SURMODICS INC
Form 10-K
December 02, 2016

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, 2016

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

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

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

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

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

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

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

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

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, 2016 was approximately $182 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 November 25, 2016 was 13,207,541.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s Proxy Statement for the Registrant’s 2017 Annual Meeting of Shareholders are incorporated by reference into Part III.

Table of Contents

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, including our whole-product solutions strategy, financial prospects, product development programs including development of the SurVeil® drug-coated balloon (“SurVeil DCB”), 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 leadi provider of medical device and in vitro diagnostic technologies to the healthcare industry. In fiscal 2016, our business performance continued to be driven by growth in our core Medical Device and In Vitro Diagnostics ("IVD") businesses as well as the acquisitions of Creagh Medical Ltd. ("Creagh Medical") and NorMedix, Inc. ("NorMedix") in our Medical Device segment. Our mission is to improve the treatment and detection of disease by using our technology to provide solutions to difficult medical device and diagnostic challenges. Our business segments 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.

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 12 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 ("R&D,"), 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 Segment

Advances in medical device technology have helped drive improved device efficacy and patient outcomes. 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. We believe the benefits of combining drugs and biologics with implantable and minimally invasive devices are becoming increasingly valuable in applications in cardiology, peripheral artery disease, ophthalmology, orthopedics and other large markets.

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 for hydrophilic (i.e., lubricious or slippery) coatings and other coating technologies.

Our Medical Device segment provides surface modification coating technologies that impart lubricity, prohealing or biocompatibility characteristics, or drug delivery capabilities, as well as vascular device, catheter and balloon design, development and manufacturing capabilities. Historically, we have provided surface modification technologies to enhance our customers' medical devices and delivery systems. Since fiscal 2013, with our investment in our drug-coated balloon ("DCB") platform, we have been focused on a strategy to develop and manufacture proprietary medical device products that combine our surface modification coatings with medical devices or delivery systems ("whole-product solutions"). Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs, and partner with them on successful commercialization. During fiscal 2016, we made significant progress on our whole-product solutions strategy with the acquisitions of Creagh Medical and NorMedix, and initiated a first in-human early feasibility study of the Surmodics SurVeil DCB. This strategy does not change our focus

on our core surface modification technologies but we believe it will greatly increase our relevance in the industry, and is key to our future growth and profitability, given the prospect of capturing more revenue with whole-product solutions.

Overview of Interventional Peripheral Market and Surmodics' Technologies

Peripheral artery disease ("PAD") is a condition that causes a narrowing of the blood vessels supplying the extremities, most often due to plaque buildup in the arterial walls. Left untreated, PAD may lead to symptoms such as large non-healing ulcers, infections, or gangrene, and may require limb amputation or, in extreme cases, result in death.

The American Heart Association has reported that an estimated 8.5 million Americans and 202 million people worldwide are living with PAD. The number of people affected by PAD is expected to increase as a result of an aging population, coupled with increasing prevalence of conditions linked to PAD, such as diabetes and obesity. Awareness of PAD in the general population as well as among physicians, in conjunction with emphasis on PAD education, has resulted in more diagnoses and earlier detection. PAD is often treated through recommended lifestyle changes, such as diet and exercise, and by prescribing prescription drugs. However, these responses, along with being difficult and costly to maintain, do not treat the underlying obstructions. As a result, procedural intervention is often necessary to prevent or correct symptoms as they become more severe. The interventional PAD market utilizes a variety of access and therapy catheters to treat PAD. These technologies are delivered through a number of access points into the vascular system including femoral (leg), radial (wrist or arm) and pedal (foot).

A key aspect of our strategy is the acquisition of state-of-the-art medical device design, development and manufacturing capabilities to complement our leadership in surface modification coating technologies for the purpose of developing whole-product solutions for the PAD and other vascular disease markets. The Creagh Medical 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. The NorMedix acquisition provides ultra-thin-walled, minimally invasive catheter technologies. With these acquisitions, we now engage in contract R&D, as well as manufacturing access and therapy catheters, integrating our catheter, balloon, and surface modification technologies to design and develop proprietary products. We plan to enter into agreements with third party medical device companies who will sell our products to end users. We expect our first product to receive regulatory approval in late fiscal 2017.

Surmodics is focused on the development of drug coated balloons to treat PAD. In the first quarter of fiscal 2016, we received Investigational Device Exemption ("IDE") approval from the U.S. Food and Drug Administration ("FDA") to move forward with our first in-human early feasibility study using the SurVeil DCB. That study was initiated in the third quarter of fiscal 2016. The SurVeil DCB is not approved for commercial sale and treats PAD in the leg above the knee. The development of the SurVeil DCB is a major step forward in our strategy to offer whole-product solutions for the medical device industry. This approval allowed us to take the steps required to start an early feasibility clinical trial. We continue to enroll patients in the study and expect results early in calendar 2017.

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 combination products, potentially leading to more efficient and effective products as well as new product applications. We have a growing portfolio of proprietary technologies, market expertise and insight, and unique collaborative research, development and manufacturing capabilities —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. 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 blood clot formation),

when bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices.

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, the process 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 excellent lubricity without compromising durability. The properties that make coatings more lubricious—absorbing and exuding water—also can make them more susceptible to mechanical degradation. In August 2015, the FDA issued a position paper that identifies a list of characteristics that should be considered when evaluating the durability of coatings on vascular and neurological devices. Prior to the FDA communication, we launched our Serene® hydrophilic coating platform which optimizes lubricity and durability while significantly reducing particulates generation. 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 (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 site-specific drug delivery while limiting systemic exposure; and (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

Clinical Benefits

- Device Drug Delivery. We provide drug delivery polymer technology to enable controlled, site-specific or systemic delivery of therapeutic agents. As an example, a DCB is used during angioplasty to deliver drug(s) to the vessel wall to inhibit unwanted tissue growth which could lead to re-closure of the artery, 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 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.

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 generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 46.5%, 51.3% and 52.7% of our total revenue in fiscal 2016, 2015 and 2014, 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. 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. 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-upon 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, and size of the potential market. 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.

We have 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 18, 22 and 16 new licenses in fiscal 2016, 2015 and 2014, respectively.

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’ R&D 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), ev3 Inc. (a subsidiary of Medtronic), Medtronic, OrbusNeich Medical, Inc., Spectranetics Corporation and St. Jude Medical, Inc.

In Vitro Diagnostics Segment

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-quality 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, or improve a current, diagnostic test. During product development, these companies will look to source the critical components of the test with reagents it produces internally or with reagents from a supplier, such as Surmodics.

As IVD tests are developed and various reagents are tested, companies 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 a company initiates the development of a 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, the test can be sold in the marketplace. It may take several years for the 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.

Antigens. We are the exclusive distributor in the United States, Canada and Puerto Rico (and non-exclusive distributor in Japan) of DIARECT AG's line of antigens. Because of the lack of high-quality antigens from natural sources, DIARECT produces the majority of these antigens 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 R&D personnel work to enhance and expand our technology and product offerings in the area of drug delivery, surface modification, whole-product solutions, 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 business development 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, integrating our technologies and know-how into customer manufacturing operations and developing whole-product solutions that meet customers' needs by integrating our coating, medical device and medical device delivery technologies.

In fiscal 2016, 2015 and 2014, our R&D expenses were $18.5 million, $16.2 million and $15.6 million, respectively. We intend to continue investing in R&D to advance our surface modification coatings, 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 2017 primarily related to whole-product solutions 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.

Medical Device Segment

As treatment technologies become more sophisticated and increasingly leverage minimally invasive techniques, we believe the need for improved medical devices that benefit from surface modification and device drug delivery will continue to grow. We intend to continue our development efforts to expand our capabilities in surface modification, device drug delivery and whole-product solutions to better meet these needs across multiple medical markets and to capture more of the final product value. We are doing this by developing or acquiring technologies and funding development activities which may include pre-clinical and human clinical studies.

