivery techniques for injectable therapeutics, including microparticles, nanoparticles, and implants. Customers include pharmaceutical and biotechnology companies addressing a range of clinical applications including ophthalmology, oncology, dermatology and neurology, among others. Based in Birmingham, Alabama, the Pharmaceuticals business operates the Company's cGMP manufacturing facility.

## **Table of Contents**

*In Vitro Diagnostics*, consisting of component products and technologies for diagnostic test kits and biomedical research applications. Products include microarray slide technologies, protein stabilization reagents, substrates and antigens.

In addition, in December 2010, we announced that the Board of Directors of the Company had authorized the Company to explore strategic alternatives for the Company's Pharmaceuticals business, including a potential sale of that business. This decision by the Board reflects our focus on returning the Company to profitable growth, and our renewed commitment to pursuing growth opportunities and investments in our Medical Device and In Vitro Diagnostics businesses. We have retained Piper Jaffray & Co. as our financial advisor in connection with this process. The Company has made no decision to enter into any transaction regarding the Pharmaceuticals business, and there can be no assurance that we will enter into such a transaction in the future. Additional details concerning this announcement can be found in the Company's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on or before December 20, 2010.

In December 2010, we also announced that Gary R. Maharaj has been named President and Chief Executive Officer of the Company, with such appointment to be effective December 27, 2010. Mr. Maharaj will also serve as a member of the Company's Board of Directors. Mr. Maharaj previously served as President and Chief Executive Officer of Arizant Inc., a provider of patient temperature management in hospital operating rooms. Additional details concerning this announcement can be found in the Company's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on or before December 20, 2010.

## **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 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, extended 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

## **Table of Contents**

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 extended 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 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 (within minutes to 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.

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 has also been used on our I-vation™ TA (triamcinolone acetate) intravitreal implant. 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 where the drug can then be released as the polymer degrades in the body over time.

Our proprietary PhotoLink<sup>®</sup> 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.

## **Table of Contents**

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, 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***

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.

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 have developed long-acting implants with biodegradable and non-biodegradable polymers.

**Table of Contents*****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. 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.

*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. Based on internal and customer evaluations, when compared with uncoated surfaces, our PhotoLink coatings have reduced the friction on surfaces by more than 90%, depending on the surface being coated. Lubricity also reduces tissue irritation and damage caused by products such as catheters, guidewires and endoscopy devices. Further, lubricious coatings can improve deliverability of a medical device, which can enhance the physician's ability to place a medical device in the intended anatomical site within the patient's body.

*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 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.

**Table of Contents*****SurModics Drug Delivery and Surface Modification Technologies Applications***

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

<b>Market Segment Served</b>	<b>Desired Surface Property and Examples of Applications</b>
<b>Interventional Cardiology and Vascular Access</b>	<i>Lubricity</i> : catheters, guidewires, delivery systems <i>Hemocompatibility</i> : vascular stents, catheters, distal protection devices <i>Drug/biologics delivery</i> : vascular stents, catheters <i>Prohealing</i> : vascular stents, vascular grafts
<b>Cardiac Rhythm Management</b>	<i>Lubricity</i> : pacemaker and defibrillator leads, electrophysiology devices <i>Hemocompatibility</i> : electrophysiology devices <i>Prohealing</i> : pacemaker and defibrillator leads <i>Drug/biologics delivery</i> : pacemaker and defibrillator leads
<b>Cardiothoracic Surgery</b>	<i>Prohealing</i> : heart valves, septal defect repair devices <i>Hemocompatibility</i> : minimally invasive bypass devices, vascular grafts, ventricular assist devices
<b><i>In Vitro</i> Diagnostics</b>	<i>Lubricity</i> : microfluidic devices <i>Hemocompatibility</i> : blood/glucose monitoring devices, biosensors <i>Biomolecule immobilization</i> : DNA and protein arrays, protein attachment to synthetic extracellular matrix for cell culture applications
<b>Interventional Neurology and Neurosurgery</b>	<i>Lubricity</i> : catheters, guidewires <i>Prohealing</i> : neuroembolic devices <i>Tissue engineering</i> : aneurysm repair devices
<b>Urology and Gynecology</b>	<i>Lubricity</i> : urinary catheters, incontinence devices, ureteral stents, fertility devices <i>Drug/biologics delivery</i> : prostatic stents, microparticle injections <i>Tissue engineering</i> : female sterilization devices
<b>Ophthalmology</b>	<i>Drug/biologics delivery</i> : sustained drug delivery implants and microparticle injections
<b>Orthopedics</b>	<i>Cell growth and tissue integration</i> : bone and cartilage growth <i>Infection resistance</i> : orthopedic and trauma implants <i>Drug/biologics delivery</i> : orthopedic and trauma implants and microparticle injections
<b>Metabolic Disease</b>	<i>Drug/biologics delivery</i> : microparticle injections <i>Tissue engineering</i> : cell encapsulation
<b>Central Nervous System Disorders</b>	<i>Drug/biologics delivery</i> : microparticle injections, polymer implants
<b>Dermatology</b>	<i>Drug/biologics delivery</i> : polymer implants

*Tissue engineering*: tissue bulking, space filling materials

## **Table of Contents**

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.

We generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 49.0%, 62.1% and 53.4% of our total revenue in fiscal 2010, 2009 and 2008, respectively. Revenue from these licensing arrangements typically includes license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensee's product sales. We also generate revenue from sales of chemical reagents to licensees for use in their coating processes, and from polymer sales under our Lakeshore Biomaterials brand. Our In Vitro Diagnostics business unit generates revenue from: sales of stabilization products, substrates, antigens and microarray slides to diagnostics customers. Product sales represented 28.9%, 15.9% and 20.6% of total revenue in fiscal 2010, 2009 and 2008, respectively. Research and development fees represented 22.1%, 22.0% and 26.0% of total revenue in fiscal 2010, 2009 and 2008, respectively.

The licensing process begins with the customer specifying a desired product feature to be created such as lubricity, drug delivery, etc. Because each device and drug is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating research and development revenue. Once the feasibility phase has been completed in a manner satisfactory to the customer, the customer funds a development project to optimize the formulation to meet the customer'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.

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 generally are limited to a specific field of use, allowing us the opportunity to further license technology to other customers. The royalty rate on a substantial number of the agreements has traditionally been in the 2% to 3% range, but there are certain contracts with lower or higher rates. Royalty rates in certain more recent agreements have been trending higher, especially where the relevant SurModics technology is an enabling component of the customer's device (i.e., the device could not perform as desired without our technology). The amount of the license fees, milestone payments, and the royalty rate are based on various factors, including the stage of development of the product or technology being licensed, whether the arrangement is exclusive or nonexclusive, the perceived value of our technology to the customer's product, size of the

potential market, and customer preferences. Most of our agreements also incorporate a minimum royalty to be paid by the licensee. Royalties are generally paid one quarter after the customer's actual product sales occur because of the delay in reporting sales by our licensees.

## **Table of Contents**

As of September 30, 2010, we had 102 licensed product classes (customer products utilizing SurModics technology) already on the market generating royalties and 110 customer product classes incorporating our technology pending regulatory approval. These 212 product classes are being sold or developed by 108 licensed customers. We signed 21 new licenses in fiscal 2010, compared with 22 in fiscal 2009.

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, Clinuvel Pharmaceuticals, Cook Medical, Cordis Corporation (a subsidiary of Johnson & Johnson), Edge Therapeutics, Inc., Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott Laboratories), Elixir Medical Corporation, ev3 Inc. (a subsidiary of Covidien PLC), F. Hoffmann-La Roche, Ltd. and its subsidiary Genentech, Inc., Medtronic, Inc., Nexeon MedSystems, Inc., NuPathe, Inc, OrbusNeich Medical, Inc., Spectranetics Corporation, St. Jude Medical, Inc., and ThermopeutiX, Inc.

### ***In Vitro Diagnostics 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 baculovirus/Sf9 expression system for autoimmune antigens as well as *E. coli* systems for particular expression tasks.

#### ***Microarray Slide Products***

SurModics offers 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.

### **Research and Development**

Our research and development (R&D) personnel work to enhance and expand our technology and product offerings in the area of drug delivery, surface modification, and *in vitro* diagnostics 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,

## **Table of Contents**

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.

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, advanced stabilization reagents, slide-based microarray technologies and drug delivery platforms for ophthalmic applications.

In fiscal 2010, 2009 and 2008, our R&D expenses were \$36.1 million, \$34.4 million and \$40.5 million, respectively. Of the above amounts, \$17.9 million, \$21.2 million and \$21.3 million were spent on internal R&D in fiscal 2010, 2009 and 2008, respectively, and \$18.2 million, \$13.2 million and \$19.2 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.

## **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 filing and maintaining patent rights covering a variety of coatings, drug delivery methods, reagents, and formulations, as well as particular clinical device applications. Generally, we seek patent protection in the United States for many of our proprietary technologies. We may also file international patent applications in the locations matching the major markets of our customers (primarily in North America, Europe, and Japan). In fiscal 2010, we filed 46 United States patent applications, as well as 43 international patent applications, expanding the portfolio protection around our current technologies as well as enabling pursuit of new technology concepts, innovations, and directions.



We have licensed our patented Bravo<sup>tm</sup> Drug Delivery Polymer Matrix ( Bravo ) to Cordis Corporation, a subsidiary of Johnson & Johnson, for utilization with its Cypher<sup>®</sup> Sirolimus-eluting Coronary Stent. In particular, we have six issued U.S. patents, three pending U.S. patent applications, 30 issued international patents and two pending international patent applications protecting various aspects of Bravo, including composition and methods of manufacturing and coating products. The expiration dates for these patents range from 2019 to 2023.

## **Table of Contents**

Additionally, we have licensed our Photolink® hydrophilic technology to a number of our customers for use in a variety of medical device applications, including those described in SurModics Drug Delivery and Surface Modification Technologies Applications above. In particular, we have 8 issued U.S. patents, 13 issued international patents, and 4 pending international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture, and methods of coating devices. The expiration dates for these patents range from 2015 to 2020.

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, 2010, we had 187 pending United States patent applications, 12 of which were exclusively licensed from others, and 244 foreign patent applications, of which 42 were exclusively licensed from others. Likewise, as of September 30, 2010, we owned 109 issued United States patents, 16 of which were exclusively licensed from others, and 192 international patents, of which 65 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. 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* diagnostics 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.

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

## **Table of Contents**

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 \$5.8 million related to achievement of milestones, and the sellers are still eligible to receive up to \$16.3 million in additional consideration. 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 \$3.5 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 \$3.1 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 certain milestones.

## **Significant Customers**

We have two customers that each provided more than 10% of our revenue in fiscal 2010. Revenue from Johnson & Johnson and Medtronic represented approximately 17% and 14%, respectively, of our total revenue for the year ended September 30, 2010. The loss of one or more of our largest customers could have a material adverse effect on our business, financial condition, results of operations, and cash flow as discussed in more detail below.

## **Competition**

The ability for 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

## **Table of Contents**

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, other than the manufacture of our *in vitro* diagnostics products which we sell to our customers, all of which we manufacture in our Eden Prairie, Minnesota facility. 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 and on occasion, even commercial product. 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 warehouse and office space and constructed a cGMP manufacturing facility there in order to upgrade our manufacturing capabilities. This facility was opened and qualified in 2010. In December 2010, we announced that the Board of Directors of the Company had authorized the Company to explore strategic alternatives for the Company's Pharmaceuticals business, including a potential sale of that business, divestiture of our manufacturing facility, or other transactions that could result in the cGMP facility not being available to us to meet our manufacturing needs.

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

We follow quality management procedures in accordance with applicable regulations and guidance for the development and manufacture of materials and pharmaceutical, device, biotechnology or combination products that support clinical trials and commercialization. In an effort to better meet our customers' needs in this area, our Eden Prairie, Minnesota facility received ISO 13485:2003 and ISO 9001:2000 certification in fiscal 2004 and has received updated certifications in each subsequent year. In fiscal 2010, our Birmingham, Alabama facility received ISO

9001:2008 and ISO 13485:2003 certification.

**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

**Table of Contents**

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, 2010, we had 215 employees, of whom 166 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 69 of our employees, 27 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.

**EXECUTIVE OFFICERS OF THE REGISTRANT**

As of December 9, 2010, the names, ages and positions of the Company's executive officers are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Philip D. Ankeny	47	Interim Chief Executive Officer, Senior Vice President and Chief Financial Officer
Timothy J. Arens	43	General Manager, In Vitro Diagnostics
Charles W. Olson	46	Senior Vice President and General Manager, Medical Device
Bryan K. Phillips	39	Senior Vice President, General Counsel and Secretary
Eugene C. Rusch	62	Vice President, Manufacturing
Joseph J. Stich	45	Vice President of Marketing, Corporate Development and Strategy
Arthur J. Tipton, Ph.D.	53	Senior Vice President and General Manager, Pharmaceuticals
Jan M. Webster	51	Vice President of Human Resources



*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. In June 2010, Mr. Ankeny assumed the role of Interim Chief Executive Officer. Prior to joining SurModics, he served as Chief Financial Officer for Cognicity, Inc. from 1999 to 2002. 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.

**Table of Contents**

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.

*Timothy J. Arens* joined the Company in February 2007 as Director, Business Development. Mr. Arens became Director of Financial Planning and Analysis in October 2007. He was promoted to his current role as Senior Director of Financial Planning and Analysis and General Manager, In Vitro Diagnostics in October 2010. Prior to joining SurModics, Mr. Arens was employed at St. Jude Medical, a medical technology company, from 2003 to 2007 in positions of increasing responsibility related to business development and strategic planning functions. Mr. Arens received a B.S. in Finance from the University of Wisconsin Eau Claire in 1989 and an M.B.A. from the University of Minnesota's Carlson School of Management in 1996.

*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, Mr. Olson was named Vice President of our Cardiovascular business unit, in March 2010 he was named Senior Vice President, Business Development and Marketing, and in October 2010, he was named Senior Vice President and General Manager, Medical Device. 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 Vice President, General Counsel and Corporate Secretary in September 2008 and was promoted to Senior Vice President in October 2010. 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.

*Eugene C. Rusch* joined the Company in March 2010 as Vice President of Manufacturing. Prior to joining SurModics, Mr. Rusch served Alkermes, Inc., a biotechnology company, as Vice President/General Manager-Manufacturing Operations beginning in 2004. Prior to that, he worked for over 20 years for Hoffmann-LaRoche Pharmaceutical in several managerial positions. Mr. Rusch received his B.S. degree in Microbiology from Rutgers University.

*Joseph J. Stich* joined the Company in March 2010 as Vice President of Marketing, Corporate Development and Strategy. Before joining SurModics, Mr. Stich was Vice President of Corporate Development for Abraxis BioScience, LLC, a biotechnology company focused on oncology therapeutics. Prior to joining Abraxis, he was a Vice President of MGI Pharma, Inc., a biopharmaceutical company, from 2005 to 2009. Mr. Stich's prior experience also includes serving as President/COO of Pharmaceutical Corp. of America (a subsidiary of Publicis Healthcare Specialty Group), and positions of increasing responsibility in sales and marketing at Sanofi-Aventis Pharmaceuticals. He received his B.B.A. from the University of Wisconsin Whitewater in 1988, and his M.B.A. from Rockhurst University in Kansas City in 1996.

*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 was named Senior Vice President and Chief Scientific Officer in February 2010 and in October 2010 he was named Senior Vice President,

Pharmaceuticals. Dr. Tipton joined Southern Research Institute in 2004 as Vice President of Pharmaceutical Formulations and then became President and CEO of SurModics Pharmaceuticals in January 2005 when it was launched as a new company based on Southern Research Institute's pharmaceutical formulations business. 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),

**Table of Contents**

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 Board of the Biotechnology Association of Alabama. 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.

**Table of Contents**

**ITEM 1A. RISK FACTORS.**

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

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

During periods of economic slowdown or recession, such as the United States and world economies are currently experiencing, many of our customers are forced to delay or terminate some of their product development plans. Because we rely on licensing and commercialization of our technology by third parties, we may be severely impacted by the decreasing research and development budgets of our customers. In addition, in an environment of decreasing research and development spending, sales of our In Vitro Diagnostics products may similarly suffer as a result of the decreased utilization of research-focused products. 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, specialty pharmaceutical, 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 2010. Revenue from Johnson & Johnson and Medtronic represented approximately 17% and 14%, respectively, of our total revenue for the fiscal year ended September 30, 2010. 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<sup>tm</sup> intravitreal implant. 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 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.

**Table of Contents**

***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 products. 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.

***We could face adverse consequences as a result of the actions of a major stockholder.***

According to a Schedule 13D, filed with the Securities Exchange Commission on November 17, 2010, by Ramius LLC and certain of its affiliates, Ramius beneficially owned approximately 12% of our common stock as of the date of the filing. Ramius has publicly and privately expressed opinions with respect to the operation of our business, our business strategy, and other matters. In addition, Ramius has nominated a slate of directors for election to our Board of Directors. To the extent that Ramius is successful in preventing the Company from executing on its long-term business strategy, our business and operating results could be negatively impacted. The uncertainty and negative publicity resulting from the activities of Ramius could also have a material adverse effect on our ability to attract new employees (or retain current employees), new customers and to do additional business with our existing customers. Finally, the expenses incurred in connection with, and management distraction caused by, the actions of Ramius and our responses to those actions could 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.



**Table of Contents**

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. For example, in the fourth quarter of fiscal 2010 we recognized a goodwill impairment charge of \$13.8 million, which represented a full impairment of the remaining goodwill associated with our SurModics Pharmaceuticals acquisition. 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 necessary to commercialize such acquired technology. We cannot guarantee that we will be able to successfully complete any investments or acquisitions or that we will realize any anticipated benefits from investments or acquisitions that we complete.

***Goodwill or other assets on our balance sheet may become impaired, which could have a material adverse effect on our operating results.***

As a result of our acquisitions, we have recorded a significant amount of goodwill on our balance sheet. As required by the accounting guidance for goodwill, we evaluate at least annually the potential impairment of goodwill. Testing for impairment of goodwill involves the determination of the fair value of our reporting units. The estimation of fair values involves a high degree of judgment and subjectivity in the assumptions used. We also evaluate other assets on our balance sheet, including intangible assets, whenever events or changes in circumstances indicate that their carrying value may not be recoverable. Our estimate of the fair value of the assets may be based on fair value appraisals or discounted cash flow models using various inputs.

