SURMODICS INC
Form 10-K
December 04, 2015

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, 2015

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 o No x

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 x No o

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

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

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

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2015 was approximately $245 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 1, 2015 was 12,944,326.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Registrant's 2016 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 s that is not a historical fact, 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 and transformation strategy, financial prospects, product development programs including development of the Surveil™ drug-coated balloon, sales efforts, the impact of significant customer agreements, including its agreements with Medtronic plc (“Medtronic”) and the impact of acquisitions. You should carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. The Company undertakes no obligation to update any forward-looking statement. Investors are advised not to place undue reliance upon the Company’s forward-looking statements and to consult any further disclosures by the Company on such topics in this and other 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.

PART I

ITEM 1. BUSINESS.

Overview – General

SurModics, Inc. and subsidiaries (referred to as "SurModics," "the Company," "we," "us," "our" and other like terms) is a leading provider of surface modification and in vitro diagnostic technologies to the healthcare industry. Our business units are organized and managed in two reportable segments, Medical Device and In Vitro Diagnostics. The Medical Device and In Vitro Diagnostic units represented approximately 74% and 26% of our revenue, respectively, for the fiscal year ended September 30, 2015.

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 component products and technologies. We currently function in two business units that 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 in our Medical Device business unit include surface modification coating technologies that impart lubricity, prohealing or biocompatibility characteristics, or drug delivery capabilities. We are focused on a strategy to transform our Medical Device business from being a provider of coating technologies to offering whole product solutions to medical device customers. To that end, we received approval from the United States Food and Drug Administration ("FDA") on October 2, 2015 to commence a first in human early feasibility study with our Surveil™ drug-coated balloon (DCB). Further, on November 20, 2015 we acquired Creagh Medical Ltd. ("Creagh"), an innovative developer and manufacturer of percutaneous transluminal angioplasty (PTA) balloon catheters. With the acquisition of Creagh subsequent to fiscal year 2015, the Medical Device segment now engages in contract research and development, as well as manufacturing of balloons catheters used for a variety of interventional cardiology applications.

We believe that this acquisition will be a major step forward in our transformation strategy as it complements our capabilities by adding a world-class balloon catheter platform and state-of-the-art manufacturing facility. Our In Vitro Diagnostics business unit provides high quality 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 expand our core technologies to provide us with opportunities for longer term sustained growth.

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.

The information below provides an overview of the principal products and services and principal markets for each of our two business units. For more information regarding domestic and foreign revenue and revenue by our business units, also known as our operating segments, for each of our last three fiscal years, see Note 13 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The discussion of other aspects of our business including research and development, intellectual property, marketing and sales, future acquisition strategy, significant customers, competition, manufacturing, government regulation and our employees applies to our business in general and we describe material segment information within these sections where relevant.

Medical Device Business Unit

Our surface modification technologies are utilized by our customers to enhance 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.

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 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.

We commercialize our surface modification and device drug delivery 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 and applications.

Revenue from our licensing arrangements typically includes commercial 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 commercial development fees, we generate revenue from the manufacture and sale of a variety of products including reagent chemicals used by our customers in coating their products pursuant to licensing arrangements. We also generate revenue by providing contract coating services prior to technology transfer to certain of our licensed customers. With our acquisition of Creagh, and our transformation to offering whole-product solutions, we believe we will be able to enhance our ability to support customers from design and development through manufacturing and commercialization.

Surface Modification and Device Drug Delivery Markets

Medical Device Industry

Advances in medical device technology have helped drive improved device efficacy and patient outcomes. 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. Drug-coated balloons have further transformed intravascular therapies by enhancing patient outcomes while not leaving stents in the vascular system. Transcatheter heart valve repair or replacement via a minimally invasive catheter-based system has enabled the treatment of patients suffering from heart valve disease who are too ill to undergo open-heart surgery. Positive clinical outcomes and acceptance of these and other similar innovations by patients, physicians and insurance companies has helped certain segments of the United States ("U.S.") medical device industry grow at a faster pace than the economy as a whole. The attractiveness of the industry has drawn intense competition among the companies participating in this area. In an effort to improve their existing products or develop entirely new devices, a growing number of medical device manufacturers are exploring or using surface modification and device drug delivery technologies as product differentiators or device enablers. In addition, the continuing trend toward minimally invasive surgical procedures, which often employ catheter-based delivery technologies, has increased the demand drug delivery for hydrophilic, lubricious and hemocompatible coatings and other technologies.

Convergence of the Medical Device, Biotechnology and Pharmaceutical Industries

The convergence of the pharmaceutical, biotechnology and medical device industries, often made possible by surface modification and device drug delivery technologies, presents an 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.

Overview of SurModics' Surface Modification and Device Drug Delivery Technologies

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

Coatings for Surface Modification and Device Drug Delivery

Key differentiating characteristics of our coating platforms are their flexibility, durability and ease of use. In terms of flexibility, coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents. This flexibility allows customers to be innovative in the design of their products without significantly changing the dimensions or other physical properties of the device. Additionally, the surface modification process can be tailored to provide customers with the ability to improve the performance of their devices by choosing the specific coating properties desired for particular applications. Our surface modification technologies also can be combined to deliver multiple surface-enhancing characteristics on the same device.

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 durable and resilient.

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

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.

A long-standing challenge for the medical device industry has been the availability of device coatings that offer both excellent lubricity and lower particulates. The properties that make coatings more lubricious—absorbing and exuding water—also can make them more susceptible to generating particulates. The U.S. FDA has also raised concerns related to particulate generation. In January 2013, we launched our Serene™ hydrophilic coating platform that optimizes lubricity and durability while significantly reducing particulates. This next-generation coating has demonstrated excellent lubricity on a wide range of substrates, and has been used on FDA-cleared coronary, peripheral and structural heart devices. Serene™ coatings are applied using our PhotoLink® process.

Our device 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. Examples of short term use drug delivery devices would include drug coated balloons and examples of longer term drug delivery devices would include drug eluting stents. We work with companies in the medical device and biotechnology 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.

On October 2, 2015, we received FDA Investigational Device Exemption ("IDE") approval to move forward in pursuing our first-in-human early feasibility study using the SurModics SurVeil™ drug-coated balloon (DCB). The development of the SurVeil™ DCB is a major step forward in our strategy to transform our Medical Device business from being a provider of coating technologies to offering whole-product solutions to the medical device industry. This approval allows us to take the steps required to start an early feasibility clinical trial. We have identified our clinical investigators and are developing plans for up to three clinical sites in the U.S. and expect to enroll the first patient in the second quarter of fiscal 2016. Our acquisition of Creagh on November 20, 2015 is anticipated to further strengthen our capabilities in design, development and manufacture of balloon catheters, significantly advancing our drug-coated balloon program.

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 such as our SynBiosys platform that can be used for drug delivery applications. The SynBiosys platform has similar drug loading and drug release variability capabilities as the Bravo matrix, and offers the added feature where polymer coating matrix can fully biodegrade after releasing the drug (degradable from several months to over a year). 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.

Clinical Benefits

- Device 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 minutes, days, weeks or months. For instance, when a DCB is expanded for a

period of thirty seconds to several minutes, it transfers a drug to the surface of the arterial wall to inhibit unwanted tissue growth, thereby reducing the occurrence of re-closure of the artery which is known as 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 (the formation of a clot on the stent 30 days to one year after implant).
- 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.

SurModics' Surface Modification and Device Drug Delivery Technologies — Applications

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

Market Segment	Desired Surface Property and Examples of Applications
Cardiac Rhythm Management	Lubricity: Cardiac Resynchronization Therapy (CRT) leads, Brady pacemaker and Tachy defibrillator leads, delivery systems, electrophysiology (EP) devices Drug/biologics delivery: pacemaker and defibrillator leads Prohealing: CRT, Brady pacemaker and Tachy defibrillator leads
Cardiothoracic Surgery	Prohealing: heart valves, septal defect repair devices Hemocompatibility: minimally invasive bypass devices, vascular grafts, ventricular assist devices
Central Nervous System Disorders	Drug/biologics delivery: polymer implants
Diabetes	Lubricity: access/delivery systems Hemocompatibility: glucose sensors
Electrophysiology	Hemocompatibility: EP mapping and ablation 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 Cardiology and Vascular Access	Lubricity: balloon catheters, microcatheter, guidewires, chronic total occlusion (CTO) catheters, Imaging catheters, delivery systems for implants Hemocompatibility: vascular stents, catheters, distal protection devices Drug/biologics delivery: vascular stents, catheters, drug-coated balloons Prohealing: vascular stents, vascular grafts

Interventional Neurology and Neurosurgery	Lubricity: microcatheters, guidewires, delivery systems, stroke therapy devices Prohealing: neuroembolic devices Drug Delivery: implants Tissue engineering: aneurysm repair devices
Metabolic Disease	Tissue engineering: cell encapsulation
Oncology	Tissue engineering: female sterilization devices Lubricity: microcatheters, guidewires, delivery systems
Ophthalmology	Lubricity: access devices, microcatheters
Orthopedics	Cell growth and tissue integration: bone and cartilage growth Infection resistance: orthopedic and trauma implants Drug/biologics delivery: orthopedic and trauma implants
Structural Heart	Lubricity: transcatheter valve delivery systems, aortic embolic protection devices, sheath introducer, closure devices
Urology and Gynecology	Lubricity: urinary catheters, incontinence devices, ureteral stents, fertility devices Drug/biologics delivery: prostatic stents

Examples of medical devices on which our surface modification and drug delivery technologies are used include guidewires, angiography catheters, intra vascular ultra sound (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, and hydrocephalic shunts, among other devices.

Licensing Arrangements

We commercialize our surface modification and device drug delivery technologies primarily through licensing arrangements with medical device 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 implement them easily into their own manufacturing processes so customers can control production and quality internally without the need to send their products to a contract manufacturer. We actively seek to upgrade our customers to advanced generations of our technology although there can be no assurance that we will be successful in doing so.

We generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 51.3%, 52.7% and 53.0% of our total revenue in fiscal 2015, 2014 and 2013, respectively. Greater than 97% of our royalties and license fees revenue in this three-year period were generated from hydrophilic coating licenses. 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 reagent chemicals to licensees for use in their coating processes.

The licensing process begins with the customer specifying a desired product feature to be created such as lubricity or drug delivery. Because each device and coating application is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating commercial development revenue. Feasibility studies can range in duration from several months to a year. After we complete a feasibility study, our customers cannot market their product until they receive regulatory approval. As further described under the caption "Government Regulation," the regulatory approval process varies in each country and ranges from several months to four or more years. At any time prior to a customer's commercial launch, 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. Typically, we complete a technology transfer to most customers which enables those customers to apply the coating at their own facilities.

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. In cases where the royalty obligation extends beyond the life of the applicable patent, it is because the license also includes rights to our know-how or other proprietary rights, in which case, the royalty rate is also reduced. Under these circumstances, the royalty obligation typically continues at a reduced royalty rate for a specified number of years generally following the date on which the customer's product was

first sold. We actively seek to upgrade our customers to advanced generations of our hydrophilic coating technology although there can be no assurance that we will be successful in doing so.

Our license agreements may include certain license fees and/or milestone payments. The license can be either exclusive or nonexclusive, but substantially all 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. In certain agreements, our royalty is based on an agreed amount per unit. 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. Royalty payments generally commence one quarter after the customer's actual product sales occur because of the delay in reporting sales by our licensees.

As of September 30, 2015, we had over 150 licensed product classes (customer products utilizing SurModics technology) already in the market generating royalties and greater than 100 customer product classes incorporating our technology in various stages of pre-commercialization. We signed 22, 16 and 17 new licenses in fiscal 2015, 2014 and 2013, respectively. Our Serene™ platform was licensed to multiple companies during fiscal 2015, 2014 and 2013.

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 expected timing for regulatory approval and commercialization for the product classes pending regulatory approval is can vary greatly.

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 Corporation (a subsidiary of Cardinal Health, Inc.) ("Cordis"), Covidien PLC (a subsidiary of Medtronic), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), Elixir Medical Corporation, ev3 Inc. (a subsidiary of Medtronic), Medtronic, OrbusNeich Medical, Inc., Spectranetics Corporation and St. Jude Medical, Inc.

Contract Research, Development and Manufacturing

On November 20, 2015, we acquired Creagh, an innovative developer and manufacturer of percutaneous transluminal angioplasty (PTA) balloon catheters. This acquisition is a major step forward in our strategy to transform our Medical Device business from being a provider of coating technologies to offering whole-product solutions to medical device customers. Creagh is based in Ballinasloe, Ireland, ideally located near the Galway and Athlone medical device hubs. Creagh's state-of-the-art facility is equipped for medical device research, development and manufacturing and has room for future growth. As a result of our acquisition of Creagh, we now have the capability to support customers from concept to commercialization, including turn-key manufacturing of innovative whole-product solutions. In addition, we will continue to deliver on Creagh's customer contracts, at various stages of development and manufacturing.

In Vitro Diagnostics Business Unit

Our In Vitro Diagnostics (“IVD”) business unit generates revenue from sales of stabilization products, substrates, antigens and surface coatings to diagnostics customers. We manufacture or sell components for in vitro diagnostic immunoassay and molecular tests and we manufacture and sell surface coatings to the diagnostic, biomedical research, and life science markets.

Immunoassay Diagnostics. An immunoassay is a biochemical test that measures the presence or concentration of a target molecule, or “analyte”, in a biological fluid or sample. Analyte levels are correlated to the disease state or medical condition of a patient to diagnose the presence, absence or severity of disease. Analytes are typically proteins or small molecules such as hormones. Immunoassays are developed and produced using multiple components. The selection and optimization of those components confer the quality and performance of the assay in terms of sensitivity and specificity. IVD companies select these critical biochemical and reagent components to meet the clinical specifications of the assay. We develop, manufacture and sell high-performing, consistent and

stable immunoassay component products to enable our customers' diagnostic tests to detect the absence or presence of disease accurately.

Molecular Diagnostics - 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. 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.

The sales cycle for our IVD products generally begins when an IVD company initiates the process to develop a new IVD test or improve a current IVD test. As development of the IVD begins, an IVD company will look to source the critical components of the test with reagents it produces internally or with reagents from a supplier of critical IVD test components such as SurModics.

As IVD tests are developed and various reagents are tested, an IVD company will generally seek to optimize the sensitivity (reduction of false negatives), specificity (reduction of false positives), speed (time from sample to results), convenience (ideally as few steps as possible) and cost effectiveness of the test.

The time from when an IVD company initiates the development of an IVD test to achieving regulatory approval (e.g., PMA) or clearance of the test (e.g., 510k) can vary greatly, and depends on several factors. These factors include the disease state of the test, the relative complexity of the test, whether the test is being used as a companion diagnostic, among other factors. Upon regulatory approval or clearance of the test, the IVD test company will launch the test into the marketplace. Once launched, it may take several years for an IVD test to achieve peak market share. As such, revenue for SurModics reagents will vary based on the commercial success of the newly launched IVD test.

Overview of In Vitro Diagnostics Products

Protein Stabilizers. We offer a full line of stabilization products for the in vitro diagnostics market. These products increase sensitivity and extend the shelf life of diagnostic tests, thereby producing more consistent assay results. Our stabilization products are ready-to-use, eliminating the preparation time and cost of producing stabilization and blocking reagents by manufacturing in-house.

Substrates. We also provide colorimetric and chemiluminescent substrates to the in vitro diagnostics market under our BioFX trademark. A substrate is the component of a diagnostic test kit that detects and signals that a reaction has taken place so that a result can be recorded. Colorimetric substrates signal a positive diagnostic result through a color change. Chemiluminescent substrates signal a positive diagnostic result by emitting light. We believe that our substrates offer a high level of stability, sensitivity and consistency.

Recombinant Human Antigens. We are 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 recombinant technology.

Surface Coatings for Molecular Diagnostic Applications. We offer custom coatings for molecular diagnostic applications, including DNA, RNA and protein microarrays. Our TRIDIA surface coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive

groups. This proprietary technology immobilizes DNA and protein to adhere to testing surfaces. We offer other surface coatings that improve flow characteristics through membranes and microfluidic channels on diagnostic devices including point-of-care components.

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.

With the acquisition of Creagh, we strengthened our capabilities and broadened our capacity for R&D activities with a state-of-the-art facility in Ballinasloe, Ireland. The facility is fully equipped for R&D and manufacturing and is focused on value-driven design and manufacture of high-quality balloon catheters. The suite of capabilities available include balloon forming, extrusion, coating and final finished product. The facility was purposefully built and equipped for medical device R&D and manufacturing with space for future growth.

We work together with our customers to integrate the best possible surface modification and device drug delivery technologies with their products, not only to meet their performance requirements, but also to perform services quickly so that the product may reach the market ahead of the competition. To quickly solve problems that might arise during the development and optimization process, we have developed 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 surface modification and device drug delivery will continue to grow. We intend to continue our development efforts to expand our surface modification and device drug delivery technologies to provide additional optimized properties to meet these needs across multiple medical markets. In addition, we are expanding our surface modification and device drug delivery 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. For example, we spent considerable development and preclinical efforts in the past three years developing a DCB. In fiscal 2014, we froze the design of our SurVeil™ DCB for use in the superficial femoral and popliteal arteries. We received FDA approval to commence an early feasibility study of this balloon in October 2015 and plan to initiate this study by the end of the second quarter fiscal 2016.

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 activities currently in progress include additional coatings for biopassive, bioactive and biointeractive platforms to support our core and core expansion efforts.

Our research and development efforts to grow our IVD business unit include identifying and addressing unmet needs that exist in the global IVD market place. Our pipeline of IVD products includes components for immunoassay and molecular diagnostic applications, such as, new protein stabilizers, detection technologies, accessory reagents and surface coatings that have the potential to add greater sensitivity, specificity, speed, convenience and lower cost for IVD test manufacturers. In June of 2014, we launched BioFx Liquid NovaStop solution. This accessory reagent for enzyme-linked immunosorbent assay (“ELISA”) tests delivers top performance and stability for IVD tests, and for the safety of lab personnel, is non-corrosive to skin and eyes. In July of 2014, we launched StabilZyme Protein Free AP. This new stabilizer eliminates protein-related interference and cross-reactivity for assays that utilize alkaline phosphatase and offers excellent performance. The retained activity of StabilZyme Protein-Free AP Stabilizer is comparable to its protein-containing counterpart—StabilZyme AP Conjugate Stabilizer—and superior to other protein-free/BSA-free stabilizers on the market.

In fiscal 2015, 2014 and 2013, our R&D expenses were $16.2 million, $15.6 million and $15.1 million, respectively. We intend to continue investing in R&D to advance our surface modification, device drug delivery, whole product solutions and in vitro diagnostic technologies and to expand uses for our technology platforms. We anticipate an increase in R&D expenses in fiscal 2016 primarily related to proprietary product development, including our DCB

activities. 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 SurModics' business. The Company aggressively pursues patent protection covering the proprietary technologies that we consider strategically important to our business. In addition to seeking patent protection in the U.S., we also generally file patent applications in European countries and, on a selective basis, other foreign countries, including Australia, Brazil, Canada, China, India, Japan, Mexico and Russia. We strategically manage our patent portfolio so as to ensure that we have valid and enforceable patent rights protecting our technological innovations.

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. During fiscal 2015, SurModics filed 18 original U.S. patent applications, as well as 4 international patent applications, expanding the portfolio protection around our current technologies as well as enabling pursuit of new technology concepts, innovations and directions. As of September 30, 2015,

SurModics had 83 pending U.S. patent applications, 2 of which were exclusively licensed from others, and 112 foreign patent applications, of which one was exclusively licensed from others. Likewise, as of the same date, SurModics owned 151 issued U.S. patents, 16 of which were exclusively licensed from others, and 195 international patents, of which 21 were exclusively licensed from others.