With the acquisitions of Creagh Medical and NorMedix, we have strengthened our capabilities and broadened our capacity for R&D activities. Our state-of-the-art facility in Ballinasloe, Ireland 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. In the first quarter of fiscal 2017, we completed an expansion of R&D and manufacturing clean rooms as well as an analytical lab to support our whole-product solutions strategy. With the acquisition of NorMedix, we obtained a differentiated catheter-technology platform and additional design and development expertise that will enhance the value we offer our medical device customers. We plan to continue to develop surface modification coating and DCB chemistry technologies in our facilities in Eden Prairie, Minnesota. Proprietary whole-product solutions will integrate our surface modification coatings, catheter and balloon technologies and will be developed with a combined team from our U.S. and Irish facilities. Other than DCB, we plan to develop 12-15 whole-product solutions products over the

next 5 years. Additional planned activities include initiation of surface modification experiments that improve medical device performance.

In fiscal 2016, we launched a single-coat formulation of our Serene hydrophilic coating. Specifically formulated for individual medical device applications, Serene Single-Coat solutions allow customers to leverage their legacy coating process to apply this surface treatment.

In fiscal 2014, we froze the design of our SurVeil DCB. We received FDA approval to commence an early feasibility study of this product in the first quarter of fiscal 2016 and are continuing enrollment in a first-in-human clinical study using the SurVeil DCB. Additional clinical trials and subsequent regulatory approvals will need to be obtained prior to commercialization of this product.

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.

In Vitro Diagnostics Segment

Our R&D 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 fiscal 2016 we launched StabilBlock® Immunoassay Stabilizer, our most advanced stabilizer product.

Clinical Trials

In fiscal 2016, we initiated a first in-human early feasibility study of the SurVeil DCB. In connection with our whole-product solutions strategy, we plan to continue to sponsor and support clinical investigations to evaluate patient safety and clinical efficacy in support of regulatory approval or clearance for new product initiatives. We will generate the clinical data necessary to receive regulatory approval or clearance for our existing and emerging products. Clinical trials provide information about the performance and safety of a device in a controlled setting.

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. 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 2016, Surmodics filed 16 original U.S. patent applications, as well as 21 international patent applications. As of September 30, 2016, Surmodics owned or had exclusive rights to 54 pending U.S. patent applications and 106 foreign patent applications. Likewise, as of the same date, Surmodics owned or had exclusive rights to 148 issued U.S. patents, and 187 international patents.

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 24 issued U.S. patents, 14 pending U.S. patent applications, 29 issued international patents, and 36 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 2016 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, the third generation of our PhotoLink technology is protected by a family of patents that expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). In addition, the fourth generation of our PhotoLink technology is protected by a family of patents that is expected to expire in early 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 our third generation technology which has not yet converted, or is not in the process of converting, to one of our advanced generation technologies was approximately 17% of our fiscal 2016 revenue.

Approximately 24% of our total revenue in fiscal 2016 was generated from the fourth generation of our PhotoLink technology, which are protected by a family of patents that will begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration.

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, 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 team of dedicated business development professionals who focus on specific markets and target 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 12 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.

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 customers. 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 customer, 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 recent acquisitions of Creagh Medical and NorMedix have 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 highly differentiated products that address important unmet clinical needs, and partner with them on successful commercialization of these products.

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 or enhance 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 25% of our total revenue for the year ended September 30, 2016 and was generated from multiple products and fields of use. The percentage of revenue from Medtronic decreased in fiscal 2016 as our customer base was diversified with the acquisitions of Creagh Medical and NorMedix. No other customer provided more than 6% of our consolidated revenue in fiscal 2016.

Competition

Medical Device Segment

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. Following our recent acquisitions of Creagh Medical and NorMedix, we plan to market our whole-product solutions to medical device companies that will leverage their existing sales force. Our core balloon and 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 balloons and catheters. We seek to provide differentiated whole-product solutions that integrate our surface modification, catheter, balloon and other proprietary technologies.

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. As we typically seek to license our surface modification coating technologies on a non-exclusive basis, we benefit 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 surface modification 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 our whole-product solutions and licensees with medical devices that utilize our surface modification coatings, such as regulatory approval, marketing and sales efforts of our customers and 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 and whole-product solutions customers or that they will otherwise be able to compete effectively. Many of our existing and potential competitors have greater financial, technical and marketing resources than we have.

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, peripheral 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.

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 products 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.

In Vitro Diagnostics Segment

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. Some 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 gain market share, 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 contract 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. Our state-of-the-art facility in Ballinasloe, Ireland is fully equipped for value-driven design and manufacture of high-quality balloon catheters and offers a suite of capabilities, including balloon forming, extrusion, coating and top assembly. In the first quarter of fiscal 2017, we completed an expansion of R&D and manufacturing clean rooms as well as analytical labs to support our whole-product solutions strategy. 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 is certified to ISO 13485 and ISO 9001. Our facility in Ballinasloe, Ireland is certified to ISO 13485. Each of these facilities is registered with the U.S. FDA as a "Contract Manufacturer."

Government Regulation

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 surface modification coating 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). With respect to our customers' products that incorporate our technologies, the burden of securing regulatory approval typically rests with our customers as the medical device manufacturers. During fiscal 2016 and 2015, Surmodics had multiple customers obtain regulatory clearance on medical devices incorporating our Serene coating platform. With respect to our whole-product solutions, including the SurVeil DCB, the burden of securing regulatory approval will rest on us unless we partner with other organizations to pursue such approval.

In support of our customers' regulatory filings, we maintain various confidential Device Master Files with the FDA and provide technical information to other regulatory agencies outside the U.S. regarding the nature, chemical structure and biocompatibility of our reagents. Our licensees generally do not have direct access to these files. However, 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 November, 2016, we had 219 employees. Of these employees we employ 72 outside the U.S., primarily in R&D 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 2, 2016, the names, ages and positions of the Company's executive officers are as follows:

Name	Age	Position
Gary R. Maharaj	53	President and Chief Executive Officer
Timothy J. Arens	49	Vice President of Corporate Development and Strategy
Thomas A. Greaney	50	Executive Vice President of Medical Devices
Andrew D. C. LaFrence	53	Vice President of Finance and Information Systems and Chief Financial Officer
Charles W. Olson	52	Senior Vice President of Commercial and Business Development, Medical Devices
Bryan K. Phillips	45	Senior Vice President, Legal and Human Resources, General Counsel and Secretary
Joseph J. Stich	51	Vice President and General Manager, In Vitro Diagnostics
Gregg S. Sutton	57	Vice President of Research and Development

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 Creagh Medical, after we acquired it. In August 2016 Mr. Greaney was promoted to Executive Vice President of Medical Devices. 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 Medical, 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 and was also named Vice President of Information Systems in August 2016. Prior to joining Surmodics, he served as Chief Financial Officer for CNS Therapeutics, which developed and marketed pharmaceuticals for site-specific drug delivery to the central nervous system, 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 October 2010, he was named Senior Vice President and General Manager, Medical Device, and in August 2016 he was named Senior

Vice President of Commercial and Business Development, Medical Devices. 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.

Gregg S. Sutton joined the Company in January 2016 as Vice President of Research and Development. Prior to joining Surmodics, he served as President and CEO of NorMedix, Inc., which we acquired in fiscal 2016, since June 2009. Mr. Sutton is a veteran medical device designer and developer with over 25 years of engineering experience in the medical device industry. He co-founded and held executive positions at several highly successful, early-stage development device companies, including Atritech, Angioguard, Vascular Solutions, and Navarre Biomedical, leading teams in development and launch of high-profile, first-of-their-kind devices. With a degree in mechanical engineering and over 50 patents granted, he has substantial experience in all aspects of medical device development, including intellectual property, design, product development, and manufacturing.

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 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.