Future impairment of our goodwill or other assets could materially adversely affect our results of operations. For example, in the fourth quarter of fiscal 2010 we recognized an impairment charge of \$13.8 million related to goodwill associated with our acquisition of SurModics Pharmaceuticals, Inc. In addition, in fiscal 2010, we recognized asset impairment charges totaling \$4.9 million.

***Research and development costs 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 our business and integrate acquisitions could seriously harm our operating results and business.***

Executing our business strategy and integrating our past acquisitions 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 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

## **Table of Contents**

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 most 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, 2010, 2009 and 2008, we derived approximately 49%, 62% and 53% 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 results in connection with the achievement of development or commercialization milestones may also suffer. For example, Merck terminated their collaboration with us relating to the development and potential commercialization of our I-vation™ 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 revenue we derive from our customers' research and development as well as 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 or are unable to successfully manage the transition of our BioFX manufacturing operations.***

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. We have recently begun the process of migrating the production of our BioFX products from our leased facilities in Maryland to our headquarters in Eden Prairie, Minnesota. There are a number of risks associated with this move, including the loss of personnel associated with closing our Maryland facilities, damage to equipment, decreased efficiency associated with the relocation, product quality issues related to the transition, lack of continuity in key support functions and damaged customer relationships as a result of any of the above disruptions. If we experience any of the above issues in the relocation of our production

operations, we could experience material adverse effects on our business, financial condition and results of operations.

In addition, 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

## **Table of Contents**

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, and we may be subject to adverse consequences if we fail to comply with applicable regulations or contractual obligations.***

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. In addition, as part of our strategy to utilize our cGMP manufacturing facility, we may manufacture products for customers other than our licensees, substantially increasing our exposure to risks related to manufacturing beyond those previously associated with our core business.

The manufacture of pharmaceutical or biotechnology products can be an expensive, time consuming, and complex process with which we have limited experience, and which we may not fully understand the operational or cost aspects of. For example, we have limited experience in the financial planning of contract manufacturing operations, and may not fully understand our cost structures, or may enter into contract manufacturing arrangements with customers based on financial assumptions that turn out not to be true. Any failure on our part to anticipate such issues could adversely affect our business, financial condition and results of operations.

Further, any manufacturer of pharmaceutical and biotechnology products is subject to applicable cGMP regulations as prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities. 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 fines and 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 in most cases our customer agreements provide indemnification against such claims, there can be no guarantee 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, experiences 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

## **Table of Contents**

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, and we generally do not enter into employment agreements, except for with certain executive officers. Although we have non-compete agreements with most employees, there can be no assurance that such agreements will be enforceable. The loss of the services of one or more key employees or the failure to attract and retain additional qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

## **RISKS RELATING TO OUR INTELLECTUAL PROPERTY**

*If we cannot adequately protect our technologies and proprietary information, we may be unable to sustain a competitive advantage.*

Our success depends, in large part, on our ability to obtain and maintain patents, operate without infringing on the proprietary rights of third parties and protect our proprietary rights against infringement by third parties. We have been granted U.S. and foreign patents and have U.S. and foreign patent applications pending related to our proprietary technologies. There can be no assurance that any pending patent application will be approved, that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties, or that the patents of others will not prevent the commercialization of products incorporating our technologies. Furthermore, there can be no assurance that others will not independently develop similar technologies, duplicate any of our technologies or design around our patents.

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

Our commercial success also will depend, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property 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 certain other administrative 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



## **Table of Contents**

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 new legislation intended 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 our products, or the amounts of reimbursement available for their products from governmental agencies or third-party payors. Because 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.

On March 23, 2010, the Patient Protection and Affordable Care Act was signed into law. The legislation imposes significant new taxes on medical device makers who make up a significant portion of our customers. The legislation, if fully enacted, will have a significant total cost to the medical device industry, which could have a material, negative impact on both the financial condition of our customers as well as on our customers' ability to attract financing, their willingness to commit capital to development projects or their ability to commercialize their products utilizing our technology, any of which could have a material adverse effect on our business, financial condition and results of operations. There continues to be substantial risk to our customers, and therefore us, from the uncertainty which continues to surround the future of health care delivery and reimbursement both in the United States and abroad.

***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 our technologies are subject to regulation by the FDA and other regulatory authorities. In order to obtain regulatory approval for products incorporating our technologies, extensive preclinical studies as well as clinical trials in humans may be required. Clinical development, including preclinical testing, is a long, expensive and uncertain process. The burden of securing regulatory approval for these products typically rests with our licensees, the medical device or

## **Table of Contents**

pharmaceutical manufacturers. However, we have prepared Drug Master Files and Device Master Files which may be accessed by the FDA and other regulatory authorities to assist them in their review of the applications filed by our licensees.

The process of obtaining FDA and other required regulatory approvals is expensive and time-consuming. Historically, most medical devices incorporating our technologies have been subject to the FDA's 510(k) marketing 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, if 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.

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, as a result of large sales executed by significant holders of our stock, and also because of significant short positions taken by investors from time to time in our stock. In the fiscal year ended September 30, 2010, the closing sale price for our common stock ranged from \$10.67 to \$30.69 per share. In addition, since the end of our fiscal year through November 30, 2010 the closing sale price for our common stock has ranged from \$8.33 to \$13.11 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 may be unrelated to the operating performance of particular companies.

**Table of Contents**

**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, and have leased additional warehouse space near our owned facility.

In addition to our Eden Prairie facilities, 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 which we have constructed a cGMP (current good manufacturing practice) development and manufacturing facility. We also lease facilities in Owings Mills, Maryland that are used for general office space and manufacturing for our BioFX operations. We also lease office space in Irvine, California, which we vacated and subleased in connection with our March 2010 reorganization. In December 2010, we announced that the Board of Directors of the Company had authorized the Company to explore strategic alternatives for the Company's Pharmaceuticals business, including a potential sale of that business, divestiture of our manufacturing facility, or other transactions that could result in the cGMP facility not being available to us to meet our manufacturing needs.

**ITEM 3. LEGAL PROCEEDINGS.**

See Note 9 to the Consolidated Financial Statements for information regarding commitments and contingencies.

**ITEM 4. (REMOVED AND RESERVED).**

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

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

<b>Fiscal Quarter Ended:</b>	<b>High</b>	<b>Low</b>
September 30, 2010	\$ 16.68	\$ 10.62
June 30, 2010	22.25	15.00
March 31, 2010	23.31	19.00
December 31, 2009	31.00	22.05
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

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 9, 2010, there were 217 holders of record of our common stock and approximately 6,493 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, 2010, by the Company or on behalf of the Company or any affiliated purchaser of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

	(a)	(b)	(c)	(d)
	Total Number	Average	Total	Approximate Dollar
	of Shares	Price Paid	Number	Value of
			of Shares	Shares That
			Purchased	May Yet Be
			as Part of	Purchased
			Publicly	Under the
			Announced	Plans or
			Plans or	

<b>Period</b>	<b>Purchased(1)</b>	<b>per Share(1)</b>	<b>Programs</b>	<b>Programs(2)</b>
7/1/10 7/31/10	10,769	\$ 13.28	0	\$ 5,302,113
8/1/10 8/31/10	0	NA	0	\$ 5,302,113
9/1/10 9/30/10	841	\$ 10.93	0	\$ 5,302,113
Total	11,610	\$ 13.11	0	\$ 5,302,113

- (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 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, 2010, pursuant to this authorization we have repurchased a cumulative 1,024,181 shares at an average price of \$29.00 per share. Under the current authorization, the Company has \$5.3 million available for authorized share repurchases as of September 30, 2010. The repurchase authorization does not have an expiration date.

**Table of Contents**

**Stock Performance Chart**

The following chart compares the cumulative total shareholder return on the Company's Common Stock with the cumulative total return on the Nasdaq Stock Market and the Nasdaq Medical Industry Index (Medical Devices, Instruments and Supplies). The comparison assumes \$100 was invested on September 30, 2005 and assumes reinvestment of dividends.



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

The data presented below as of and for the fiscal years ended September 30, 2010, 2009 and 2008 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, 2007 and 2006 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.

	2010	2009	Fiscal Year 2008	2007	2006
	(Dollars in thousands, except per share data)				
Statements of Operations Data:					
Total revenue	\$ 69,898	\$ 121,534	\$ 97,051	\$ 73,164	\$ 69,884
Operating (loss) income	(14,053)	57,501	27,261	9,899	36,163
Net (loss) income	(21,089)	37,550	14,739	3,347	20,334
Diluted net (loss) income per share	(1.21)	2.15	0.80	0.18	1.09
Balance Sheet Data:					
Cash, short-term and long-term investments	\$ 56,786	\$ 47,868	\$ 71,978	\$ 70,225	\$ 106,571
Total assets	170,279	185,562	191,028	171,331	157,402
Retained earnings	82,900	103,989	66,439	51,620	48,273
Total stockholders' equity	154,359	172,372	141,806	130,922	145,203
Statements of Cash Flows Data:					
Net cash provided by operating activities	\$ 22,008	\$ 31,321	\$ 39,822	\$ 50,715	\$ 35,279

**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 March 2010 we announced a change in our operational structure to better align functional expertise, which resulted in the elimination of the Company's business units.

The organizational change did not diminish the Company's continued market focus. The Therapeutic market includes revenue from: (1) Cardiovascular, which provides drug delivery and surface modification technologies to customers in the cardiovascular market; (2) Ophthalmology, which is focused on 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) Other Markets, which is focused on a variety of clinical markets principally in the pharmaceutical and biotechnology industries. The Diagnostic market includes revenue from the Company's microarray slide technologies, our stabilization products, antigens and substrates for immunoassay diagnostic tests, and our *in vitro* diagnostic format technology.

In October 2010, we announced initiatives intended to reduce our cost structure. As part of these initiatives, the Company implemented a change in its organizational structure to reflect our three complementary, but distinct business units: Medical Device, Pharmaceuticals, and In Vitro Diagnostics. Because this change occurred in fiscal 2011 and is therefore not useful in explaining our fiscal 2010 results, we will describe our business below as it was conducted in fiscal 2010. Beginning with the first quarter of fiscal 2011, we will describe our business under the new reporting structure.

**Table of Contents**

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 we manage our sales and marketing efforts and our expenses on a company-wide basis. In addition, a significant percentage of our employees provide support services (including research and development) to a variety of customers, and our technologies and products are marketed to the same or similar customers.

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-va<sup>TM</sup>TA (triamcinolone acetonide) intravitreal implant. Under the terms of the Merck agreements, we received an upfront 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-va<sup>TM</sup> 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, 2010 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.

On October 5, 2009, we entered into a License and Development Agreement with F. Hoffmann-La Roche, Ltd. ( Roche ) and Genentech, Inc., a 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<sup>®</sup> (ranibizumab injection) utilizing SurModics' proprietary biodegradable microparticles drug delivery system. Under the terms of the agreement, we received an upfront 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 product.

**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

## **Table of Contents**

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. The Company licenses technology to third parties and collects royalties. Royalty revenue is generated when a customer sells products incorporating the Company's licensed technologies. Royalty revenue is recognized as our licensees report it to us, and payment is typically submitted concurrently with a quarterly report. This revenue recognition model is similar to usage fee accounting. Minimum royalty fees are recognized in the period earned, provided that collectability is reasonably assured. For stand-alone license agreements, up-front license fees are recognized over the economic life of the technology.

Revenue related to a performance milestone is recognized upon achievement of the milestone and meeting specific revenue recognition criteria. 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.

Revenue arrangements with multiple deliverables have been accounted for based on accounting guidance in existence at the time the arrangement commences. Prior to October 1, 2009, arrangements such as license and development agreements were analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and development, could be separated, or whether they must be accounted for as a single unit of accounting in accordance with accounting guidance. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately. If the license was considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations could not be determined, the arrangement would then be accounted for as a single unit of accounting, and the license payments and payments for performance obligations would be recognized as revenue over the estimated period of when the performance obligations are performed, or the economic life of the technology licensed to the customer. When we determined that an arrangement should be accounted for as a single unit of accounting, we recognized the related revenue on a time-based accounting model.

The Company had one significant multiple element arrangement prior to October 1, 2009 that was accounted for as a single unit of accounting resulting in deferral and recognition of all related payments received for license and research and development activities using a time-based model. This arrangement was terminated during the first quarter of fiscal 2009.

In October 2009, the accounting standards for multiple deliverable revenue arrangements were amended to:

- (i) provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated;
- (ii) require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling

price (TPE); and

(iii) eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

We elected to early adopt this accounting guidance at the beginning of our first quarter of fiscal 2010, on a prospective basis, for applicable transactions originating or materially modified after October 1, 2009. In connection with the adoption of the amended accounting standard we also changed our policy prospectively

## **Table of Contents**

for multiple element arrangements, whereby we account for revenue using a multiple attribution model in which consideration allocated to research and development activities is recognized as performed, and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive. Accordingly, in situations where a unit of accounting includes both a license and research and development activities, and when a license does not have stand-alone value, the Company applies a multiple attribution model in which consideration allocated to the license is recognized ratably, consideration allocated to research and development activities is recognized as performed and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive.

The Company enters into license and development arrangements that may consist of multiple deliverables which could include a license(s) to SurModics technology, research and development activities, manufacturing services, and product sales based on the needs of its customers. For example, a customer may enter into an arrangement to obtain a license to SurModics intellectual property which may also include research and development activities, and supply of products manufactured by SurModics. For these services provided, SurModics could receive upfront license fees upon signing of an agreement and granting the license, fees for research and development activities as such activities are performed, milestone payments contingent upon advancement of the product through development and clinical stages to successful commercialization, fees for manufacturing services and supply of product, and royalty payments based on customer sales of product incorporating SurModics technology. Our license and development arrangements generally do not have refund provisions if the customer cancels or terminates the agreement. Typically all payments made are non-refundable.

We evaluate each deliverable in a multiple element arrangement for separability. We are then required to allocate revenue to each separate deliverable using a hierarchy of VSOE, TPE, or ESP. In certain instances, we are not able to establish VSOE for all deliverables in an arrangement with multiple elements which may be a result of SurModics infrequently selling each element separately. When VSOE cannot be established, SurModics establishes a selling price of each element based on TPE. TPE is determined based on competitor prices for similar deliverables when sold separately.

When we are unable to establish a selling price using VSOE or TPE, we use ESP in our allocation of arrangement consideration. The objective of ESP is to determine the price at which SurModics would transact a sale if the product or service were sold on a stand-alone basis. ESP is generally used for highly customized offerings.

SurModics determines ESP for undelivered elements by considering multiple factors including, but not limited to, market conditions, competitive landscape and past pricing arrangements with similar characteristics.

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.* Accounting guidance requires us to 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 and intangibles. If such events or circumstances were to indicate that the carrying amount of these assets would not be recoverable, we would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) or other measure of fair value were less than the carrying amount of the assets, we would recognize an impairment charge.

In fiscal 2010, we recognized asset impairment charges totaling \$4.9 million. We wrote down facility-related assets in Alabama by \$1.9 million to their fair value based on a decision to sell the assets, however based on further analysis of

various factors associated with the consolidation of facilities we later decided not to sell the facility. The carrying value of the facility is \$2.1 million at September 30, 2010, which is based on a real estate appraisal obtained during our negotiations. We also wrote down certain project- and technology-related assets totaling \$1.7 million, as there were very limited business opportunities expected in light of current market conditions and general economic environment. SurModics also incurred a charge of \$1.3 million associated with certain fixed assets in Minnesota given the current level of business activity and overall economic conditions. Each of these events included analysis of expected future cash flows or real estate market data which was compared to the carrying values of the assets to



**Table of Contents**

determine the impairment charges that were recognized. The assets associated with these charges had limited remaining value and as such were written down to zero value at September 30, 2010.

*Goodwill.* We record all assets and liabilities acquired in purchase acquisitions, including goodwill, at fair value as required by accounting guidance for business combinations. The initial recognition of goodwill requires management to make subjective judgments concerning estimates of how the acquired assets will perform in the future using valuation methods including discounted cash flow analysis.

Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment in accordance with accounting guidance for goodwill. Under certain situations, interim impairment tests may be required if events occur or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount.

Evaluating goodwill for impairment involves the determination of the fair value of our reporting units in which we have recorded goodwill. A reporting unit is a component of an operating segment for which discrete financial information is available and reviewed by management on a regular basis.

We have determined that our reporting units are our SurModics Pharmaceuticals, Inc. (SurModics Pharma) subsidiary, the In Vitro Diagnostics operations and the SurModics drug delivery and hydrophilic coatings operations. The Company reorganized in March 2010 which resulted in the elimination of the Company's business units. The reporting units with goodwill resulted from the acquisitions of SurModics Pharma and BioFX Laboratories, Inc. in fiscal 2007. Inherent in the determination of fair value of our reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations as well as our strategic plans with regard to our operations.

We performed our annual impairment test of goodwill in the fourth quarter of fiscal 2010 and recognized a non-cash goodwill impairment charge of \$13.8 million, which represented a full impairment of the goodwill associated with our SurModics Pharma reporting unit. Prior to testing goodwill for impairment we tested our definite-lived assets, property, plant and equipment as well as intangible assets, under the provisions of the accounting guidance for impairment or disposal of long-lived assets, and determined that there were no impairments of these assets. We did not record any goodwill impairment charges during fiscal 2009 or 2008.

The goodwill impairment in fiscal 2010 reflected a significant decline in the estimated fair value of our reporting units, which resulted from a slowdown in business activity which was most pronounced in the fourth quarter of fiscal 2010, higher operating costs with our recently placed in-service cGMP manufacturing facility, and a significant decrease in our stock price during the year. Our stock price declined from \$24.13 per share at October 1, 2009 to \$12.03 per share at the date of our annual impairment test, which was August 31, 2010. While we continually evaluate whether any indications of impairment are present that would require an impairment analysis on an interim basis, no such indicators were considered present prior to the fourth quarter of fiscal 2010. Prior to the fourth quarter, based on our outlook for future results and the fact that our market capitalization exceeded our book value by a margin of 64% at June 30, 2010, we did not believe that the events and circumstances in existence at our interim reporting dates indicated that it was more likely than not that the fair value of any of our reporting units would be less than its carrying amount.

