SURMODICS INC
Form 10-K
December 14, 2011
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UNITED STATES 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, 2011

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 74th Street **Eden Prairie, Minnesota** *(Address of Principal Executive Offices)*	**55344** *(Zip Code)*

(Registrant s Telephone Number, Including Area Code)

(952) 500-7000

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.05 par value	**NASDAQ Global Select Market**

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

None

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

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

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

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 þ 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 þ
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 þ

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2011 was approximately $163 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, 2011 was 17,527,547.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for the Registrant s 2012 Annual Meeting of Shareholders are incorporated by reference into Part III.

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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. Any statement that is not a including estimates, projections, future trends and the outcome of events that have not yet occurred, is a forward-looking statement. The Company s forward-looking statements generally relate to its growth strategy, financial prospects, product development programs, sales efforts, and the impact of the Medtronic, Inc. (Medtronic) and Cordis Corporation (a subsidiary of Johnson & Johnson) (Cordis), agreements, as well as other significant customer agreements. You should carefully consider forward-looking statements and understand that such statements

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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 (SEC). 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.

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PART I

ITEM 1. *BUSINESS.*

Overview Recent Sale of Pharmaceuticals Business

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.

In December 2010, we announced that the Board of Directors of the Company had authorized the Company to explore strategic alternatives for our Pharmaceuticals business, including a potential sale of that business. This decision by the Board reflected 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. On November 1, 2011, we entered into a definitive agreement (the Purchase Agreement) to sell substantially all of the assets of our wholly-owned subsidiary, SurModics Pharmaceuticals, Inc. (SurModics Pharmaceuticals) to Evonik Degussa Corporation (Evonik). We closed the sale (the Pharma Sale) on November 17, 2011. The total consideration received from the sale was $30.0 million in cash. Of the total consideration, $3.275 million was placed in escrow at closing for any inventory shortfall and the payment of certain contingent consideration obligations related to our acquisition of SurModics Pharmaceuticals in July 2007.

Under the terms of the Purchase Agreement, the entire portfolio of products and services of SurModics Pharmaceuticals and its Current Good Manufacturing Practice (cGMP) development and manufacturing facility located in Birmingham, Alabama, were acquired by Evonik. As part of the Pharma Sale, we agreed not to compete in the restricted business (as defined in the Purchase Agreement) for a period of five years and to indemnify Evonik against specified losses in connection with the SurModics Pharmaceuticals business, including certain contingent consideration obligations related to the acquisition by SurModics Pharmaceuticals of the portfolio of intellectual property and drug delivery projects from PR Pharmaceuticals, Inc. (PR Pharma). We also retained responsibility for certain obligations of the SurModics Pharmaceuticals business, including contingent consideration obligations of $2.9 million related to our acquisition of SurModics Pharmaceuticals in July 2007 and repayment obligations related to an agreement with various governmental authorities to obtain financial incentives associated with creation of jobs in Alabama. The foregoing summary of the Purchase Agreement is qualified in its entirety by reference to the full text of the Purchase Agreement, which is attached as Exhibit 2.1 to the Company s Current Report on Form 8-K filed on November 7, 2011. We refer you to the Purchase Agreement for more details on the Pharma Sale.

We acquired SurModics Pharmaceuticals in July 2007 to increase 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. A significant part of that business included manufacturing services for clinical trial materials as well as for commercial products through the state-of-the-art cGMP facility we constructed and qualified.

In November 2008, we acquired a portfolio of intellectual property and collaborative drug delivery projects from PR Pharma, a drug delivery company specializing in injectable, biodegradable sustained release formulations. Total consideration paid through September 30, 2011 was $5.6 million and the sellers of PR Pharma are still eligible to receive up to an additional $3.0 million in cash based on successful achievement of specified milestones.

Because the Pharma Sale closed subsequent to our fiscal year ended September 30, 2011, the discussion of the Company and its business operations and financial results in this Form 10-K for all applicable periods prior to such sale includes the Company s Pharmaceuticals segment, unless the context indicates otherwise. We will report the Pharmaceuticals segment as discontinued operations beginning in the first quarter of fiscal 2012, as disclosed in Note 1 to the consolidated financial statements.

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Overview General

Our mission is to exceed our customers expectations and enhance the well-being of patients by providing the world s foremost, innovative surface modification technologies and in vitro diagnostic chemical components. We partner with many of the world s leading and emerging medical device, diagnostic and life science companies to develop and commercialize innovative products designed to improve patient diagnosis and treatment. Our core offerings include 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 product and technical leadership in our core fields of surface modification technologies and in vitro diagnostic products, and expanding our core technologies to provide us with opportunities for longer term sustained growth.

Our surface modification technologies are utilized by our customers to alter the characteristics of the surfaces of devices and biological materials (e.g., lubricity or hemocompatibility). For example, 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.

Additionally, our surface modification technologies can create new functions for the surfaces of the devices (e.g., lubricity or heomcompatability). For example our patented drug 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).

We believe that site specific, localized drug delivery from medical devices has the potential to improve life changing therapies. 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 additional opportunities exist for site specific drug delivery from a range of other medical devices. Working with medical device companies, we believe we are poised to exploit this market opportunity as drugs and devices converge to create improved products and therapies.

In June 2011 we received an announcement from Cordis regarding the cessation of the manufacture of the CYPHER® and CYPHER SELECT® Plus stents by the end of 2011. This event is more fully discussed in Item 7 Management s Discussion and Analysis of Financial Condition and Result of Operations of this Form 10-K.

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 complementary, but distinct business units:

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.

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.

Pharmaceuticals, incorporates a broad range of drug delivery techniques for injectable therapeutics, including microparticles, nanoparticles, and implants. As noted above, we sold substantially all of our assets related to our Pharmaceuticals business to Evonik in November 2011, including its cGMP manufacturing facility.

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. In fiscal 2011 we consolidated all of our In Vitro Diagnostics business into BioFX and renamed the entity SurModics IVD, Inc. (SurModics IVD).

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We commercialize our drug delivery and surface modification technologies primarily through licensing and royalty arrangements with medical device manufacturers. We believe this approach allows us to focus our resources on the further development of our core technologies and enables us to expand our licensing activities into new markets.

Revenue from our licensing arrangements typically includes research and development revenue, license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees product sales. In addition to 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. Additionally, through our CodeLink® 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 of 1934 (the Exchange Act) on our website, 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 website as a part of, or incorporating it by reference into our Form 10-K.

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.

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

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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 (Bravo) is a durable coating and has been used in a variety of applications. 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® coating technology is a versatile, easily applied, coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. PhotoLink coatings can impart many performance enhancing characteristics, such as advanced lubricity (slippery) and hemocompatibility (preventing clot formation), when bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices. Our PhotoLink technology utilizes proprietary, light activated (photochemical) reagents, which include advanced polymers or active biomolecules having desired surface characteristics and an attached light reactive chemical compound (photogroup). When the reagent is exposed to a direct light source, typically ultraviolet light, a photochemical reaction creates a covalent bond between the photogroup and the surface of the medical device, thereby imparting the desired property to the surface. A covalent bond is a very strong chemical bond that results from the sharing of electrons between carbon atoms of the substrate and the applied coating, making the coating very durable and resilient.

Our proprietary PhotoLink reagents can be applied to a variety of substrates. Our reagents are easily applied to the material surface by a variety of methods including, but not limited to, dipping, spraying, roll coating, ink jetting or brushing. We continue to expand our portfolio of proprietary reagents for use by our customers. These reagents enable our customers to develop novel surface features for their devices, satisfying the expanding requirements of the healthcare industry. We are also continually working to expand the list of materials that are compatible with our drug delivery and surface modification reagents. Additionally, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput and cost requirements of our customers.

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

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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.

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 matrices that 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.

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

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our microarray slide product line which had previously been marketed by GE Healthcare under the CodeLink® trademark. As part of this transaction, we obtained the right to use the CodeLink® trademark from GE Healthcare in the sale and marketing of the product lines we re-acquired. Protein microarrays are used as diagnostic and research tools to determine the presence and/or quantity of proteins in a biological sample. The most common type of protein microarray is the antibody microarray, where antibodies are spotted onto a surface and used as capture molecules for protein detection.