A significant portion of our revenue is derived from a relatively small number of customers. We have one customer that provided more than 10% of our revenue in fiscal 2016. Revenue from Medtronic represented approximately 25% of our total revenue for the fiscal year ended September 30, 2016 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.

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, device drug delivery and medical device products 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. With respect to commercialization of our whole-product solutions, we expect to face competitive pricing pressures from larger OEM suppliers, as well as some of our largest medical device partners that have in-house resources that produce similar products. 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.

We may not be successful in implementing our whole-products solutions strategy and related important strategic initiatives

Since fiscal 2013, with our investment in our DCB platform, we have been focused on a key growth strategy for our medical device business by expanding to offer whole-product solutions to our medical device customers. Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs, and partner with them on successful commercialization. Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on our resources and management's time.

Successfully implementing our whole-products solutions strategy and related strategic initiatives will require, among other things:

- continued enhancement of our medical device R&D capabilities, including those needed to support the clinical evaluation and regulatory approval for our whole-product solutions;
- effective coordination and integration of our research facilities and teams, particularly those located in different facilities;
- successful hiring and training of personnel;
- effective management of a business geographically distributed both in the United States and Ireland;
- development of customer relationships with third party medical device distributors that will sell our products to end users;
- sufficient liquidity; and
- increased marketing and sales-support activities.

There is no assurance that we will be able to successfully implement our transformation strategy and related strategic initiatives in accordance with our expectations, which may result in an adverse impact on our business and financial results.

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, or we may be unable to execute acquisitions due to competition from buyers with more resources. If we do not make suitable investments and acquisitions, we may find it more difficult to realize our growth objectives.

The process of integrating acquired businesses into our operations, including those acquired during our fiscal 2016, 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 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 a significant amount of goodwill and intangible assets on our balance sheet in connection with our acquisitions. As of September 30, 2016, we had $26.6 million of goodwill and an indefinite-lived trademark intangible asset on our consolidated balance sheet related to our Medical Device and IVD segments, of which $18.5 million related to our fiscal 2016 acquisitions. 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 2017, we expect to continue the clinical evaluation of the SurVeil DCB which may result in significant costs 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 or products. There can be no assurance that we will be successful in developing new technologies or products, or that any such technology will be commercialized.

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.

As described below in “Part II, Item 7 Management’s Discussion and Analysis of Financial Condition and Results of Operations.”, the FASB issued new revenue recognition guidance for recognizing revenue from contracts with customers in May 2014. We are currently evaluating the impact that the adoption of this standard will have on our business model and consolidated results of operations, cash flows and financial position. We currently believe the impact may be material due to the potential acceleration of minimum license fees and a one quarter acceleration of royalty revenue pursuant to our hydrophilic license agreements.

We have identified a material weakness in our internal control over financial reporting. If we do not maintain effective internal control over financial reporting, our operating results could require material modification and our financial reports may not be reliable.

As described below in “Part II, Item 9A. Controls and Procedures.”, a material weakness related to the design and operating effectiveness of our transactional and review controls related to recognition of royalty revenue existed as of September 30, 2015. This material weakness was not remediated as of September 30, 2016, given that the additional controls have not operated for an appropriate amount of time to determine their operational effectiveness. The Company conducted an evaluation under the supervision and with the participation of the Company’s management, including the Company’s Chief Executive Officer and Chief Financial Officer regarding the effectiveness of the design and operation of the Company’s disclosure controls and procedures pursuant to Rule 13a-15(b) of the Exchange Act. Based upon that evaluation and because of the material weakness noted above, the Chief Executive Officer and Chief Financial Officer concluded that the Company’s disclosure controls and procedures were not effective as of September 30, 2016.

Although we are committed to continuing to improve our internal control processes to ensure the adequacy of the internal controls over financial reporting, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that, in the future, additional material weaknesses or significant deficiencies will not exist or otherwise be discovered. If our efforts to address the material weakness identified are not successful, or if other deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, a restatement of our financial statements for one or more prior periods, a decline in our stock price and investor confidence or other material effects on our business, reputation, results of operations, financial condition or liquidity.

With our acquisition of Creagh Medical, we have expanded our business to include foreign operations which exposes us to certain risks related to fluctuations in currency exchange rates.

In a period where the U.S. dollar is strengthening or weakening as compared to the Euro, our revenue and expenses denominated in the Euro are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. In addition, we have Euro-denominated contingent consideration liabilities that are subject to exchange rate fluctuations, which are scheduled to be paid in the first quarter of our fiscal 2019. We do not believe the effects of exchange rate fluctuations will be material to our fiscal 2017 operating results, but as our foreign operations expand, the effects may become material.

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, 2016, 2015 and 2014, we have derived 47%, 51%, and 53%, respectively, from royalties and license fees. Although we do market certain diagnostic products and reagents, we do not currently market, distribute or sell our own medical devices or diagnostic immunoassay or molecular tests to end users, 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, or failure of third parties to sell whole-products solutions to third parties 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.

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 many of our IVD products outside of the United States 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 distributor in the United States, Canada and Puerto Rico for DIARECT AG for its recombinant and 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.

Inaccuracies in these reports has resulted in and could result in another overpayment or underpayment of royalties, which could have a material adverse effect on our business, financial condition and results of operations.

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

We manufacture all of 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 Medical we also manufacture balloon catheter products at our facility in Ballinasloe, Ireland. Similarly, as a result of our acquisition of NorMedix we now manufacture catheter-based medical devices in limited quantities in Plymouth, Minnesota. If 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. In most cases our customer license agreements provide indemnification against such claims arising from the sale of medical device products that utilize our coatings. However, there can be no guarantee that product liability claims will not be filed against us for such products, or for medical device products that we manufacture as part of our

whole-product solutions strategy, 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. 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 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 our patents 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 2016 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 October 2016 (in certain other countries). The royalty revenue associated with our third generation technology was approximately 17% of our fiscal 2016 revenue.

Approximately 24% of our total revenue in fiscal 2016 was generated from the fourth generation of our PhotoLink technology, which are protected by a family of patents that will begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration.

In recent years, we have successfully converted a number of our customers' products utilizing these early generation technologies 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 DCB platform.

During fiscal 2016, we commenced a first in-human clinical early feasibility study and continued preclinical evaluation of other potential applications of our DCB platform. In fiscal 2017, we expect to continue the clinical evaluation of the SurVeil DCB. The results of the data from 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 payers 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 payers. Because a significant portion of our revenue is currently 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. Although significant components of these taxes have been suspended for calendar 2016 and 2017, their status is unclear for 2018 and subsequent years. 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.

Whole-product solutions medical devices and other products incorporating our technologies are subject to continuing regulations and extensive approval or clearance processes. If we or our licensees are unable to obtain or maintain the necessary regulatory approvals or clearances for such products, then to the products may not be commercialized 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 we or our licensees will be able to obtain regulatory approval for 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 licensees' 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 by us or 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, 2016, the sale price for our common stock ranged from $17.45 to $30.28 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 and Ballinasloe, Ireland, where we own a building that has approximately 30,000 square feet of space. We lease a warehouse near our Eden Prairie facility and a R&D-focused facility in Plymouth, Minnesota. We also own an undeveloped parcel of land adjacent to our principal facility, which we intend to use to accommodate our growth needs.

ITEM 3. LEGAL PROCEEDINGS.

See the discussion of “Litigation” in Note 11 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, 2016	$30.28	$22.58
June 30, 2016	24.23	18.45
March 31, 2016	21.45	17.45
December 31, 2015	24.98	19.64
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

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 25, 2016, there were 159 holders of record of our common stock.

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, 2016, 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, 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, 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. An aggregate of $20.0 million of the fiscal 2015 authorization was utilized in fiscal 2015, leaving $10.0 million available for future repurchases. The share repurchase program does not have a fixed expiration date.

As of December 2, 2016, 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, 2011 and assume reinvestment of dividends.

ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of September 30, 2016 and 2015 and for the fiscal years ended September 30, 2016, 2015 and 2014 is derived from our audited consolidated financial statements included elsewhere in this report. The data as of September 30, 2014, 2013 and 2012 and for the years ended September 30, 2013 and 2012 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				
	2016	2015	2014	2013	2012
	(Dollars in thousands, except per share data)				
Statement of Operations Data:					
Total revenue	$71,366	$61,898	$57,439	$56,132	$51,928
Operating income from continuing operations	16,859	19,089	18,576	18,820	16,342
Income from continuing operations	9,985	11,947	12,207	14,579	10,129
(Loss) income from discontinued operations	—	—	(176)	588	102
Net income	9,985	11,947	12,031	15,167	10,231
Diluted income (loss) per share:					
Continuing operations	$0.76	$0.90	$0.88	$0.99	$0.58
Discontinued operations	—	—	(0.01)	0.04	0.01
Net income	0.76	0.90	0.87	1.03	0.59
Balance Sheet Data:					
Cash, short-term and long-term investments	$46,941	$55,588	$63,374	$58,104	$58,090
Total assets	132,894	98,710	104,889	101,923	104,319
Retained earnings	98,146	88,161	93,881	91,036	75,869
Total stockholders' equity	106,833	91,873	98,751	93,817	94,988
Statement of Cash Flows Data:					
Net cash provided by operating activities from continuing operations	$25,166	$15,066	$18,537	$17,781	$17,626

Note: Fiscal 2016 figures include the effects of our acquisitions of Creagh Medical and NorMedix, as further discussed below.

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 2016, our business performance continued to be driven by growth from our core Medical Device and IVD businesses as well as the acquisitions of Creagh Medical and NorMedix in our Medical Device segment (collectively, “Fiscal 2016 Acquisitions”). Revenue in the Medical Device business consists of hydrophilic coatings royalty revenue and product sales as well as contract coating. Following the Fiscal 2016 Acquisitions, our Medical Device business now offers whole-product solutions including medical device product sales, as well as device design and development services. Our In Vitro Diagnostics business is driven by product sales of diagnostic technology.

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 manufacturing balloons and catheters used for a variety of interventional cardiology, peripheral and other applications, 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 as well as 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 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) product revenues from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; 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.

Greater than 96% of our royalty and license fee revenue in fiscal 2016, 2015 and 2014 is associated with the licensing of our hydrophilic coating technologies. We have an extensive portfolio of U.S. and international patents and 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 2016 to 2033. 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 October 2016 (in certain other countries). The royalty revenue associated with our third generation technology was approximately 17% of our fiscal 2016 revenue. Approximately 24% of our total revenue in fiscal 2016 was generated from fourth generation hydrophilic coating technologies, which are protected by a family of patents that begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. The remainder of our royalty revenues are derived from other Surmodics coatings that are protected by a number of patents that extend to at least fiscal 2032.

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 Degussa Corporation (“Evonik”). 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.

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 their reporting. 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, which consist of direct and distributor sales, 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 R&D is recorded as performance progresses under the applicable contract.

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 definite-lived intangible assets. 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 2016, 2015 and 2014, 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 whole-product solutions, device drug delivery and hydrophilic coatings operations known as our Medical Device unit. As of September 30, 2016 and 2015, $8.0 million of goodwill was related to the In Vitro Diagnostics reporting unit and represents the gross value from our acquisition of BioFX in 2007. As of September 30, 2016, $18.5 million of goodwill was related to the Medical Device unit and represented the gross value from our fiscal 2016 acquisitions of Creagh Medical ($14.1 million) and NorMedix ($4.4 million). 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 as of August 31, 2016. Due to the acquisitions discussed above, we elected to perform the two-step impairment test to determine if impairment exists and to provide for a baseline against which qualitative factors can be compared going forward. Based on the results of the Step 1 fair value assessment, we determined that each of the reporting units' fair values were greater than their carrying values and thus we did not record any goodwill impairment charges during fiscal 2016 and did not need to proceed to Step 2. We also did not record any goodwill impairment charges related to the In Vitro Diagnostics reporting unit during fiscal 2015 or 2014 based on our Step 0 analysis.

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 $5.0 million as of September 30, 2016 and $7.3 million as of September 30, 2015, including valuation allowances of $3.8 million as of September 30, 2016 and $5.7 million as of September 30, 2015. As of September 30, 2016 the valuation allowances related to two items: first, losses on strategic investments, including other-than-temporary losses that were unrealized for tax purposes, were recorded and we did not foresee future capital gain to offset the future capital loss associated with the reversal of the book versus tax basis difference. As such, no tax benefit was recorded in the consolidated statements of income for these items. Therefore, as of September 30, 2016, a valuation allowance has been recorded for other-than-temporary impairment losses as realized tax capital losses from sales of the underlying strategic assets have not occurred. Second, deferred tax assets related to net operating losses of Creagh Medical, including those incurred prior to the acquisition and in fiscal 2016, have been offset by a valuation allowance as it is not more likely than not that the tax assets will be realized in future periods, due to Creagh Medical’s history of taxable losses. Accordingly, the allocation of the purchase price of Creagh Medical to the acquired deferred tax assets related to the net operating loss carryforwards was also offset by a valuation allowance. As of September 30, 2015 the valuation allowances related to losses on strategic investments that were unrealized for tax purposes, for which we did not foresee future capital gain to offset the future capital loss associated with the reversal of the book versus tax basis difference.

During the fourth quarter of fiscal 2016, we monetized $7.5 million of realized capital losses by accelerating built-in gain in our IVD subsidiary. This resulted in an increase in our tax basis in IVD and a $2.6 million reduction in both deferred tax assets and the valuation allowance as of September 30, 2016.

We applied the accounting guidance associated with uncertain tax positions which defines 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, 2016, 2015 and 2014 was $1.5 million, $1.2 million and $1.2 million, respectively, excluding accrued interest and penalties. Of these unrecognized tax benefits, $1.2 million, $0.9 million and $0.9 million would affect our effective tax rate for fiscal 2016, 2015 and 2014, respectively. Interest and penalties recorded for uncertain tax positions are included in our income tax provision. As of September 30, 2016, 2015 and 2014, $0.6 million of interest and penalties were accrued at each fiscal year-end, 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 2013 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. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years

prior to 2011. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to the respective acquisition dates, pursuant to the terms of the related purchase agreements.

In the event that we have determined not to file tax returns with a particular state or local jurisdiction, all years remain subject to examination by the tax authorities. The ultimate outcome of tax matters may differ from our estimates and assumptions. Unfavorable settlement of any particular issue would require the use of cash and could result in increased income tax expense. Favorable resolution could result in reduced income tax expense. Within the next 12 months, we do not expect that our unrecognized tax benefits will change significantly. See Note 8 to the consolidated financial statements 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 2016, 2015 and 2014.

Valuation of business combinations. The fair value of consideration, including contingent consideration, transferred in acquisitions accounted for as business combinations is first allocated to the identifiable tangible and intangible assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. Any excess purchase consideration is allocated to goodwill. Further, for those arrangements that involve liability classified contingent consideration, we record on the date of acquisition a liability equal to the discounted fair value of the estimated additional consideration we may be obligated to make in the future. Liability classified contingent consideration is adjusted to its fair value each reporting period through earnings. Acquisition transaction costs are expensed as incurred.

The fair value of identifiable intangible assets requires management estimates and judgments based on market participant assumptions. Using alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows, discount rates, estimated useful lives, and probabilities surrounding the achievement of milestones could result in different fair value estimates of our net tangible and intangible assets and related amortization expense in current and future periods.