In evaluating whether goodwill was impaired, we compared the fair value of the reporting units to which goodwill is assigned to their carrying values (Step 1 of the impairment test). In calculating fair value, we used the income approach as our primary indicator of fair value, with the market approach used as a test of reasonableness. The income approach is a valuation technique under which we estimate future cash flows using the reporting units' financial forecasts. Future estimated cash flows are discounted to their present value to calculate fair value. The market

approach establishes fair value by comparing our company to other publicly traded guideline companies or by analysis of actual transactions of similar businesses or assets sold. The income approach is tailored to the circumstances of our business, and the market approach is completed as a secondary test to ensure that the results of the income approach are reasonable and in line with comparable companies in the industry. The summation of our reporting units' fair values was compared and reconciled to our market capitalization as of the date of our impairment test.

In the situation where a reporting unit's carrying amount exceeds its fair value, the amount of the impairment loss must be measured. The measurement of the impairment (Step 2 of the impairment test) is calculated by determining the implied fair value of a reporting unit's goodwill. In calculating the implied fair value of goodwill,

**Table of Contents**

the fair value of the reporting unit is allocated to all other assets and liabilities of that unit based on their fair values. The excess of the fair value of a reporting unit over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. The goodwill impairment is measured as the excess of the carrying amount of goodwill over its implied fair value.

In determining the fair value of our SurModics Pharma reporting unit under the income approach, our expected cash flows are affected by various assumptions. Fair value on a discounted cash flow basis used forecasts over a ten year period with an estimation of residual growth rates thereafter. We use our business plans and projections as the basis for expected future cash flows. The most significant assumptions incorporated in these forecasts for the most recent goodwill impairment tests included annual revenue changes based on current customer programs and expected progression of programs into different phases of development. A discount rate of 15 percent was used in the 2010 analysis to reflect the relevant risks of the higher growth assumed for this reporting unit. Given the significant difference between the reporting unit's fair value and carrying value, any change in the discount rate would not have changed the evaluation of impairment.

In estimating the fair value of our company under the market approach, we considered the relative merits of commonly applied market capitalization multiples based on the availability of data. Based on our analysis, we utilized the guideline public company method to support the valuation of the reporting units.

Based on the goodwill analysis performed as of August 31, 2010, the \$13.8 million of goodwill in the SurModics Pharma reporting unit failed Step 1 of the impairment test, and Step 2 of the impairment test indicated that goodwill was fully impaired. We also anticipate that this reporting unit may achieve additional milestone obligations of \$5.7 million in fiscal 2011 and we may record a goodwill impairment charge for this amount in fiscal 2011. The indicated excess in fair value over carrying value of the Company's In Vitro Diagnostics reporting unit in Step 1 of the impairment test at August 31, 2010 was approximately 82% and as such the \$8.0 million of goodwill related to this reporting unit is not impaired. To the extent that actual results or other assumptions about future economic conditions or potential for our growth and profitability in this business changes, it is possible that our conclusion regarding the goodwill could change, which could have a material effect on our financial position and results of operations. The SurModics drug delivery and hydrophilic coatings operations does not have any goodwill and was included in the analysis to assist in reconciling the fair value of all reporting units to the Company's market capitalization at August 31, 2010. See Note 2 to the consolidated financial statements for further information.

*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, 2010. Our investment policy calls for no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. Available-for-sale investments are reported at fair value with unrealized gains and losses 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. Our evaluation of the available-for-sale investments resulted in no loss recognition in fiscal 2010 and 2009. Investments for which management has the intent and ability to hold to maturity are classified as held-to-maturity and reported at amortized cost. If there was an other-than-temporary impairment in the fair value of any individual security classified as held-to-maturity, the Company would 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. See Notes 2 and 3 to the consolidated financial statements for further information.

*Income tax accruals and valuation allowances.* When preparing the consolidated financial statements, we are required to estimate the income tax obligations 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

**Table of Contents**

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 returns in future years, for which we have already recorded the expense in our consolidated statements of operations. 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, 2010 and 2009, including valuation allowances of \$6.5 million as of September 30, 2010 and \$3.3 million as of September 30, 2009. The valuation allowances related to impairment losses on investments 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. In addition, we recorded a valuation allowance related to state net operating losses based on the uncertainty regarding the realization of the net operating losses in the carryforward periods.

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, 2010, 2009 and 2008 was \$1.9 million, \$2.0 million and \$1.5 million, respectively, excluding accrued interest and penalties. Of these unrecognized tax benefits, \$1.9 million, \$2.0 million and \$1.5 million would affect our effective tax rate for fiscal years 2010, 2009 and 2008, respectively. Interest and penalties recorded for uncertain tax positions are included in our income tax provision. As of September 30, 2010, 2009 and 2008, \$0.7 million, \$0.6 million and \$0.4 million, respectively, of interest and penalties were accrued, excluding the tax benefits of deductible interest. The Internal Revenue Service has commenced an examination of our United States income tax return for fiscal 2009 in the first quarter of fiscal 2011. Fiscal years 2007 and 2008 remain subject to examination by federal tax authorities. Tax returns for state and local jurisdictions for fiscal years 2003 through 2009 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 changes in unrecognized tax benefits during fiscal 2010, 2009 and 2008.

**Table of Contents****Results of Operations***Years Ended September 30, 2010 and 2009*

<i>(Dollars in thousands)</i>	<b>Fiscal 2010</b>	<b>Fiscal 2009</b>	<b>Increase/ (Decrease)</b>	<b>% Change</b>
Revenue:				
Therapeutic				
Cardiovascular	\$ 40,155	\$ 39,841	\$ 314	1%
Ophthalmology	7,617	52,102	(44,485)	(85)%
Other Markets	10,932	13,114	(2,182)	(17)%
Total Therapeutic	58,704	105,057	(46,353)	(44)%
Diagnostic	11,194	16,477	(5,283)	(32)%
Total revenue	\$ 69,898	\$ 121,534	\$ (51,636)	(42)%

*Revenue.* Fiscal 2010 revenue was \$69.9 million, a decrease of \$51.6 million, or 42%, from fiscal 2009. The decreases in Therapeutic and Diagnostic revenue, as detailed in the table above, are further explained in the narrative below.

*Therapeutic.* Revenue in Therapeutic was \$58.7 million in fiscal 2010, a 44% decrease compared with \$105.1 million in the prior-year period. The decrease in total revenue principally reflects the recognition in fiscal 2009 of revenue of approximately \$45 million associated with the Merck collaborative research and license agreement, which was terminated effective in the first quarter of fiscal 2009. Excluding this significant event-specific item in fiscal 2009, Therapeutic revenue decreased \$1.4 million, or 2%.

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<sup>®</sup> Sirolimus-eluting Coronary Stent. The CYPHER<sup>®</sup> stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. The CYPHER<sup>®</sup> stent faces continuing competition from Boston Scientific, Medtronic, and Abbott Laboratories. Stents from these companies compete directly with the CYPHER<sup>®</sup> stent both domestically and internationally. For the last several years, royalty and reagent product sales have decreased due to lower CYPHER stent sales. We anticipate that royalty revenue from the CYPHER<sup>®</sup> stent are likely to decrease in fiscal 2011 and beyond as the various marketers of drug-eluting stents compete, and as others enter the marketplace. We also receive a royalty on sales of delivery systems used to deliver the Medtronic Endeavor<sup>®</sup> and Endeavor<sup>®</sup> Rolute drug-eluting stents. These stent delivery systems incorporate our proprietary hydrophilic technology and are sold in the United States and internationally.

Cardiovascular revenue increased \$0.3 million, or 1%, in fiscal 2010, compared with the prior-year principally as a result of higher license fees which included recognition of fees of \$1.25 million associated with a terminated agreement, and higher reagent product sales, partially offset by lower research and development revenue. Cordis CYPHER<sup>®</sup> stent sales decreased approximately 26% during fiscal 2010 which resulted in lower royalty revenue from this agreement.

Ophthalmology revenue decreased \$44.5 million, or 85%, in fiscal 2010, compared with the prior-year. The significant decrease relates to the recognition of previously deferred revenue associated with the terminated collaborative research and license agreement with Merck in fiscal 2009. In September 2008, following a strategic review of Merck's business and product development portfolio, Merck gave notice that it was terminating the collaborative research and license agreement as well as the supply agreement entered into in June 2007. The termination became effective in December 2008. We recognized the revenue previously deferred totaling \$34.8 million, and we received and recognized a \$9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program.

**Table of Contents**

Ophthalmology revenue, when excluding the Merck event-specific items of fiscal 2009, increased by \$0.5 million, or 7%, principally as a result of a license fee milestone event.

Other Markets revenue decreased \$2.2 million, or 17%, in fiscal 2010, compared with the prior-year period. Lower research and development revenue was the primary reason for the decrease. Fiscal 2010, like fiscal 2009, continued to see selected customers delay, slow or cancel development projects as a result of various factors, including current economic conditions, financing challenges, and issues in the pharmaceutical industry. Other Markets revenue is derived from more than 50 customers.

*Diagnostic.* Diagnostic revenue was \$11.2 million in fiscal 2010, a decrease of 32% compared with \$16.5 million in the prior-year period. The decrease was attributable to lower royalties and license fees in fiscal 2010. In past years, Diagnostic derived a significant percentage of revenue from Abbott Laboratories. Royalty revenue from our diagnostic format patent license agreement with Abbott was \$4.9 million in fiscal 2009. There was no royalty revenue from Abbott in fiscal 2010 because the patents had expired. In addition to the lower royalties and license fees, product sales decreased less than 1% compared with fiscal 2009 as customers continued to be cautious with their purchasing activity. We anticipate modest growth in product sales for fiscal 2011.

*Product costs.* Product costs were \$9.4 million in fiscal 2010, a 26% increase from the prior year. Overall product margins averaged 53%, compared with 61% in the prior year. The decrease in product margins reflected the mix of products sold in fiscal 2010, as there were higher polymer product sales, which products carry lower margins than our reagent and diagnostic products. There was an inventory impairment charge totaling \$0.4 million recognized in fiscal 2010. The gross margin, when adjusting for this impairment, was 55%.

*Customer research and development expenses.* Customer research and development ( Customer R&D ) expenses were \$18.1 million, an increase of 38% compared with fiscal 2009. The increase principally reflects the impact of higher fixed costs attributable to our Alabama research and development operations. Customer R&D margins were negative 18%, compared with 51% in fiscal 2009. Fiscal 2009 margins were 32% after adjusting for Merck deferred revenue recognition and final billings. The increase in fiscal 2010 costs reflects the higher fixed overhead costs in Alabama as well as increased material costs. We anticipate fiscal 2011 costs associated with our cGMP facility to increase because of maintenance and validation activities.

*Other research and development expenses.* Other research and development ( Other R&D ) expenses were \$17.9 million, a decrease of 15% compared with fiscal 2009. Overhead costs allocated to Other R&D decreased compared with fiscal 2009, and our research and development headcount decreased in fiscal 2010 compared with fiscal 2009 as a result of our March 2010 reorganization and attrition, resulting in lower labor costs. These reductions were partially offset by higher project material costs.

*Selling, general and administrative expenses.* Selling, general and administrative ( SG&A ) expenses were \$18.5 million, an increase of 7% compared with fiscal 2009. The increase principally reflects higher professional services fees, higher bad debt expenses and additional operating costs with our Alabama facilities that are allocated to SG&A, partially offset by lower stock-based compensation expense and lower SG&A headcount.

*Restructuring charges.* In March 2010, we announced an organizational change designed to support future growth by better meeting customer needs, leveraging our multiple competencies across the organization, and building on our pharmaceutical industry experience. We eliminated approximately 4% of our workforce with the terminations occurring across various functions. SurModics recorded total restructuring charges of approximately \$1.3 million in connection with the reorganization, consisting of \$0.8 million associated with severance pay and benefits expenses and \$0.5 million of facility-related costs. SurModics vacated and subleased its leased office facility in Irvine, California and a warehouse in Birmingham, Alabama.



In November 2008, we announced a functional reorganization which resulted in elimination of 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 this reorganization. These pre-tax charges consisted of \$0.5 million of severance pay and benefits expenses and \$1.3 million of facility-related costs.

**Table of Contents**

Costs totaling \$1.9 million have been paid associated with both restructurings, and we anticipate paying the remaining \$1.2 million within the next three years, with the majority in the next twelve months.

We also announced an additional restructuring subsequent to fiscal 2010 which resulted in a reduction to our cost structure and renewed focus on business units. This change resulted in the elimination of approximately 13% of our workforce with anticipated restructuring charges in the first quarter of fiscal 2011 in the range of \$1.3 million to \$1.7 million.

*Asset impairment charges.* In fiscal 2010, we recorded a \$1.9 million asset impairment charge associated with writing down one of our facilities in Alabama to fair value based on a decision to sell the facility, which we later determined not to sell. The \$2.1 million carrying value of this facility is based on a real estate market appraisal obtained during our negotiations.

We also recorded a \$1.3 million asset impairment charge associated with certain long-lived assets where very limited business is expected in the near term based on current market conditions. Furthermore, a \$1.3 million asset impairment charge associated with certain fixed asset costs located in Minnesota and a \$0.4 million asset impairment charge associated with prototypes and other equipment related to a development project for which very limited use is expected in the near term in light of current market conditions. The assets associated with these charges had limited remaining value and as such were written down to zero value.

*Goodwill impairment charge.* In fiscal 2010, we recorded a \$13.8 million goodwill impairment charge associated with our SurModics Pharmaceuticals reporting unit. The goodwill impairment charge in fiscal 2010 reflected a significant decline in the estimated fair value of our reporting units, mainly our SurModics Pharmaceuticals reporting unit, which resulted from a slowdown in business activity most pronounced in the fourth quarter of fiscal 2010, higher operating costs with our recently placed in-service cGMP manufacturing facility, and a significant decrease in our stock price during the year. Our stock price declined from \$24.13 per share at October 1, 2009 to \$12.03 per share at the date of our annual impairment test, which was August 31, 2010. We continually evaluate whether any indications of impairment are present that would require an impairment analysis on an interim basis. Prior to the fourth quarter, based on our outlook for future results and the fact that our market capitalization exceeded our book value by a margin of 64% at June 30, 2010, we did not believe that the events and circumstances in existence at our interim reporting dates indicated that it was more likely than not that the fair value of any of our reporting units would be less than its carrying amount.

*Other income (loss), net.* Other loss was \$6.6 million in fiscal 2010, compared with income of \$2.0 million in fiscal 2009. Income from investments was \$1.0 million in fiscal 2010, compared with \$1.8 million in fiscal 2009. The decrease primarily reflects lower yields generated from our investment portfolio in fiscal 2010. The fiscal 2010 loss primarily reflects a total of \$7.9 million of impairment losses in connection with our portfolio of strategic investments.

We recognized an impairment loss on our investment in Nexeon MedSystems totaling \$5.3 million in the fourth quarter of fiscal 2010 based on the valuations associated with potential new rounds of financing. In addition, we recognized a \$2.4 million loss on our investment in a medical technology company in the third quarter of fiscal 2010 based on market valuations and a pending financing round for this company. Another entity in which the Company had a strategic investment sold the majority of its assets in the third quarter of fiscal 2010 resulting in an impairment loss of \$0.2 million.

*Income tax expense.* The income tax provision was \$0.4 million in fiscal 2010, compared with \$22.0 million in fiscal 2009. The effective tax rate in fiscal 2010 is not meaningful because a tax expense was recorded on a pretax loss. The effective tax rate, when excluding the impact of the goodwill impairment charge of \$13.8 million and impairment losses on investments of \$7.9 million was 39.3% since SurModics does not currently foresee offsetting capital gains

that could offset these capital losses, and therefore no benefit has been recorded. The effective tax rate in fiscal 2009 was 36.9%. The increase in the effective tax rate, adjusted for the one-time items noted, is primarily a

**Table of Contents**

result of non-deductible stock-based compensation expenses, offset partially by lower state taxes resulting from adjustments to state deferred taxes.

*Years Ended September 30, 2009 and 2008*

<i>(Dollars in thousands)</i>	<b>Fiscal 2009</b>	<b>Fiscal 2008</b>	<b>Increase/ (Decrease)</b>	<b>% Change</b>
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. 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<sup>®</sup> Sirolimus-eluting Coronary Stent. The CYPHER<sup>®</sup> stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions.

Cardiovascular revenue decreased \$7.8 million, or 16%, in fiscal 2009, compared with the prior-year 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<sup>®</sup> stent sales.

Ophthalmology revenue increased \$41.9 million, or 408%, in fiscal 2009, compared with the prior-year. 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. Lower research and development revenue was the primary reason for the decrease. Selected customers delayed, slowed or cancelled

development projects in fiscal 2009 as a result of various factors including economic conditions.

*Diagnostic.* Revenue in Diagnostic was \$16.5 million in fiscal 2009, a decrease of 22% compared with \$21.2 million in the prior-year. 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.

**Table of Contents**

*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 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 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 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.

*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. The effective tax rate, when excluding the impact of the \$4.3 million impairment loss in fiscal 2008 was 38.9% since the Company did not foresee offsetting capital gains that could offset this capital loss, no tax benefit was recorded. 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.