We have licensed our Photolink® hydrophilic technology on a non-exclusive basis to a number of our customers for use in a variety of medical device surface applications, including those described above. In particular, we have 16 issued U.S. patents, seven pending U.S. patent applications, 28 issued international patents, and 24 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 2033. Moreover, these patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers. Among these, an early generation of our Photolink® technology is protected by a family of patents that expired in November 2015 (in the U.S.) and are expected to expire in October 2016 (in certain other countries). In addition, another early generation of our Photolink® technology is protected by a family of patents that is expected to expire in fiscal 2020. As noted above in “Licensing Arrangements,” the royalty obligation in our typical license agreement is generally for a specified number of years or the life of our patents, whichever is longer. In cases where the royalty obligation extends beyond the life of the applicable patent, it is because the license also includes rights to our know-how or other proprietary rights. Under these circumstances, the royalty obligation will continue at a reduced royalty rate for a specified number of years, as determined based on the specific terms and conditions of the applicable customer agreement, the date on which the customer’s product was first sold, and other factors. In recent years, we have successfully converted a number of our customer’s products utilizing this early generation technology to one of our advanced generation technologies.

The royalty revenue associated with this early generation technology that expired in November 2015 (in the U.S.) and is expected to expire in October 2016 (in certain other countries) which has not yet converted, or that is not in the process of converting, to one of our advanced generation technologies was approximately 18% of our fiscal 2015 revenue. Of the revenue generated by the early generation technology, approximately 81% will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. The royalty obligation for these customer products extends beyond the expiration of these patents because the license also includes rights to our know-how or other proprietary rights. While we are actively seeking to convert our customers to one of our advanced generation of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, will sell products utilizing our technology which will generate earned royalty revenue for us.

We also rely upon trade secrets, trademarks 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 develop independently 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 working within our Medical Device business work in concert with business unit personnel to coordinate customer activities. The specialization of

our sales professionals fosters an in-depth knowledge of the issues faced by our customers within these markets such as industry trends, technology changes, biomaterial changes and the regulatory environment. With respect to our diagnostics products, we enter into sales and marketing relationships with third parties to distribute those products around the world. We also offer those products for sale through our website. See Note 13 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K 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 to our licensees. 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. Some of these services are billable to customers, mainly feasibility and optimization activities.

While our acquisition of Creagh has strengthened our development and manufacturing capability and capacity, it does not change our business model of working with medical device customers. Our offerings are expanding as we now have the capabilities to support our customers from design and development through manufacturing and commercialization. Our aim is to provide our customers earlier access to strongly differentiated products that address important unmet clinical needs, and partner with them on these products' successful commercialization.

Acquisitions

To further our strategic objectives and strengthen our existing businesses, we intend to continue to explore acquisitions and strategic collaborations to diversify and grow our business. As a result, we expect to make future acquisitions where we believe that we can broaden our technology offerings and expand our sources of revenue and the number of markets in which we participate. Mergers and acquisitions of medical and diagnostic 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.

We have been proactively seeking to acquire and integrate strategic assets and capabilities to become a world-class medical device innovator, developer and manufacturer, most recently with our acquisition of Creagh described above. We are disciplined in our approach for acquisitions recognizing that investments must accelerate our transformation in two key areas: innovative device design and development capabilities, and automated and integrated manufacturing.

On November 20, 2015 ("the Creagh acquisition date"), the Company acquired 100% of the outstanding common shares and voting interest of Creagh located in Ballinasloe, Ireland. The results of Creagh's operations will be included in the Company's consolidated financial statements as of the Creagh acquisition date. The acquisition was financed with cash on hand. The Company acquired Creagh for €30 million ($32.1 million), including an upfront payment of €18 million ($19.3 million), and up to €12 million ($12.8 million) based on achievement of revenue and value-creating operational milestone earned through September 30, 2018. The payment of the milestones will occur in the quarter ending December 31, 2018.

Creagh is dedicated to providing innovative, efficient and cost-effective design and manufacture of high-quality PTA balloon catheters to meet the needs of medical device customers. Established in 2006 in the west of Ireland, the heart of the Irish medical device industry, the company is able to attract skilled and talented resources, with extensive medical device experience ranging from polymer science, mechanical design, and product design engineering. Creagh's facility is purpose-built and equipped to the highest standard with all catheter technologies on site. Since 2006, the company has continued to grow its technical and product capability with PTA products approved throughout the world, including Europe, the United States, and Japan. With these resources, the company is uniquely positioned to offer a total solutions approach from product design and development, through in-house extrusion, balloon forming, top-assembly, packaging and regulatory capabilities to approved products for exclusive distribution.

The Company has excluded the purchase price allocation and pro forma disclosures for the Creagh acquisition as the initial accounting is currently incomplete. The Company is currently in the process of obtaining an initial valuation related to the acquired assets and assumed liabilities.

Significant Customers

Revenue from Medtronic represented approximately 26% of our total revenue for the year ended September 30, 2015 and was generated from multiple products and fields of use. The percentage of revenue from Medtronic increased in fiscal 2015 as a result of Medtronic's merger with Covidien PLC on January 26, 2015. No other customer provided more than 7% of our consolidated revenue in fiscal 2015. There are no customers, other than Medtronic with respect to our Medical Device business unit, that if lost would have a material adverse effect on either of our segments.

Competition

The ability for surface modification and device drug delivery technologies to improve the performance of medical devices and drugs and to enable new product categories has resulted in increased competition in these markets. Some of our competitors offer device drug delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies 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 surface modification and device drug delivery. Following our recent acquisition of Creagh, our core balloon catheter capabilities compete with larger original equipment manufacturer (OEM) suppliers, as well as some of our largest medical device partners that have in-house resources to produce balloon catheters. 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, 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 typically seek to license our technologies on a non-exclusive basis, we may further benefit from competition within the medical device markets by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us. While we seek to license our products to established manufacturers, in certain cases our licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities. We also are unable to control other factors that may impact commercialization of coated devices or drug products, such as regulatory approval, marketing and sales efforts of our licensees or competitive pricing pressures within the particular market. There can be no assurance that products employing our technologies will be successfully commercialized by our licensees or that such licensees will otherwise be able to compete effectively.

Competition in the diagnostics market is highly fragmented. In the product lines in which we compete (protein stabilization reagents, substrates, recombinant autoimmune antigens and surface chemistry technologies), we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Many of our competitors have substantially more capital resources, marketing experience, R&D 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

We manufacture our surface modification and drug delivery reagents, and our IVD products in our Eden Prairie, Minnesota facility. In certain limited circumstances, we also provide manufacturing services for our customers, including, for example, coating their medical devices that are intended for pre-clinical and clinical development (including human clinical trials), and products that are sold for commercial use by our customers. Through our acquisition of Creagh after the fiscal year ending September 30, 2015, we acquired a state-of-the-art facility in Ballinasloe, Ireland that is fully equipped for R&D and manufacturing. Creagh has been focused on value-driven design and manufacture of high-quality balloon catheters and offers a suite of capabilities, including balloon forming, extrusion, coating and top assembly. The facility was purposefully built and equipped for medical device R&D and manufacturing with space for future growth.

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 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 most recently received ISO 13485:2003/NS-EN13485:2012 and ISO 9001:2008 recertification in fiscal 2014.

Government Regulation

Although our surface modification and device drug delivery technologies themselves are not directly regulated by the U.S. FDA, the medical devices, IVD and biotechnology products incorporating our technologies are required to undergo long, expensive and uncertain regulatory review processes that are governed by the U.S. FDA and other international regulatory authorities. 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 several months (e.g., for medical device products seeking regulatory approval under the 510(k) approval process) to several years (e.g., for medical device products seeking regulatory approval under the PMA approval process). The burden of securing regulatory approval typically rests with our customers as the medical device manufacturers. During fiscal 2015 and 2014, SurModics had multiple customers obtain regulatory clearance with our Serene™ coating platform.

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, 2015, we had approximately 168 employees. Of these employees we employ approximately 36 outside the U.S. in research and development and manufacturing operations functions. We are not a party to any collective bargaining agreements.

We believe that our future success will depend in part on our ability to attract and retain qualified technical, management and marketing personnel. We are committed to developing and providing our employees opportunities to contribute to our growth and success.

EXECUTIVE OFFICERS OF THE REGISTRANT

As of December 1, 2015, the names, ages and positions of the Company's executive officers are as follows:

Name	Age	Position
Gary R. Maharaj	52	President and Chief Executive Officer

Timothy J. Arens	48	Vice President of Corporate Development and Strategy
Thomas A. Greaney	49	Vice President of Operations and General Manager of SurModics Ireland
Andrew D. C. LaFrence	52	Vice President of Finance and Chief Financial Officer
Charles W. Olson	51	Senior Vice President and General Manager, Medical Device
Bryan K. Phillips	44	Senior Vice President, Legal and Human Resources, General Counsel and Secretary
Joseph J. Stich	50	Vice President 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

approximately 30 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 Vice President of Finance and Interim Chief Financial Officer in August 2011 and in February 2013 became Vice President Corporate Development and Strategy. Prior to joining SurModics, Mr. Arens was employed at St. Jude Medical, Inc., 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.

Thomas A. Greaney joined the Company in November 2015 as Vice President of Operations and General Manager of SurModics Ireland. Prior to joining SurModics he served as Chief Executive Officer for Creagh Medical, from September 2005 to November 2015. Prior to his tenure in Creagh, Mr. Greaney served in a variety of roles with Boston Scientific for 10 years including the world-wide operations responsibility for the Taxus Stent commercialization. From 1989 to 1995 he worked for a number of Electronics companies in a variety of engineering and management roles. Mr. Greaney received a B.E in Industrial Engineering in 1988 and a post grad Diploma in Quality Assurance in 1989 both from the National University of Ireland Galway.