Contingent consideration liabilities are remeasured to fair value each reporting period using projected revenues, discount rates, probabilities of payment, and projected payment dates. Increases or decreases in the fair value of the contingent consideration liability can result from changes in the timing and amount of revenue estimates or in the timing or likelihood of achieving value-enhancing milestones, and changes in discount periods and rates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. See further discussion of contingent payments to Creagh Medical and NorMedix above under “Future Investments and Contingent Consideration Related to Acquisitions” in this Item 2 and in Note 3, “Business Combinations,” to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

Results of Operations

Years Ended September 30, 2016, 2015 and 2014

Revenue. Fiscal 2016 revenue was $71.4 million, a $9.5 million, or 15% increase from fiscal 2015 revenue of $61.9 million. Fiscal 2015 revenue increased $4.5 million, or 8%, from fiscal 2014. Fiscal 2016 revenue includes $4.1 million from acquisitions consummated in the first two quarters of fiscal 2016. The table below provides a summary of each operating segment’s annual revenue for the three-year period ended September 30, 2016.

	For the Year Ended September 30,			Increase/(Decrease)		Increase/(Decrease)	
(dollars in thousands)	2016	2015	2014	2016 vs. 2015		2015 vs. 2014	
Revenue							
Medical Device	$53,202	$45,944	$43,068	$ 7,258	16 %	$ 2,876	7 %
In Vitro Diagnostics	18,164	15,954	14,371	2,210	14 %	1,583	11 %
Total Revenue	$71,366	$61,898	$57,439	$ 9,468	15 %	$ 4,459	8 %

Medical Device. Revenue in Medical Device was $53.2 million in fiscal 2016, a 16% increase from $45.9 million in fiscal 2015. The increase in fiscal 2016 revenue was a result of growth in each of our revenue categories, driven primarily by increased demand for reagents as well as incremental product and research, development and other revenue from our Fiscal 2016 Acquisitions. Product revenue increased by $1.5 million from reagents sales and $2.4 million from our Fiscal 2016 Acquisitions. Royalty and licensing revenue improved by $1.4 million, of which $2.9 million was from a catch-up payment for previously unreported royalties owed to the Company by one customer for

the period from fiscal 2009 through fiscal 2016. This was offset by a revenue adjustment to correct a cumulative overstatement of royalty revenue related to a settlement agreement entered into with a customer pursuant to which we agreed to pay the customer $1.4 million to refund overpaid royalties, of which $1.0 million was out-of-period and related to years prior to fiscal 2016. The overstatement was not material to any prior periods. Further, we realized a $3.1 million increase in other hydrophilic royalties which was offset by $2.1 million decline in hydrophilic royalties as a result of the expiration of patents protecting the third generation of our PhotoLink hydrophilic technology. The increase in research, development and other revenue of $1.9 million was primarily due to incremental revenue from the Fiscal 2016 Acquisitions.

During fiscal 2016 and 2015, $12.1 million and $11.0 million, respectively, of Medical Device royalty revenue was generated from our third generation of our PhotoLink technology. As discussed above, the family of patents that protects this technology expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). While we believe we will retain a majority of this royalty revenue, there is a royalty rate step down for licensed customers at the time these patents expire. We are actively seeking to convert

customers using this generation of PhotoLink coatings to our Serene® coating technologies. We expect overall declines of $5.0 million to $6.0 million in hydrophilic coating royalties in fiscal 2017 as the result of these patent expirations.

Revenue in Medical Device was $45.9 million in fiscal 2015, a 7% increase from $43.1 million in 2014. The increase in fiscal 2015 revenue was generated by each of our revenue categories with increased royalty and licensing revenue of $1.5 million, of which $0.6 million was from a one-time catch up payment related to periods prior to fiscal 2015, as well as increased customer demand resulting in increased R&D revenue of $0.8 million and increased reagent product sales of $0.5 million.

In Vitro Diagnostics. In Vitro Diagnostics revenue was $18.2 million in fiscal 2016, a 14% increase from $16.0 million in fiscal 2015. The increase in 2016 revenue was the result of unit volume increases in substantially all product lines.

In Vitro Diagnostics revenue was $16.0 million in fiscal 2015, an 11% increase from $14.4 million in fiscal 2014. The increase in fiscal 2015 revenue was attributable to a $1.6 million increase in product sales. Fiscal 2015 benefited from a lower prior-year comparison as the In Vitro Diagnostic revenue declined as a result of customer inventory rebalancing activities in the second quarter fiscal 2014, which resulted in lower comparable sales. There were limited product price increases in fiscal 2016 and fiscal 2015.

The following is a summary of major costs and expenses as a percentage of total revenue:

	For the Year Ended September 30,								
	2016			2015			2014		
(dollars in thousands)	Amount	% Total Revenue		Amount	% Total Revenue		Amount	% Total Revenue	
Product costs	$10,908	15	%	$8,619	14	%	$8,016	14	%
Research and development	18,498	26	%	16,165	26	%	15,550	27	%
Selling, general and administrative	18,000	25	%	14,906	24	%	14,691	26	%
Acquisition transaction, integration and other costs	3,187	4	%	—	—		—	—	
Acquired intangible asset amortization	2,422	3	%	619	1	%	606	1	%
Contingent consideration accretion expense	1,492	2	%	—	—		—	—	
Claim settlement	—	—		2,500	4	%	—	—	

Product costs. Product costs were $10.9 million, $8.6 million, and $8.0 million in fiscal 2016, 2015 and 2014, respectively, or 15%, 14% and 14% of total revenue in each respective year. Product gross margins (defined as product sales less related product costs) were 65% of product sales in fiscal 2016, 2015 and 2014. The increase in product costs was largely the result of increased product sales, driven by our Fiscal 2016 Acquisitions. We expect product gross margins to decrease slightly in fiscal 2017 as we prepare for larger-scale manufacturing in our Irish facility. It may take one-to-two years to optimize the manufacturing and supply chain infrastructure at this facility as we execute our whole-product solutions strategy.

Research and development expenses. R&D expenses were $18.5 million, $16.2 million, and $15.6 million for fiscal 2016, 2015 and 2014, respectively, or 26%, 26% and 27% of total revenue in each respective fiscal year. The fiscal 2016 increase from fiscal 2015 of $2.3 million, or 14%, was primarily the result of $1.8 million from our Fiscal 2016 Acquisitions, and the remainder from our DCB development activities. The fiscal 2015 increase from fiscal 2014 of $0.6 million, or 4%, was primarily the result of increased spending for our DCB development activities. We anticipate

up to a 50% increase in R&D expenses in fiscal 2017 primarily related to development of proprietary products, including our DCB activities.

Selling, general and administrative expenses. Selling, general and administrative (“SG&A”) expenses were $18.0 million, $14.9 million and $14.7 million for fiscal 2016, 2015 and 2014, respectively, or 25%, 24% and 26% of total revenue in each respective fiscal year. The fiscal 2016 increase of $3.1 million or 21%, compared with fiscal 2015 was primarily the result of $1.4 million of higher stock-based compensation expense as the result of favorable trends in revenue, including the impact of the Fiscal 2016 Acquisitions, and earnings before income tax, depreciation and amortization (”EBITDA”), which is a non-GAAP measure used by management to determine incentive compensation, from the historical Medical Device and In Vitro Diagnostics businesses. Additionally, $1.7 million of additional SG&A expenses were attributable to fiscal 2016 acquisitions. The fiscal 2015 increase of $0.2 million or 1%, compared with fiscal 2014 was primarily related to increased compensation and legal fee expenses.

Acquisition transaction, integration and other costs. In fiscal 2016, we incurred $3.2 million in acquisition transaction, integration and other costs related to the Fiscal 2016 Acquisitions.

Acquisition related intangible asset amortization. As a result of our Fiscal 2016 Acquisitions, we acquired certain intangible assets which are being amortized over periods ranging from four to 14 years. In addition, for comparison purposes, we have reclassified amortization expense of $0.6 million, from fiscal 2015, to the acquisition-related intangible asset amortization expense line, which was originally reported in SG&A expense. The amortization that was reclassified was related to the fiscal 2007 BioFx acquisition. The increase in amortization expense of $1.8 million in fiscal 2016 is the result of the intangible assets acquired with the Fiscal 2016 Acquisitions.