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SurModics Drug Delivery and Surface Modification Technologies Applications

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

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

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Examples of applications for our coating technologies include guidewires, angiography catheters, IVUS catheters, neuro microcatheters/infusion catheters, PTCA/PTA laser and balloon angioplasty catheters, atherectomy systems, chronic total occlusion catheters, stent delivery catheters, cardiovascular stents, embolic protection devices, vascular closure devices, EP catheters, pacemaker leads, drug infusion catheters, wound drains, ureteral stents, urological catheters and implants, hydrocephalic shunts, and 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 45.1%, 49.0% and 62.1% of our total revenue in fiscal 2011, 2010 and 2009, respectively. Revenue from these licensing arrangements typically includes license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees product sales. We also generate revenue from sales of chemical reagents to licensees for use in their coating processes, and, prior to the Pharma Sale, 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 33.9%, 28.9% and 15.9% of total revenue in fiscal 2011, 2010 and 2009, respectively. Research and development fees represented 21.0%, 22.1% and 22.0% of total revenue in fiscal 2011, 2010 and 2009, 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.

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As of September 30, 2011, we had over 100 licensed product classes (customer products utilizing SurModics technology) already on the market generating royalties and greater than 100 customer product classes incorporating our technology in various stages of pre-commercialization. We signed 26 new licenses in fiscal 2011, compared with 21 in fiscal 2010.

All of our product classes that were under development or pending regulatory approval as of September 30, 2011, are subject to the terms of license agreements between us and our customers. Generally, medical device, biotechnology and pharmaceutical products incorporating our technologies are required to undergo long, expensive and uncertain regulatory review processes that are governed by the United States (U.S.) Food and Drug Administration (FDA) and other international regulatory authorities. The time required to obtain regulatory approval and, hence market introduction, for these products varies considerably depending on the product, its clinical application, the jurisdiction where approval is being sought, and the extent of clinical testing needed. This timing can range anywhere from several months (e.g., for medical device products seeking regulatory approval in the U.S. under the 510(K) approval process) to several years (e.g., for pharmaceutical products seeking regulatory approval in the U.S. under the new drug application process, or medical device products under the pre-market approval process).

Under our agreements with our customers, the responsibility for securing regulatory approval for, and ultimately commercializing these products rests with our customers. Our reliance on our customers in this regard and the potential risks to our operations as a result are discussed in Item 1A Risk Factors of this Form 10-K. Moreover, we are often contractually obligated to keep the details concerning our customers research and development efforts (including the timing of expected regulatory filings, approvals and market introductions) confidential. As a result of the significant uncertainty inherent in product development and regulatory approval processes, the fact that those efforts are outside of our control, and because of our contractual obligations to our customers, the expected timing for regulatory approval and commercialization for the product classes pending regulatory approval is uncertain.

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 (Abbott), Boston Scientific Corporation (Boston Scientific), Cook Medical, Cordis, Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), Elixir Medical Corporation, ev3 Inc. (a subsidiary of Covidien PLC), Medtronic, Nexeon MedSystems, Inc. (Nexeon), 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 SurModics IVD 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.

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Recombinant Human Antigens

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

Microarray Slide Products

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, 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, to measure coating thickness and smoothness, and to map the distribution of chemicals throughout coatings. 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, 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.

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In fiscal 2011, 2010 and 2009, our R&D expenses were $30.7 million, $36.1 million and $34.4 million, respectively. Of the above amounts, $12.3 million, $17.9 million and $21.2 million were spent on internal R&D in fiscal 2011, 2010 and 2009, respectively, and $18.4 million, $18.2 million and $13.2 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 surface modification and in vitro diagnostic 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 U.S. 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). Excluding filings related to the Pharmaceuticals business, since October 1, 2010 SurModics filed 42 U.S. patent applications, as well as 45 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 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 eight issued U.S. patents, four pending U.S. patent applications, 13 issued international patents, and six 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 and anticipated expiration dates of the patent applications range from 2015 to 2031.

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, China 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 December 1, 2011, after the Pharma Sale, SurModics had 133 pending U.S. patent applications, six of which were exclusively licensed from others, and 182 foreign patent applications, of which 21 were exclusively licensed from others. Likewise, as of December 1, 2011, SurModics owned 68 issued U.S. patents, 17 of which were exclusively licensed from others, and 137 international patents, of which 69 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

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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

To further our strategic objectives and strengthen our existing businesses, we intend to continue to explore acquisitions, investments and strategic collaborations to diversify and grow our business. As a result, we expect to make future investments or acquisitions where we believe that we can broaden our technology offerings and expand our sources of revenue and the number of markets in which we participate. See Note 2 to the consolidated financial statements for further information regarding our minority equity investments. Mergers and acquisitions of medical technology companies are inherently risky, and no assurance can be given that any of our previous or future acquisitions will be successful or will not materially adversely affect our consolidated results of operations, financial condition, or cash flows. Several acquisitions relating to our Pharmaceuticals business are discussed above in Overview Recent Sale of Pharmaceuticals Business.

In August 2007, we acquired 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 $3.0 million in additional consideration through calendar 2011. Potential milestones of $0.5 million were not earned and lapsed in fiscal 2011.

Significant Customers

We have two customers that each provided more than 10% of our revenue in fiscal 2011. Revenue from Medtronic and Johnson & Johnson represented approximately 15% and 13%, respectively, of our total revenue for the year ended September 30, 2011. 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. In June 2011, we received an announcement from Cordis, a Johnson & Johnson subsidiary, regarding the cessation of the manufacture of the CYPHER® and CYPHER SELECT® Plus stents by the end of 2011.

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.

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Some of our competitors offer drug delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target ophthalmology applications, while others target cardiovascular or other medical device applications. In addition, because of the many product possibilities afforded by surface modification technologies, many of the large medical device manufacturers have developed, or are engaged in efforts to develop, internal competency in the area of drug delivery and surface modification. Many of our existing and potential competitors have greater financial, technical and marketing resources than we have.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value-added approach to drug delivery and surface modification technology. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility, etc.), ease of manufacturing, time-to-market, intellectual property protection, ability to produce multiple properties from a single process, compliance with manufacturing regulations, ability to manufacture clinical and commercial products (especially for SurModics Pharmaceuticals customers), customer service and total cost of goods (including manufacturing process labor). We believe our technologies deliver exceptional performance in these areas, allowing us to compete favorably with respect to these factors. We believe that the cost and time required to obtain the necessary regulatory approvals significantly reduces the likelihood of a customer changing the manufacturing process it uses once a device or drug has been approved for sale.

Because a significant portion of our revenue depends on the receipt of royalties based on sales of medical devices incorporating our technologies, we are also affected by competition within the markets for such devices. We believe that the intense competition within the medical device market creates opportunities for our technologies as medical device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Because we seek to license our technologies on a non-exclusive basis, we may further benefit from competition within the medical device markets by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us as demonstrated by the announcement we received, in June 2011, from Cordis regarding the cessation of the manufacture of the CYPHER® and CYPHER SELECT® Plus stents by the end of 2011. 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

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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 fiscal 2010. The cGMP manufacturing facility was sold as part of the Pharma Sale. See Note 1 to the consolidated financial statements for further information regarding the sale of the SurModics Pharmaceuticals business.

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 as required. In fiscal 2010, our Birmingham, Alabama facility received ISO 9001:2008 and ISO 13485:2003 certification and received an updated certification in fiscal 2012.

Government Regulation

Although our drug delivery and surface modification technologies themselves are not directly regulated by the U.S. 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 U.S. after a 510(k) application has been cleared or a pre-market approval application (PMA) has been approved by the FDA. This process can take anywhere from three months for a 510(k) application, to two or three years or more for a PMA application. The burden of demonstrating to the FDA that a new device is either substantially equivalent to a previously marketed device (510(k) marketing clearance process), or in the case of implantable devices, safe and effective (PMA process), rests with our customers as the medical device manufacturers. New pharmaceutical and biotechnology products utilizing our technologies can only be marketed in the U.S. 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, 2011, after the Pharma Sale, we had 113 employees. We are not a party to any collective bargaining agreements, and we believe that our employee relations are good.