Andrew D. C. LaFrence joined the Company in February 2013 as Vice President of Finance and Chief Financial Officer. Prior to joining SurModics, he served as Chief Financial Officer for CNS Therapeutics from January 2011 to January 2013. Prior to joining CNS, Mr. LaFrence served as interim Chief Financial Officer of International Green Power from July 2010 to January 2011. Mr. LaFrence has over 30 years of financial and management experience including 26 years at KPMG LLP where, from 1996 to 2010, he was an audit partner focusing on supporting venture-backed, high-growth medical technology, pharmaceutical, biotech and clean tech private and public companies. Mr. LaFrence is a certified public accountant and received a bachelor's degree in accounting and a minor in business administration from Illinois State University in 1984.

Charles W. Olson joined the Company in July 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, Sales was added to his responsibilities. In November 2008, 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 President, Legal and Human Resources, General Counsel and Secretary. Prior to joining SurModics, 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 and in September 2013 his role was adjusted to Vice President 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 for MGI Pharma, Inc., a biopharmaceutical company, from 2005 to 2009. Mr. Stich’s prior experience also includes serving as President/COO of Pharmaceutical Corp. of America (a subsidiary of Publicis Healthcare Specialty Group), and positions of increasing responsibility in sales and marketing at Sanofi-Aventis Pharmaceuticals. He received 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, Missouri in 1996.

The executive officers of the Company are elected by and serve at the discretion of the Board of Directors. None of our executive officers are related to any other executive officer or any of our directors.

ITEM 1A. RISK FACTORS.

RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

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

In addition to large and established medical device companies, our customers also include start-up and other early-stage companies. These companies often find it difficult to obtain financing, 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 one customer that provided more than 10% of our revenue in fiscal 2015. Revenue from Medtronic represented approximately 26% of our total revenue for the fiscal year ended September 30, 2015 and was generated from multiple products and fields of use. The loss of Medtronic or any of our largest customers, or reductions in business from them, could have a material adverse effect on our business, financial condition, results of operations, and cash flow. There can be no assurance that revenue from any customer will continue at their historical levels. If we cannot broaden our customer base, we will continue to depend on a 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 customers. We intend to continue pursuing a strategy of licensing our technologies to a diversified base of medical device and other customers, thereby expanding the commercialization opportunities for our technologies. A significant portion of our revenue is derived from customer devices used in connection with procedures in cardiovascular, peripheral vascular and other applications. As a result, our business is susceptible to adverse trends in procedures. Further, we may also be subject to adverse trends in specific markets such as the cardiovascular industry, including declines in procedures using our customers' products as well as declines in average selling prices from which we earn royalties. Our 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 technologies for use in applications outside of cardiovascular. There can be no assurance that we will be able to identify, develop and adapt our technologies for new applications in a timely and cost-effective manner; that new license agreements will be executed on terms favorable to us; that new applications will be accepted by customers in our target markets; or that products incorporating newly licensed technology, including new applications, will gain regulatory approval, be commercialized or gain market acceptance. Delays or failures in these efforts could have an adverse effect on our business, financial condition and results of operations.

Surface modification and device drug delivery are competitive markets and carry the risk of technological obsolescence and we face increased competition in our In Vitro Diagnostics segment.

We operate in a competitive and evolving field, and new developments are expected to continue at a rapid pace. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the field of surface modification and device drug delivery. Our surface modification and device drug delivery 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. Further, in fiscal 2014, we have faced increased competition in our In Vitro Diagnostics segment related to our BioFX product offerings. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own R&D 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,

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

Failure to identify acquisition opportunities or to integrate acquired businesses into our operations successfully may limit our growth.

An important part of our growth in the future may involve the acquisition of complementary businesses or technologies. Our identification of suitable acquisition candidates involves risks inherent in assessing the technology, value, strengths, weaknesses, overall risks and profitability, if any, of acquisition candidates. We may not be able to identify suitable acquisition candidates. If we do not make suitable investments and acquisitions, we may find it more difficult to realize our growth objectives.

We recently announced our acquisition of Creagh, a company based in Ballinasloe, Ireland, which will be our first international operations, and we may acquire additional businesses in the future. 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;
- a lack of understanding of tax, legal and cultural differences;
- 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. 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 R&D efforts necessary to commercialize such acquired technology. We cannot guarantee that we will be able to successfully complete any acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

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

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

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

Our operations are expanding, and we expect this trend to continue as we execute our business strategy. Executing our business strategy has placed significant demands on management and our administrative, development, operational, information technology, manufacturing, financial and personnel resources. Accordingly, our future operating results will depend on the ability of our officers and other key employees to continue to implement and improve our operational, development, customer support and financial control systems, and effectively expand, train

and manage our employee base. Otherwise, we may not be able to manage our growth successfully.

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

We have recorded a significant amount of goodwill and intangible assets on our balance sheet in connection with previous acquisitions and expect to record additional goodwill and intangible assets associated with the acquisition of Creagh on November 20,

2015. As of September 30, 2015, we had $8.6 million of goodwill and an indefinite-lived trademark intangible asset on our consolidated balance sheet related to our IVD business unit. As required by the accounting guidance for non-amortizing intangible assets, we evaluate at least annually the potential impairment of the goodwill and trademark. Testing for impairment of non-amortizing intangible assets 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 strategic investments and 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 the goodwill or other assets on our balance sheet could materially adversely affect our results of operations.

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 recent years, we have expended considerable resources researching and developing our DCB platform. In fiscal 2014, we completed significant preclinical testing of this platform, conducted additional related development activities and froze the design of our first product: SurVeil™ DCB for superficial femoral and popliteal artery applications. In the first half of fiscal 2015, we conducted a good laboratory practice (“GLP”) animal study, and on October 2, 2015 received FDA approval to conduct a first-in-human early feasibility study using the SurVeil™ DCB to evaluate the safety and efficacy by March 31, 2016 which may result in significant cost to us. 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. There can be no assurance that we will be successful in developing new technologies or devices, or that any such technology will be commercialized.

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.

In addition in May 2014, the FASB issued new revenue recognition guidance for recognizing revenue from contracts with customers that provides a five-step analysis of transactions to determine when and how revenue is recognized. The guidance states that a Company should recognize revenue which depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. The new standard will also result in enhanced disclosures about revenue related to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The standard also requires quantitative and qualitative disclosures about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. Additionally it has provided guidance for transactions that were not previously addressed comprehensively, and improved guidance for multiple-element arrangements. The original pronouncement was effective for the Company beginning in fiscal 2018 (October 1, 2017), and early adoption was not permitted. On July 9, 2015, the FASB approved a one-year deferral of the effective date for the revenue recognition standard. As a result of the one-year deferral, the revenue recognition standard is effective for the Company beginning in fiscal 2019 (October 1, 2018), however, the Company may adopt this guidance as of the original effective date. This guidance can be adopted by the Company either retrospectively (October 1, 2016) or as a cumulative-effect adjustment as of the date of adoption. The Company is

currently evaluating the impact that the adoption of this new accounting guidance will have on the Company's results of operations, cash flows and financial position.

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.

A principal element of our business strategy is to enter into licensing arrangements with medical device and other companies that manufacture products incorporating our technologies. For the fiscal years ended September 30, 2015, 2014 and 2013, we have derived an average of 52% of our revenue in each year 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 immunoassay or molecular tests, 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, all of which are outside of our control, 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, or if they modify their products in a way such that the products no longer incorporate our technology, our revenue and profits may not reach our expectations, or may decline. Additionally, our ability to generate positive operating results in connection with the achievement of development or commercialization milestones may also suffer. We do not control the timing and other aspects of the development or commercialization of products incorporating our licensed technologies because our customers may have priorities that differ from ours or their development or marketing efforts may be unsuccessful, resulting in delayed or discontinued products. Hence, the amount and timing of revenue we derive from our customers' R&D as well as royalty payments received by us will fluctuate, and such fluctuations could have a material adverse effect on our business, financial condition and results of operations.

Under our standard license agreements, licensees can terminate the license for any reason upon 90 days' prior written notice. Existing and potential licensees have no obligation to deal exclusively with us in obtaining drug delivery or surface modification technologies and may pursue parallel development or licensing of competing technological solutions on their own or with third parties. A decision by a licensee to terminate its relationship with us could materially adversely affect our business, financial condition and results of operations.

Moreover, we rely on our customers to accurately report the sales their products incorporating our technologies and the royalties owed in connection with those sales. Inaccuracies in these reports could result in an overpayment or underpayment of royalties, which could have a material adverse effect on our business, financial condition and results of operations.

A portion of our IVD business relies on distribution agreements and relationships with various third parties and any adverse change in those relationships could result in a loss of revenue and harm that business.

We sell our IVD products outside of the United States primarily through distributors. Some of our distributors also sell our competitors' products, and if they favor our competitors' products for any reason, they may fail to market our products as effectively or to devote resources necessary to provide effective sales, which would cause our results to suffer. Additionally, we serve as the exclusive North American distributor for DIARECT AG for recombinant native antigens. The success of these arrangements with these third parties depends, in part, on the continued adherence to the terms of our agreements with them. Any disruption in these arrangements will adversely affect our financial

condition and results of operations.

We rely on our customers to accurately report and make payments under our agreements with them.

We rely on our customers to determine whether the products that they sell are royalty-bearing and, if so, report and pay the amount of royalties owed to us under our agreements with them. The majority of our license agreements with our customers give us the right to audit their records to verify the accuracy of their reports to us. However, these audits can be expensive, time-consuming and possibly detrimental to our ongoing business relationships with our customers. While we have undertaken audits of certain of our customers in the past, we generally rely on the accuracy of the reports that they provide to us. To the extent these reports are inaccurate, the payments that we collect from our customers could be materially different than the amount actually owed, and the revenue that we recognize from these customers could be adversely affected.

We have limited or no redundancy in our manufacturing facilities, and we may lose revenue and be unable to maintain our customer relationships if we lose our production capacity.