Contingent consideration accretion expense. In fiscal 2016, we recorded $1.5 million of contingent consideration expense related to our contingent consideration liabilities from the Fiscal 2016 Acquisitions, due to the passage of time (i.e. accretion) as well as a revaluation adjustment of $0.1 million recorded in the third quarter of fiscal 2016. In future years, if there are changes in the amount, probability or timing of achievement of contingent consideration milestones, there may be material adjustments in the consolidated statements of income to reflect changes in the fair value of contingent consideration liabilities.

Other (loss) income. Major classifications of other (loss) income are as follows:

	Year Ended September 30,		
(dollars in thousands)	2016	2015	2014
Investment income, net	$63	$156	$238
Gains on sales of strategic investments, contingent consideration milestone payments and other	507	496	842
Foreign exchange loss	(481)	—	—
Impairment losses on strategic investments	—	(1,500)	(1,184)
Other income (loss)	$89	$(848)	$(104)

Other (loss) income was income of $0.1 million in fiscal 2016 compared with a loss of $0.8 million in fiscal 2015 and a loss of $0.1 million in fiscal 2014. Other (loss) income has fluctuated between the fiscal years as a result of gains from available-for-sale securities and strategic investments as well as other-than-temporary impairment losses from strategic investments. Fiscal 2016 included $0.5 million of foreign currency losses related to Euro-denominated contingent consideration liabilities arising from the Creagh Medical acquisition, offset by consideration received from the sale of our ownership interest in a strategic investment of $0.5 million. Fiscal 2015 included an other-than-temporary impairment loss of $1.5 million related to our investment in CeloNova, partially offset by a gain of $0.5 million associated with the sale of our investment in Intersect ENT. Fiscal 2014 included an other-than-temporary loss of $1.2 million associated with our investment in ThermopeutiX partially offset by $0.7 million of contingent consideration milestone payments received from the sale of our ownership interest in Vessix Vascular which occurred in fiscal 2013. Income from investments was $0.1 million, $0.2 million and $0.2 million for fiscal 2016, 2015 and 2014, respectively. The decrease in investment net income from year to year primarily reflects investment balances as a result of liquidating our longer term investments in fiscal 2015 which generated higher income and allowed us to move toward a liquid short-term portfolio to meet strategic objectives. In addition, we recognized and realized investment losses of less than $0.1 million in fiscal 2016 and investment gains of $0.1 million in both fiscal 2015 and 2014.

Income tax provision. The reconciliation of the statutory U.S. federal tax rate of 35% and our effective tax rate from continuing operations is as follows:

	Year Ended September 30,		
	2016	2015	2014
Statutory U.S. federal income tax rate	35.0 %	35.0%	35.0%
State income taxes, net of federal benefit	0.8	0.4	0.6
Subsidiary capital gain	15.5	—	—
Foreign rate differential	3.7	—	—
Valuation allowance change	(14.8)	1.9	(1.6)
Federal research and development tax credit	(3.4)	(0.4)	(0.4)
Stock based compensation - excess benefit	(3.6)	—	—
Manufacturing deduction	(1.6)	—	—
Transaction costs	4.5	—	—
Contingent consideration accretion	3.1	—	—
Other	1.9	(2.4)	0.3
Effective tax rate	41.1 %	34.5%	33.9%

The difference between the U.S. federal statutory tax rate of 35.0% and our effective tax rate reflects the impact of state income taxes, permanent tax items, non-deductible acquisition items, valuation allowance changes for capital gains and losses, capital gains recognized upon restructuring a subsidiary, differences between U.S. and foreign income tax rates, stock based compensation, and other tax items. The income tax provision was $7.0 million, $6.3 million and $6.3 million, respectively, for fiscal 2016, 2015 and 2014 resulting in effective tax rates of 41.1%, 34.5% and 33.9%, respectively. The variability in our effective tax rate is primarily the result of changes in deferred tax asset valuation allowances resulting from both other-than-temporary impairment losses and gains on the sales of certain strategic investments, as well as non-deductible transaction costs, contingent consideration accretion expense and foreign currency losses associated with the Fiscal 2016 Acquisitions. Further, deferred tax assets related to net operating losses of Creagh Medical, including those incurred prior to the acquisition and those incurred in fiscal 2016, have been offset by a valuation allowance as it is not more likely than not that the tax assets will be realized in future periods, due to Creagh Medical's history of taxable losses. We have historically recorded other-than-temporary impairment losses with no income tax effect as it has not been more likely than not that we would generate sufficient capital gains to realize these benefits. Consequently, other-than-temporary impairments and capital gains, which are both discussed in detail under the caption Other (loss) income, are recorded without any income tax expense or benefit. Additionally, new guidance related to accounting for excess tax benefits (ASU No. 2016-09, Compensation – Stock Compensation (ASC Topic 718): Improvements to Employee Share-Based Payment Accounting) has been adopted prospectively, effective October 1, 2015, resulting in recognition of a tax benefit from the excess tax benefits realized from share options vested or exercised of $0.6 million for the fiscal year ended September 30, 2016. Previously, excess tax benefits have been recorded within additional paid-in capital on the consolidated balance sheets. The adoption of this accounting standard could create volatility in the Company's effective tax rate in future periods.

We recorded $0.2 million of retroactive 2015 U.S. research and development tax credit discrete benefits for the period from January 1, 2015 to September 30, 2015 in fiscal 2016 resulting from the December 2015 signing of the Protecting Americans from Tax Hikes Act ("PATH Act") of 2015. This reduced our fiscal 2016 effective rate by 1.3% in fiscal 2016. The PATH Act made the research and development tax credit permanent. Accordingly, the tax benefits associated with the credit for the period from October 1, 2015 to September 30, 2016 have also been included as a benefit and have reduced the effective rate by 2.1% in fiscal 2016.

We recorded $0.2 million of retroactive 2014 U.S. research and development tax credit discrete benefits for the period from January 1, 2014 to September 30, 2014 in fiscal 2015 resulting from the December 2014 signing of the Tax Increase Protection Act of 2014. This reduced our fiscal 2015 effective rate by 1.0% in fiscal 2015. We also recorded a federal research and development credit in fiscal 2015 generated for the period from October 1, 2014 to December 31, 2014 prior to the expiration of the benefit on December 31, 2014.

Discontinued Operations. We recorded a loss from discontinued operations in fiscal 2014 of $0.2 million associated with the resolution of a litigation matter and less than $0.1 million related to our indemnification obligations to Evonik related to a contingent consideration matter associated with the PR Pharma intellectual property purchased by Evonik in the Pharma Sale. Our discontinued operations losses are recorded net of the income tax impact of these transactions. There was no discontinued operations activity in fiscal 2016 and no loss from discontinued operations in fiscal 2015.