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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, 2011, the names, ages and positions of the Company s executive officers are as follows:

Name	Age	Position
Gary R. Maharaj	48	President and Chief Executive Officer
Timothy J. Arens	44	Vice President of Finance and Interim Chief Financial Officer
Charles W. Olson	47	Senior Vice President and General Manager, Medical Device
Bryan K. Phillips	40	Senior Vice President of Legal and Human Resources, General Counsel and Secretary
Joseph J. Stich	46	Vice President, Business Operations and General Manager, In Vitro Diagnostics

Gary R. Maharaj joined the Company in December 2010 as President and Chief Executive Officer and was also appointed to the SurModics Board of Directors at such time. Prior to joining SurModics, Mr. Maharaj served as President and Chief Executive Officer of Arizant Inc., a provider of patient temperature management systems in hospital operating rooms, from 2006 to 2010. Previously, Mr. Maharaj served in several senior level management positions for Augustine Medical, Inc. (predecessor to Arizant Inc.) from 1996 to 2006, including Vice President of Marketing, and Vice President of Research and Development. During his 23 years in the medical device industry, Mr. Maharaj has also served in various management and research positions for the orthopedic implant and rehabilitation divisions of Smith & Nephew, PLC. Mr. Maharaj holds an M.B.A. from the University of Minnesota s Carlson School of Management, an M.S. in biomedical engineering from the University of Texas at Arlington and the University of Texas Southwestern Medical Center at Dallas, and a B.Sc. in Physics from the University of the West Indies.

Timothy J. Arens joined the Company in February 2007 as Director, Business Development and became Senior Director of Financial Planning and Analysis and General Manager, In Vitro Diagnostics in October 2010. He was promoted to his current role as Vice President of Finance and Interim Chief Financial Officer in August 2011. 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. degree in Finance from the University of Wisconsin Eau Claire in 1989 and an M.B.A. degree 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. In August 2011, he became Senior Vice

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President, Legal and Human Resources, General Counsel and Secretary. 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 U.S. Patent and Trademark Office.

Joseph J. Stich joined the Company in March 2010 as Vice President of Marketing, Corporate Development and Strategy. In August 2011, he became Vice President, Business Operations and General Manager, In Vitro Diagnostics. Before joining SurModics, Mr. Stich was Vice President of Corporate Development for Abraxis BioScience, LLC, a biotechnology company focused on oncology therapeutics, from 2009 to 2010. Prior to joining Abraxis, he was a Vice President of MGI Pharmaceuticals, Inc., a biopharmaceutical company, from 2004 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 a B.B.A. degree from the University of Wisconsin Whitewater in 1988, and an M.B.A. degree from Rockhurst University in Kansas City in 1996.

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

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ITEM 1A. ***RISK FACTORS.***

RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

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

During periods of economic slowdown or recession, such as the U.S. 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. We may also be affected by a reduction in the amount of products purchased by our diagnostic customers.

The decrease in available financing for our customers and for new ventures that could potentially become our customers can reduce our potential opportunities.

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

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

We have two customers that each provided 10% or more of our revenue in fiscal 2011. Revenue from Medtronic and Johnson & Johnson represented approximately 15% and 13%, respectively, of our total revenue for the fiscal year ended September 30, 2011. 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 June 2011, Cordis announced the cessation of the manufacture of the CYPHER® and CYPHER SELECT® Plus stents by the end of 2011. In July 2011, Cordis notified us of its intention to terminate the exclusivity arrangements under the license agreement, which also results in a termination of the minimum quarterly royalty requirements beginning in the first quarter of fiscal 2012. 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

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assurance that we will be able to identify, develop and adapt our technologies for new applications in a timely and cost-effective manner; that new license agreements will be executed on terms favorable to us; that new applications will be accepted by customers in our target markets; or that products incorporating newly licensed technology, including new applications, will gain regulatory approval, be commercialized or gain market acceptance. Delays or failures in these efforts could have an adverse effect on our business, financial condition and results of operations.

Drug delivery and surface modification are competitive markets and carry the risk of technological obsolescence.

We operate in a competitive and evolving field, and new developments are expected to continue at a rapid pace. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the field of drug delivery and surface modification. Our drug delivery and surface modification technologies compete with technologies developed by 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 may face indemnity and other liability claims pursuant to our agreement with Evonik relating to the sale of substantially all of the assets of the Pharmaceuticals business.

Under the terms of the Purchase Agreement, we have agreed to indemnify Evonik against specified losses that might be incurred in connection with Evonik s utilization of the acquired assets. We have also agreed to retain responsibility for certain liabilities that may accrue and we have made representations and warranties to Evonik, including matters relating to intellectual property. Following the closing, if Evonik makes an indemnification claim because it has suffered a loss or a third party has commenced an action against Evonik, we may incur expenses to resolve Evonik s claim or to defend Evonik and ourselves against the third party action, which expense could harm our operating results. In addition, such indemnity claims may divert management attention from our continuing business. It may also be difficult to determine whether a claim from a third party stemmed from actions taken by us or by Evonik and we may expend substantial resources trying to determine which party has responsibility for the claim.

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.

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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. The process of integrating acquired businesses into our operations poses numerous risks, including:

- an inability to assimilate acquired operations, personnel, technology, information systems, and internal control systems and products;
- diversion of management s attention, including the need to manage several remote locations with a limited management team;
- difficulties and uncertainties in transitioning the customers or other business relationships from the acquired entity to us; and
- the loss of key employees of acquired companies.

In addition, future acquisitions by us may be dilutive to our shareholders, and cause large one-time expenses or create goodwill or other intangible assets that could result in significant asset impairment charges in the future. For example, in the first quarter of fiscal 2011 and the fourth quarter of fiscal 2010, we recognized goodwill impairment charges of $5.7 million and $13.8 million, respectively, which represented a full impairment of the 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 remaining goodwill of $8.0 million related to our In Vitro Diagnostics business unit or other assets could materially adversely affect our results of operations. For example, in the first quarter of fiscal 2011 we recognized a goodwill impairment charge of $5.7 million related to goodwill associated with our acquisition of SurModics Pharmaceuticals and had recognized a goodwill impairment charge of $13.8 million related to this acquisition in the fourth quarter of fiscal 2010. In addition, in fiscal 2011 and 2010, we recognized asset impairment charges totaling $17.9 million and $4.9 million, respectively.

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.

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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 (FASB) may issue new positions or revised guidance on the treatment of complex accounting matters. Changes in circumstances or third-party guidance could cause our judgments to change with respect to our interpretations of these complex standards, and transactions recorded, including revenue recognized, for one or more prior reporting periods, 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, 2011, 2010 and 2009, we derived approximately 45%, 49% and 62% 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 diagnostic test kits, 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.

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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.

Given the Pharma Sale, which included the sale of the Birmingham, Alabama manufacturing facility, we now manufacture all of the products we sell in our existing production areas in our Eden Prairie, Minnesota facility. In August 2011, we began the production of our BioFX products from our headquarters facility in Eden Prairie, Minnesota. There are a number of risks associated with this move, including 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 associated with our recent change in our production operations, we could experience material adverse effects on our business, financial condition and results of operations.

In addition, if our existing production facility becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our 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 facility, we would have no other means of manufacturing products until we were able to restore the manufacturing capability at the facility or develop an alternative manufacturing facility. Although we carry business interruption insurance to cover lost revenue and profits in an amount we consider adequate, this insurance does not cover all possible situations. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing customers resulting from our inability to produce products for them.

We 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

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production interruptions. If we lose our sole supplier of any particular reagent component or are otherwise unable to procure all components required for our reagent manufacturing for an extended period of time, we may lose the ability to manufacture the reagents our customers require to commercialize products incorporating our technology. This could result in lost royalties and product sales, which would harm our financial results. Adding suppliers to our approved vendor list may require significant time and resources since we typically thoroughly review a supplier s business and operations to become comfortable with the quality and integrity of the materials we purchase for use with our technology, including reviewing a supplier s manufacturing processes and evaluating the suitability of materials and packaging procedures the supplier uses. We routinely attempt to maintain multiple suppliers of each of our significant materials, so we have alternative suppliers, if necessary. However, if the number of suppliers of a material is reduced, or if we are otherwise unable to obtain our material requirements on a timely basis and on favorable terms, our operations may be harmed.