We manufacture all of our Medical Device coating reagents (and provide coating manufacturing services for certain customers) and our IVD products at our Eden Prairie, Minnesota facility. As a result of our acquisition of Creagh we also manufacture balloon catheter products at our facility in Ballinasloe, Ireland. If either of our existing production facilities becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our customers, including certain of our licensees. In particular, because most of our customers use our coating reagents to manufacture their own products that generate royalty revenue for us, failure by us to supply these reagents could result in decreased royalty revenue, as well as decreased revenue from the sale of products. Without our existing production facilities, we would have no other means of manufacturing products until we were able to restore the manufacturing capability at these facilities or develop one or more alternative manufacturing facilities. 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 or the use or misuse of our products.

The development and sale of medical devices and component products involves an inherent risk of product liability claims. Although in most cases our customer agreements provide indemnification against such claims, there can be no guarantee that product liability claims will not be filed against us for such products, that parties indemnifying us will have the financial ability to honor their indemnification obligations or that such manufacturers will not seek indemnification or other relief from us for any such claims. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management’s time, attention and resources. We have obtained a level of liability insurance coverage that we believe is appropriate to our activities, however, we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any recall of products or devices incorporating our technologies because of alleged defects, whether such recall is instituted by us, by a customer, or is required by a regulatory agency. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

Our revenue will be harmed if we cannot purchase sufficient reagent components we use in our manufacture of reagents.

We currently purchase some of the components we use to manufacture reagents from sole suppliers. If any of our sole suppliers becomes unwilling to supply components to us, experiences an interruption in its production or is otherwise unable to provide us with sufficient material to manufacture our reagents, we will experience production interruptions. If we lose our sole supplier of any particular reagent component or are otherwise unable to procure all 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 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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

We collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, on our networks. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached resulting from employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, and regulatory penalties, disrupt our operations and the services that we provide to our customers, damage our reputation and cause a loss of confidence in our products and services, any of which could adversely affect our business and competitive position.

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 licensed technologies will result in a reduction of the revenue derived from these arrangements which may have a material adverse effect on our 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.

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 determine that our proprietary rights have been misappropriated, we may seek to enforce our rights which would draw upon our financial resources and divert the time and efforts of our management, and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to convert our customers to our advanced generation of hydrophilic coating technology, our royalty revenue may decrease.

In our Medical Device business unit, we have licensed our Photolink® hydrophilic technology to a number of our customers for use in a variety of medical device surface applications. We have several U.S. and international issued patents and 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 the anticipated expiration dates of the patent applications range from calendar 2015 to 2033. These patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers. Among these, our third generation of Photolink® hydrophilic technology is protected by a family of patents that expired in November 2015 (in the U.S.) and are expected to expire in October 2016 (in certain other countries).

The royalty revenue associated with the third generation technology that has not yet converted, or that is not in the process of converting, to one of our advanced generation technologies comprised approximately 18% of our fiscal 2015 revenue. Of the revenue generated by the early generation technology, approximately 81% will continue to generate royalty revenue at a reduced royalty rate beyond the expiration of these patents. The royalty obligation for these customer products extends beyond the expiration of these patents because the license also includes rights to our know-how or other proprietary rights. Under these circumstances, the royalty obligation will continue at a reduced royalty rate for a specified number of years, as determined based on the specific terms and conditions of the applicable customer agreement, the date on which the customer’s commercial product was first sold, and other factors.

In recent years, we have successfully converted a number of our customer’s products utilizing this early generation technology to one of our advanced generation technologies. While we are actively seeking to convert our customers to one of our advanced generations of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, or will convert, will sell products utilizing our technology which will generate earned royalty revenue for us.

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 have agreed to meet certain research, development, commercialization, sublicensing, royalty, indemnification, insurance or 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

We may need to invest in human clinical trials involving our drug-coated balloon platform.

During fiscal 2016, we expect to commence a first in-human clinical study to evaluate the safety and efficacy of our SurVeil™ DCB as well as continue preclinical evaluation of other potential applications of our drug-coated balloon platform. Difficulties in connection with the clinical evaluation of our SurVeil™ DCB may prevent or delay us from obtaining the regulatory approvals required to continue the development of the product. Additionally, our ability to monetize successfully our SurVeil™ DCB and other applications of the platform may depend on the success of preclinical evaluations and any clinical trial that we may initiate. Ultimately, we may not be successful in finding the right strategic partner with which to enter into arrangements to commercialize the

SurVeil™ DCB which could impact our ability to realize an acceptable return, if any, on the investments we are making in this product and the platform.

The development of new products and enhancement of existing products requires significant research and development, clinical trials and regulatory approvals, all of which may be very expensive and time-consuming and may not result in commercially viable products.

The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products and enhanced products, our ability to maintain or expand our market position in the markets in which we participate may be materially adversely impacted. A delay in the development or approval of new products and technologies may also adversely impact the contribution of these technologies to our future growth.

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 during 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.

The Patient Protection and Affordable Care Act imposes significant new taxes on medical device makers who make up a significant portion of our customers. The legislation has resulted in a significant total cost increase to the medical device and diagnostic industries, 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.

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 and biotechnology products incorporating our technologies are subject to regulation by the FDA and other regulatory authorities. 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. 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 three to nine months. Supplemental or full pre-market approval reviews require a

significantly longer period, delaying commercialization. In addition, sales of medical devices 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. In addition, 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. Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of products incorporating our technologies or subject us to additional regulation. Failure or delay of our licensees in obtaining FDA and other necessary regulatory approval or clearance, or the loss of previously obtained approvals, could have a material adverse effect on our business, financial condition and results of operations.

We may face liability if we mishandle or improperly dispose of the hazardous materials used in some of our research, development and manufacturing processes.

Our research, development and manufacturing activities sometimes involve the controlled use of various hazardous materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. While we currently maintain insurance in amounts that we believe are appropriate, we could be held liable for any damages that might result from any such event. Any such liability could exceed our insurance and available resources and could have a material adverse effect on our business, financial condition and results of operations.

Additionally, certain of our activities are regulated by federal and state agencies in addition to the FDA. For example, activities in connection with disposal of certain chemical waste are subject to regulation by the U.S. Environmental Protection Agency. We could be held liable in the event of improper disposal of such materials, even if these acts were done by third parties. Some of our reagent chemicals must be registered with the agency, with basic information filed related to toxicity during the manufacturing process as well as the toxicity of the final product. Failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR SECURITIES

Our stock price has been volatile and may continue to be volatile.

The trading price of our common stock has been, and is likely to continue to be, highly volatile, in large part attributable to developments and circumstances related to factors identified in “Forward-Looking Statements” and “Risk Factors.” The market value of shares of our common stock may rise or fall sharply at any time because of this volatility, as a result of sales executed by significant holders of our stock, and also because of short positions taken by investors from time to time in our stock. In the fiscal year ended September 30, 2015, the sale price for our common stock ranged from $18.00 to $27.68 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. All of our segments operate out of this facility. 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. Effective with the acquisition of Creagh on November 20, 2015, we lease a facility in Ballinasloe, Ireland, that has approximately 30,000 square feet of space (including a 3,500 square foot validated clean room) which can be used by our Medical Device segment.

ITEM 3. LEGAL PROCEEDINGS.

See the discussion of “Litigation” in Note 12 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

ITEM 4. MINE SAFETY DISCLOSURES.

Not Applicable.

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, 2015	$27.68	$21.36
June 30, 2015	27.36	23.09
March 31, 2015	26.99	21.15
December 31, 2014	22.94	18.00
September 30, 2014	22.55	18.01
June 30, 2014	23.97	19.60
March 31, 2014	25.99	21.91
December 31, 2013	25.41	21.27

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 November 23, 2015, there were 149 holders of record of our common stock and approximately 3,757 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 declaration and payment by SurModics of future dividends, if any, on its common stock will be at the sole discretion of the Board of Directors and will depend on SurModics' continued earnings, financial condition, capital requirements and other factors that the Board of Directors deems relevant.

There were no purchases of common stock of the Company made during the three months ended September 30, 2015, 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.

On November 6, 2015, after the end of our fiscal year ended September 30, 2015, the Company's Board of Directors authorized it to repurchase up to an additional $20.0 million (fiscal 2016 authorization) of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase ("ASR") transactions, tender offers or by any combination of such methods. The share repurchase program does not have a fixed expiration date.

On November 5, 2014, after the end of our fiscal year ended September 30, 2014, the Company's Board of Directors authorized it to repurchase up to $30.0 million (fiscal 2015 authorization) of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase ASR transactions, tender offers or by any combination of such methods. The share repurchase program does not have a fixed expiration date.

As of December 4, 2015, the Company has an aggregate of $30 million available for future common stock repurchases under the fiscal 2015 authorization and the fiscal 2016 authorization.

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 US Benchmark Total Return (our broad equity market index) and the NASDAQ Medical Supplies Index (our published industry index). The comparisons assume $100 was invested on September 30, 2010 and assume reinvestment of dividends.

ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of September 30, 2015 and 2014 and for the fiscal years ended September 30, 2015, 2014 and 2013 is derived from our audited consolidated financial statements included elsewhere in this report. The data as of September 30, 2013, 2012 and 2011 and for the years ended September 30, 2012 and 2011 is derived from audited consolidated financial statements 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				
	2015	2014	2013	2012	2011
	(Dollars in thousands, except per share data)				
Statement of Operations Data (1):					
Total revenue	$61,898	$57,439	$56,132	$51,928	$52,756
Operating income from continuing operations	19,089	18,576	18,820	16,342	15,523
Income from continuing operations	11,947	12,207	14,579	10,129	10,925
(Loss) income from discontinued operations	—	(176)	588	102	(29,431)
Net income (loss)	11,947	12,031	15,167	10,231	(18,506)
Diluted income (loss) per share:					
Continuing operations	$0.90	$0.88	$0.99	$0.58	$0.63
Discontinued operations	(0.00)	(0.01)	0.04	0.01	(1.69)
Net income (loss)	0.90	0.87	1.03	0.59	(1.06)
Balance Sheet Data:					
Cash, short-term and long-term investments	$55,588	$63,374	$58,104	$58,090	$68,197
Total assets	98,710	104,889	101,923	104,319	158,026
Retained earnings	88,161	93,881	91,036	75,869	65,638
Total stockholders' equity	91,873	98,751	93,817	94,988	140,852
Statement of Cash Flows Data (1):					
Net cash provided by operating activities from continuing operations	$15,066	$18,537	$17,781	$17,626	$22,900

(1) All periods have been restated to adjust for the classification of our former Pharmaceuticals segment as discontinued operations.