## **Liquidity and Capital Resources**

*Operating Activities.* As of September 30, 2010, the Company had working capital of \$29.8 million, of which \$20.5 million consisted of cash, cash equivalents and short-term investments. Working capital increased \$0.8 million from the September 30, 2009 level, driven principally by higher income taxes receivable balances, offset by lower accounts receivable balances. Deferred revenue balances have increased as a result of the \$3.5 million upfront payment associated with the license and development agreement with Roche and Genentech

**Table of Contents**

in fiscal 2010. Our cash, cash equivalents and short-term and long-term investments totaled \$56.8 million at September 30, 2010, an increase of \$8.9 million from \$47.9 million at September 30, 2009. The increase was principally driven by cash from operations. 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 \$22.0 million in fiscal 2010, compared with \$31.3 million in fiscal 2009. The following table depicts our cash flows from operations for each of fiscal 2010 and 2009:

	<b>For the Years Ended September 30, 2010                  2009 (In thousands)</b>	
Net (loss) income	\$ (21,089)	\$ 37,550
Depreciation and amortization	7,818	5,912
Stock-based compensation	5,875	6,853
Purchased in-process research and development		3,200
Asset impairment charges	4,896	
Goodwill impairment charge	13,810	
Impairment loss on investments	7,943	
Deferred taxes and other net operating activities	774	8,672
Net change in deferred revenue	2,632	(36,050)
Net change in other operating assets and liabilities	(651)	5,184
Net cash provided by operating activities	\$ 22,008	\$ 31,321

Net (loss) income in fiscal 2010 decreased compared with fiscal 2009, which also resulted in lower cash provided by operating activities. The decrease in cash from operations reflects lower CYPHER<sup>®</sup> stent royalties and no Abbott royalties in fiscal 2010 as well as increased operating expenses associated with our facilities in Alabama. Net income was higher in fiscal 2009 principally as a result of the recognition of previously deferred revenue associated with the Merck agreement, which is a non-cash item. The Merck termination also resulted in a reduction in deferred tax asset balances, which are non-cash.

*Investing Activities.* We conduct a significant majority of our operations at our Eden Prairie, Minnesota headquarters and at our SurModics Pharmaceuticals subsidiary located in Birmingham, Alabama. In April 2008, we purchased a building for \$12.2 million with approximately 286,000 square feet of space near our original Birmingham, Alabama location. We have invested an additional \$32.9 million through fiscal 2010 in this facility, to meet the development and cGMP manufacturing needs of our pharmaceutical and biotechnology customers.



In July 2007, we made equity investments in Paragon Intellectual Properties, LLC ( Paragon ) and Apollo Therapeutics, LLC ( Apollo ), a Paragon subsidiary. The Paragon and Apollo investments totaled \$3.5 million. SurModics made an additional equity investment of \$2.5 million, based upon successful completion of specified development milestones, in fiscal 2008. In October 2008, Paragon announced that it had restructured, moving from a limited liability company with seven subsidiaries to a single C-corporation named Nexeon MedSystems, Inc. ( Nexeon ). We continued to account for our investment in Paragon and Apollo under the equity method in the first quarter of fiscal 2009, as both entities report results to us on a one-quarter lag. Commencing with the second quarter of fiscal 2009, we account for our investment in Nexeon under the cost method, as our ownership is less than 20% and we do not exert significant influence over the medical technology company s operating or financial activities.

**Table of Contents**

SurModics made an additional cash investment in Nexeon of \$500,000 in fiscal 2009. In the fourth quarter of fiscal 2010 we determined that this investment was other-than-temporarily impaired and recognized a \$5.3 million impairment loss. We held discussions with Nexeon management to understand the business status and outlook, valuations associated with potential new rounds of financing, operating metrics and other industry factors which impacted our assessment of the carrying value of this investment.

In July 2007, we entered into a stock purchase agreement with Southern Research Institute whereby we acquired 100% of the capital stock of SurModics Pharmaceuticals, Inc. (formerly known as Brookwood Pharmaceuticals, Inc.) ( SurModics Pharmaceuticals ) for \$40 million in cash on the closing date, and up to an additional \$22 million in cash upon the successful achievement of specified milestones. Additional milestones were achieved through fiscal 2010, such that \$5.8 million of additional purchase price was recorded as an increase to goodwill. The sellers are still eligible to receive up to \$16.3 million in additional consideration through calendar 2011. Based in Birmingham, Alabama, SurModics Pharmaceuticals specializes in proprietary injectable microparticles and implants to provide sustained delivery of drugs being developed by leading pharmaceutical, biotechnology and medical device clients as well as emerging companies. This acquisition has helped us broaden our technology offerings to our customers, diversify the range of markets in which we participate, expand our customer base, and enhance our pipeline of potential revenue generating opportunities. The goodwill recognized through fiscal 2010, \$13.8 million, was impaired as a result of our annual goodwill impairment testing performed at August 31, 2010. In addition, we are likely to incur certain milestone payment obligations totaling a minimum of \$5.7 million in fiscal 2011. Assuming we do, we expect to record an additional goodwill impairment charge in fiscal 2011.

In August 2007, we entered into a stock purchase agreement to acquire 100% of the capital stock of BioFX Laboratories, Inc. ( BioFX ) for \$11.3 million in cash on the closing date, and up to an additional \$11.4 million in cash upon the successful achievement of specified milestones. In fiscal 2008, a milestone was achieved and \$1.1 million of additional purchase price was recorded as an increase to goodwill. The sellers are still eligible to receive up to \$3.5 million in additional consideration through calendar 2011. Based in Owings Mills, Maryland, BioFX is a leading manufacturer of substrates, a critical component of diagnostic test kits used to detect and signal that a certain reaction has taken place. The acquisition of BioFX has broadened our product portfolio in the in vitro diagnostics market.

In November 2008, our SurModics Pharmaceuticals subsidiary entered into an asset purchase agreement with PR Pharmaceuticals, Inc. ( PR Pharma ) whereby it acquired certain contracts and assets of PR Pharma for \$2.9 million in cash on the closing date, \$0.3 million in transaction costs, and up to an additional \$6.0 million upon the successful achievement of specified milestones. In fiscal 2009, \$2.4 million of additional purchase price was paid based on achievement of certain milestones. PR Pharma is eligible to receive up to \$3.6 million in cash upon the successful achievement of additional milestones. See Note 4 to the consolidated financial statements for further information.

In August 2009, the Company invested \$2.0 million in a medical technology company with an additional \$0.5 million invested in March 2010. In the third quarter of fiscal 2010, a new round of financing was completed for this entity which resulted in significantly lower valuation when compared with previous financings. We assessed the latest information and recognized a \$2.4 million impairment loss on this investment. We account for this investment following the cost method, as our ownership level is below 20% and we do not exert significant influence over the medical technology company's operating or financial activities.

*Financing Activities.* In November 2007, our Board of Directors authorized the repurchase of up to \$35 million of the Company's common stock in open-market transactions, private transactions, tender offers, or other transactions. The repurchase authorization does not have a fixed expiration date. During fiscal 2010, we purchased 102,533 shares of common stock for \$2.0 million at an average price of \$19.81 per share. Under the current authorization, the Company has \$5.3 million remaining available for authorized share repurchases as of September 30, 2010.



**Table of Contents**

In fiscal 2009, we entered into the two-year \$25.0 million unsecured revolving credit facility. As of September 30, 2010, we had no debt outstanding under the facility. Borrowings under the credit facility, if any, will bear interest at a benchmark rate plus an applicable margin based upon the Company's funded debt to EBITDA ratio. No borrowings have yet been made on the credit facility. In connection with the credit facility, the Company is required to maintain certain financial and nonfinancial covenants. As of September 30, 2010, the Company was not in compliance with certain covenants and is working with the bank to obtain waivers. The Company expects to complete these discussions by the end of the second quarter of fiscal 2011. We believe that the noncompliance will not cause liquidity issues given the Company's investment holdings and cash flow generated by operations.

We do not have any other credit agreements and believe that our existing cash, cash equivalents and investments, together with cash flow from operations, will provide liquidity sufficient to meet the below stated needs and fund our operations for the next twelve months. There can be no assurance, however, that SurModics' business will continue to generate cash flows at current levels, and disruptions in financial markets may negatively impact the Company's ability to access capital in a timely manner and on attractive terms. Our anticipated liquidity needs for fiscal 2011 may include, but are not limited to, the following: general capital expenditures in the range of \$4 million to \$6 million; contingent consideration payments of \$5.7 million to \$6.4 million related to our acquisition of SurModics Pharmaceuticals; contingent consideration payments, if any, related to our acquisition of BioFX as well as the purchase of certain assets from PR Pharmaceuticals; and any amounts associated with the repurchase of common stock under the authorization discussed above.

*Off-Balance Sheet Arrangements and Contractual Obligations.* As of September 30, 2010, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

Presented below is a summary of contractual obligations and payments due by period (*in thousands*). See Note 9 to the consolidated financial statements for additional information regarding the below obligations.

	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More than 5 Years</b>
Operating Leases	\$ 515	\$ 258	\$ 117	\$ 124	\$ 16
Other long-term Liabilities(1)	336		187	21	128
<b>Total</b>	<b>\$ 851</b>	<b>\$ 258</b>	<b>\$ 304</b>	<b>\$ 145</b>	<b>\$ 144</b>

(1) Other long-term liability contractual obligations primarily relate to payments associated with terminated operating leases as part of our restructuring activities in fiscal 2009 and 2010.

As of September 30, 2010, our gross liability for uncertain tax positions was \$2.7 million. We are not able to reasonably estimate the amount by which the liability will increase or decrease over an extended period of time or whether a cash settlement of the liability will be required. Therefore, these amounts have been excluded from the schedule of contractual obligations.

As of September 30, 2010, our liability for financial incentives associated with creation of jobs in Alabama is \$1.7 million. We are not able to reasonably determine whether a cash settlement of the liability will be required as timing of future changes in full-time employees is uncertain at this time. Therefore, these amounts have been excluded

from the schedule of contractual obligations.

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

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

The Company's investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company's investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. SurModics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest

**Table of Contents**

rates. A one percentage point increase in interest rates would result in an approximate \$0.7 million decrease in the fair value of the Company's available-for-sale and held-to-maturity securities as of September 30, 2010, but no material impact on the results of operations or cash flows.

Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

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

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

The consolidated balance sheets as of September 30, 2010 and 2009 and the consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2010, together with Report of Independent Registered Public Accounting Firm and related footnotes (including selected unaudited quarterly financial data) begin on page F-1 of this Form 10-K.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 9A. CONTROLS AND PROCEDURES.**

**1. Disclosure Controls and Procedures.**

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the Company's management, including the Company's interim Chief Executive Officer and Chief Financial Officer regarding the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934 (the Exchange Act). Based upon that evaluation, the interim Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities Exchange Commission rules and forms, and to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosures.

**2. Internal Control over Financial Reporting.**

*a. Management's Report on Internal Control Over Financial Reporting.* Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of September 30, 2010. Deloitte & Touche LLP, the independent registered public accounting firm that

audited the financial statements included in this Annual Report on Form 10-K, has issued the attestation report below regarding the Company's internal control over financial reporting.

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

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the internal control over financial reporting of SurModics, Inc. and subsidiaries (the Company) as of September 30, 2010, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2010, based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended September 30, 2010 of the Company and our report dated December 14, 2010, expressed an unqualified opinion on those financial statements.



/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota

December 14, 2010

**Table of Contents****3. Changes in Internal Controls.**

There was no change in our internal control over financial reporting that occurred during the fourth quarter of the year covered by this Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

None.

**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The information required by Item 10 relating to directors, our audit committee, the nature of changes, if any, to procedures by which our shareholders may recommend nominees for directors, our code of ethics and compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated herein by reference to the sections entitled Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance, Corporate Governance Code of Ethics and Business Conduct, Corporate Governance Corporate Governance and Nominating Committee; Procedures & Policies and Audit Committee Report, which appear in the Company's Proxy Statement for its 2011 Annual Meeting of Shareholders. The information required by Item 10 relating to executive officers appears in Part I of this Form 10-K.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by Item 11 is incorporated herein by reference to the sections entitled Executive Compensation and Other Information, Compensation Discussion and Analysis, Director Compensation During Fiscal 2010 and Compensation Committee Report, which appear in the Company's Proxy Statement for its 2011 Annual Meeting of Shareholders.

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

The information required by Item 12 is incorporated herein by reference to the sections entitled Principal Shareholders, and Management Shareholdings which appear in the Company's Proxy Statement for its 2011 Annual Meeting of Shareholders.

**Equity Compensation Plan Information**

The following table provides information related to the Company's equity compensation plans in effect as of September 30, 2010:

(a) Number of Securities to	(b) Weighted-Average Exercise Price of	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation
-----------------------------------	--	--

<b>Plan Category</b>	<b>be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Outstanding Options, Warrants and Rights</b>	<b>Plans (Excluding Securities Reflected in Column (a))</b>
Equity compensation plans approved by shareholders	1,611,333(1)	\$ 31.02(1)	2,001,609(2)
Equity compensation plans not approved by shareholders	0	N/A	0
<b>Total</b>	<b>1,611,333</b>	<b>\$ 31.02</b>	<b>2,001,609</b>

(1) Excludes shares that may be issued under the Company's amended and restated 1999 Employee Stock Purchase Plan, but includes amounts reserved for previously-granted restricted stock and performance share awards under the 2009 Equity Incentive Plan.

(2) Includes 1,818,801 shares available for future issuance under the 2009 Equity Incentive Plan. There are 182,808 shares available under the amended and restated 1999 Employee Stock Purchase Plan.

**Table of Contents**

**ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.***

The information required by Item 13 is incorporated herein by reference to the sections entitled Corporate Governance Related Person Transaction Approval Policy, Corporate Governance Transactions With Related Parties and Corporate Governance Majority of Independent Directors; Committees of Independent Directors, which appear in the Company's Proxy Statement for its 2011 Annual Meeting of Shareholders.

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

The information required by Item 14 is incorporated herein by reference to the section entitled Independent Registered Public Accounting Firm, which appears in the Company's Proxy Statement for its 2011 Annual Meeting of Shareholders.

**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.****(a) 1. Financial Statements**

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

	<b>Page (s)</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets</u>	F-2
<u>Consolidated Statements of Operations</u>	F-3
<u>Consolidated Statements of Stockholders' Equity</u>	F-4
<u>Consolidated Statements of Cash Flows</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6 to F-32

2. *Financial Statement Schedules.* See Schedule II Valuation and Qualifying Accounts in this section of this Form 10-K. All other schedules are omitted because they are inapplicable, not required, or the information is in the consolidated financial statements or related notes.

3. *Listing of Exhibits.* The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index following the signature page.

**SurModics, Inc.**  
**Valuation and Qualifying Accounts**

<b>Column A Description</b>	<b>Column B Balance at Beginning of Period</b>	<b>Column C Additions Charged to Expenses</b>	<b>Column D Deductions From Reserves</b>	<b>Column E Balance at End of Period</b>
Year Ended September 30, 2008 Allowance for doubtful accounts	\$ 40	\$ 228	\$ 133(a)	\$ 135
Year Ended September 30, 2009 Allowance for doubtful accounts	\$ 135	\$ (34)	\$ 19(a)	\$ 82
Restructuring accrual	\$	\$ 1,763	\$ 808(b)	\$ 955
Year Ended September 30, 2010 Allowance for doubtful accounts	\$ 82	\$ 367	\$ (12)(a)	\$ 461

Restructuring accrual	\$	955	\$	1,306	\$	1,078(b)	\$	1,183
-----------------------	----	-----	----	-------	----	----------	----	-------

- (a) Uncollectible accounts written off and adjustments to the allowance.
- (b) Adjustments to the accrual account reflect payments or non-cash charges associated with the accrual.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SURMODICS, INC.

By: /s/ Philip D. Ankeny

Philip D. Ankeny  
Interim Chief Executive Officer, Senior Vice  
President and Chief Financial Officer

Dated: December 14, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant, in the capacities, and on the dates indicated.

(Power of Attorney)

Each person whose signature appears below authorizes PHILIP D. ANKENY, and constitutes and appoints said person as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, authorizing said person and granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Philip D. Ankeny Philip D. Ankeny	Interim Chief Executive Officer, Senior Vice President and Chief Financial Officer (principal executive and financial officer)	December 14, 2010
/s/ Mark A. Lehman Mark A. Lehman	Corporate Controller (principal accounting officer)	December 14, 2010
/s/ José H. Bedoya José H. Bedoya	Director	December 14, 2010
/s/ John W. Benson John W. Benson	Director	December 14, 2010

/s/ Mary K. Brainerd

Director

December 14, 2010

Mary K. Brainerd

/s/ Robert C. Buhrmaster

Director

December 14, 2010

Robert C. Buhrmaster



**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gerald B. Fischer Gerald B. Fischer	Director	December 14, 2010
Kenneth H. Keller	Director	
/s/ Susan E. Knight Susan E. Knight	Director	December 14, 2010
/s/ John A. Meslow John A. Meslow	Director	December 14, 2010
/s/ Scott R. Ward Scott R. Ward	Director	December 14, 2010

**Table of Contents**

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

**EXHIBIT INDEX TO FORM 10-K**

**For the Fiscal Year Ended September 30, 2010**

**SURMODICS, INC.**

**Exhibit**

- 2.1 Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 18, 2005, SEC File No. 0-23837.
- 2.2 Stock Purchase Agreement, dated July 31, 2007, between SurModics, Inc. and Southern Research Institute. incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated July 31, 2007, SEC File No. 0-23837.
- 3.1 Restated Articles of Incorporation, as amended incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarter ended December 31, 1999, SEC File No. 0-23837.
- 3.2 Restated Bylaws of the Company, as amended incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2009, SEC File No. 0-23837.
- 10.1\* Company's Incentive 1997 Stock Option Plan, including specimen of Incentive Stock Option Agreement incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
- 10.2\* Form of Restricted Stock Agreement under 1997 Plan incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
- 10.3\* Form of Non-qualified Stock Option Agreement under 1997 Plan incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on form SB-2, Reg. No. 333-43217.
- 10.4+ Adjusted License Agreement by and between the Company and Cordis Corporation effective as of January 1, 2003 incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2002, SEC File No. 0-23837.
- 10.5+ Reagent Supply Agreement by and between the Company and Cordis Corporation effective as of January 1, 2003 incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2002, SEC File No. 0-23837.
- 10.6\* Form of officer acceptance regarding employment/compensation incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2005, SEC File No. 0-23837.
- 10.7\* 2003 Equity Incentive Plan (as amended and restated December 13, 2005) (adopted December 13, 2005 by the board of directors and approved by the shareholders on January 30, 2006) incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed February 3, 2006, SEC File No. 0-23837.
- 10.8\* Form of SurModics, Inc. 2003 Equity Incentive Plan Nonqualified Stock Option Agreement incorporated by reference to Exhibit 99.1 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.9\* Form of SurModics, Inc. 2003 Equity Incentive Plan Incentive Stock Option Agreement incorporated by reference to Exhibit 99.2 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.10\*

Edgar Filing: SURMODICS INC - Form 10-K

- Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Agreement incorporated by reference to Exhibit 99.3 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.11\* Form of SurModics, Inc. 2003 Equity Incentive Plan Performance Share Award Agreement incorporated by reference to Exhibit 99.4 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.12\* Form of SurModics, Inc. 2003 Equity Incentive Plan Performance Unit Award (cash settled) Agreement incorporated by reference to Exhibit 99.5 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.13\* Form of SurModics, Inc. 2003 Equity Incentive Plan Restricted Stock Unit Agreement incorporated by reference to Exhibit 99.6 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.14\* Form of SurModics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (cash settled) Agreement incorporated by reference to Exhibit 99.7 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.