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

Our success is dependent upon our ability to retain and attract highly qualified management and technical personnel. We face intense competition for such qualified personnel. We do not maintain key person insurance, 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

We may not be able to obtain, maintain or protect proprietary rights necessary for the commercialization of our technologies.

Our success depends, in large part, on our ability to obtain and maintain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and protect our proprietary rights against infringement by third parties. We have been granted U.S. and foreign patents and have U.S. and foreign patent applications pending related to our proprietary technologies. There can be no assurance that any pending patent application will be approved, that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties, that the patents of others will not prevent the commercialization of products incorporating our technologies, or that others will not independently develop similar technologies or design around our patents. Furthermore, because we generate a significant amount of our revenue through licensing arrangements, the loss or expiration of patent protection for our key technologies will result in a reduction of the revenue derived from these arrangements which may have a material adverse effect on the Company s business, cash flow, results of operations, financial position and prospects.

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.

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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 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 revenue that is 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 U.S. and abroad.

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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 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.

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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, 2011, the sale price for our common stock ranged from $8.28 to $15.50 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.

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.

We sold all of the properties associated with SurModics Pharmaceuticals, including our cGMP development and manufacturing facility, located in Birmingham, Alabama, in connection with the Pharma Sale. We also lease office space in Irvine, California, which we vacated and subleased in connection with our March 2010 reorganization.

ITEM 3. ***LEGAL PROCEEDINGS.***

See the discussion of Litigation and the SRI Litigation in Note 9 to the consolidated financial statements for information regarding commitments and contingencies.

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

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PART II

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

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

Fiscal Quarter Ended:	High	Low
September 30, 2011	$ 12.95	$ 8.90
June 30, 2011	15.50	10.82
March 31, 2011	13.40	11.30
December 31, 2010	13.23	8.28
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

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, 2011, there were 217 holders of record of our common stock and approximately 4,900 beneficial owners of shares registered in nominee or street name.

To date, SurModics, has not paid or declared any cash dividends on its common stock. The payment by SurModics of dividends, if any, on its common stock in the future is subject to the discretion of the Board of Directors and will depend on SurModics continued earnings, financial condition, capital requirements and other relevant factors.

The following table presents information with respect to purchases of common stock of the Company made during the three months ended September 30, 2011, 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.

Period	Total Number of Shares Purchased(1)	Average Price Paid per Share(1)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs(2)
7/1/11 7/31/11	870	$ 11.35	0	$ 5,302,113
8/1/11 8/31/11	1,955	$ 10.66	0	$ 5,302,113

9/1/11	9/30/11	0		NA	0	$ 5,302,113
Total		2,825	$	10.87	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 $35.0 million of our outstanding common stock. As of September 30, 2011, 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, 2011. The repurchase authorization does not have an expiration date.

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Stock Performance Chart

The following chart compares the cumulative total shareholder return on the Company s Common Stock with the cumulative total return on the Nasdaq Stock Market and the Nasdaq Medical Industry Index (Medical Devices, Instruments and Supplies). The comparison assumes $100 was invested on September 29, 2006 and assumes reinvestment of dividends.

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

The data presented below as of and for the fiscal years ended September 30, 2011, 2010 and 2009 is 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, 2008 and 2007 is 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 Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 of this report and our consolidated financial statements and related notes beginning on page F-1 and other financial information included in this report.

	Fiscal Year				
	2011	2010	2009	2008	2007
	(Dollars in thousands, except per share data)				
Statement of Operations Data:					
Total revenue	$ 67,781	$ 69,898	$ 121,534	$ 97,051	$ 73,164
(Loss) income from operations	(17,518)	(14,053)	57,501	27,261	9,899
Net (loss) income	(12,778)	(21,089)	37,550	14,739	3,347
Diluted net (loss) income per share	(0.73)	(1.21)	2.15	0.80	0.18
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 68,197	$ 56,786	$ 47,868	$ 71,978	$ 70,225
Total assets	162,654	170,279	185,562	191,028	171,331
Retained earnings	70,122	82,900	103,989	66,439	51,620
Total stockholders equity	145,336	154,359	172,372	141,806	130,922
Statement of Cash Flows Data:					
Net cash provided by operating activities	$ 19,955	$ 22,008	$ 31,321	$ 39,822	$ 50,715

As noted previously, the Pharma Sale closed subsequent to our fiscal year ended September 30, 2011 and therefore the selected financial data presented above includes all SurModics Pharmaceuticals historical data since its acquisition in July 2007.

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. As further discussed in Item 1 *Overview Recent Sale of Pharmaceuticals Business*, in December 2010 we announced that the Board of Directors of the Company had authorized the Company to explore strategic alternatives for our Pharmaceuticals business, including a potential sale of that business. This decision by the Board reflected 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. On November 1, 2011, we entered into a Purchase Agreement to sell substantially all of the assets of SurModics Pharmaceuticals to Evonik. The Pharma Sale closed on November 17, 2011. The total consideration received

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from the sale was $30.0 million in cash. Of the total consideration, $3.275 million was placed in escrow at closing for any inventory shortfall and the payment of certain contingent consideration obligations related to our acquisition of SurModics Pharmaceuticals in July 2007.

Because the Pharma Sale closed subsequent to our fiscal year ended September 30, 2011, the discussion for all fiscal years includes our Pharmaceuticals segment results as reported. We will report the Pharmaceuticals segment as discontinued operations beginning in the first quarter of fiscal 2012, as disclosed in Note 1 to the consolidated financial statements.

In October 2010, we announced a change in our organizational structure moving from a functional structure into one consisting of three business units: Medical Device, Pharmaceuticals, and In Vitro Diagnostics. We believe this structure improves the visibility, marketing and adoption of the Company s broad array of technologies within specific markets and helps our customers in the medical device, pharmaceutical and life science industries better solve unmet clinical needs.

The October 2010 organizational change resulted in the Company presenting revenue and operating results according to its three segments, as follows: (1) the Medical Device unit, which is 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, and neuro-vascular, and urology, among others; (2) the Pharmaceuticals unit, which incorporates a broad range of drug delivery technologies for injectable therapeutics, including microparticles, nanoparticles, and implants addressing a range of clinical applications including ophthalmology, oncology, dermatology and neurology, among others. Based in Birmingham, Alabama, the Pharmaceuticals business includes our cGMP manufacturing facility; and (3) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic test kits and biomedical research applications. Products include microarray slide technologies, protein stabilization reagents, substrates, and antigens.

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 for the three reportable segments noted above. We made this determination based on how we manage our operations and the information provided to our chief operating decision maker who is our Chief Executive Officer.

In June 2007, we entered into a License and Research Collaboration Agreement and separate Supply Agreement with Merck related to our I-vation TA intravitreal implant. Under the terms of the Merck agreements, we received an upfront license fee of $20.0 million and were eligible to receive up to an additional $288.0 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 Merck s business and product development portfolio, Merck gave notice to SurModics that it was terminating the collaborative license and research agreement, as well as the supply agreement entered into in June 2007. This decision was not based on any concerns about the safety or efficacy of the I-vation system. The termination was effective in December 2008, and we recognized revenue related to the termination of approximately $45.0 million in fiscal 2009, principally from amounts that previously had

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been deferred and amortized under the accounting treatment required by accounting guidance for revenue arrangements with multiple deliverables. The $45.0 million included a $9.0 million milestone payment from Merck associated with the termination of the triamcinolone acetonide development program.

Overview of Research and Development Activities

We manage our customer-sponsored R&D programs (Customer R&D), based largely on the requirements of our customers. In this regard, our customers typically establish the various measures and metrics that are used to monitor a program s progress, including key deliverables, milestones, timelines, and an overall program budget. The customer is ultimately responsible for deciding whether to continue or terminate a program, and does so based on research results (relative to the above measures and metrics) and other factors, including their own strategic and/or business priorities. Customer R&D programs are mainly in our Medical Device and Pharmaceuticals segments and the processes do not differ significantly.