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

The following discussion and analysis of our financial condition and results of operations 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 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 medical device and in vitro diagnostic technologies to the healthcare industry. In fiscal 2015, our business performance continued to be driven by growth from our two core businesses: Medical Device, including surface modification coating technologies, and In Vitro Diagnostics (IVD). Revenues in the Medical Device business are driven by hydrophilic coatings royalty revenue, product sales and contract coating services included in research and development revenue. Our In Vitro Diagnostics business is driven by product sales of diagnostic technology.

Since fiscal 2013, with our investment in our DCB platform, we have been focused on a strategy to transform our Medical Device business from being a provider of coating technologies to offering whole-product solutions to our medical device customers. This transformation will greatly increase our relevance in the industry, and is key to our future growth and profitability, given the ability to capture more revenue with whole-product solutions. Our transformation does not change our focus on our core medical device coatings and IVD businesses. Our aim is to provide customers earlier access to strongly differentiated products that address unmet clinical needs, and partner with them on successful commercialization.

A key step in our Medical Device transformation strategy is the acquisition of state-of-the-art device design, development and manufacturing capabilities to complement our leadership in coating technologies. In November 2015, we announced the acquisition of Creagh. This acquisition brings a state-of-the-art R&D and manufacturing facility offering robust extrusion, balloon-forming, top-assembly, packaging and regulatory capabilities focused on balloon catheters. We believe Creagh will be a strong complement to our capabilities to become a world-class medical device innovator, developer and manufacturer. With the acquisition of Creagh subsequent to fiscal year 2015, we now engage in contract research and development, as well as manufacturing of balloons catheters used for a variety of interventional cardiology applications.

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. For financial accounting and reporting purposes, we report our results for the two reportable 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, with end markets that include coronary, peripheral, and neurovascular, and urology, among others, and (2) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic immunoassay and molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings. 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.

We derive our revenue from three primary sources: (1) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies and in vitro diagnostic formats to customers; the vast majority (typically in excess of 90%) of revenue in the “royalties and license fees” category is in the form of royalties; (2) the sale of reagent chemicals to licensees and the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets; and (3) research and commercial 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 our 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; and the value of reagent chemicals and other products sold to our customers.

We have several U.S. and international issued patents and 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 the anticipated expiration dates of the patent applications range from 2015 to 2033. Among these, the third generation of our Photolink® hydrophilic technology is protected by a family of patents that expired in November 2015 (in the U.S.) and are expected to expire in October 2016 (in certain other countries). The royalty revenue associated with our third generation technology that has not yet converted, or that is not in the process of converting, to one of our advanced generation technologies was approximately 18% of our fiscal 2015 revenue. Of the revenue generated by the early generation technology, approximately 81% revenue from this earlier generation) will continue to generate royalty revenue at a reduced royalty rate beyond the expiration of these patents. The royalty obligation for these customer products extends beyond the expiration of these patents because the license also includes rights to our know-how or other proprietary rights. While we are actively seeking to convert our customers to one of our advanced generations of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, or will convert, will sell products utilizing our technology which will generate earned royalty revenue for us.

On November 1, 2011, we entered into a purchase agreement to sell substantially all of the assets of a former subsidiary SurModics Pharmaceuticals, Inc. (“SurModics Pharmaceuticals”) to Evonik. Under the terms of the purchase

agreement, the entire portfolio of products and services of SurModics Pharmaceuticals, including its cGMP development and manufacturing facility located in Birmingham, Alabama, were sold. The sale closed on November 17, 2011. We retained all accounts receivable and the majority of liabilities associated with the SurModics Pharmaceuticals business incurred prior to the closing. The total consideration received from the sale was $30.0 million in cash. We have reported the Pharmaceuticals segment as discontinued operations beginning in the first quarter of fiscal 2012. Accordingly, all results of operations, cash flows, assets and liabilities of SurModics Pharmaceuticals for all periods presented are classified as discontinued operations. All information in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Form 10-K includes only results from continuing operations (excluding SurModics Pharmaceuticals) for all periods presented, unless otherwise noted.

Overview of Research and Development Activities

We manage our customer-sponsored R&D programs 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 segment.

Our internal R&D activities are engaged in the exploration, discovery and application of technologies that solve meaningful problems in the diagnosis and treatment of disease. Our key R&D activities include efforts that support and expand our core offerings. These efforts include completing activities that support the development of our coating technologies that enhance drug-coated balloons. In addition, in fiscal 2014 we launched new in vitro diagnostic products including a non-corrosive, non-hazardous stop solution for TMB microwell substrates and a protein-free AP stabilizer. In the second quarter of fiscal 2013, we completed development activities and launched our next generation hydrophilic coating platform which is now commercially available under the tradename Serene™ (formerly referred to as Gen 5). We also launched in July 2013 a new in vitro diagnostic product, StabliZyme ® Protein-Free Stabilizer, which focuses on stabilizing biomolecule activity in assay tests. Additional planned activities include initiation of surface modification experiments that improve medical device performance and developing chemistries to support molecular diagnostic applications. In the fourth quarter of fiscal 2014, we froze the design of our SurVeil™ paclitaxel DCB for use in the superficial femoral and popliteal arteries. In fiscal 2015 we completed a GLP study and gained FDA approval to conduct a first in human early feasibility study, with plans to initiate a first-in-human study using the SurVeil™ DCB in the first half of fiscal 2016.

We prioritize our internal R&D programs in our segments 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 vary based on the program, and typically include 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 consist of labor, materials and overhead costs (for example, utilities, depreciation, and indirect labor) for both customer R&D and internal R&D programs. We manage our R&D organization in a flexible manner, balancing workloads/resources between customer R&D and internal R&D programs primarily based on the level of customer program activity. Therefore, costs incurred for customer R&D and internal R&D can shift as customer activity increases or decreases.

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 consolidated 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 in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K). Actual results may differ from these estimates under different assumptions or conditions and could materially impact our results of operations. Critical accounting policies are those policies that require the application of management's most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. 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. 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, we recognize each separable deliverable as it is earned. We license technology to third parties and collect royalties. Royalty revenue is generated when a customer sells products incorporating our 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.

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.

Product sales to third parties consist of direct and distributor sales and are recognized at time of shipment. Our sales terms provide no right of return outside of our standard warranty policy. Payment terms are generally set at 30-45 days.

Multiple deliverable revenue arrangements require us to:

(i) disclose whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated;

(ii) 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 account for revenue using a multiple attribution model in which consideration allocated to R&D 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 R&D activities, and when a license does not have stand-alone value, we apply a multiple attribution model in which consideration allocated to the license is recognized ratably, consideration allocated to R&D activities is recognized as performed and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive.

We enter into license and development arrangements that may consist of multiple deliverables which could include a license(s) to our technology, R&D activities, manufacturing services, and product sales based on the customer needs. For example, a customer may enter into an arrangement to obtain a license to our intellectual property which may also include R&D activities, and supply of products manufactured by us. For these services provided, we could receive upfront license fees upon signing of an agreement and granting the license, fees for R&D 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 our technology. Our license and development arrangements generally do not have refund provisions if the customer cancels or terminates the agreement. Typically all payments made are non-refundable.

We are 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. This may be a result of us infrequently selling each element separately or having a limited history with multiple element arrangements. When VSOE cannot be established, we attempt 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.

We determine 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 management, taking into consideration the marketing strategies for each business unit.

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 evaluate periodically 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 with finite lives. 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 fiscal 2015, 2014 and 2013, there were no impairment charges relating to our long-lived assets as there were no events or circumstances that occurred that affected the recoverability of such assets.

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.

Goodwill is evaluated for impairment based on an 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 (Step 0). 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.

The two-step impairment test requires us to compare the fair value of the reporting units to which goodwill was assigned to their respective carrying values (Step 1 of the impairment test). In calculating fair value, we would use 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 would 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 us to other publicly traded guideline companies or by analysis of actual transactions of similar businesses or assets sold. The income approach would be tailored to the circumstances of our business, and the market approach would be 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 would be 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.

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 In Vitro Diagnostics operations known as our In Vitro Diagnostics unit, which contains our BioFX branded products, and our device drug delivery and hydrophilic coatings operations known as our Medical Device unit. The $8.0 million of goodwill at September 30, 2015 and 2014 is related to the In Vitro Diagnostics reporting unit and represents the gross value from our acquisition of BioFX in 2007. Inherent in the determination of fair value of our reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations as well as our strategic plans with regard to our operations.

We performed our annual impairment test of goodwill (Step 0) as of August 31, 2015, and did not record any goodwill impairment charges during fiscal 2015 as there were no indicators of impairment associated with the In Vitro Diagnostics reporting unit. We also did not record any goodwill impairment charges related to the In Vitro Diagnostics reporting unit during fiscal 2014 or 2013.