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

- 10.15\* Form of SurModics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (stock settled) Agreement incorporated by reference to Exhibit 99.8 to the Company's 8-K filed March 20, 2006, SEC File No. 0-23837.
- 10.16\* Change in Control Agreement with Philip D. Ankeny, dated April 19, 2006 incorporated by reference to Exhibit 99.2 to the Company's Form 8-K filed April 25, 2006, SEC File No. 0-23837.
- 10.17 The Company's Board Compensation Policy, Amended and Restated as of February 8, 2010.\*\*
- 10.18 Credit Agreement dated as of February 27, 2009, by and between SurModics, Inc. and Wells Fargo Bank, National Association as Sole Lead Arranger and Administrative Agent incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed March 4, 2009, SEC File No. 0-23837.
- 10.19\* Amendment to Change of Control Agreement, dated as of December 23, 2008, between SurModics, Inc. and Philip D. Ankeny. incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2009, SEC File No. 0-23837.
- 10.20\* Second Amendment to Change of Control Agreement, dated as of April 19, 2009, between SurModics, Inc. and Philip D. Ankeny. incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2009, SEC File No. 0-23837.
- 10.21+ License and Development Agreement between Genentech, Inc., F. Hoffmann-La Roche, Ltd., and SurModics, Inc., dated October 5, 2009 incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed February 5, 2010, SEC File No. 0-23837.
- 10.22+ Master Services Agreement by and between Genentech, Inc., F. Hoffmann-La Roche, Ltd. and SurModics, Inc., dated October 5, 2009 incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed February 5, 2010, SEC File No. 0-23837.
- 10.23\* SurModics, Inc. 2009 Equity Incentive Plan. incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q filed May 7, 2010, SEC File No. 0-23837.
- 10.24\* SurModics, Inc. 1999 Employee Stock Purchase Plan (as amended and restated November 30, 2009). incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed May 7, 2010, SEC File No. 0-23837.
- 10.25\* Form of Incentive Stock Option Agreement for the SurModics, Inc. 2009 Equity Incentive Plan incorporated by reference to Exhibit 10.4 to the Company's Form 10-Q filed May 7, 2010, SEC File No. 0-23837.
- 10.26\* Form of Non-Statutory Stock Option Agreement for the SurModics, Inc. 2009 Equity Incentive Plan incorporated by reference to Exhibit 10.5 to the Company's Form 10-Q filed May 7, 2010, SEC File No. 0-23837.
- 10.27\* Form of Performance Share Agreement for the SurModics, Inc. 2009 Equity Incentive Plan incorporated by reference to Exhibit 10.6 to the Company's Form 10-Q filed May 7, 2010, SEC File No. 0-23837.
- 10.28\* Form of Restricted Stock Agreement for the SurModics, Inc. 2009 Equity Incentive Plan incorporated by reference to Exhibit 10.7 to the Company's Form 10-Q filed May 7, 2010, SEC File No. 0-23837.
- 21 Subsidiaries of the Registrant.\*\*
- 23 Consent of Deloitte & Touche LLP.\*\*
- 24 Power of Attorney (included on signature page of this Form 10-K).\*\*
- 31.1 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002.\*\*
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002.\*\*

\* Management contract or compensatory plan or arrangement

\*\* Filed herewith

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

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of SurModics, Inc. and subsidiaries (the Company) as of September 30, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2010. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of SurModics, Inc. and subsidiaries as of September 30, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2010, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 30, 2010, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 14, 2010, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota  
December 14, 2010

F-1

---

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

	<b>2010</b>	<b>2009</b>
	<b>(In thousands, except share data)</b>	
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 11,391	\$ 11,636
Short-term investments	9,105	8,932
Accounts receivable, net of allowance for doubtful accounts of \$461 and \$82 as of September 30, 2010 and 2009, respectively	8,987	11,320
Inventories	3,047	3,330
Deferred tax asset	247	353
Prepays and other	4,701	1,443
Total Current Assets	37,478	37,014
Property and equipment, net	65,395	66,915
Long-term investments	36,290	27,300
Deferred tax asset	2,606	2,548
Intangible assets, net	15,257	17,458
Goodwill	8,010	21,070
Other assets, net	5,243	13,257
Total Assets	\$ 170,279	\$ 185,562
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 3,341	\$ 3,468
Accrued liabilities:		
Compensation	930	926
Accrued income taxes payable		186
Accrued other	1,753	1,637
Deferred revenue	562	905
Other current liabilities	1,061	862
Total Current Liabilities	7,647	7,984
Deferred revenue, less current portion	3,598	623
Other long-term liabilities	4,675	4,583
Total Liabilities	15,920	13,190
Commitments and Contingencies (Note 9)		

Stockholders' Equity		
Series A preferred stock \$ .05 par value, 450,000 shares authorized; no shares issued and outstanding		
Common stock \$ .05 par value, 45,000,000 shares authorized; 17,423,601 and 17,471,472 shares issued and outstanding	871	874
Additional paid-in capital	69,702	66,005
Accumulated other comprehensive income	886	1,504
Retained earnings	82,900	103,989
 Total Stockholders' Equity	 154,359	 172,372
 Total Liabilities and Stockholders' Equity	 \$ 170,279	 \$ 185,562

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



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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands, except net income (loss) per share)</b>		
Revenue			
Royalties and license fees	\$ 34,277	\$ 75,464	\$ 51,788
Product sales	20,184	19,333	20,052
Research and development	15,437	26,737	25,211
<b>Total revenue</b>	<b>69,898</b>	<b>121,534</b>	<b>97,051</b>
Operating costs and expenses			
Product	9,425	7,508	8,476
Customer research and development	18,147	13,183	19,187
Other research and development	17,916	21,179	21,311
Selling, general and administrative	18,451	17,200	20,816
Purchased in-process research and development		3,200	
Restructuring charges	1,306	1,763	
Asset impairment charges	4,896		
Goodwill impairment charge	13,810		
<b>Total operating costs and expenses</b>	<b>83,951</b>	<b>64,033</b>	<b>69,790</b>
<b>(Loss) income from operations</b>	<b>(14,053)</b>	<b>57,501</b>	<b>27,261</b>
Other (loss) income			
Investment income, net	1,023	1,839	3,329
Impairment loss on investments	(7,943)		(4,314)
Other income, net	314	184	616
<b>Other (loss) income, net</b>	<b>(6,606)</b>	<b>2,023</b>	<b>(369)</b>
<b>(Loss) income before income taxes</b>	<b>(20,659)</b>	<b>59,524</b>	<b>26,892</b>
Income tax provision	(430)	(21,974)	(12,153)
<b>Net (loss) income</b>	<b>\$ (21,089)</b>	<b>\$ 37,550</b>	<b>\$ 14,739</b>
Basic net (loss) income per share	\$ (1.21)	\$ 2.15	\$ 0.82
Diluted net (loss) income per share	\$ (1.21)	\$ 2.15	\$ 0.80
Weighted average shares outstanding			
Basic	17,372	17,435	18,026
Dilutive effect of outstanding stock options and non-vested stock		34	304

Diluted	17,372	17,469	18,330
---------	--------	--------	--------

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

F-3

---

**Table of Contents****SurModics, Inc. and Subsidiaries****Consolidated Statements of Stockholders' Equity  
For the Years Ended September 30, 2010, 2009 and 2008**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss) (In thousands)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance September 30, 2007	18,165	\$ 909	\$ 76,670	\$ 1,723	\$ 51,620	\$ 130,922
Components of comprehensive income, net of tax:						
Net income					14,739	14,739
Unrealized holding losses on available-for-sale securities arising during the period				(5,882)		(5,882)
Add reclassification for losses included in net income, net of tax provision of \$167				4,052		4,052
Comprehensive income						12,909
Issuance of common stock	16	1	516			517
Common stock repurchased	(342)	(17)	(13,954)			(13,971)
Common stock options exercised, net	114	4	2,514			2,518
Purchase of common stock to pay employee taxes	77	4	(1,678)			(1,674)
Excess tax benefit from stock-based compensation plans			1,081			1,081
Stock-based compensation			9,652			9,652
Other			(228)			(228)
Accounting change for income taxes					80	80
Balance September 30, 2008	18,030	901	74,573	(107)	66,439	141,806
Components of comprehensive income, net of tax:						
Net income					37,550	37,550
Unrealized holding gains on available-for-sale securities arising during the period				2,123		2,123
Add reclassification for gains included in net income, net of tax provision of \$299				(512)		(512)

Comprehensive income							39,161
Issuance of common stock	40	2	611				613
Common stock repurchased	(624)	(31)	(14,967)				(14,998)
Common stock options exercised, net	15	1	65				66
Purchase of common stock to pay employee taxes	10	1	(569)				(568)
Excess tax benefit from stock-based compensation plans			(366)				(366)
Stock-based compensation			6,853				6,853
Other			(195)				(195)
Balance September 30, 2009	17,471	874	66,005	1,504	103,989		172,372
Components of comprehensive loss, net of tax:							
Net loss					(21,089)		(21,089)
Unrealized holding losses on available-for-sale securities arising during the period				(437)			(437)
Add reclassification for gains included in net loss, net of tax benefit of \$118				(181)			(181)
Comprehensive loss							(21,707)
Issuance of common stock	40	2	608				610
Common stock repurchased	(102)	(6)	(2,026)				(2,032)
Common stock options exercised, net	14	1	281				282
Purchase of common stock to pay employee taxes	1		(545)				(545)
Excess tax benefit from stock-based compensation plans			(496)				(496)
Stock-based compensation			5,875				5,875
Balance September 30, 2010	17,424	\$ 871	\$ 69,702	\$ 886	\$ 82,900	\$	154,359

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

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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
Operating Activities			
Net (loss) income	\$ (21,089)	\$ 37,550	\$ 14,739
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	7,818	5,912	6,071
(Gain) loss on equity method investments and sales of investments	(299)	(103)	415
Amortization of premium on investments	128	139	70
Impairment loss on investments	7,943		4,314
Stock-based compensation	5,875	6,853	9,652
Purchased in-process research & development		3,200	
Asset impairment charges	4,896		
Goodwill impairment charge	13,810		
Deferred tax	446	8,229	(3,428)
Excess tax benefit from stock-based compensation plans	496	366	(1,081)
Loss on disposals of property and equipment	3	291	78
Other		(250)	
Change in operating assets and liabilities:			
Accounts receivable	2,333	3,269	1,548
Inventories	284	(679)	(154)
Accounts payable and accrued liabilities	1,135	(624)	(264)
Income taxes	(4,121)	2,656	(5,003)
Deferred revenue	2,632	(36,050)	11,452
Prepays and other	(282)	562	1,413
Net cash provided by operating activities	22,008	31,321	39,822
Investing Activities			
Purchases of property and equipment	(9,679)	(29,364)	(23,866)
Sales of property and equipment			32
Purchases of available-for-sale investments	(34,919)	(33,568)	(22,857)
Sales/maturities of investments	25,986	55,263	29,258
Purchases of held-to-maturity investments			(6,485)
Investment in other strategic assets	(500)	(2,500)	(2,562)
Purchase of licenses and patents	(210)	(631)	(2,452)
Acquisitions, net of cash acquired	(750)	(8,585)	(3,219)
Repayment of notes receivable			5,870
Other investing activities		(187)	(228)
Net cash used in investing activities	(20,072)	(19,572)	(26,509)

Edgar Filing: SURMODICS INC - Form 10-K

Financing Activities			
Excess tax benefit from stock-based compensation plans	(496)	(366)	1,081
Issuance of common stock	892	679	3,037
Repurchase of common stock	(2,032)	(14,998)	(13,971)
Purchase of common stock to pay employee taxes	(545)	(568)	(1,674)
Repayment of notes payable		(236)	(222)
Net cash used in financing activities	(2,181)	(15,489)	(11,749)
Net change in cash and cash equivalents	(245)	(3,740)	1,564
Cash and Cash Equivalents			
Beginning of year	11,636	15,376	13,812
End of year	\$ 11,391	\$ 11,636	\$ 15,376
Supplemental Information			
Cash paid for income taxes	\$ 4,105	\$ 11,285	\$ 21,058
Noncash transaction acquisition of property, plant, and equipment on account	\$ 565	\$ 1,247	\$ 1,745
Noncash transaction acquisition of intangibles on account	\$	\$ 210	\$

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

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

**Notes to Consolidated Financial Statements**

**September 30, 2010 and 2009**

**1. Description**

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

***Basis of Presentation***

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

***Subsequent Events***

Subsequent events have been evaluated through the date the financial statements were issued.

On October 14, 2010 the Company announced an organizational change to reduce its cost structure and renew its focus on business units. The Company reorganized into three market-focused business units: Medical Device, Pharmaceuticals and In Vitro Diagnostics (IVD). Previously the Company operated under a functional expertise alignment. As a result of these organizational changes, which included a 13% reduction in total workforce, the Company will incur a one-time restructuring charge of approximately \$1.3 million to \$1.7 million in the first quarter of fiscal 2011. Beginning with the first quarter of fiscal 2011, the Company will describe its business under the new reporting structure.

The Company has incurred a \$0.8 million milestone payment obligation related to the SurModics Pharmaceuticals, Inc. (SurModics Pharmaceuticals) acquisition in the first quarter of fiscal 2011.

In November 2010, the Company received notice from the Internal Revenue Service that it was awarded approximately \$1.3 million of federal grants for qualified investments made in qualified therapeutic discovery projects. These grants will be recognized in fiscal 2011 as a reduction to the Company's Other Research and Development expenses.

In addition, in December 2010, we announced that the Board of Directors of the Company had authorized the Company to explore strategic alternatives for the Company's Pharmaceuticals business, including a potential sale of that business. This decision by the Board reflects our focus on returning the Company to profitable growth, and our renewed commitment to pursuing growth opportunities and investments in our Medical Device and In Vitro Diagnostics businesses. We have retained Piper Jaffray & Co. as our financial adviser in connection with this process. The Company has made no decision to enter into any transaction regarding the Pharmaceuticals business, and there can be no assurance that we will enter into such a transaction in the future. Additional details concerning this announcement can be found in the Company's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on or before December 20, 2010.

In December 2010, we also announced that Gary R. Maharaj has been named President and Chief Executive Officer of the Company, with such appointment to be effective December 27, 2010. Mr. Maharaj will also serve as a member of the Company's Board of Directors. Mr. Maharaj previously served as President and Chief Executive Officer of Arizant Inc., a provider of patient temperature management in hospital operating rooms. Additional details concerning this announcement can be found in the Company's Current Report on Form 8-K expected to be filed with the Securities and Exchange Commission on or before December 20, 2010.

F-6

---



**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies and Select Balance Sheet Information*****Cash and Cash Equivalents***

Cash and cash equivalents consist of financial instruments with original maturities of three months or less and are stated at cost which approximates fair value.

***Investments***

Investments consist principally of U.S. government and government agency obligations and mortgage-backed securities and are classified as available-for-sale or held-to-maturity at September 30, 2010 and 2009. Available-for-sale investments are reported at fair value with unrealized gains and losses net of tax excluded from operations and reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other income (loss). This adjustment results in a new cost basis for the investment. Investments that 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.

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

		<b>2010</b>			
	<b>Original Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>		<b>Fair Value</b>
U.S. government obligations	\$ 25,968	\$ 395	\$ (34)	\$	26,329
Mortgage-backed securities	4,711	164	(48)		4,827
Municipal bonds	3,079	72			3,151
Asset-backed securities	1,146	8	(42)		1,112
Corporate bonds	5,828	24			5,852
Total	\$ 40,732	\$ 663	\$ (124)	\$	41,271

		<b>2009</b>			
	<b>Original Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>		<b>Fair Value</b>

Edgar Filing: SURMODICS INC - Form 10-K

U.S. government obligations	\$	10,837	\$	253	\$	11,090
Mortgage-backed securities		7,938		177	(106)	8,009
Municipal bonds		7,210		232		7,442
Asset-backed securities		2,334		65	(143)	2,256
Corporate bonds		1,181		3		1,184
Total	\$	29,500	\$	730	\$	(249)
						\$ 29,981

F-7

---

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

The original cost and fair value of investments by contractual maturity at September 30, 2010 were as follows (*in thousands*):

	<b>Amortized Cost</b>	<b>Fair Value</b>
Debt securities due within:		
One year	\$ 8,075	\$ 8,092
One to five years	27,046	27,541
Five years or more	5,611	5,638
Total	\$ 40,732	\$ 41,271

The following table summarizes sales of available-for-sale securities for the years ended September 30, 2010, 2009 and 2008 (*in thousands*):

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Proceeds from sales	\$ 23,986	\$ 55,263	\$ 29,258
Gross realized gains	\$ 302	\$ 823	\$ 454
Gross realized losses	\$ (3)	\$ (12)	\$ (26)

At September 30, 2010, the amortized cost and fair market value of held-to-maturity debt securities were \$4.1 million and \$4.3 million, respectively. Investments in securities designated as held-to-maturity consist of tax-exempt municipal bonds and have maturity dates ranging between three months and three years from September 30, 2010. At September 30, 2009, the amortized cost and fair market value of held-to-maturity debt securities were \$6.3 million and \$6.4 million, respectively.