For our internal R&D programs (included in Other R&D) in our three segments, we utilize R&D review committees to prioritize these programs based on a number of factors, including a program s strategic fit, commercial impact, potential competitive advantage, technical feasibility, and the amount of investment required. The measures and metrics used to monitor a program s progress varies based on the program, and typically includes many of the same factors discussed above with respect to our Customer R&D programs. We typically make decisions to continue or terminate a program based on research results (relative to the above measures and metrics) and other factors, including our own strategic and/or business priorities, and the amount of additional investment required.

With respect to cost components, R&D expenses in each of our three segments consist of labor, materials and overhead costs (utilities, depreciation, indirect labor, etc.) for both Customer R&D and Other R&D programs. We manage our R&D organization in a flexible manner, balancing workloads/resources between Customer R&D and Other R&D programs primarily based on the level of customer program activity. Therefore, costs incurred for Customer R&D and Other R&D can shift as customer activity increases or decreases. As a result of the recent economic conditions, some customers have delayed, slowed or cancelled development projects, which has affected the R&D expense mix between Customer R&D and Other R&D.

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 U.S. (GAAP). 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. When there are additional performance requirements, revenue is recognized when all such requirements have been satisfied. Under revenue arrangements with multiple deliverables, the Company recognizes each separable deliverable as it is earned. 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 the report. For stand-alone license agreements, up-front license fees are recognized over the term of the related licensing agreement. Minimum royalty fees are recognized in the period earned.

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Revenue related to a performance milestone is recognized upon the 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.

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 FASB amended the accounting standards for multiple deliverable revenue arrangements 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 on or after October 1, 2009. In connection with the adoption of the amended accounting standard we also changed our policy prospectively 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.

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Under the accounting guidance, we are still required to 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 many 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 or having a limited history with multiple element arrangements. When VSOE cannot be established, SurModics attempts to establish 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 features. The determination of ESP is made through consultation with the Company s management, taking into consideration the marketing strategies for each business unit.

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.

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 may 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) were less than the carrying amount of the assets, we would recognize an impairment charge to reduce such assets to their fair value.

In the fourth quarter of fiscal 2011, we recognized asset impairment charges totaling $17.9 million associated with our Pharmaceuticals segment. We wrote down long-lived assets (fixed assets of $14.8 million and intangibles of $3.1 million), associated with our Pharmaceuticals segment, based on the current valuation of the assets relative to their carrying value. The Company had been exploring strategic alternatives for the Pharmaceuticals segment, including a potential sale. The assets of the Pharmaceuticals business did not qualify as held-for-sale as of September 30, 2011, because we had not committed to a plan to sell at that time. However, our assessment of options available as of September 30, 2011 resulted in a probability-weighted value of expected future cash flows below the carrying value of these assets, which required us to determine the fair value of the long-lived assets of the Pharmaceuticals segment using the probability-weighted value of the expected future cash flows. Asset impairment charges of $17.9 million were recognized based on this assessment. Subsequently, the Company sold substantially all of its Pharmaceuticals assets for $30.0 million on November 17, 2011. See Note 1 to the consolidated financial statements for further information regarding the sale of SurModics Pharmaceuticals.

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 was $2.1 million at September 30, 2010, which was 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 no ongoing business opportunities expected in light of current market conditions and general economic environment. SurModics also recognized a charge of $1.3 million associated with certain construction-in-progress fixed assets in Minnesota, given the level of business activity and overall economic conditions. Each of these events included analysis of expected future cash flows or real estate market

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data which was compared with the carrying values of the assets to 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 in fiscal 2011 was based on new goodwill accounting guidance which was early adopted by SurModics in the fourth quarter of fiscal 2011. The new accounting guidance involves assessment of qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test becomes unnecessary.

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 subsidiary, the In Vitro Diagnostics operations known as our In Vitro Diagnostics reporting unit which contains the BioFX branded products, and the SurModics drug delivery and hydrophilic coatings operations known as our Medical Device business unit. The reporting units with goodwill resulted from the acquisitions of SurModics Pharmaceuticals and SurModics IVD 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.

The $8.0 million of goodwill at September 30, 2011 is related to the In Vitro Diagnostics reporting unit. We performed our annual impairment test of goodwill as of August 31, 2011, and did not record any goodwill impairment charges as there were no indicators of impairment associated with the In Vitro Diagnostics reporting unit.

We recognized a goodwill impairment charge of $5.7 million in the first quarter of fiscal 2011 associated with our SurModics Pharmaceuticals reporting unit. Two milestone events were achieved associated with the July 2007 acquisition of SurModics Pharmaceuticals and $5.7 million of additional purchase price was recorded as an increase to goodwill. During our annual test of goodwill in the fourth quarter of fiscal 2010, we determined the goodwill related to our SurModics Pharmaceuticals reporting unit was fully impaired and we recognized a non-cash goodwill impairment charge of $13.8 million. There had been no substantial changes in operating results for SurModics Pharmaceuticals in the first quarter of fiscal 2011 when compared with fiscal 2010, and as such we concluded that the goodwill associated with the milestone events was fully impaired.

Prior to testing goodwill for impairment in fiscal 2010, we tested our definite-lived assets, property 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 goodwill impairment 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

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business activity which was most pronounced in the fourth quarter of fiscal 2010, higher operating costs with our cGMP manufacturing facility, and a significant decrease in our stock price during fiscal 2010. 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 evaluated 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 in fiscal 2010, 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, 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 Pharmaceuticals reporting unit under the income approach, the expected cash flows of SurModics Pharmaceuticals were 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 used our business plans and projections as the basis for expected future cash flows. The most significant assumptions incorporated in these forecasts for the fiscal 2010 goodwill impairment test included annual revenue changes based on then current customer programs and expected progression of these programs into different phases of development. A discount rate of 15% was used in the fiscal 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 fiscal 2010 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 in fiscal 2010.

Based on the goodwill analysis performed as of August 31, 2010, the $13.8 million of goodwill in the SurModics Pharmaceuticals 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 was 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 changed, 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

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delivery and hydrophilic coatings operations do not have any goodwill and were included in the fiscal 2010 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.

We did not record any goodwill impairment charges during fiscal 2009.

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, 2011. 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 2011, 2010 or 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 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 $9.4 million as of September 30, 2011 and $2.9 million as of September 30, 2010, including valuation allowances of $7.7 million as of September 30, 2011 and $6.5 million as of September 30, 2010. The valuation allowances related to impairment losses on investments were 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 are recognized. As such, no tax benefit has been recorded in the consolidated statements of operations. 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

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benefit is measured and recognized as the largest amount of tax benefit that, in our judgment, is greater than 50% likely to be realized. The total gross amount of unrecognized tax benefits as of September 30, 2011, 2010 and 2009 was $1.7 million, $1.9 million and $2.0 million, respectively, excluding accrued interest and penalties. Of these unrecognized tax benefits, $1.7 million, $1.9 million and $2.0 million would affect our effective tax rate for fiscal 2011, 2010 and 2009, respectively. Interest and penalties recorded for uncertain tax positions are included in our income tax provision. As of September 30, 2011, 2010 and 2009, $0.8 million, $0.7 million and $0.6 million, respectively, of interest and penalties were accrued, excluding the tax benefits of deductible interest. The Internal Revenue Service (IRS) commenced an examination of our U.S. income tax return for fiscal 2010 in the first quarter of fiscal 2012. The IRS completed an examination of our U.S. income tax return for fiscal 2009 and a payment was made in the third quarter of fiscal 2011 associated with timing adjustments. U.S. income tax returns for fiscal 2007 and 2008 remain subject to examination by federal tax authorities. Tax returns for state and local jurisdictions for fiscal years 2003 through 2010 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 2011, 2010 and 2009.

Use of Non-GAAP Financial Information.