Investments. Investments consist principally of U.S. government and government agency obligations, asset-backed securities, mortgage-backed securities and investment grade, interest-bearing corporate and municipal debt securities

with varying maturity dates and are classified as available-for-sale securities at September 30, 2014. During fiscal 2015, the Company liquidated its investment portfolio to support corporate initiatives, and as a result, the ending balance of available-for-sale investments as of September 30, 2015 was zero. Our investment policy excludes ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Our investment policy requires that no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. Available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the consolidated statements of income and reported in the consolidated statements of comprehensive income as well as a separate component of stockholders' equity in the consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other (loss) income. This adjustment results in a new cost basis for the investment. Our evaluation of the available-for-sale investments resulted in no loss recognition in fiscal 2015, 2014 or 2013. Investments for which management has the intent and ability to hold to maturity are classified as held-to-maturity and reported at amortized cost. When an other-than-temporary impairment in the fair value of any individual security classified as held-to-maturity occurs, we write down the security to fair value with a corresponding adjustment to other (loss) income. Our strategic investments are subject to other-than-temporary impairment

assessment which resulted in impairment losses of $1.5 million, $1.2 million and $0.2 million in fiscal 2015, 2014 and 2013, respectively. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in other (loss) income. Realized gains and losses from the sales of debt securities, which are included in other (loss) income, are determined using the specific identification method. See Notes 2 and 4 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K 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 income. We must assess the likelihood that our deferred tax assets will be recovered from future taxable income, and to the extent we believe that recovery is not likely, we must establish a valuation allowance against those deferred tax assets. Deferred tax liabilities generally represent items for which we have already taken a deduction in our tax return, but we have not yet recognized the items as expense in our results of operations. Significant judgment is required in evaluating our tax positions, and in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our deferred tax assets. We had total deferred tax assets in excess of total deferred tax liabilities of $7.3 million as of September 30, 2015 and $7.1 million as of September 30, 2014, including valuation allowances of $5.7 million as of September 30, 2015 and $4.8 million as of September 30, 2014. The valuation allowances related to impairment losses on strategic investments were recorded as we do not currently foresee future capital gains within the allowable carryforward and carryback periods to offset these capital losses. As such, no tax benefit has been recorded in the consolidated statements of income.

We applied the accounting guidance associated with uncertain tax positions which define standards for recognizing the benefits of tax return positions in the consolidated financial statements as “more-likely-than-not” to be sustained by the taxing authorities based solely on the technical merits of the position. If the recognition threshold is met, the tax benefit is measured and recognized as the largest amount of tax benefit that, in our judgment, is greater than 50% likely to be realized. The total gross amount of unrecognized tax benefits as of September 30, 2015, 2014 and 2013 was $1.2 million, $1.2 million and $1.3 million, respectively, excluding accrued interest and penalties. Of these unrecognized tax benefits, $0.9 million, $0.9 million and $1.0 million would affect our effective tax rate for fiscal 2015, 2014 and 2013, respectively. Interest and penalties recorded for uncertain tax positions are included in our income tax provision. As of September 30, 2015, 2014 and 2013, $0.6 million, $0.6 million and $0.7 million, respectively, of interest and penalties were accrued, excluding the tax benefits of deductible interest. The Internal Revenue Service (“IRS”) completed an examination of the Company’s U.S. income tax return for fiscal 2012 in fiscal 2014. U.S. income tax returns for years prior to fiscal 2012 are no longer subject to examination by federal tax authorities. For tax returns for state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2006.

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 9 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K for further information regarding changes in unrecognized tax benefits during fiscal 2015, 2014 and 2013.

Results of Operations

Years Ended September 30, 2015, 2014 and 2013

Revenue. Fiscal 2015 revenue was $61.9 million, a $4.5 million, or 8% increase from fiscal 2014 revenue of $57.4 million. Fiscal 2014 revenue increased $1.3 million, or 2%, from fiscal 2013. The table below provides a summary of each operating segment's annual revenue for the three-year period ended September 30, 2015.

(dollars in thousands)	For the Year Ended September 30, 2015	Increase/(Decrease)	Increase/(Decrease)

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The foregoing assumptions are reviewed quarterly and are subject to change based primarily on management's assessment of the probability of the events described occurring. Accordingly, changes to these assessments could materially affect the valuation.

NOTE 11 - RELATED PARTY TRANSACTIONS

The Company previously sublet its office space from an affiliate owned by its officers. Total rent expense for the period ended March 31, 2011 was $7,500. The related party also paid $750 in utilities for the period ended March 31, 2011.

NOTE 12 - SUBSEQUENT EVENTS

The Company has evaluated all events that occur after the balance sheet date through the date when the financial statements were issued to determine if they must be reported. The management of the Company determined that there were certain reportable subsequent events to be disclosed as follows:

Issuance of common stock

The Company issued 22,024,668 shares of common stock for the conversion of $68,750 of convertible notes at a share price of $0.0 0312 per share.

The Company converted 2,000,000 shares of Series B Convertible Stock for 2,000,000 shares of common stock.

On April 4, 2011 the Company entered into a joint marketing agreement with YesDTC Holdings, Inc. As part of the marketing agreement and in exchange for the cancellation of certain reimbursements due, the Company agreed to issue YesDTC Holdings, Inc. 21,536,585 shares of common stock.

On June 1, 2011 the Company issued promissory notes to Sonoma Winton, LLC totaling $6,000 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Sonoma Winton, LLC's payments of certain debts owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 1,463,414 shares of common stock at $0.0041.

On June 8, 2011 the Company issued promissory notes to Biotech Development Group, LLC and totaling $15,000 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Biotech Development's payment of certain debt owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 3,658,536 shares of common stock at $0.0041.

On June 8, 2011 the Company issued promissory notes to Emerging Growth Research, LLC totaling $845.00 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Emerging Growth Research's payment of certain debts owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 206,097 shares of common stock at $0.0041.

On June 20, 2011 the Company issued promissory notes to Sonoma Winton, LLC totaling $2,827.70 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Sonoma Winton, LLC's payments of certain debts owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 689,682 shares of common stock at $0.0041.

On July 21, 2011 the Company issued promissory notes to BIOTECH Development Group, LLC and totaling $2,538.00 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Biotech Development's payment of certain debts owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 619,024 shares of common stock at $0.0041.

On July 21, 2011 the Company issued promissory notes to BIOTECH Development Group, LLC and totaling $4,000.00 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Biotech Development's payment of certain debts owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 975,609 shares of common stock at $0.0041.

On July 27, 2011 the Company issued promissory notes to Sonoma Winton, LLC totaling $3,000 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. These notes were issued as a result of Sonoma Winton, LLC's payments of certain debts owed by the Company. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 731,707 shares of common stock at $0.0041.

On July 27, 2011 the Company issued promissory notes to Usa Pungmuang totaling $5,000 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 1,219,512 shares of common stock at $0.0041.

On August 1, 2011 the Company issued promissory notes to Biotech Development Group, LLC and totaling $73,500 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 17,926,829 shares of common stock at $0.0041.

On August 16, 2011 the Company issued promissory notes to Biotech Development Group, LLC and totaling $5,000 for the Company, a form which is convertible into shares of the Company's common stock at a fixed conversion price equal to the lesser of the fixed conversion price of $0.0041, or seventy five percent (75%) of the average of the closing bid price of the common stock as reported by Bloomberg LP for the principal market for the 5 trading days preceding the conversion date. As part of this transaction the Company also issued to the subscriber a warrant to purchase an additional 1,219,512 shares of common stock at $0.0041.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This section of the Quarterly Report on Form 10-Q includes a number of forward-looking statements that reflect our current views with respect to future events and financial performance. Forward-looking statements are often identified by words like believe, expect, estimate, anticipate, intend, project and similar expressions, or words which, by their nature, refer to future events. You should not place undue certainty on these forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our predictions.

Plan of Operation

The Company has taken the proven PERS system and upgraded it with a new state-of-the-art technology. We are introducing a 2-way voice speakerphone pendant that connects to a monitored call center. In an emergency, the current systems require the user to be near the base station in order to communicate with the monitoring center. This leaves the user confined to a one-room radius of the base station at all times. Our system enables the user to communicate directly through their wearable pendant, leaving them free to move anywhere in and around the home.

Our primary focus is in the sale of our medical devices. We intend to link, install and monitor the medical alarm systems to a pre-designated central station. Our home communicator connects to a telephone line and our medical pendent, when activated, sends an automated digital telephone signal to a monitoring facility. Within seconds, a highly trained monitoring professional follows a prescribed response protocol to quickly assess the situation and provide an appropriate response. This may include calling the police, fire, or ambulance to respond to the situation, or calling family, friends, or neighbors.

In addition, we have a retail division that allows individuals who prefer not to pay the monthly fee, to make a one-time purchase of the unit. The unit will connect them to a designated personal contact or simply to 911.

Results of Operations

For the nine months ended March 31, 2011, we had a gross profit in the amount of $271,661. Operating expenses for the nine months ended March 31, 2011 totaled $1,394,492, resulting in a net operating loss of $1,122,831.

Capital Resources and Liquidity

As of March 31, 2011, we had $0 in cash.

We believe we cannot satisfy our cash requirements for the next twelve months with our current cash and, unless we receive additional financing, we may be unable to proceed with our plan of operations. We do not anticipate the purchase or sale of any significant equipment. We also do not expect any significant additions to the number of our employees. The foregoing represents our best estimate of our cash needs based on current planning and business conditions. Additional funds are required, and unless we receive proceeds from financing, we may not be able to proceed with our business plan for the development and marketing of our core services. Should this occur, we will suspend or cease operations.

We anticipate incurring operating losses in the foreseeable future. Therefore, our auditors have raised substantial doubt about our ability to continue as a going concern.

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Recent Accounting Pronouncements

In June 2003, the SEC adopted final rules under Section 404 of the Sarbanes-Oxley Act of 2002, as amended by SEC Release No. 33-9072 on October 13, 2009. Commencing with its annual report for the fiscal year ended June 30, 2010, the Company was required to include a report of management on its internal control over financial reporting. The internal control report must include a statement:

- of management's responsibility for establishing and maintaining adequate internal control over its financial reporting;
- of management's assessment of the effectiveness of its internal control over financial reporting as of year end; and
- of the framework used by management to evaluate the effectiveness of the Company's internal control over financial reporting.

Furthermore, the Company is required to file the auditor's attestation report control over financial reporting on whether it believes that the Company has maintained, in all material respects, effective internal control over financial reporting.

In June 2009, the FASB approved the "FASB Accounting Standards Codification" (the "Codification") as the single source of authoritative nongovernmental U.S. GAAP to be launched on July 1, 2009. The Codification does not change current U.S. GAAP, but is intended to simplify user access to all authoritative U.S. GAAP by providing all the authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the Codification will be considered non-authoritative. The Codification is effective for interim and annual periods ending after September 15, 2009.