***Inventories***

Inventories are principally stated at the lower of cost or market using the specific identification method and include direct labor, materials and overhead. Inventories consisted of the following as of September 30 (*in thousands*):

	<b>2010</b>	<b>2009</b>
Raw materials	\$ 1,140	\$ 1,287
Finished products	1,907	2,043
Total	\$ 3,047	\$ 3,330

***Property and Equipment***

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the assets. The Company recorded depreciation expense of \$6.2 million, \$3.8 million and \$3.1 million for the years ended September 30, 2010, 2009 and 2008, respectively.

The September 30, 2010 and 2009 balances in construction-in-progress include the cost of enhancing the capabilities of the Company's Eden Prairie, Minnesota and Birmingham, Alabama facilities. As assets are placed in service, construction-in-progress is transferred to the specific property and equipment categories and depreciated over the estimated useful lives of the assets.

In fiscal 2010, the Company recorded a \$1.9 million asset impairment charge associated with writing down one of our facilities in Alabama to fair value based on a decision to sell the facility, which decision was reversed later in fiscal 2010 (\$0.5 million related to Land, \$1.2 million related to Building and improvements and \$0.2 million related to Laboratory fixtures and equipment). The Company also recognized a \$0.8 million asset impairment charge associated with certain long-lived assets included in Laboratory fixtures and equipment where very limited

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

business is expected in the near term based on current market conditions. In addition, the Company recorded a \$1.3 million asset impairment charge associated with certain fixed asset costs located in Minnesota that were included in Construction-in-progress at September 30, 2009.

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

	<b>Useful Life (In years)</b>	<b>2010</b>	<b>2009</b>
Land		\$ 6,886	\$ 7,409
Laboratory fixtures and equipment	3 to 12	25,958	19,549
Building and improvements	1 to 39	47,084	15,911
Office furniture and equipment	3 to 10	5,879	4,550
Construction-in-progress		4,386	40,210
Less accumulated depreciation		(24,798)	(20,714)
Property and equipment, net		\$ 65,395	\$ 66,915

***Other Assets***

Other assets consist principally of strategic investments. In fiscal 2010, the balance in other assets decreased primarily as a result of impairments of three investments.

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

	<b>2010</b>	<b>2009</b>
Investment in OctoPlus	\$ 2,624	\$ 3,700
Investment in Nexeon MedSystems	285	5,651
Investment in TherapeutiX	1,185	1,185
Investment in ViaCyte (formerly Novocell)	559	559
Other	590	2,162
Other assets, net	\$ 5,243	\$ 13,257

In January 2005, the Company made an initial equity investment of approximately \$3.9 million in OctoPlus N.V. (OctoPlus), a company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers. Subsequent investments brought the Company's total investment to \$6.0 million. In October 2006, OctoPlus common stock began trading on an international exchange following an initial public offering of its common stock. With a readily determinable fair market value, the Company now treats the investment in OctoPlus as an available-for-sale investment rather than a cost method investment. Available-for-sale

investments are reported at fair value with unrealized gains and losses reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations, recorded in the other income (loss) section of the consolidated statements of income, and result in a new cost basis for the investment. As of September 30, 2010, the investment in OctoPlus represented an ownership interest of less than 10%. The Company recorded no realized gain or loss related to this investment in fiscal 2010 and 2009. The Company recognized an impairment loss on the investment totaling \$4.3 million in fiscal 2008 based on a significant decline in the stock price of OctoPlus as a result of market conditions. The cost basis in the Company's investment in OctoPlus is \$1.7 million.

Beginning in May 2005, the Company has invested \$1.2 million in ThermopeutiX, Inc. (ThermopeutiX), a California-based early stage company developing novel medical devices for the treatment of vascular and neurovascular diseases. In addition to the investment, SurModics has licensed its hydrophilic and hemocompatible

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

coating technologies to ThermoPeutiX for use with its devices. The Company's investment in ThermoPeutiX, which is accounted for under the cost method, represents an ownership interest of less than 20%.

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

In July 2007, the Company made equity investments in Paragon Intellectual Properties, LLC (Paragon) and Apollo Therapeutics, LLC (Apollo), a Paragon subsidiary, totaling \$3.5 million. SurModics made an additional equity investment in fiscal 2008 totaling \$2.5 million, based upon successful completion of specified development milestones. In addition to the investments, the Company has licensed its Finale<sup>tm</sup> prohealing coating technology and provides development services on a time and materials basis to Apollo. In October 2008, Paragon announced that it had restructured, moving from a limited liability company with seven subsidiaries to a single C-corporation named Nexeon MedSystems, Inc. (Nexeon). SurModics continued to account for the investments in Paragon and Apollo under the equity method in the first quarter of fiscal 2009, as both entities reported results to us on a one-quarter lag. Commencing with the second quarter of fiscal 2009, SurModics accounted for the investment in Nexeon under the cost method as the Company's ownership level is less than 20%, and the Company did not exert significant influence over Nexeon's operating or financial activities. The Company made an additional investment of \$500,000 in Nexeon in fiscal 2009. In the fourth quarter of fiscal 2010 the Company held discussions with Nexeon management to understand the business status and outlook, valuations associated with potential new rounds of financing, operating metrics and other industry factors which impacted the Company's assessment of the carrying value of this investment. As a result of its assessment, the Company recognized a \$5.3 million impairment loss on this investment as it was determined the investment was other-than-temporarily impaired.

In August 2009, the Company invested \$2.0 million in a medical technology company and made a follow-on investment of \$0.5 million in March 2010. The Company recognized an impairment loss on this investment totaling \$2.4 million in fiscal 2010, based on market valuations and a pending financing round for this company. The Company's investment in the medical technology company is accounted for under the cost method, as the Company's ownership interest is less than 20% and the Company did not exert significant influence over the medical technology company's operating or financial activities. Another entity in which the Company had a strategic investment sold the majority of its assets in fiscal 2010, resulting in an impairment loss of \$0.2 million to the Company. These investments are included in the category titled "Other" in the table above.

In the years ended September 30, 2010, 2009 and 2008, the Company recognized revenue of \$1.5 million, \$1.4 million and \$4.1 million, respectively, from activity with companies in which it had a strategic investment.

***Intangible Assets***

Intangible assets consist principally of acquired patents and technology, customer relationships, licenses, and trademarks. The Company recorded amortization expense of \$1.6 million, \$2.1 million, and \$3.0 million for the years ended September 30, 2010, 2009 and 2008, respectively.

In fiscal 2010, the Company recognized an asset impairment charge of \$0.7 million associated with certain patent rights. Management applied the accounting guidance associated with long-lived assets and determined an impairment occurred for these assets as very limited business is expected in the near term based on current market conditions.



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

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

	<b>Useful Life (In years)</b>	<b>2010</b>	<b>2009</b>
Customer lists	9-11	\$ 8,657	\$ 8,657
Core technology	8-18	8,330	8,330
Patents and other	2-20	2,376	3,076
Trademarks		600	600
Less accumulated amortization		(4,706)	(3,205)
Intangible assets, net		\$ 15,257	\$ 17,458

Based on the intangible assets in service as of September 30, 2010, estimated amortization expense for the next five fiscal years is as follows (*in thousands*):

2011	\$ 1,546
2012	1,544
2013	1,544
2014	1,544
2015	1,533

***Goodwill***

The following table summarizes the changes in the carrying amount of goodwill (*in thousands*):

Balance at October 1, 2008	\$ 18,001
Acquisitions	3,016
Adjustment	53
Balance at September 30, 2009	21,070
Acquisitions	750
Goodwill Impairment	(13,810)
Balance at September 30, 2010	\$ 8,010

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. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that the carrying amount of goodwill may be impaired.

The Company has determined that the reporting units are the SurModics Pharmaceuticals, Inc. subsidiary, the In Vitro Diagnostics operations and the SurModics drug delivery and hydrophilic coatings operations. The reporting units with goodwill resulted from the acquisitions of SurModics Pharma and BioFX Laboratories, Inc. in fiscal 2007. Inherent in the determination of fair value of the reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations as well as the Company's strategic plans with regard to its operations.

The Company performed its annual impairment test of goodwill in the fourth quarter of fiscal 2010 and recognized a goodwill impairment charge of \$13.8 million, which represented a full impairment of the goodwill associated with the SurModics Pharma reporting unit. Prior to testing goodwill for impairment the Company tested its definite-lived assets, property, plant and equipment as well as intangible assets, under the provisions of the accounting guidance for impairment or disposal of long-lived assets, and determined that there were no impairments of these assets. The Company did not record any goodwill impairment charges during fiscal 2009 or 2008.

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

The goodwill impairment in fiscal 2010 reflected a significant decline in the estimated fair value of the Company's reporting units, which resulted from a slowdown in business activity which was most pronounced in the fourth quarter of fiscal 2010, higher operating costs with the recently placed in-service current Good Manufacturing Practices (cGMP) manufacturing facility, and a significant decrease in the Company's stock price during the year. The stock price declined from \$24.13 per share at October 1, 2009 to \$12.03 at the date of the annual impairment test, which was August 31, 2010. While the Company continually evaluates whether any indications of impairment are present which would require an impairment analysis on an interim basis, no such indicators were considered present prior to the fourth quarter of fiscal 2010. Prior to the fourth quarter, based on the Company's outlook for future results and the fact that the market capitalization exceeded the Company's book value by a margin of 64% at June 30, 2010, Company management did not believe that the events and circumstances in existence at interim reporting dates indicated it was more likely than not that the fair value of any of the Company's reporting units would be less than its carrying amount.

In evaluating whether goodwill was impaired, the Company compared the fair value of the reporting units to which goodwill is assigned to their respective carrying values (Step 1 of the impairment test). In calculating fair value, the Company used the income approach as the primary indicator of fair value with the market approach used as a test of reasonableness. The income approach is a valuation technique under which the Company estimates future cash flows using the reporting units' financial forecasts. Future estimated cash flows are discounted to their present value to calculate fair value. The market approach establishes fair value by comparing SurModics to other publicly traded guideline companies or by analysis of actual transactions of similar businesses or assets sold. The income approach is tailored to the circumstances of the Company's business, and the market approach is completed as a secondary test to ensure that the results of the income approach are reasonable and in line with comparable companies in the industry. The summation of the reporting units' fair values were compared and reconciled to the Company's market capitalization as of the date of the impairment test.

In the situation where a reporting unit's carrying amount exceeds its fair value, the amount of the impairment loss must be measured. The measurement of the impairment (Step 2 of the impairment test) is calculated by determining the implied fair value of a reporting unit's goodwill. In calculating the implied fair value of goodwill, the fair value of the reporting unit is allocated to all other assets and liabilities of that unit based on their fair values. The excess of the fair value of a reporting unit over the amount assigned to its other assets and liabilities is the implied fair value of goodwill. The goodwill impairment is measured as the excess of the carrying amount of goodwill over its implied fair value.

In determining the fair value of the SurModics Pharma reporting unit under the income approach, the SurModics Pharma expected cash flows are affected by various assumptions. Fair value on a discounted cash flow basis used forecasts over a ten year period with an estimation of residual growth rates thereafter. The Company uses its business plans and projections as the basis for expected future cash flows. The most significant assumptions incorporated in these forecasts for the most recent goodwill impairment tests included annual revenue changes based on current customer programs and expected progression of programs into different phases of development. A discount rate of 15 percent was used in the 2010 analysis to reflect the relevant risks of the higher growth assumed for this reporting unit. Given the significant difference between the reporting unit's fair value and carrying value any change in the discount rate would not have changed the evaluation of impairment.

In estimating the fair value of the Company under the market approach, management considered the relative merits of commonly applied market capitalization multiples based on the availability of data. Based on the analysis, the Company utilized the guideline public company method to support the valuation of the reporting units.

Based on the goodwill analysis performed as of August 31, 2010, goodwill in the SurModics Pharma reporting unit failed Step 1 of the impairment test and Step 2 of the impairment test indicated that goodwill was fully impaired. The indicated excess in fair value over carrying value of the Company's In Vitro Diagnostics reporting unit in Step 1 of the impairment test at August 31 2010 was approximately 82% and as such the \$8.0 million of goodwill related to this reporting unit is not impaired. The SurModics drug delivery and hydrophilic coatings

F-12

---

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

operations does not have any goodwill and was included in the analysis to assist in reconciling the fair value of all reporting units to the Company's market capitalization at August 31, 2010.

***Impairment of Long-Lived Assets***

The Company periodically evaluates whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of long-lived assets, such as property and equipment, intangible assets and investments. If such events or circumstances were to indicate that the carrying amount of these assets would not be recoverable, the Company would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) or other measure of fair value were less than the carrying amount of the assets, the Company would recognize an impairment loss reducing the carrying value to fair market value. See the Property and Equipment, Other Assets and Intangible Assets sections in Note 2 for further information on impairments that were recognized in fiscal 2010.

***Revenue Recognition***

The Company recognizes revenue 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. When there are additional performance requirements, revenue is recognized when all such requirements have been satisfied.

The Company's revenue is derived from three primary sources: (1) royalties and license fees from licensing its proprietary drug delivery and surface modification technologies to customers; (2) the sale of polymers and reagent chemicals, stabilization products, antigens, substrates and microarray slides to the diagnostics and biomedical research industries; and (3) research and development fees generated on customer projects.

Taxes collected from customers and remitted to governmental authorities are excluded from revenue and amounted to \$0.1 million, \$0.2 million and \$0.3 million for the years ended September 30, 2010, 2009 and 2008, respectively.

*Royalties and licenses fees.* The Company licenses technology to third parties and collects royalties. Royalty revenue is generated when a customer sells products incorporating the Company's licensed technologies. Royalty revenue is recognized as licensees report it to the Company, and payment is typically submitted concurrently with the report. This revenue recognition model is similar to usage fee accounting. Minimum royalty fees are recognized in the period earned, provided that collectability is reasonably assured. For stand-alone license agreements, up-front license fees are recognized over the economic life of the technology.

*Milestone payments.* Revenue related to a performance milestone is recognized based upon the achievement of the milestone, as defined in the respective agreements and provided the following conditions have been met:

The milestone payment is non-refundable;

The milestone involved a significant degree of risk, and was not reasonably assured at the inception of the arrangement;

Edgar Filing: SURMODICS INC - Form 10-K

Accomplishment of the milestone involved substantial past effort/performance;

The amount of the milestone payment is commensurate with the related effort and risk;

The milestone payment is reasonable in comparison to all of the deliverables and payment terms in the arrangement; and

A reasonable amount of time passed between the initial license payment and the first and subsequent milestone payments.

F-13

---

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

If these conditions have not been met, the milestone payment is deferred and recognized over the economic life of the technology.

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

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

*Arrangements with multiple deliverables.* Prior to October 1, 2009, arrangements such as license and development agreements were analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and development, could be separated, or whether they must be accounted for as a single unit of accounting in accordance with accounting guidance. If the fair value of the undelivered performance obligations could be determined, such obligations would then be accounted for separately. If the license was considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations could not be determined, the arrangement would then be accounted for as a single unit of accounting, and the license payments and payments for performance obligations would be recognized as revenue over the estimated period of when the performance obligations are performed, or the economic life of the technology licensed to the customer. When the Company determined that an arrangement should be accounted for as a single unit of accounting, it recognized the related revenue on a time-based accounting model.

The Company had one significant multiple element arrangement prior to October 1, 2009 that was accounted for as a single unit of accounting resulting in deferral and recognition of all related payments received for license and research and development activities using a time-based model. This arrangement was terminated during the first quarter of fiscal 2009 as described in Note 1 above.

In October 2009, the accounting standards for multiple deliverable revenue arrangements were amended to:

- (i) provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated;
- (ii) require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and
- (iii) eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

The Company elected to early adopt this accounting guidance at the beginning of its first quarter of fiscal 2010, on a prospective basis, for applicable transactions originating or materially modified after October 1, 2009. In connection with the adoption of the amended accounting standard the Company also changed its policy prospectively for multiple

element arrangements, whereby the Company accounts for revenue using a multiple attribution model in which consideration allocated to research and development activities is recognized as performed, and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive. Accordingly, in situations where a unit of accounting includes both a license and research and development activities, and when a license does not have stand-alone value, the Company applies a multiple attribution model in which consideration allocated to the license is recognized ratably, consideration allocated to research and development activities is recognized as performed and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive.

F-14

---



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

The Company enters into license and development arrangements that may consist of multiple deliverables which could include a license(s) to SurModics technology, research and development activities, manufacturing services, and product sales based on the needs of its customers. For example, a customer may enter into an arrangement to obtain a license to SurModics intellectual property which may also include research and development activities, and supply of products manufactured by SurModics. For these services provided, SurModics could receive upfront license fees upon signing of an agreement and granting the license, fees for research and development activities as such activities are performed, milestone payments contingent upon advancement of the product through development and clinical stages to successful commercialization, fees for manufacturing services and supply of product, and royalty payments based on customer sales of product incorporating SurModics technology. The Company's license and development arrangements generally do not have refund provisions if the customer cancels or terminates the agreement. Typically all payments made are non-refundable.

The Company evaluates each deliverable in a multiple element arrangement for separability. The Company is then required to allocate revenue to each separate deliverable using a hierarchy of VSOE, TPE, or ESP. In certain instances, the Company is not able to establish VSOE for all deliverables in an arrangement with multiple elements which may be a result of the Company infrequently selling each element separately. When VSOE cannot be established, the Company establishes a selling price of each element based on TPE. TPE is determined based on competitor prices for similar deliverables when sold separately.

When the Company is unable to establish a selling price using VSOE or TPE, the Company uses ESP in its allocation of arrangement consideration. The objective of ESP is to determine the price at which the Company would transact a sale if the product or service were sold on a stand-alone basis. ESP is generally used for highly customized offerings.

The Company determines ESP for undelivered elements by considering multiple factors including, but not limited to, market conditions, competitive landscape and past pricing arrangements with similar characteristics.