In addition to disclosing financial results in accordance with GAAP, this report includes certain non-GAAP financial results including non-GAAP operating income (or loss). We believe these non-GAAP measures provide meaningful insight into our operating performance, excluding certain event-specific charges, and provide an alternative perspective of our results of operations. We use non-GAAP measures, including certain of those set forth in this report, to assess our operating performance and to determine payout under our executive compensation programs. We believe that presentation of certain non-GAAP measures allows investors to review our results of operations from the same perspective as management and our Board of Directors and facilitates comparisons of our current results of operations. The method we use to produce non-GAAP results is not in accordance with GAAP and may differ from the methods used by other companies. Non-GAAP results should not be regarded as a substitute for corresponding GAAP measures but instead should be utilized as a supplemental measure of operating performance in evaluating our business. Non-GAAP measures do have limitations in that they do not reflect certain items that may have a material impact upon our reported financial results. As such, these non-GAAP measures presented should be viewed in conjunction with our consolidated financial statements prepared in accordance with GAAP.

Results of Operations

Years Ended September 30, 2011 and 2010

(in thousands)	**Fiscal 2011**	**Fiscal 2010**	**Increase/ (Decrease)**	**% Change**
Revenue:				
Medical Device	$ 39,576	$ 43,211	$ (3,635)	(8)%
Pharmaceuticals	15,055	15,493	(438)	(3)%
In Vitro Diagnostics	13,150	11,194	1,956	17%
Total revenue	$ 67,781	$ 69,898	$ (2,117)	(3)%

Revenue. Fiscal 2011 revenue was $67.8 million, a decrease of $2.1 million, or 3%, from fiscal 2010. The above table provides a summary of each operating segment s revenue with the narrative that follows providing additional explanations.

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Medical Device. Revenue in Medical Device was $39.6 million in fiscal 2011, an 8% decrease compared with $43.2 million in the prior-year period. The decrease in total revenue reflected lower license fees and royalties as well as lower R&D revenue, partially offset by higher product sales. Fiscal 2010 included $1.3 million in license fee revenue that was one-time in nature.

In fiscal 2011, we had a $2.7 million decrease, or 37%, in royalty revenue from Cordis, compared with the prior-year period. Growth of approximately 4% in royalty revenue from our hydrophilic coating license agreements was not strong enough to offset the decrease in royalty revenue from Cordis.

As we have disclosed in previous filings, Medical Device has derived a substantial amount of revenue from royalties and license fees and product sales attributable to Cordis, on its CYPHER® Sirolimus-eluting Coronary Stent. The CYPHER® stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. The CYPHER® stent faces continuing competition from Boston Scientific, Medtronic, and Abbott. In June 2011, Cordis announced the cessation of the manufacture of the CYPHER® and CYPHER SELECT® Plus stents by the end of 2011. In July 2011, Cordis notified the Company of its intention to terminate the exclusivity arrangements under the license agreement, which also results in a termination of the minimum quarterly royalty requirements beginning in the first quarter of fiscal 2012. For the last several years, royalty revenue and reagent product sales have decreased as a result of lower CYPHER® stent sales, and we had anticipated that royalty revenue from CYPHER® stents would continue to decrease in fiscal 2011 until it reached minimum royalty levels per the license agreement with Cordis. The decline in CYPHER® stent sales in fiscal 2011 resulted in SurModics recognizing minimum quarterly royalty income of $1.0 million for the third and fourth quarters per the terms of our license agreement with Cordis. Beginning with our first quarter of fiscal 2012, since the minimum royalty requirements have been eliminated, royalties under the license agreement will be based on a percentage of CYPHER® sales, if any.

Pharmaceuticals. Pharmaceuticals revenue was $15.1 million in fiscal 2011, a decrease of 3% compared with $15.5 million in the prior-year period. The decrease principally reflected lower license fee revenue, as one customer achieved a milestone event in fiscal 2010, as well as lower R&D revenue.

In Vitro Diagnostics. In Vitro Diagnostics revenue was $13.2 million in fiscal 2011, an increase of 17%, compared with $11.2 million in the prior-year period. The increase was primarily attributable to higher sales of our BioFX branded products as well as our stabilization and antigen products.

Product costs. Product costs were $8.3 million in fiscal 2011, a 12% decrease from the prior year. Overall product margins averaged 64%, compared with 53% in the prior year. The increase in product margins reflected the mix of products sold in fiscal 2011, as there were higher levels of diagnostic and reagent product sales compared with prior year results. In addition, our polymer products gross margin improved, mainly attributable to lower fixed costs. In fiscal 2010 we recognized an inventory impairment charge totaling $0.4 million. The gross margin for fiscal 2010, when adjusting for this impairment, was 55%.

Customer research and development expenses. Customer R&D expenses were $18.4 million, an increase of 1% compared with fiscal 2010. The increase principally reflects the impact of higher fixed overhead costs attributable to our Alabama research and development operations, offset somewhat by lower project material costs. Customer R&D margins were negative 29%, compared with negative 18% in fiscal 2010. Customer R&D expenses in the Pharmaceuticals segment were $16.3 million and $15.6 million in fiscal 2011 and 2010, respectively.

Other research and development expenses. Other R&D expenses were $12.2 million, a decrease of 32% compared with fiscal 2010. All three expense categories (labor, materials and overhead) included in Other R&D decreased in fiscal 2011 compared with fiscal 2010. Lower fiscal 2011 labor costs of $2.2 million compared with fiscal 2010 was mainly the result of our March and October 2010 reorganizations which reduced our research and development headcount. In addition, we received a grant under the federal qualified therapeutic discovery project program (recorded as a reduction of Other R&D expense) which was approximately $0.8 million and with fewer research projects we spent less on project materials. Overhead allocated to Other R&D also declined based on the

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lower headcount levels. We also had a reduction of $1.7 million in Other R&D expenses in our Pharmaceuticals business, compared with fiscal 2010 expenses, based on a decision to limit its internal R&D activities in fiscal 2011.

Selling, general and administrative expenses. Selling, general and administrative (SG&A) expenses were $20.5 million, an increase of 11% compared with fiscal 2010. The increase principally reflects higher variable compensation costs of $1.8 million.

Restructuring charges. In August 2011, we announced a realignment of our business to optimize the Company s resources according to our strategic plan. As a result of the organizational change, we eliminated approximately 9% of our workforce. These employee terminations occurred across various functions, and the reorganization plan was completed by the end of the fourth quarter of fiscal 2011. We recorded total pre-tax restructuring charges of $1.0 million in the fourth quarter of fiscal 2011, which consisted of severance pay and benefits expenses.

In October 2010, we announced initiatives to reduce our cost structure and renew our focus on business units to more closely match operations and cost structure with the current customer environment. As a result of the organizational change, we eliminated 30 positions, or approximately 13% 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 2011. The reorganization also resulted in SurModics vacating a leased production facility in Birmingham, Alabama and relocating the production activities to one of our owned facilities in Birmingham. We recorded total pre-tax restructuring charges of $1.2 million in the first quarter of fiscal 2011, which consisted of $1.2 million of severance pay and benefits expenses and less than $0.1 million of facility-related costs.

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. As a result of the reorganization, we eliminated approximately 4% of our workforce. These employee terminations occurred across various functions and the reorganization was completed by the end of the third quarter of fiscal 2010. SurModics also vacated and subleased its leased sales office in Irvine, California and vacated a leased warehouse in Birmingham, Alabama. We 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.

Cumulative costs totaling $4.3 million have been paid associated with the fiscal 2011, 2010 and 2009 restructurings, and we anticipate paying the remaining $1.0 million within the next 27 months, with the majority in the next 12 months.

Asset impairment charges. In the fourth quarter of fiscal 2011, we recognized asset impairment charges totaling $17.9 million. We wrote down long-lived assets (fixed assets of $14.8 million and intangibles of $3.1 million), associated with our Pharmaceuticals segment, based on the current valuation of the assets relative to their carrying value. The Company had been exploring strategic alternatives for the Pharmaceuticals segment, including a potential sale. The assets of the Pharmaceuticals business did not qualify as held-for-sale as of September 30, 2011, because we had not committed to a plan to sell at that time. However, our assessment of options available as of September 30, 2011 resulted in a probability-weighted value of expected future cash flows below the carrying value of these assets, which required us to determine the fair value of the long-lived assets of the Pharmaceuticals segment using the probability-weighted value of the expected future cash flows. Asset impairment charges of $17.9 million were recognized based on this assessment. Subsequently, the Company sold substantially all of its Pharmaceuticals assets for $30.0 million on November 17, 2011. See Note 1 to the consolidated financial statements for further information regarding the sale of SurModics Pharmaceuticals.

