SURMODICS INC
Form 10-K
December 05, 2014
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2014

Commission file number 0-23837

SURMODICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(Registrant s Telephone Number, Including Area Code)

(952) 500-7000

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

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

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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 þ No ¨

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

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

Large accelerated filer ¨ Accelerated filer þ
Non-accelerated filer ¨ Smaller reporting company ¨
(Do not check if a smaller reporting company)
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No þ

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2014 was approximately $235 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, 2014 was 12,857,743.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for the Registrant s 2015 Annual Meeting of Shareholders are incorporated by reference into Part III.

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Forward-Looking Statements

Certain statements contained in this Form 10-K, or in other reports of the Company and other written and oral statements made from time to time by the Company, do not relate strictly to historical or current facts. As such, they are considered forward-looking statements that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as anticipate, believe, could, estimate, expect, forecast, intend, may, plan, possible, project, will and similar words or expressions. Any statement that is not a including estimates, projections, future trends and the outcome of events that have not yet occurred, is a forward-looking statement. The Company s forward-looking statements generally relate to its growth strategy, financial prospects, product development programs, sales efforts, and the impact of significant customer agreements, including its agreement with Medtronic, Inc. (Medtronic). 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 United States Securities and Exchange Commission (SEC). Factors that could cause our actual results to differ from those discussed in the forward-looking statements include, but are not limited to, those described in Item 1A Risk Factors below.

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PART I

ITEM 1. *BUSINESS.*

Overview 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 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. Our In Vitro Diagnostics business unit provides 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.

On November 17, 2011, we sold substantially all of the assets of our subsidiary, SurModics SMP, LLC (formerly, SurModics Pharmaceuticals, Inc., or SurModics Pharmaceuticals) to Evonik Degussa Corporation (Evonik). We have reported the Pharmaceuticals segment as discontinued operations beginning in the first quarter of fiscal 2012. All information in this Form 10-K includes only results from continuing operations (excluding SurModics Pharmaceuticals) for all periods presented, unless otherwise noted. For more information regarding the sale of SurModics Pharmaceuticals, see Note 3 to the consolidated financial statements in Item 8. Financial Statements and Supplementary Data in this Annual Report on Form 10-K.

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® surface modification technology enhances the maneuverability of minimally invasive devices (e.g., dilatation catheters and guidewires) within the body by improving the lubricity of the device surface.

Additionally, our surface modification technologies can create new functions for the surfaces of the devices. For example, our patented drug delivery technologies can create new device capabilities by enabling site-

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specific, extended release drug delivery in cases where devices (e.g., stents or balloon catheters) are themselves necessary to treat a medical condition and in cases where devices serve only as a vehicle to deliver a drug (e.g., ophthalmology).

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.

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. 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 for hydrophilic, lubricious coatings, 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. In addition, the ability to create sustained release formulations of drugs and biologics presents another opportunity for us.

Overview of SurModics Surface Modification and Device Drug Delivery Technologies

We believe SurModics is positioned to exploit the continuing trend of incorporating surface modification and device drug delivery technologies into the design of products such as devices and drugs, potentially leading

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to more efficient and effective products as well as creating entirely new product applications. We have a growing portfolio of proprietary technologies, market expertise and insight, and unique collaborative research and development capabilities; all key ingredients to bring innovation together for the benefit of patients, 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. 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

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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.

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 the 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.

In the fourth quarter of fiscal 2014, we froze the design of our SurVeil paclitaxel drug coated balloon product designed to treat peripheral arterial disease. *SurVeil* is a development stage drug coated balloon product and is currently not approved for sale in any country. We plan to initiate a preclinical study under good laboratory practice (GLP) and a first-in-human study using the *SurVeil* drug coated balloon product in fiscal 2015.

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 days, weeks or months. For instance, when a drug-eluting stent is implanted into a patient, the drug releases from the surface of the stent into the blood vessel wall where it can act to inhibit unwanted tissue growth, thereby reducing the occurrence of re-closure of the vessel 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).

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

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Market Segment	Desired Surface Property and Examples of 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 value 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.

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We generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 52.7%, 53.0% and 52.9% of our total revenue in fiscal 2014, 2013 and 2012, respectively. Greater than 96% 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. However, we complete a technology transfer to most customers who perform the coating work internally once a product has received regulatory approval and is being actively marketed.

The term of a license agreement is generally for a specified number of years or the life of our patents, whichever is longer, although a license generally may be terminated by the licensee for any reason upon 90 days advance written notice. 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, 2014, we had over 100 licensed product classes (customer products utilizing SurModics technology) already on the market generating royalties and greater than 100 customer product classes incorporating our technology in various stages of pre-commercialization. We signed 16, 17 and 17 new licenses in fiscal 2014, 2013 and 2012, respectively. Our *Serene* platform was licensed to multiple companies during fiscal 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)

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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 uncertain.

Under most of our licensing agreements, we are required to keep the identity of our customers confidential unless they approve of such disclosure. Some of our licensed customers who allow the use of their name are: Abbott Laboratories (Abbott), Boston Scientific Corporation (Boston Scientific), Cook Medical, Cordis Corporation (a subsidiary of Johnson & Johnson) (Cordis), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), Elixir Medical Corporation, ev3 Inc. (a subsidiary of Covidien PLC), Medtronic, OrbusNeich Medical, Inc., Spectranetics Corporation and St. Jude Medical, Inc.

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 also 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 source these critical biochemical and reagent components from companies that produce high-performing, consistent and stable products to meet the clinical specifications of the assay. We develop, manufacture and sell 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.

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Overview of IVD 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. Since our acquisition of BioFX Laboratories, Inc. (BioFX) in August 2007, we have provided colorimetric and chemiluminescent substrates to the *in vitro* diagnostics market. A substrate is the component of a diagnostic test kit that detects and signals that a reaction has taken place so that a result can be recorded. Colorimetric substrates signal a positive diagnostic result through a color change. Chemiluminescent substrates signal a positive diagnostic result by emitting light. We believe that our substrates offer a high level of stability, sensitivity and consistency.

Recombinant Human Antigens. We are the exclusive North American distributor (and non-exclusive distributor in Japan) of DIARECT AG s line of recombinant autoimmune and infectious disease 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.

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

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development and preclinical efforts in the past three years developing a drug coated balloon product. In fiscal 2014, we froze the design of our *SurVeil* paclitaxel drug coated balloon product for use in the superficial femoral and popliteal arteries. We plan to initiate GLP and first-in-human studies using the *SurVeil* drug coated balloon product in fiscal 2015. There can be no assurance that we will be successful in developing or acquiring additional technologies or devices, or that any such technology will be commercialized.

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 July 2013, we launched StabilZyme® Protein-Free Stabilizer, the first high performance protein free stabilizer specially formulated to eliminate interference and cross-reactivity caused by protein. Our *StabilZyme* Protein-Free Stabilizer provides market leading performance with no cross-reactivity, allowing developers of IVD tests the confidence needed to maximize performance even in the most sensitive immunoassays. In June of 2014, we launched BioFX® Liquid NovaStop solution. This accessory reagent for 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 Stabilizer. 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 2014, 2013 and 2012, our R&D expenses were $15.6 million, $15.1 million and $14.1 million, respectively. We intend to continue investing in R&D to advance our surface modification, device drug delivery and *in vitro* diagnostic technologies and to expand uses for our technology platforms. We anticipate an increase of approximately 5% to 7% in R&D expenses in fiscal 2015 primarily related to our drug coated balloon 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 2014, SurModics filed 19 original U.S. patent applications, as well as nine 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, 2014, SurModics had 91 pending U.S. patent applications, two of which were exclusively licensed from others, and 134 foreign patent applications, of which one was exclusively licensed from others. Likewise, as of the same date, SurModics owned 152 issued U.S. patents, 18 of which were exclusively licensed from others, and 257 international patents, of which 23 were exclusively licensed from others.

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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 expire in November 2015 (in the U.S.) and October 2016 (in certain other countries). The royalty revenue associated with this early generation technology which has not yet converted, or that is not in the process of converting, to one of our advanced generation technologies was approximately 19% of our fiscal 2014 revenue. 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, in which case, the royalty rate is also reduced. 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. While we are actively seeking to convert our customers to one of our advanced generations of our hydrophilic coating technology, such as *Serene*, and have been successful in several situations in fiscal 2014 and 2013, there can be no assurance that we will be highly 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.

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 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 also 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.

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We also offer ongoing customer service and technical support to our customers and 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.

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.

Significant Customers

Revenue from Medtronic represented approximately 19% of our consolidated revenue for the year ended September 30, 2014 and was generated from multiple products and fields of use. On June 15, 2014, Medtronic and Covidien PLC (Covidien) announced that they had entered into an agreement under which Medtronic would acquire Covidien. This transaction is expected to close in early 2015. If the transaction is successfully consummated, our revenue from the combined Medtronic/Covidien entity, on a post-merger basis, would represent a higher concentration of our future consolidated revenue. No other customer provided more than 10% of our consolidated revenue in fiscal 2014. There are no customers, other than the combined Medtronic and Covidien entity 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. 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 tech-

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nologies 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.

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. Food and Drug Administration (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 2014, SurModics had multiple customers obtain regulatory clearance with our *Serene* coating platform.

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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.

Our *SurVeil* drug coated balloon product is a development stage product designed to treat peripheral arterial disease. *SurVeil* is currently not approved for sale in any country. Prior to gaining marketing approval for this product, we will be required to conduct human clinical trials which, if undertaken in the United States, would follow the PMA approval process.

Employees

As of December 1, 2014, we had 120 employees. 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. Such experienced personnel are in high demand, and we must compete for their services with other companies that may be able to offer more favorable compensation packages or benefits.

EXECUTIVE OFFICERS OF THE REGISTRANT

As of December 5, 2014, the names, ages and positions of the Company s executive officers are as follows:

Name	Age	Position
Gary R. Maharaj	51	President and Chief Executive Officer
Timothy J. Arens	47	Vice President of Corporate Development and Strategy
Andrew D. C. LaFrence	51	Vice President of Finance and Chief Financial Officer
Charles W. Olson	50	Senior Vice President and General Manager, Medical Device
Bryan K. Phillips	43	Senior Vice President, Legal and Human Resources, General Counsel and Secretary
Joseph J. Stich		