Net sales as reported and pro forma net sales that would have been reported for the year ended September 30, 2010, if the transactions entered into or materially modified after September 30, 2009 were subject to the Company's accounting policies under the previous accounting guidance, are shown in the following table (*in thousands*):

	<b>As Reported</b>	<b>Pro Forma Basis as if the Previous Accounting Guidance Were in Effect</b>
Total multiple element arrangement revenue	\$ 4,232	\$ 378

The impact to revenue for the fiscal year ended September 30, 2010 associated with adoption of the new accounting guidance was primarily related to research and development activities. The Company's accounting policies under the previous accounting guidance would have resulted in partial recognition of the research and development revenue in the current periods with the remainder deferred and recognized over the economic life of the technology. Under the new accounting guidance, the Company is recognizing research and development revenue as the activities are performed. The Company notes that this new accounting guidance will result in current revenue recognition of

research and development activities in the period the activities are performed with the revenue generated changing from period to period based on the stage of project development. The amount of revenue that is recognized could be material in any reporting period.

In April 2010, the FASB issued updated authoritative accounting guidance which provides a consistent framework for applying the milestone method of revenue recognition in arrangements that include research or development deliverables. The amendments are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. The Company is evaluating the guidance and does not expect the adoption to have a material impact on the Company's consolidated financial statements.

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

*Merck Agreement.* On June 27, 2007 the Company announced a license and research collaboration agreement with Merck & Co., Inc. (Merck). The agreement called for SurModics and Merck to pursue the joint development and commercialization of SurModics I-vation sustained drug delivery system with TA (triamcinolone acetonide), and other products combining certain of Merck's proprietary drug compounds and the I-vation system for the treatment of serious retinal diseases. Under the terms of the agreement, Merck led and funded development and commercialization activities. SurModics received an up-front license fee of \$20 million in fiscal 2007 and additional license fees totaling \$11 million in fiscal 2008. In addition, the Company was paid for its activities in researching and developing the combination products. Research and development fees totaling \$5.8 million were billed in fiscal 2008. The Company recognized out-of-pocket reimbursements, totaling \$1.6 million in fiscal 2008, as revenue in the period since the related costs were incurred when commensurate value was transferred to Merck in exchange for the reimbursement received.

In September 2008, following a strategic review of Merck's business and product development portfolio, Merck gave notice to SurModics of its intent to terminate the collaborative research and license agreement as well as the supply agreement entered into in June 2007. The termination was effective December 2008. The Company recognized all remaining deferred revenue related to the Merck agreement, totaling \$34.8 million, as revenue in fiscal 2009. The Company also recognized a \$9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program in fiscal 2009.

The Company recognized revenue from the up-front license fee, additional license fees and research and development fees over the economic life of the technology licensed to Merck, which was 16 years, prior to termination of the contract.

***Deferred Revenue***

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets, with deferred revenue to be recognized beyond one year being classified as non-current deferred revenue. As of September 30, 2010 and 2009, the Company had deferred revenue of \$4.2 million and \$1.5 million, respectively.

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

***Research and Development***

Research and development costs are expensed as incurred. Some research and development costs are related to third party contracts, and the related revenue is recognized as described in Revenue Recognition above. The research and development costs are presented in the consolidated statements of operations in two categories; those associated with customer-related projects and those associated with other research and development costs.

Costs associated with customer-related research and development include specific project direct labor costs and material expenses as well as an allocation of overhead costs based on direct labor dollars.

***Use of Estimates***

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

F-16

---

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

***New Accounting Pronouncements***

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

**3. Fair Value Measurements**

The accounting guidance on fair value measurements defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. The guidance is applicable for all financial assets and liabilities and for all nonfinancial assets and liabilities recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Fair value is defined as the exchange price that would be received from selling an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and also considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

***Fair Value Hierarchy***

Accounting guidance on fair value measurements requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1 Quoted (unadjusted) prices in active markets for identical assets or liabilities.

The Company's Level 1 asset consists of its investment in OctoPlus (see Note 2 for further information). The fair market value of this investment is based on the quoted price of OctoPlus shares as traded on the Amsterdam Stock Exchange.

Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

The Company's Level 2 assets consist of money market funds, U.S. Treasury securities, corporate bonds, municipal bonds, U.S. agency securities, agency and municipal securities and certain asset-backed securities and mortgage-backed securities. Fair market values for these assets are based on quoted vendor prices and broker pricing where all significant inputs are observable.

Level 3 Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

The Company's Level 3 assets include a U.S. government agency security and certain asset-backed and mortgage-backed securities. The fair market values of these investments were determined by broker pricing where not

all significant inputs were observable.

In valuing assets and liabilities, the Company is required to maximize the use of quoted market prices and minimize the use of unobservable inputs.

We did not significantly change our valuation techniques from prior periods.

F-17

---

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)*****Assets and Liabilities Measured at Fair Value on a Recurring Basis***

In instances where the inputs used to measure fair value fall into different levels of the fair value hierarchy, the fair value measurement has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular item to the fair value measurement in its entirety requires judgment, including the consideration of inputs specific to the asset or liability. The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2010 (*in thousands*):

	<b>Quoted Prices in Active Markets for Identical Instruments (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total Fair Value as of September 30, 2010</b>
Assets:				
Cash equivalents	\$	\$ 10,128	\$	\$ 10,128
Available for sale debt securities				
US government obligations		25,626	704	26,330
Mortgage backed securities		4,757	69	4,826
Municipal bonds		3,150		3,150
Asset backed securities		1,113		1,113
Corporate bonds		5,852		5,852
Other assets	2,624			2,624
Total assets measured at fair value	\$ 2,624	\$ 50,626	\$ 773	\$ 54,023

Short-term and long-term investments disclosed in the consolidated balance sheets include held-to-maturity investments totaling \$4.1 million as of September 30, 2010. Held-to-maturity investments are carried at amortized cost.

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2009 (*in thousands*):

	<b>Quoted Prices in Active Markets for Identical Instruments</b>	<b>Significant Other Observable Inputs</b>	<b>Significant Unobservable Inputs</b>	<b>Total Fair Value as of September 30,</b>
--	--	--	--	---

Edgar Filing: SURMODICS INC - Form 10-K

	(Level 1)	(Level 2)	(Level 3)	2009
Assets:				
Cash equivalents	\$	\$ 9,108	\$	\$ 9,108
Available for sale debt securities				
US government obligations		9,960	1,130	11,090
Mortgage backed securities		7,935	73	8,008
Municipal bonds		7,443		7,443
Asset backed securities		2,256		2,256
Corporate bonds		1,184		1,184
Other assets	3,700			3,700
Total assets measured at fair value	\$ 3,700	\$ 37,886	\$ 1,203	\$ 42,789

F-18

---



**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)*****Changes in Level 3 Instruments Measured at Fair Value on a Recurring Basis***

The following tables (*in thousands*) provide a reconciliation of fiscal 2010 and 2009 financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3). Transfers of instruments into and out of Level 3 are based on beginning of year values.

**Fair Value Measurements Using Significant  
Unobservable Inputs (Level 3)  
For the Year Ended September 30, 2010  
Available-for-Sale Debt Securities**

	U.S.		
	Government Obligations	Mortgage Backed	Total
Balance, September 30, 2009	\$ 1,130	\$ 73	\$ 1,203
Transfers into Level 3		148	148
Transfers out of Level 3	(36)	(145)	(181)
Total realized and unrealized gains (losses):			
Included in other comprehensive (loss) income	(33)	3	(30)
Purchases, issuances, sales and settlements, net	(357)	(10)	(367)
Balance, September 30, 2010	\$ 704	\$ 69	\$ 773

**Fair Value Measurements Using Significant  
Unobservable Inputs (Level 3)  
For the Year Ended September 30, 2009  
Available-for-Sale Debt Securities**

	U.S.			
	Government Obligations	Corporate	Mortgage Backed	Total
Balance, September 30, 2008	\$ 74	\$ 190	\$	\$ 264
Transfers into Level 3	1,273		79	1,352
Transfers out of Level 3	(581)	(199)		(780)
Total realized and unrealized gains (losses):				
Included in other comprehensive income (loss)	15	9	1	25
Purchases, issuances, sales and settlements, net	349		(7)	342
Balance, September 30, 2009	\$ 1,130	\$	\$ 73	\$ 1,203

As of September 30, 2010, marketable securities measured at fair value using Level 3 inputs were comprised of \$0.7 million of an Other U.S. government security and \$0.1 million of a mortgage-backed security within the Company's available-for-sale investment portfolio. These securities were measured using observable market data and Level 3 inputs as a result of the lack of market activity and liquidity. The fair value of these securities was based on the Company's assessment of the underlying collateral and the creditworthiness of the issuer of the securities.

***Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis***

The Company's investments in non-marketable securities of private companies are accounted for using the cost method as the Company does not exert significant influence over the investees' operating or financial activities. These investments, as well as held-to-maturity securities, are measured at fair value on a non-recurring basis when they are deemed to be other-than-temporarily impaired. In determining whether a decline in value of non-marketable equity investments in private companies has occurred and is other-than-temporary, an assessment is made by considering available evidence, including the general market conditions in the investee's industry, the investee's product development status and subsequent rounds of financing and the related valuation and/or the Company's participation in such financings. The Company also assesses the investee's ability to meet business milestones and the financial condition and near-term prospects of the individual investee, including the rate at

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

which the investee is using its cash and the investee's need for possible additional funding at a potentially lower valuation. The valuation methodology for determining the decline in value of non-marketable equity securities is based on inputs that require management judgment and are Level 3 inputs. The Company wrote down three investments totaling \$7.9 million in the year ended September 30, 2010, as the investments were deemed to be other-than-temporarily impaired. A pending round of financing at a substantially lower valuation at one of the private companies resulted in impairment loss of \$2.4 million. Another company sold off assets in light of current market conditions and this action resulted in impairment loss of \$0.2 million. In addition, an impairment loss of \$5.3 million was recognized related to a third company, which continues to face operational and financing difficulties and potential rounds of financing at lower valuations. Management utilized Level 3 inputs which included information about pending financings as well as market input to determine the fair value of these investments.

The Company also incurred long-lived asset impairment charges totaling \$4.9 million in fiscal 2010. Fair value measurements used in the impairment reviews of property and equipment and intangible assets are Level 3 measurements that require management judgment. The Company recorded a \$1.9 million asset impairment charge associated with writing down one of its facilities in Alabama to fair value based on a decision to sell the facility, which decision was reversed later in fiscal 2010. The \$2.1 million carrying value of this facility is based on a real estate market appraisal obtained during the Company's negotiations.

The Company also recorded a \$1.3 million asset impairment charge associated with certain long-lived assets where very limited business is expected in the near term based on current market conditions. Furthermore, a \$1.3 million asset impairment charge associated with certain fixed asset costs located in Minnesota and a \$0.4 million asset impairment charge associated with prototypes and other equipment related to a development project for which very limited business is expected in the near term in light of current market conditions were also recognized. The assets associated with these charges had limited remaining value and as such were written down to zero value.

See Note 2 for additional information related to these impairments

**4. Acquisitions**

*PR Pharmaceuticals, Inc.* On November 4, 2008, the Company's SurModics Pharmaceuticals, Inc. (formerly known as Brookwood Pharmaceuticals, Inc.) subsidiary entered into an asset purchase agreement with PR Pharmaceuticals, Inc. (PR Pharma), whereby it acquired certain contracts and assets of PR Pharma for \$5.6 million consisting of \$2.9 million in cash on the closing date, additional consideration of \$2.4 million upon successful achievement of specified milestones and \$0.3 million in transaction costs. PR Pharma is eligible to receive up to an additional \$3.6 million in cash upon the successful achievement of milestones for contract signing and invoicing, successful patent issuances and product development. Management believes this acquisition strengthens the Company's portfolio of drug delivery technologies for the pharmaceutical and biotechnology industries. The purchase price was allocated as follows as of November 4, 2008 (*in thousands*):

Core technology	\$ 1,400
Customer relationships	900
In-process research and development	3,200
Trade names	20
Non-compete agreements	50

Total purchase price

\$ 5,570

The acquired developed technology is being amortized on a straight-line basis over 18 years, customer relationships are being amortized over 9 years, and non-compete agreements are being amortized over 2 years. The trade names had a life of less than one year and were fully amortized in fiscal 2009. As part of the acquisition, the

F-20

---

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

Company recognized fair value associated with in-process research and development (IPR&D) of \$3.2 million. The IPR&D was expensed on the date of acquisition and relates to polymer-based drug delivery systems. The value assigned to IPR&D is related to projects for which the related products have not achieved commercial feasibility and have no future alternative use. The amount of purchase price allocated to IPR&D was based on estimating the future cash flows of each project and discounting the net cash flows back to their present values. The discount rate used was determined at the time of acquisition in accordance with accepted valuation methods. These methodologies include consideration of the risk of the project not achieving commercial feasibility. The research efforts ranged from 5% to 50% complete at the date of acquisition. The Company used the Relief from Royalty valuation method to assess the fair value of the projects with a risk-adjusted discount rate of 25%. The Company determined the method was appropriate based on the nature of the projects and future cash flow streams. The research and development work performed is billed to customers, in most cases, using standard commercial billing rates which include a reasonable markup. Accordingly, the Company has no fixed cost obligations to carry projects forward. There have been no significant changes to the development plans for the acquired incomplete projects. Significant net cash inflows would commence with the commercial launch of customer products that are covered by the intellectual property rights and related agreements acquired from PR Pharma.

**5. Revolving Credit Facility**

In February 2009, the Company entered into a two-year \$25.0 million unsecured revolving credit facility. Borrowings under the credit facility, if any, will bear interest at a benchmark rate plus an applicable margin based upon the Company's funded debt to EBITDA ratio. In connection with the credit facility, the Company is required to maintain certain financial and nonfinancial covenants. As of September 30, 2010, the Company had no debt outstanding and was not in compliance with certain covenants. The Company is working with the bank to obtain waivers and expects to complete these activities by the end of the second quarter of fiscal 2011. The Company believes that noncompliance will not cause liquidity issues given the Company's investment holdings and cash flow generated by operations.

**6. Stockholders Equity**

The Company has stock-based compensation plans under which it grants stock options, restricted stock awards and performance share awards. Accounting guidance requires all share-based payments to be recognized as an operating expense, based on their fair values, over the requisite service period. The Company's stock-based compensation expenses for the years ended September 30 were allocated to the following expense categories (*in thousands*):

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Product	\$ 139	\$ 87	\$ 161
Customer research and development	772	815	1,794
Other research and development	2,399	2,806	1,999
Selling, general and administrative	2,565	3,145	5,698
Total	\$ 5,875	\$ 6,853	\$ 9,652

As of September 30, 2010, approximately \$4.8 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.4 years. The unrecognized compensation costs above exclude \$1.2 million associated with performance share awards that are currently not anticipated to be fully expensed because the performance conditions are not expected to be met.

F-21

---

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

The Company uses the Black-Scholes option pricing model to determine the weighted average grant date fair value of stock options granted. The weighted average per share fair value of stock options granted during fiscal 2010, 2009, and 2008 was \$6.78, \$8.95, and \$14.85, respectively. The assumptions used as inputs in the model for the years ended September 30 were as follows:

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Risk-free interest rates	1.95%	2.30%	2.80%
Expected life	4.8 years	4.8 years	4.6 years
Expected volatility	41%	40%	37%
Dividend yield	0%	0%	0%

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

The Company's Incentive Stock Options (ISO) are granted at a price of at least 100% of the fair market value of the common stock of the Company on the date of the grant or 110% with respect to optionees who own more than 10% of the total combined voting power of all classes of stock. ISOs generally expire in seven years or upon termination of employment and generally are exercisable at a rate of 20% per year commencing one year after the date of grant. Non-qualified stock options are granted at fair market value on the date of grant. Non-qualified stock options expire in 7 to 10 years or upon termination of employment or service as a Board member. Non-qualified stock options granted prior to May 2008 generally become exercisable with respect to 20% of the shares on each of the first five anniversaries following the grant date, and nonqualified stock options granted subsequent to May 2008 generally become exercisable with respect to 25% on each of the first four anniversaries following the grant date. Shareholders approved the 2009 Equity Incentive Plan (2009 Plan) at the February 8, 2010 Annual Meeting of Shareholders. The 2009 Plan has 1,500,000 shares authorized, plus the number of shares that have not yet been awarded under the 2003 Equity Incentive Plan, or were awarded and subsequently returned to the pool of available shares under the 2003 Equity Incentive Plan pursuant to its terms. At September 30, 2010, there were 1,819,000 shares available for future awards. As of September 30, 2010, the aggregate intrinsic value of the option shares outstanding and option shares exercisable was not meaningful, as the Company's stock price of \$11.92 per share on September 30, 2010 was below the value of option shares outstanding and exercisable. At September 30, 2010, the average remaining contractual life of options outstanding and options exercisable was 4.3 and 3.3 years, respectively. There was no intrinsic value associated with options exercised during fiscal 2010 as the Company's stock price of \$11.92 per share on September 30, 2010 was below the value of options exercised. The intrinsic value of options exercised during fiscal 2009 and 2008 was \$0.2 million and \$2.9 million, respectively.





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

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding at September 30, 2007	1,401,420	\$ 31.29
Granted	392,917	41.86
Exercised	(163,297)	27.45
Forfeited	(108,250)	33.59
Outstanding at September 30, 2008	1,522,790	\$ 34.26
Granted	268,700	24.06
Exercised	(17,600)	8.82
Forfeited	(104,320)	35.33
Outstanding at September 30, 2009	1,669,570	\$ 32.82
Granted	388,635	22.88
Exercised	(20,350)	20.74
Forfeited	(545,534)	30.58
Outstanding at September 30, 2010	1,492,321	\$ 31.22
Exercisable at September 30, 2010	843,112	\$ 33.10

***Restricted Stock Awards***

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of common stock (Restricted Stock). Under accounting guidance these shares are considered to be non-vested shares. The Restricted Stock will be released to the key employees if they are employed by the Company at the end of the vesting period. Compensation has been recognized for the estimated fair value of the 41,072 common shares and is being charged to income over the vesting term. The stock-based compensation table includes the Restricted Stock expenses recognized related to these awards, which totaled \$1.0 million, \$1.8 million and \$2.2 million during fiscal 2010, 2009 and 2008, respectively.