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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 was based on a real estate market appraisal obtained during our negotiations.

We also recorded a $1.3 million asset impairment charge in fiscal 2010 associated with certain long-lived assets where no ongoing business was expected in the foreseeable future based on market conditions. Furthermore, we recorded 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 no ongoing business was expected in the foreseeable future in light of market conditions. The assets associated with these charges had limited remaining value and as such were written down to zero value.

Goodwill impairment charges. We recognized a goodwill impairment charge of $5.7 million in the first quarter of fiscal 2011 associated with our SurModics Pharmaceuticals reporting unit. Two milestone events were achieved associated with the July 2007 acquisition of SurModics Pharmaceuticals and $5.7 million of additional purchase price was recorded as an increase to goodwill. There had been no substantial changes in operating results for SurModics Pharmaceuticals in the first quarter of fiscal 2011 when compared with fiscal 2010, and as such we concluded that the goodwill associated with the milestone events was fully impaired.

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 cGMP manufacturing facility, and a significant decrease in our stock price during fiscal 2010. 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 evaluated whether any indications of impairment were 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 income was $1.0 million in fiscal 2011, compared with a loss of $6.6 million in fiscal 2010. Income from investments was $0.6 million in fiscal 2011, compared with $1.0 million in fiscal 2010. The decrease primarily reflects lower yields generated from our investment portfolio in fiscal 2011. 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 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 benefit (provision). The income tax benefit was $3.7 million in fiscal 2011, compared with an income tax provision of $0.4 million in fiscal 2010. The effective tax rate in fiscal 2011 was 22.5%, and when excluding the impact of the goodwill impairment charge of $5.7 million, the rate was 34.3%. The fiscal 2010 effective tax rate is not meaningful because a tax expense was recorded on a pre-tax loss. The fiscal 2010 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 we do not currently foresee offsetting capital gains that could offset these capital losses, and therefore no benefit was recorded. The decrease in the effective tax rate, adjusted for the one-time items noted, is primarily a result of lower state taxes resulting from adjustments to state deferred taxes.

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Segment Operating Results

Operating (loss) income for each of our reportable segments was as follows (*in thousands*):

	2011	2010
Operating (loss) income:		
Medical Device	$ 19,847	$ 19,524
Pharmaceuticals	(32,522)	(26,479)
In Vitro Diagnostics	4,275	3,304
Corporate	(9,118)	(10,402)
Total	$ (17,518)	$ (14,053)

Medical Device. Operating income was $19.8 million in fiscal 2011, compared with $19.5 million in fiscal 2010. The increased operating income was driven by $1.5 million in lower development costs (reflecting the $0.8 million federal qualified therapeutic discovery project program and lower customer and internal project material expense), $1.3 million in lower compensation costs resulting from our August 2011 and October 2010 reorganizations and $0.6 million in lower product costs. The savings from these reduced operating costs were substantially offset by lower revenue.

Pharmaceuticals. Operating loss was $32.5 million in fiscal 2011, compared with a loss of $26.5 million in fiscal 2010. Fiscal 2011 loss included a goodwill impairment charge of $5.7 million and asset impairment charges of $17.9 million. Adjusting for the event-specific items, the operating loss was $8.9 million. The fiscal 2010 loss included a goodwill impairment charge of $13.8 million and asset impairment charges of $1.9 million. Adjusting for these one-time items, operating loss was $10.8 million. The decrease in the fiscal 2011 operating loss (as adjusted) was driven primarily by a $1.1 million reduction in product costs, $0.9 million reduction in research and development operating expenses, mostly related to lower external costs associated with the cGMP facility, and $0.7 million reduction in SG&A expenses, offset partially by $0.6 million in lower revenue.

In Vitro Diagnostics. Operating income was $4.3 million in fiscal 2011, compared with $3.3 million in fiscal 2010. The gross margin increase of $1.4 million, associated with the $2.0 million revenue increase, was the primary contributor to the operating income increase, partially offset by $0.2 million in higher compensation costs and $0.1 million in higher sales and marketing expenses.

Corporate. Operating loss was $9.1 million in fiscal 2011, compared with a loss of $10.4 million in fiscal 2010. Both periods included restructuring charges and fiscal 2010 included an asset impairment charge; when these charges are excluded, our adjusted operating losses were $6.9 million and $6.1 million for fiscal 2011 and 2010, respectively. The increased operating loss was driven primarily by higher variable compensation costs.

Results of Operations

Years Ended September 30, 2010 and 2009

(in thousands)	Fiscal 2010	Fiscal 2009	Increase/ (Decrease)	% Change
Revenue:				
Medical Device	$ 43,211	$ 86,546	$ (43,335)	(50)%
Pharmaceuticals	15,493	18,511	(3,018)	(16)%
In Vitro Diagnostics	11,194	16,477	(5,283)	(32)%
Total revenue	$ 69,898	$ 121,534	$ (51,636)	(42)%

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Revenue. Fiscal 2010 revenue was $69.9 million, a decrease of $51.6 million, or 42%, from fiscal 2009. The above table provides a summary of each operating segment s revenue with the narrative that follows providing additional explanations.

Medical Device. Revenue in Medical Device was $43.2 million in fiscal 2010, a 50% decrease compared with $86.5 million in the prior-year period. The decrease in total revenue principally reflected the recognition in fiscal 2009 of revenue of approximately $45.0 million associated with the Merck collaborative license and research agreement, which was terminated effective in the first quarter of fiscal 2009. Excluding this significant event-specific item in fiscal 2009, Medical Device revenue increased $1.7 million, or 4%.

Royalty and license fee revenue increased $1.5 million or 5%, when excluding fiscal 2009 Merck license fee revenue, principally from milestone payments of $1.0 million associated with one customer. Product sales increased 13% based on higher reagent sales to Cordis. R&D revenue declined 16%, when excluding fiscal 2009 Merck R&D revenue, based on the timing of activities with one particular R&D program.

Pharmaceuticals. Pharmaceuticals revenue was $15.5 million in fiscal 2010, a decrease of 16% compared with $18.5 million in the prior-year period. The decrease was mainly attributable to lower R&D revenue. Certain customer R&D programs were delayed, slowed or cancelled in fiscal 2010 as a result of various factors, including economic conditions, financing challenges, and issues in the pharmaceutical industry. Increases in new or existing customer R&D programs were not enough to offset declines from two existing programs.

In Vitro Diagnostics. In Vitro Diagnostics 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, In Vitro Diagnostics derived a significant percentage of revenue from Abbott. There was no royalty revenue from a diagnostic format patent license agreement with Abbott in fiscal 2010 because the patents had expired. Royalty revenue from Abbott was $4.9 million in fiscal 2009. In addition to the lower royalties and license fees, product sales decreased $0.2 million or 2% in fiscal 2010 compared with fiscal 2009 as customers were cautious with their purchasing activity.

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 levels of 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 R&D expenses were $18.1 million in fiscal 2010, an increase of 38% compared with fiscal 2009. The increase principally reflected the impact of higher fixed costs attributable to our Alabama research and development operations. Customer R&D margins were negative 18%, compared with positive 51% in fiscal 2009. Fiscal 2009 margins were positive 32% after adjusting for Merck deferred revenue recognition and final billings. The increase in fiscal 2010 costs reflected the higher fixed overhead costs in Alabama as well as increased material costs. Customer R&D expenses in the Pharmaceuticals segment were $15.6 million and $13.2 million in fiscal 2010 and 2009, respectively.

Other research and development expenses. Other R&D expenses were $17.9 million in fiscal 2010, 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 as well as employee attrition, resulting in lower labor costs. These reductions were partially offset by higher project material costs.

Selling, general and administrative expenses. SG&A expenses were $18.5 million in fiscal 2010, an increase of 7% compared with fiscal 2009. The increase principally reflected 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.