In August 2009, the FASB issued the FASB Accounting Standards Update No. 2009-04, "Accounting for Redeemable Equity Instruments - Amendment to Section 480-10-S99," which represents an update to section 480-10-S99, distinguishing liabilities from equity, per EITF Topic D-98, "Classification and Measurement of Redeemable Securities." The Company does not expect the adoption of this update to have a material impact on its consolidated financial position, results of operations or cash flows.

In August 2009, the FASB issued the FASB Accounting Standards Update No. 2009-05 "Fair Value Measurement and Disclosures Topic 820 – Measuring Liabilities at Fair Value," which provides amendments to subtopic 820-10, Fair Value Measurements and Disclosures – Overall, for the fair value measurement of liabilities. This update provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following techniques: 1. A valuation technique that uses: a. The quoted price of the identical liability when traded as an asset b. Quoted prices for similar liabilities or similar liabilities when traded as assets. 2. Another valuation technique that is consistent with the principles of topic 820; two examples would be an income approach, such as a present value technique, or a market approach, such as a technique that is based on the amount at the measurement date that the reporting entity would pay to transfer the identical liability or would receive to enter into the identical liability. The amendments in this update also clarify that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability. The amendments in this update also clarify that both a quoted price in an active market for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. The Company does not expect the adoption of this update to have a material impact on its consolidated financial position, results of operations or cash flows.

In September 2009, the FASB issued the FASB Accounting Standards Update No. 2009-08 “Earnings Per Share – Amendments to Section 260-10-S99”, which represents technical corrections to topic 260-10-S99, Earnings per share, based on EITF Topic D-53, “Computation of Earnings Per Share for a Period that includes a Redemption or an Induced Conversion of a Portion of a Class of Preferred Stock” and EITF Topic D-42, “The Effect of the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock.” The Company does not expect the adoption of this update to have a material impact on its consolidated financial position, results of operations or cash flows.

In September 2009, the FASB issued the FASB Accounting Standards Update No. 2009-09 "Accounting for Investments-Equity Method and Joint Ventures and Accounting for Equity-Based Payments to Non-Employees". This update represents a correction to Section 323-10-S99-4, "Accounting by an Investor for Stock-Based Compensation Granted to Employees of an Equity Method Investee." Additionally, it adds observer comment "Accounting Recognition for Certain Transactions Involving Equity Instruments Granted to Other Than Employees " to the Codification. The Company does not expect the adoption to have a material impact on its consolidated financial position, results of operations or cash flows.

In September 2009, the FASB issued the FASB Accounting Standards Update No. 2009-12 "Fair Value Measurements and Disclosures Topic 820 – Investment in Certain Entities That Calculate Net Assets Value Per Share (or Its Equivalent)," which provides amendments to Subtopic 820-10, " Fair Value Measurements and Disclosures-Overall, " for the fair value measurement of investments in certain entities that calculate net asset value per share (or its equivalent). The amendments in this update permit, as a practical expedient, a reporting entity to measure the fair value of an investment that is within the scope of the amendments in this update on the basis of the net asset value per share of the investment (or its equivalent) if the net asset value of the investment (or its equivalent) is calculated in a manner consistent with the measurement principles of Topic 946 as of the reporting entity's measurement date, including measurement of all or substantially all of the underlying investments of the investee in accordance with Topic 820. The amendments in this update also require disclosures by major category of investment about the attributes of investments within the scope of the amendments in this update, such as the nature of any restrictions on the investor's ability to redeem its investments on the measurement date, any unfunded commitments (for example, a contractual commitment by the investor to invest a specified amount of additional capital at a future date to fund investments that will be made by the investee), and the investment strategies of the investees. The major category of investment is required to be determined on the basis of the nature and risks of the investment in a manner consistent with the guidance for major security types in U.S. GAAP on investments in debt and equity securities in paragraph 320-10-50-1B. The disclosures are required for all investments within the scope of the amendments in this update regardless of whether the fair value of the investment is measured using the practical expedient. The Company does not expect the adoption to have a material impact on its consolidated financial position, results of operations or cash flows.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the accompanying financial statements.

Critical Accounting Policies and Estimates

Our financial statements and related public financial information are based on the application of U.S. GAAP. U.S. GAAP requires the use of estimates; assumptions, judgments and subjective interpretations of accounting principles that have an impact on the assets, liabilities, revenues and expense amounts reported. These estimates can also affect supplemental information contained in our external disclosures including information regarding contingencies, risk and financial condition. We believe our use of estimates and underlying accounting assumptions adhere to U.S. GAAP and are consistently and conservatively applied. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from these estimates under different assumptions or conditions. We continue to monitor significant estimates made during the preparation of our financial statements.

Use of Estimates: In preparing financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and revenues and expenses during the reported period. Actual results could differ from those estimates.

Revenue Recognition: Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed or determinable and collectability is assured.

Stock-Based Compensation:

The Company accounts for its stock-based compensation under the provisions of SFAS No.123(R), “Accounting for Stock Based Compensation.” Under SFAS No. 123(R), the Company is permitted to record expenses for stock options and other employee compensation plans based on their fair value at the date of grant. Any such compensation cost is charged to expense on a straight-line basis over the periods the options vest. If the options have cashless exercise provisions, the Company utilizes variable accounting.

Common stock, stock options and common stock warrants issued to other than employees or directors are recorded on the basis of their fair value, as required by SFAS No. 123(R), which is measured as of the date required by EITF Issue 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.” In accordance with EITF 96-18, the stock options or common stock warrants are valued using the Black-Scholes model on the basis of the market price of the underlying common stock on the valuation date, which for options and warrants related to contracts that have substantial disincentives to nonperformance is the date of the contract, and for all other contracts is the vesting date. Expense related to the options and warrants is recognized on a straight-line basis over the shorter of the period over which services are to be received or the vesting period. Where expense must be recognized prior to a valuation date, the expense is computed under the Black-Scholes model on the basis of the market price of the underlying common stock at the end of the period, and any subsequent changes in the market price of the underlying common stock up through the valuation date is reflected in the expense recorded in the subsequent period in which that change occurs.

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123(R), requiring prominent disclosure in annual and interim financial statements regarding a company's method for accounting for stock-based employee compensation and the effect of the method on reported results.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as “special purpose entities” (SPEs).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 4T. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. Howard Teicher, our Chief Executive Officer, and Ronnie Adams, our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of our fiscal quarter ended March 31, 2011 pursuant to Rule 13a-15(b) or Rule 15d-15(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, as appropriate to allow timely decisions regarding required disclosure. Based on his evaluation, Mr. Teicher concluded that our disclosure controls and procedures were not effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the

SEC’s rules.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

(b) Changes in internal control over financial reporting. In order to rectify our ineffective disclosure controls and procedures, we are developing a plan to ensure that all information will be recorded, processed, summarized and reported accurately, and as of the date of this report, we have taken the following steps to address the above-referenced material weaknesses in our internal control over financial reporting:

- We will continue to educate our management personnel to comply with the disclosure requirements of the Exchange Act and Regulation S-K; and

- We will increase management oversight of accounting and reporting functions in the future.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

On or about November 24, 2009, LogicMark filed a lawsuit in U.S. Federal Court for the Eastern District of Virginia against Medical Alarm Concepts Holdings Inc., Medical Alarm Concepts LLC, and Mr. Nevin Jenkins, an individual residing in Florida. The complaint essentially alleges that (a) the Company's Medipendant product infringes on several claims of a patent which LogicMark recently purchased from a bankrupt British company; (b) Mr. Jenkins, the inventor of the patents which the Company has acquired failed to include certain inventorship information in his patent application with the U.S. Patent and Trademark Office; and (c) the Company misrepresented in its advertising and marketing of the Medipendant product that the Company was the first company to market a monitored Personal Emergency Response System product. The Company has denied the claims asserted in the lawsuit and filed its own infringement claims against LogicMark. The Company will vigorously defend against the LogicMark claims and believes the lawsuit will be successfully resolved. The lawsuit has had no adverse impact on the Company's business operations as it continues to manufacture and market its product and is distributing the Medipendant to dealers and customers.

On April 16, 2010, the Company and LogicMark reached a settlement agreement resolving the litigation. As a result of the settlement, all outstanding causes of action between the parties have been dismissed, without acknowledgement of liability by either party, and the parties retain their rights in their respective intellectual property. The parties agreed to file a joint motion to dismiss with prejudice and both parties covenant not to bring any further suits against the parties for a period of twenty-four (24) months following the settlement. The terms of the settlement agreement are confidential.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On July 5, 2010, the Company issued 200,000 shares of its common stock at its fair market value of $0.01 per share or $2,000 in cash. The sale of the shares of common stock was made in reliance upon the exemption from securities registration afforded by Section 4(2) of the Securities Act of 1933, as amended.

During the quarter ended December 31, 2010, the Company issued 18,065,500 shares of its common stock at its fair market value of $0.01 per share or $180,655 in cash. The sale of the shares of common stock was made in reliance upon the exemption from securities registration afforded by Section 4(2) of the Securities Act of 1933, as amended.

During the quarter ended March 31, 2011, the Company issued 8,000,000 shares of its common stock at its fair market value of $0.005 per share or $40,000 in cash. The sale of the shares of common stock was made in reliance upon the exemption from securities registration afforded by Section 4(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits.

(a) Exhibits

31.1 Certifications pursuant to Section 302 of Sarbanes Oxley Act of 2002

31.2 Certifications pursuant to Section 302 of Sarbanes Oxley Act of 2002

32.1 Certifications pursuant to Section 906 of Sarbanes Oxley Act of 2002

32.2 Certifications pursuant to Section 906 of Sarbanes Oxley Act of 2002

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDICAL ALARM CONCEPTS HOLDING, INC.

Date: August 26, 2011

By: /s/ Howard Teicher
Howard Teicher
Chief Executive Officer

By: /s/ Ronnie Adams
Ronnie Adams
Chief Financial Officer