	<b>Number of Shares</b>	<b>Weighted Average Grant Price</b>
Balance at September 30, 2007	206,191	\$ 35.89
Granted	12,383	42.18
Vested	(40,336)	38.76
Forfeited	(21,109)	32.83
Balance at September 30, 2008	157,129	\$ 36.06
Granted	7,700	23.93

Edgar Filing: SURMODICS INC - Form 10-K

Vested	(59,047)		34.44
Forfeited	(4,887)		41.91
Balance at September 30, 2009	100,895	\$	35.80
Granted	30,440		18.49
Vested	(83,195)		36.32
Forfeited	(7,068)		33.39
Balance at September 30, 2010	41,072	\$	22.33

F-23

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

The Company has entered into Performance Share agreements with certain key employees, covering the issuance of common stock (Performance Shares). The Performance Shares vest upon the achievement of all or a portion of certain performance objectives, which must be achieved during the performance period. Compensation is recognized in each period based on management's best estimate of the achievement level of the grants' specified performance objectives and the resulting vesting amounts. In fiscal 2010, the Company recognized expense of \$32,000 related to specific performance objectives achieved by certain individuals. In fiscal 2009, the Company reversed expenses previously recognized of \$207,000 relating to three-year Performance Shares awarded in May 2008 and one-year Performance Shares awarded in September 2008, which was partially offset by an expense of \$164,000 related to the estimated value of Performance Shares awarded to individuals based on likely achievement of specific performance objectives. The Company recorded compensation expense of \$1.9 million in fiscal 2008 related to 30,552 one-year Performance Shares and 30,552 three-year Performance Shares awarded in May 2008 and 7,600 Performance Shares that vested for certain individuals that met various specific performance objectives. The stock-based compensation table includes the Performance Shares expenses.

***1999 Employee Stock Purchase Plan***

Under the 1999 Employee Stock Purchase Plan (Stock Purchase Plan), the Company is authorized to issue up to 400,000 shares of common stock. The number of authorized shares was increased by 200,000 effective with shareholder approval at the February 8, 2010 Annual Meeting. All full-time and part-time employees can choose to have up to 10% of their annual compensation withheld, with a limit of \$25,000, to purchase the Company's common stock at purchase prices defined within the provision of the Stock Purchase Plan. As of September 30, 2010 and 2009, there were \$321,000 and \$376,000 of employee contributions, respectively, included in accrued liabilities in the accompanying consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan totaled \$250,000, \$265,000, and \$199,000 during fiscal 2010, 2009, and 2008, respectively. The stock-based compensation table includes the Stock Purchase Plan expenses.

**7. Restructuring Charges**

In March 2010, the Company announced an organizational change designed to support future growth by better meeting customer needs, leveraging its multiple competencies across the organization, and building on its pharmaceutical industry experience. As a result of the reorganization, the Company eliminated 11 positions, or approximately 4% of the Company's workforce. These employee terminations occurred across various functions and the reorganization plan was completed by the end of the third quarter of fiscal 2010. The Company also announced that it was vacating its leased sales office in Irvine, California and a leased warehouse in Birmingham, Alabama, as part of the reorganization plan. Both leased spaces were vacated by March 31, 2010.

The Company recorded total restructuring charges of approximately \$1.3 million in connection with the fiscal 2010 reorganization. These pre-tax charges consisted of \$0.8 million of severance pay and benefits expenses and \$0.5 million of facility-related costs.

In November 2008, the Company announced a functional reorganization to allow the Company to better serve its customers and improve its operating performance. As a result of the reorganization, the Company eliminated 15 positions, or approximately five percent of the Company's 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 Company also vacated a leased facility in Eden Prairie, Minnesota, consolidating into its owned office and research facility also in Eden Prairie, as part of the reorganization plan.

The Company recorded total restructuring charges of approximately \$1.8 million in connection with the reorganization. These pre-tax charges consisted of \$0.5 million of severance pay and benefits expenses and

F-24

---

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

\$1.3 million of facility-related costs which were recorded in fiscal 2009. The restructuring was expected to result in approximately \$2.0 million in annualized cost savings.

Cash payments related to both restructuring events totaled \$1.1 million in fiscal 2010, resulting in a balance of \$1.2 million at September 30, 2010.

The following table summarizes the restructuring accrual activity for fiscal 2010 (*in thousands*):

	<b>Employee Severance and Benefits</b>	<b>Facility- Related Costs</b>	<b>Total</b>
Balance at September 30, 2008	\$	\$	\$
Accruals during the year	513	1,250	1,763
Cash payments	(513)	(295)	(808)
Balance at September 30, 2009	\$	\$ 955	\$ 955
Accruals during the year	818	488	1,306
Cash payments	(814)	(264)	(1,078)
Balance at September 30, 2010	\$ 4	\$ 1,179	\$ 1,183

The charges above have been shown separately as restructuring charges on the consolidated statements of operations. The remaining accrual for both the fiscal 2010 and 2009 restructurings is expected to be paid within the next 39 months. As such, the current portion totaling \$1.0 million is recorded as a current liability within other accrued liabilities and the long-term portion totaling \$0.2 million is recorded as a long-term liability within other long-term liabilities on the consolidated balance sheets.

**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****8. Income Taxes**

The Company accounts for income taxes under the asset and liability method prescribed in accounting guidance. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in this assessment. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date of such change.

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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Current provision:			
Federal	\$ (331)	\$ 12,257	\$ 13,534
State and foreign	277	1,362	1,516
Total current provision	(54)	13,619	15,050
Deferred provision (benefit):			
Federal	1,019	7,483	(2,832)
State	(535)	872	(65)
Total deferred provision (benefit)	484	8,355	(2,897)
Total provision	\$ 430	\$ 21,974	\$ 12,153

The reconciliation of the difference between amounts calculated at the statutory federal tax rate for the fiscal years ended September 30 and the Company's effective tax rate is as follows (*in thousands*):

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Amount at statutory federal income tax rate	\$ (7,231)	\$ 20,833	\$ 9,387
Change because of the following items:			
State taxes	(209)	1,206	715
Other	(20)	(481)	223
Stock-based compensation	276	416	239

Edgar Filing: SURMODICS INC - Form 10-K

Valuation allowance	2,780		1,589
Goodwill impairment	4,834		
Income tax provision	\$ 430	\$ 21,974	\$ 12,153

F-26

---

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

The components of deferred income taxes consisted of the following as of September 30 and result from differences in the recognition of transactions for income tax and financial reporting purposes (*in thousands*):

	2010	2009
Depreciable assets	\$ (5,795)	\$ (2,951)
Deferred revenue	1,666	261
Accruals and reserves	780	526
Stock options	5,947	5,258
Impaired investments	6,130	3,264
Unrealized losses on investments	(563)	(962)
Other	1,211	844
Valuation allowance	(6,523)	(3,339)
Total deferred tax asset	2,853	2,901
Less current deferred tax asset	(247)	(353)
Noncurrent deferred tax asset	\$ 2,606	\$ 2,548

In fiscal 2010, the Company recorded a \$3.1 million valuation allowance which primarily relates to potential capital losses created by the impairment of the Company's investments in Nexeon and two additional medical technology companies (see Note 3 for further information). The valuation allowance was recorded because the Company does not currently foresee future capital gains within the allowable carryforward and carryback periods to offset these capital losses when they were recognized. As such, no tax benefit has been recorded in the consolidated statements of operations.

On October 1, 2007, the Company adopted new accounting guidance on the accounting for uncertainty in income taxes. Unrecognized tax benefits are the differences between a tax position taken, or expected to be taken in a tax return, and the benefit recognized for accounting purposes pursuant to accounting guidance. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (*in thousands*):

	2010	2009	2008
Beginning of fiscal year	\$ 2,042	\$ 1,540	\$ 1,120
Increase in tax positions for prior years		280	194
Decrease in tax positions for prior years	(104)	(7)	
Increases in tax positions for current year	92	260	237
Settlements with taxing authorities			
Lapse of the statute of limitations	(82)	(31)	(11)
End of fiscal year	\$ 1,948	\$ 2,042	\$ 1,540



The total amount of unrecognized tax benefits including interest and penalties that, if recognized, would affect the effective tax rate as of September 30, 2010, 2009 and 2008, respectively, are \$1.9 million, \$2.0 million and \$1.5 million. Currently, the Company does not expect the liability for unrecognized tax benefits to change significantly in the next twelve months with the above balances classified on the consolidated balance sheets as a part of long-term liabilities. Interest and penalties related to unrecognized tax benefits are recorded in income tax expense. As of September 30, 2010, 2009 and 2008, a gross balance of \$0.7 million, \$0.6 million and \$0.4 million, respectively, has been accrued related to the unrecognized tax benefits balance for interest and penalties.

The Company files tax returns, including returns for its subsidiaries, in the United States (U.S.) federal jurisdiction and in various state jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. The Internal Revenue Service has commenced an examination of the Company's U.S. income tax return for fiscal 2009 in the first quarter of fiscal 2011. Fiscal years 2007 and 2008 remain subject to examination by

F-27

---

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

federal tax authorities. Tax returns for state and local jurisdictions for fiscal years ended September 30, 2003 through 2009 remain subject to examination by state and local tax authorities.

**9. Commitments and Contingencies**

*Litigation.* From time to time, the Company has been, and may become, involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. The outcomes of these legal actions are not within the Company's complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, which, if granted, could require significant expenditures or result in lost revenues. The Company records a liability in the consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued. If a loss is possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

*SRI Litigation.* On July 31, 2009, the Company's SurModics Pharmaceuticals subsidiary was named as a defendant in litigation pending in the circuit court of Jefferson County, Alabama, between SRI and two of SRI's former employees (the Plaintiffs). In the litigation, the Plaintiffs allege that they contributed to or invented certain intellectual property while they were employed at SRI, and pursuant to SRI's policies then in effect, they are entitled to, among other things, a portion of the purchase price consideration paid by the Company to SRI as part of the Company's acquisition of Brookwood Pharmaceuticals, Inc., pursuant to a stock purchase agreement made effective on July 31, 2007 (the Stock Purchase Agreement). A trial has not yet been scheduled. Pursuant to the Stock Purchase Agreement, the Company has certain rights of indemnification against losses (including without limitation, damages, expenses and costs) incurred as a result of the litigation. The Company's consolidated financial statements do not include any expenses or liabilities related to the above litigation as the probability of the outcome is currently not determinable and any potential loss is not estimable. The Company believes that it has meritorious defenses to the Plaintiff's claims and will vigorously defend and prosecute this matter.

*InnoRx, Inc.* In January 2005, the Company entered into a merger agreement whereby SurModics acquired all of the assets of InnoRx, Inc. (InnoRx), an early stage company developing drug delivery devices and therapies for the ophthalmology market. SurModics will be required to issue up to approximately 480,059 additional shares of its common stock to the stockholders of InnoRx upon the successful completion of the remaining development and commercial milestones involving InnoRx technology acquired in the transaction.

*BioFX Laboratories, Inc.* In August 2007, the Company acquired 100% of the capital stock of BioFX Laboratories, Inc. (BioFX), a provider of substrates to the *in vitro* diagnostics industry. The sellers of BioFX are still eligible to receive up to \$3.5 million in additional consideration based on specific revenue targets through calendar 2011.

*SurModics Pharmaceuticals, Inc.* In July 2007, the Company acquired 100% of the capital stock of Brookwood Pharmaceuticals Inc. (now known as SurModics Pharmaceuticals, Inc.) (SurModics Pharmaceuticals), a drug delivery company that provides proprietary polymer-based technologies to companies developing pharmaceutical products. The sellers of SurModics Pharmaceuticals are still eligible to receive up to \$16.3 million in additional consideration based on successful achievement of specific milestones through calendar 2011. A project milestone event was

achieved in the first quarter of fiscal 2011 and as such an obligation of \$0.8 million was recognized.

*Alabama Jobs Commitment.* In April 2008, the Company purchased a 286,000 square foot office and warehouse facility to support cGMP manufacturing needs of customers. At the same time, SurModics Pharmaceuticals entered into an agreement with various governmental authorities to obtain financial incentives associated with creation of jobs in Alabama. Some of the governmental agencies have recapture rights in connection with the financial incentives if the number of full-time employees are not hired by June 2012, with an extension to June 2013

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

if circumstances or events occur that are beyond the control of SurModics Pharmaceuticals or could not have been reasonably anticipated by SurModics Pharmaceuticals. As of September 30, 2010, SurModics Pharmaceuticals has received \$1.7 million in connection with the agreement, and the Company has recorded the payment in other long-term liabilities.

*Operating Leases.* The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the years ended September 30, 2010, 2009, and 2008 was \$0.3 million, \$1.0 million, and \$0.8 million, respectively. Annual commitments pursuant to operating lease agreements are as follows:

**Year Ended September 30,**

2011	\$ 258,000
2012	57,000
2013	60,000
2014	62,000
2015	62,000
Thereafter	16,000
Total minimum lease payments	\$ 515,000

**10. Defined Contribution Plans**

The Company has a 401(k) retirement and savings plan for the benefit of qualifying employees. The Company matches 50% of employee contributions on the first 6% of eligible compensation. Effective April 1, 2009, the Company changed its matching contribution to a discretionary approach and the Company ceased matching contributions. Effective April 1, 2010, the Company re-instated its matching contribution at the previous level. Company contributions totaling \$0.2 million, \$0.2 million, and \$0.5 million have been expensed for the years ended September 30, 2010, 2009, and 2008, respectively.

**11. Operating Segments**

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. In October 2010, the Company announced it was changing its operational structure to renew focus on business units and the Company will now be organized into three business units: Medical Device, Pharmaceuticals and In Vitro Diagnostics (IVD). Beginning in the first quarter of fiscal 2011, the Company will describe its business under the new reporting structure.

In March 2010, prior to the fiscal 2011 change noted above, the Company announced it changed its organizational structure to better align functional expertise, which also resulted in the elimination of the company's business units. The Company evaluates revenue results and opportunities on the basis of the clinical market areas in which the Company's customers participate as noted in the table below. The Therapeutic market includes revenue from: (1) Cardiovascular, which provides drug delivery and surface modification technologies to customers in the

cardiovascular market; (2) Ophthalmology, which is focused on 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) Other Markets, which is focused on a variety of clinical markets principally in the pharmaceutical and biotechnology industries. The Diagnostic market includes revenue from the Company's microarray slide technologies, stabilization products, antigens and substrates for immunoassay diagnostics tests, and its *in vitro* diagnostic format technology.

For fiscal years ended September 30, 2010, 2009, and 2008, the Company's results are aggregated into one reportable segment, as the Company manages its expenses on a company-wide basis, as well as its sales and marketing efforts.

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

The table below presents revenue from the markets identified above, with Therapeutic broken out further by focus area, for the years ended September 30, as follows (*in thousands*):

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Therapeutic			
Cardiovascular	\$ 40,155	\$ 39,841	\$ 47,675
Ophthalmology	7,617	52,102	10,252
Other Markets	10,932	13,114	17,875
Total Therapeutic	58,704	105,057	75,802
Diagnostic	11,194	16,477	21,249
Total revenue	\$ 69,898	\$ 121,534	\$ 97,051

**Major Customers**

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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Johnson & Johnson	17%	11%	20%
Medtronic, Inc.	14%	**	**
Merck & Company	**	37%	**
Abbott Laboratories	**	**	10%

\*\* - less than ten percent

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

**Geographic Revenue**

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

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Domestic	78%	84%	79%
Foreign	22%	16%	21%



**Table of Contents****SurModics, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****12. Quarterly Financial Data (Unaudited)**

The following is a summary of the unaudited quarterly results for the years ended September 30, 2010, 2009, and 2008 (in thousands, except per share data).

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
<b>Fiscal 2010</b>				
Revenue	\$ 17,381	\$ 18,360	\$ 18,608	\$ 15,549
Income (loss) from operations	2,768	(952)	2,220	(18,089)
Net income (loss)	1,917	(427)	(916)	(21,663)
Net income (loss) per share(1):				
Basic	0.11	(0.02)	(0.05)	(1.25)
Diluted	0.11	(0.02)	(0.05)	(1.25)
<b>Fiscal 2009</b>				
Revenue	\$ 63,216	\$ 20,925	\$ 18,186	\$ 19,207
Income from operations	42,667	6,200	4,661	3,973
Net income	27,085	4,216	3,539	2,710
Net income per share(1):				
Basic	1.53	0.24	0.20	0.16
Diluted	1.53	0.24	0.20	0.16
<b>Fiscal 2008</b>				
Revenue	\$ 23,829	\$ 25,707	\$ 24,276	\$ 23,239
Income from operations	7,571	7,181	7,184	5,325
Net income (loss)	5,646	5,107	4,800	(814)
Net income (loss) per share(1):				
Basic	0.31	0.28	0.27	(0.05)
Diluted	0.31	0.28	0.26	(0.05)

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

In the second quarter of fiscal 2010, the Company recorded a restructuring charge of \$1.3 million, associated with a functional reorganization and an asset impairment charge of \$2.1 million, associated with consolidation of the Company's multiple facilities in Birmingham, Alabama.

In the third quarter of fiscal 2010, the Company recorded a \$2.6 million non-cash impairment loss on its investment in two private medical technology companies and adjusted the asset impairment charge associated with the Birmingham, Alabama facilities by \$0.2 million.

In the fourth quarter of fiscal 2010, the Company recorded a \$0.4 million non-cash inventory impairment charge, a \$1.3 million in non-cash asset impairment charge associated with long-lived assets, a \$1.3 million non-cash asset



impairment loss associated with certain fixed assets costs in Minnesota, a \$13.8 million non-cash goodwill impairment charge associated with the Company's SurModics Pharmaceuticals reporting unit, and a \$5.3 million non-cash impairment loss on its investment in Nexeon MedSystems.

**Table of Contents**

**SurModics, Inc. and Subsidiaries**

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

In the first quarter of fiscal 2009, the Company recorded income that had previously been deferred of \$34.8 million associated with the Merck contract termination, a \$9 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program, a \$3.2 million charge for in-process research and development acquired in connection with the purchase of certain contracts and assets of PR Pharma, as well as a \$1.8 million restructuring charge associated with a functional reorganization.

In the fourth quarter of fiscal 2009, the Company recorded \$1.3 million in royalty income in connection with the settlement of previously disclosed litigation involving Abbott Laboratories and Church & Dwight Co, Inc.

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