Segment Operating Results

Operating income for each of our reportable segments was as follows:

(dollars in thousands)	For the Year Ended September 30, 2016	2015	2014	Increase/(Decrease) 2016 vs. 2015		Increase/(Decrease) 2015 vs. 2014	
Operating income (loss)							
Medical Device	$16,975	$21,192	$22,636	$ (4,217)	(20)%	$ (1,444)	(6)%
In Vitro Diagnostics	7,115	4,484	3,459	2,631	59 %	1,025	30 %
Total segment operating income	24,090	25,676	26,095	(1,586)	(6)%	(419)	(2)%
Corporate	(7,231)	(6,587)	(7,519)	(644)	10 %	932	(12)%
Total operating income from continuing operations	$16,859	$19,089	$18,576	$ (2,230)	(12)%	$ 513	3 %

Medical Device. Operating income was $17.0 million, $21.2 million and $22.6 million in fiscal 2016, 2015 and 2014, respectively. Operating income decreased by 20% in fiscal 2016 from fiscal 2015. The decrease was primarily the result of $10.0 million in higher

non-product operating expenses, partially offset by $2.2 million of incremental product gross margin stemming from a $7.3 million increase in revenue. Revenue for fiscal 2016 includes increased royalty and licensing revenue of $1.4 million. This increase included the previously discussed increase from a catch-up payment of $2.9 million which was partially offset by a $1.4 million revenue settlement to correct a cumulative overstatement of royalty revenue, of which $1.0 million was out-of-period and related to periods prior to fiscal 2016. Royalty revenue also reflected a decline of $2.1 million as the result of expiration patents protecting the third generation of our Photolink hydrophilic technology. The remaining increase in revenue in fiscal 2016 was generated by increased product sales of $3.9 million and research, development and other revenue of $1.9 million. Our Fiscal 2016 Acquisitions accounted for $4.1 million of the increases in these two revenue categories. Operating expenses, excluding product costs, increased as a result of transaction, integration, amortization, and contingent consideration accretion expenses totaling $6.5 million in fiscal 2016 associated with the Fiscal 2016 Acquisitions. Additionally, the Medical Device segment incurred $3.5 million in higher SG&A and R&D expenses as a result of our Fiscal 2016 Acquisitions.

Operating income decreased by 6% in fiscal 2015 from fiscal 2014. The decrease was primarily the result of $4.2 million in higher expenses, partially offset by a $2.9 million increase in revenue. The largest increases to expenses in fiscal 2015 compared to fiscal 2014 resulted from a $2.5 million claim settlement (for further information refer to Note 11 of the Consolidated Financial Statements), $0.6 million in higher compensation costs, $0.6 million in higher planned spending on R&D primarily related to drug-coated balloon activities and a $0.4 million higher cost of sales as a result of increased revenue. The increase in revenue in fiscal 2015 was generated by each of our revenue categories with increased royalty and licensing revenue of $1.5 million, of which $0.6 million was from a one-time catch up payment related to periods prior to fiscal 2015, as well as increased customer demand resulting in increases in R&D revenue of $0.8 million and reagent product sales of $0.5 million.

In Vitro Diagnostics. Operating income was $7.1 million, $4.5 million and $3.5 million in fiscal 2016, 2015 and 2014, respectively. Operating income increased by 59% in fiscal 2016 compared with fiscal 2015 resulting from higher revenue of $2.2 million, partially offset by a related product cost increase of $0.7 million, as well as lower SG&A costs. Fiscal 2016 operating income benefited from increased demand across all product categories. Product gross margins were steady at 64% in both fiscal 2016 and 2015. Direct SG&A expenses decreased by $0.7 million in fiscal 2016 compared with fiscal 2015 as a result of lower legal expenses from the settlement of a legal matter in the fourth quarter of fiscal 2015.

Operating income increased by 30% in fiscal 2015 compared with fiscal 2014 resulting from higher revenue of $1.6 million and a related product costs increase of $0.2 million. Fiscal 2015 operating margin was positively impacted by product mix which included higher stabilization and lower antigen sales. Fiscal 2015 benefited from a lower prior-year comparison as the In Vitro Diagnostic revenue declined as a result of customer inventory rebalancing activities in the second quarter of fiscal 2014 which resulted in lower comparable prior-year revenue. Product gross margins improved to 64% in fiscal 2015, which is up from 61% in fiscal 2014.The improvement in gross margins is primarily driven by favorable product mix shifts to stabilization sales and improved operating leverage. Direct operating expenses increased by $0.4 million in fiscal 2015 compared with fiscal 2014 principally from higher legal expenses associated with the above noted litigation matter that was settled in the fourth quarter of fiscal 2015.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive, corporate accounting, legal, human resources and Board of Directors related fees and expenses that have not been fully allocated to the Medical Device and In Vitro Diagnostics segments. Corporate also may include expenses, such as litigation, which if not specific to a segment are not allocated to our operating segments. The unallocated Corporate expense operating loss was $7.2 million, $6.6 million and $7.5 million in fiscal 2016, 2015 and 2014, respectively. The $0.6 million, or 10% increase in corporate expenses in fiscal 2016 compared to fiscal 2015 was due to a $0.9 million increase in stock-based compensation expense, offset by reductions in other corporate expenses. The $0.9 million, or 12%, decrease in corporate expense in fiscal 2015 compared to fiscal 2014 was primarily a result of higher comparable expenses in fiscal 2014 resulting from a $0.9 million expense associated with accelerated vesting of Board of Director stock awards and the granting of an equity award to the former Chairman of the Company’s Board in

recognition of his contributions to the Company during his years of service on the Board of Directors.

Liquidity and Capital Resources

As of September 30, 2016, we had working capital of $48.4 million, a decrease of $14.7 million from September 30, 2015. Working capital is defined by us as current assets minus current liabilities. The decrease from the prior-year end is a result of several factors including an increase in investing activities, partially offset by cash provided by operating activities. Our cash and cash equivalents and available-for-sale investments totaled $46.9 million as of September 30, 2016, a decrease of $8.7 million from $55.6 million as of September 30, 2015, principally associated with cash flow from operating activities of $25.2 million offset by the $25.9 million net cash payments related to our Fiscal 2016 Acquisitions and $8.2 million of plant and equipment expenditures.

The Company’s investment policy excludes ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. During the second quarter of fiscal 2015, the Company liquidated its investment portfolio to support corporate initiatives. As a result, the ending balance of available-for-sale investments as of September 30, 2015 was zero. During 2016, as a result of cash on hand in excess of operating needs, the Company made several investments in available for sale securities, resulting in an ending balance as of September 30, 2016 of $22.0 million. Our investment policy requires that for investments with a duration of greater than one year, no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity. Management plans to continue to direct its investment advisors to manage the Company’s securities investments primarily for the safety of principal for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

In the fourth quarter of fiscal 2014, Intersect ENT, which was previously recorded as a strategic investment of the Company, completed its initial public offering. We reclassified our investment in Intersect ENT from other assets to an available-for-sale security as of September 30, 2014. In the second quarter of fiscal 2015, our shares were liquidated and a gain of $0.5 million recognized and realized in the consolidated statement of income.

On November 4, 2013, we entered into a three-year $20.0 million secured revolving credit facility. On November 2, 2016, we amended and restated the secured revolving credit facility pursuant to an Amended and Restated Credit Agreement (the "Credit Agreement") with Wells Fargo Bank, National Association (the "Bank"). The Credit Agreement increases availability under the secured revolving line of credit from $20.0 million to $30.0 million and extends the maturity of the previous facility by three years. The Company's obligations under the Credit Agreement are secured by substantially all of its and its subsidiaries' assets, other than intellectual property and real estate. The Company has also pledged the majority of the stock of its subsidiaries to secure such obligations. Interest expense under the Credit Agreement is reduced as compared to the Company's prior secured revolving credit facility and accrues at a benchmark rate, plus an applicable margin ranging from 1.00% to 1.75%. A facility fee is payable quarterly on unused commitments at a rate of 0.15% per annum. The interest rate margins are determined based on the Company's ratio of total funded debt to EBITDA (as defined in the Credit Agreement).

The Credit Agreement contains affirmative and negative covenants customary for a transaction of this type which, among other things, require the Company to meet certain financial tests. The Credit Agreement also contains covenants which, among other things, limit the Company's ability to: incur unfinanced capital expenditures in an amount greater than $10.0 million in the aggregate during any fiscal year; incur additional debt; make certain investments; create or permit certain liens; create or permit restrictions on the ability of subsidiaries to pay dividends or make other distributions; consolidate or merge; and engage in other activities customarily restricted in such agreements, in each case subject to exceptions permitted by the Credit Agreement. The Credit Agreement also contains customary events of default, the occurrence of which would permit the Bank to terminate its commitment and accelerate the loans.

Concurrent with the signing of the new credit agreement in November 2016, we entered into a three-year $5.0 million multicurrency overdraft facility in Ireland.

On July 31, 2014, we filed a registration statement with the Securities and Exchange Commission, using a “shelf” registration process. Under this shelf process we may sell, either separately or together, debt securities, preferred stock, depositary shares, common stock and security warrants in one or more offerings up to an aggregate initial offering price of $175.0 million. As of September 30, 2016, we have not completed any securities offerings associated with the registration statement.

We believe that our existing cash, cash equivalents and investments, together with our $30.0 million credit facility and $175.0 million shelf registration statement, will provide liquidity sufficient to fund our operations and planned capital

expenditures in the next twelve months. There can be no assurance, however, that our business will continue to generate cash flows at current levels, and disruptions in financial markets or an increase in interest rates may negatively impact our ability to access capital in a timely manner and on attractive terms. In the event Creagh Medical begins to generate taxable income in future years, repatriation of its earnings may result in substantial U.S. tax cost. Our current plans do not foresee a need to repatriate funds that are designated as permanently reinvested in order to fund our operations or meet currently anticipated liquidity and capital investment needs.

The following table depicts our cash flows provided by operating activities from continuing operations for fiscal 2016, 2015 and 2014:

	For the Years Ended September 30,		
	2016	2015	2014
(dollars in thousands)			
Net income	$9,985	$11,947	$12,031
Loss from discontinued operations	—	—	176
Depreciation and amortization	4,873	2,805	2,715
Stock-based compensation	3,844	2,381	3,337
Contingent consideration accretion and unrealized foreign exchange loss	1,936	—	—
Impairment losses on strategic investments	—	1,500	1,184
Deferred taxes	261	93	(352)
Net other operating activities	(567)	(963)	(1,076)
Net change in other operating assets and liabilities	4,834	(2,697)	522
Net cash provided by operating activities from continuing operations	$25,166	$15,066	$18,537

Operating Activities. We generated cash flows from operating activities from continuing operations of $25.2 million, $15.1 million and $18.5 million in fiscal 2016, 2015 and 2014, respectively. The fiscal 2016 increase compared with fiscal year 2015, relates primarily to increases in non-cash depreciation, amortization, stock-based compensation and contingent consideration accretion expenses, due primarily to the Fiscal 2016 Acquisitions. Additionally, changes in working capital including accelerated collection of customer receivables, which reduced accounts receivable $0.6 million, and increased amounts due to customers of $0.8 million, as well as a $2.6 million increase in accrued compensation expenses including payroll taxes and a $0.4 million increase in other accrued expenses.

The fiscal 2015 decrease compared with fiscal year 2014, relates primarily to a $3.3 million increase in use of cash in accounts receivable related to timing of customer payments and higher product revenue generation, in addition to $0.7 million increased use of cash for inventory to support safety stock requirements, partially offset by $1.1 million of lower use in account payable and accruals primarily resulting from higher incentive compensation accruals.

Investing Activities. While we used cash in investing activities from continuing operations of $55.5 million in fiscal 2016, we generated cash flows from investing activities from continuing operations of $16.7 million and $22.4 million in fiscal 2015 and 2014, respectively. We invested $8.2 million, $1.9 million and $2.3 million in property and equipment in fiscal 2016, 2015 and 2014, respectively. The increase in fiscal 2016 property and equipment additions was the result of purchasing the Creagh Medical facility for $2.8 million and other investments in our whole-products strategy. We acquired Creagh Medical and NorMedix in fiscal 2016 for $25.9 million of net cash. We also purchased available-for-sale securities for $22.0 million, net of sales proceeds, in fiscal 2016. In addition, we received $0.5 million of sales proceeds from the sale of a strategic investment. In fiscal 2015, we received cash proceeds aggregating $18.8 million net, from sales of available-for-sale securities as we adjusted our investment portfolio, moving toward a liquid short-term portfolio to meet strategic objectives. In addition, we received cash proceeds of $0.5 million from our sale of Intersect ENT shares in fiscal 2015, $0.7 million from contingent consideration milestone events related to the sale of our Vessix strategic investment in fiscal 2014, and $2.3 million from the sale of our Vessix and OctoPlus strategic investments in fiscal 2013.

Financing Activities. We used cash flows from financing activities from continuing operations of $(0.2) million, $(19.7) million and $(12.9) million in fiscal 2016, 2015 and 2014, respectively. The primary financing activities in fiscal 2016 related to the payment of contingent consideration required by the terms of a prior-year acquisition in our IVD segment and payments of $0.4 million to purchase common stock to pay employee taxes resulting primarily from the issuance of common shares associated with our fiscal 2013-2015 performance share program. The primary

financing activity in fiscal 2015 and 2014 was related to the repurchase of common stock of $20.0 million and $12.5 million, respectively. We also generated $0.5 million, $0.7 million and $0.5 million in fiscal 2016, 2015 and 2014, respectively, from the sale of common stock pursuant to our stock-based compensation arrangements.

On November 6, 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. This share repurchase program does not have a fixed expiration date.

On November 5, 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 transactions, tender offers or by any combination of such methods. This share repurchase program does not have a fixed expiration date.

On November 11, 2014, the Company entered into an accelerated share repurchase program with Wells Fargo Bank, National Association. In connection with the agreement, the Company made an initial $20.0 million payment to the bank and immediately received an initial delivery of 758,143 shares of its common stock with a fair value of $16.0 million as of the purchase date. Effective as of the date of the initial share purchase in fiscal 2015, the transaction was accounted for as a share retirement, resulting in a reduction of common stock of less than $0.1 million, additional paid-in capital of $2.5 million and retained earnings of $13.5 million. The remaining $4.0 million of the Company's payment was also reported as a reduction in retained earnings. The specific number of shares that the Company ultimately purchased under the ASR agreement was based on the volume weighted average price ("VWAP") of the Company's common stock during the purchase period, less an agreed upon discount. In the aggregate, the Company purchased 847,864 shares under the ASR program for an average price of $23.59 per share. Based on the facts associated with the agreement, the forward contract was indexed to the Company's common stock and met the U.S. GAAP requirements to be classified as permanent equity. The contract was completed July 8, 2015.

As of December 2, 2016, the Company has an aggregate of $30.0 million available for future common stock purchases under the fiscal 2015 authorization and fiscal 2016 authorization.

During fiscal 2014, we repurchased 485,577 shares of common stock for an aggregate amount of $12.5 million, including $1.1 million in open market repurchases which existed as of September 30, 2013, at an average price of $23.77 per share.

Discontinued Operations. Our Pharmaceuticals discontinued operations used operating cash of less than $0.1 million and $0.4 million in fiscal 2015 and 2014, respectively. Cash generated from financing activities of less than $0.1 million in fiscal 2015 related to transfers of cash from continuing operations of Surmodics and consisted of cash used to make payments on accrual balances. Cash used in discontinued operations in fiscal 2015 related to payments of certain accounts payable balances. Cash used in discontinued operations in fiscal 2014 related to payments made in connection with the resolution of the SRI litigation matter as well as the Evonik indemnification matter both discussed in Note 12 to the consolidated financial statements included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K, and payments of certain accounts payable balances.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to us. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Medtronic is our largest customer at approximately 25% of total consolidated revenue for fiscal 2016. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 4% of our total revenue. No other individual customer using licensed technology constitutes more than 6% of our total revenue.

Our licensing agreements with many of our customers, including most of our significant customers, cover many licensed products that each separately generates royalty revenue. This structure reduces the potential risk to our operations that may result from reduced sales (or the termination of a license) of a single product for any specific customer.

Off-Balance Sheet Arrangements and Contractual Obligations. As of September 30, 2016, we did not have any off-balance sheet arrangements.

Presented below is a summary of contractual obligations and payments due by period (in thousands). See Note 11 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report

on Form 10-K for additional information regarding the below obligations.

(dollars in thousands)	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases	$407	$135	$186	$86	