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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. As a result of the reorganization, we eliminated approximately 4% of our workforce with the terminations occurring across various functions. The reorganization was completed by the end of the third quarter of fiscal 2010. SurModics also vacated and subleased its leased sales office in Irvine, California and vacated a leased warehouse in Birmingham, Alabama. SurModics recorded total pre-tax restructuring charges of approximately $1.3 million in connection with the fiscal 2010 reorganization, which consisted of $0.8 million associated with severance pay and benefits expenses and $0.5 million of facility-related costs.

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 pre-tax restructuring charges of $1.8 million in connection with the fiscal 2009 reorganization, which consisted of $0.5 million of severance pay and benefits expenses and $1.3 million of facility-related costs.

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 was based on a real estate market appraisal obtained during our negotiations.

We also recorded a $1.3 million asset impairment charge in fiscal 2010 associated with certain long-lived assets where no ongoing business was expected in the foreseeable future based on market conditions. Furthermore, we recorded 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 no ongoing business was expected in the foreseeable future in light of market conditions. The assets associated with these charges had limited remaining value and as such were written down to zero value.

Goodwill impairment charges. 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 cGMP manufacturing facility, and a significant decrease in our stock price during fiscal 2010. 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 evaluated whether any indications of impairment were 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 reflected lower yields generated from our investment portfolio in fiscal 2010. The fiscal 2010 loss primarily reflected 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 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

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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 provision. 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 pre-tax 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 did not foresee offsetting capital gains that could offset these capital losses, and, therefore no benefit was 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 result of non-deductible stock-based compensation expenses, offset partially by lower state taxes resulting from adjustments to state deferred taxes.

Segment Operating Results

Operating (loss) income for each of our reportable segments was as follows (in thousands):

	2010	2009
Operating (loss) income:		
Medical Device	$ 19,524	$ 62,472
Pharmaceuticals	(26,479)	(5,248)
In Vitro Diagnostics	3,304	8,081
Corporate	(10,402)	(7,804)
Total	$ (14,053)	$ 57,501

Medical Device. Operating income was $19.5 million in fiscal 2010, compared with $62.5 million in fiscal 2009. Fiscal 2009 operating income, excluding $45.0 million associated with the Merck contract termination, was $17.5 million. The increase in fiscal 2010, after adjusting for this event in fiscal 2009, was $2.0 million and driven principally by $1.5 million in higher royalty and license fee revenue and lower compensation costs.

Pharmaceuticals. Pharmaceuticals operating loss was $26.5 million in fiscal 2010, compared with a loss of $5.2 million in fiscal 2009. The $21.3 million increase in the fiscal 2010 operating loss was driven primarily by a $12.5 million increase in event-specific charges, $3.0 million reduction in revenue (principally lower R&D revenue) and $4.9 million in increased operating expenses, mostly related to the cGMP facility which became operational in fiscal 2010.

In Vitro Diagnostics. Operating income was $3.3 million in fiscal 2010, compared with $8.1 million in fiscal 2009. Royalty revenue decreased $5.1 million in fiscal 2010 compared with the prior period, and was the primary contributor of the operating income decrease. Fiscal 2009 was the last year in which we received royalty revenue from our diagnostic format patent license agreement with Abbott. Royalty revenue from Abbott was $4.9 million in fiscal 2009.

Corporate. Operating loss was $10.4 million in fiscal 2010, compared with a loss of $7.8 million in fiscal 2009. Fiscal 2010 included $4.3 million in restructuring and asset impairment charges while fiscal 2009 included $1.8 million in restructuring charges. The operating losses for fiscal 2010 and 2009, when adjusted to exclude these charges, were $6.1 million and $6.0 million, respectively. The minor increase in operating loss for fiscal 2010, on an adjusted basis, reflected higher bad debt expense.

Liquidity and Capital Resources

Operating Activities. As of September 30, 2011, the Company had working capital of $42.7 million, of which $38.4 million consisted of cash, cash equivalents and short-term investments. Working capital increased

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$12.9 million from the September 30, 2010 level, driven principally by higher cash and short-term investment balances, offset by higher accrued compensation and other current liabilities. Our cash, cash equivalents and short-term and long-term investments totaled $68.2 million at September 30, 2011, an increase of $11.4 million from $56.8 million at September 30, 2010. The increase was principally driven by cash generated from operations less payments related to a prior acquisition. The Company s investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate and municipal 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 $20.0 million in fiscal 2011, compared with $22.0 million in fiscal 2010. The following table depicts our cash flows from operations for each of fiscal 2011 and 2010:

	For the Years Ended September 30,	
	2011	2010
	(In thousands)	
Net loss	$ (12,778)	$ (21,089)
Depreciation and amortization	7,145	7,818
Stock-based compensation	4,252	5,875
Asset impairment charges	17,890	4,896
Goodwill impairment charge	5,650	13,810
Impairment loss on investments		7,943
Deferred taxes	(5,892)	446
Other net operating activities	(131)	328
Net change in deferred revenue	37	2,632
Net change in other operating assets and liabilities	3,782	(651)
Net cash provided by operating activities	$ 19,955	$ 22,008

Net cash provided by operating activities decreased $2.1 million in fiscal 2011 compared with fiscal 2010. This decrease was driven by continued lower CYPHER® stent royalties, which declined $2.7 million compared with fiscal 2010, as well as to $1.3 million higher restructuring related payments.

Investing Activities. In fiscal 2011, we invested $3.5 million in capital expenditures compared with $9.7 million in fiscal 2010. The majority of the fiscal 2010 capital expenditures were for our cGMP facility 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 2011 in this facility, to meet the development and cGMP manufacturing needs of our pharmaceutical and biotechnology customers. We also made milestone payments of $5.7 million in fiscal 2011 compared with $0.8 million in fiscal 2010 associated with the July 2007 SurModics Pharmaceuticals acquisition. Subsequent to fiscal 2011, we completed the Pharma Sale for $30.0 million in cash.

We believe the Company has sufficient cash and investments on hand as of September 30, 2011, which totaled $68.2 million, to finance foreseeable future needs.

Financing Activities. In fiscal 2011, our financing activities were primarily associated with stock issued under our employee stock purchase plan. In fiscal 2010, our financing activities were driven by common stock repurchases. In November 2007, our Board of Directors authorized the repurchase of up to $35.0 million of the

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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. There were no repurchases of common stock in fiscal 2011 under the repurchase authorization. Under the current authorization, the Company has $5.3 million remaining available for authorized share repurchases as of September 30, 2011.

In February 2011, we extended our unsecured revolving credit facility through March 2012 and reduced the credit facility to $15.0 million. 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, 2011, the Company had no debt outstanding under the credit facility and was in compliance with all covenants.

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 12 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 2012 may include, but are not limited to, the following: general capital expenditures in the range of $1.5 million to $3.0 million; contingent consideration payments, if any, related to our acquisitions of SurModics Pharmaceuticals and SurModics IVD as well as the purchase of certain assets from PR Pharma; and any amounts associated with the repurchase of common stock under the authorization discussed above.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to the Company. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Medtronic is our largest customer at 15% of total revenue in fiscal 2011. Medtronic has several separately licensed products that generate royalty revenue for SurModics. In addition, there has been a decline in royalty revenue from one of our largest customers, Cordis, and with their June 2011 announcement of the cessation of the manufacture of the CYPHER® and CYPHER SELECT® Plus stents by the end of 2011, our royalty stream from this customer reached the contractual $1.0 million minimum quarterly level per the agreement in the third and fourth quarters of fiscal 2011. Beyond fiscal 2011, since the minimum levels in the agreement have been eliminated, we expect an earned royalty amount based on a percentage of CYPHER® sales, if any, until the products are no longer sold. No other individual customer product using licensed technology constitutes more than 5% of SurModics total revenue. Further, our licensing agreements with many of our customers, including most of our significant customers, cover many licensed products that each separately generate royalty revenue. This situation reduces the potential risk to our operations that may result from reduced sales (or the termination of a license) of a single product for any specific customer.

Off-Balance Sheet Arrangements and Contractual Obligations. As of September 30, 2011, 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.

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases					