SURMODICS INC
Form 10-K
November 30, 2018

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, 2018

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 every Interactive Data File required to be submitted 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 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” and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller Reporting Company
	Emerging Growth Company

If an emerging growth company, indicated by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 1(a) of the Exchange Act.

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, 2018 was approximately $255 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 26, 2018 was 13,398,036.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s Proxy Statement for the Registrant’s 2019 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 and our ability to develop and commercialize medical device products, financial prospects, product development programs including development and commercialization of the SurVeil® drug-coated balloon ("SurVeil DCB"), including related license fee revenue and the estimated cost associated with the TRANSCEND clinical trial and other clinical trials, sales efforts, the impact of significant customer agreements, including its agreements with Medtronic plc ("Medtronic") and Abbott Vascular, Inc. ("Abbott"), the impact of acquisitions, the Company's whole-products solutions strategy, and our expectations related to expenses and regulatory approvals. 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

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. 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. We aim to develop highly differentiated products designed to improve patient outcomes through enhanced treatment of vascular disease. Additionally, both our Medical Device and In Vitro Diagnostics operating segments partner with many of the world's leading and emerging medical device, diagnostic and life sciences companies to commercialize our proprietary medical device, surface modification and diagnostics technologies.

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 SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public may obtain any documents that we file with the SEC at http://www.sec.gov. We file annual reports, quarterly reports, proxy statements, and other documents with the SEC under the Exchange Act.

The information below provides an overview of the principal products, services and markets for each of our two business units. 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 coatings and device drug-delivery technologies, (together, "surface modification coating 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 vascular disease, neurology, ophthalmology, orthopedic and other large interventional markets.

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 coating technologies as product differentiators or device enablers. 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, including drug-delivery coatings. For example, stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures or 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 by patients, physicians and insurance

companies of such innovations 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.

For many years, we have provided surface modification coating technologies that impart lubricity, prohealing or biocompatibility characteristics, as well as drug delivery capabilities 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"). This strategy does not change our focus on the development and commercialization

of our core surface modification coating technologies. However, 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 and operating margin with whole-product solutions.

Over the past three years, we have enhanced our medical device design, development and manufacturing capabilities through internal growth and acquisition, with the goal of developing and commercializing 12-15 medical device products by the end of fiscal 2023. To that end, we have invested in state-of-the-art R&D and manufacturing facilities in Ireland and the U.S. and have begun integrating our balloon catheter, ultra-thin-walled catheter and surface modification coating technologies into several new products and product platforms. Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs through development and commercialization of novel vascular devices.

During fiscal 2018, we continued investing in our whole-product solutions strategy and achieved several meaningful strategic milestones. On February 26, 2018, we entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® DCB to treat the superficial femoral artery ("SurVeil DCB") (the "Abbott Agreement"), which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous ("AV") fistula DCB products, which are currently in pre-clinical development. We will collaborate with Abbott on product development, clinical trials and regulatory activities to obtain marketing clearances in the U.S. and the European Union for the SurVeil DCB. Expenses related to these activities will primarily be paid by Surmodics. We received an upfront payment of $25 million and may earn up to an additional $67 million upon achievement of certain milestones related to regulatory approval and clinical trial activities. Upon the regulatory approval of the SurVeil DCB, Surmodics will be responsible for manufacturing clinical and commercial quantities of the product and will realize revenue from product sales to Abbott, as well as a share of profits resulting from sales to third parties. The agreement with Abbott represents a significant step forward in our whole-product solutions strategy. We recognized revenue of $4.4 million in fiscal 2018 related to the Abbott Agreement, which is included in royalties and license fees in our medical device segment. Revenue from the upfront fee is recognized as regulatory and clinical activities are performed. Revenue from the contingent milestones will begin to be recognized if and when the contingencies are resolved.

In May 2018, we entered into an agreement with Embolitech, LLC ("Embolitech") to acquire an innovative thrombectomy platform technology and related intellectual property with broad potential peripheral vascular applications. Under the agreement, Surmodics paid $5.0 million in fiscal 2018 and will pay additional amounts in future years related to achievement of various regulatory milestones. The Embolitech technology platform is designed to remove difficult, organized (hard) blood clots. Surmodics plans to leverage its design, development and manufacturing capabilities to advance the technology platform for a variety of peripheral and vascular applications as part of our whole-product solutions pipeline. As a result of this agreement, we recognized acquired in-process research and development expense totaling $7.9 million in fiscal 2018, representing the present value of probable payments to be made under the agreement. Additionally, Surmodics is obligated to pay $3.5 million in several installments beginning December 2019 and ending December 2023. These payments may be accelerated upon the occurrence of certain sales and regulatory milestones. An additional $2.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033.

Overview of Interventional Peripheral Market and Whole-Product Solutions Strategy

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. 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).

Our business model for our whole-product solutions strategy is to design, develop and manufacture highly differentiated products for our customers that incorporate our proprietary catheter, balloon and surface modification coating technologies to improve patient outcomes and reduce procedure costs, while maintaining patient safety. Additionally, we are focused on developing devices that consider the needs of various care settings ranging from hospitals to alternate care facilities, in order to provide improved care. The strategy has been built on our investment in proprietary device technologies, as well as state-of-the-art medical

device design, development and manufacturing capabilities. Combined with our leadership in surface modification coating technologies, we will develop whole-product solutions to address unmet needs in the treatment of PAD and other vascular diseases.

Our development efforts to date have yielded several device technology platforms that serve the interventional vascular market, with a primary focus on treatment of PAD.

Drug-coated balloons

Drug-coated balloons are currently used in a variety of vascular interventions and may be helpful in preventing restenosis, or the narrowing of vessels after treatment. Surmodics is focused on the development of DCB's to treat PAD and the development of the SurVeil DCB over the past several years has been a major component of our whole-product solutions strategy. During fiscal 2016, we initiated PREVEIL, an early feasibility clinical trial of the SurVeil DCB, which is intended to treat PAD in the leg above the knee. Enrollment in PREVEIL was completed in the second quarter of fiscal 2017 and the study met its primary endpoint by demonstrating peak paclitaxel plasma concentrations post-index procedure. Consistent with pre-clinical data, systemic levels were low and cleared rapidly. Data from the PREVEIL study continues to demonstrate positive results and showed no clinically driven target lesion revascularization after 12 months. We began enrollment in the TRANSCEND SurVeil DCB pivotal clinical study in the first quarter of fiscal 2018, with the objective of obtaining data necessary to support regulatory approvals and reimbursement for this device in the U.S. We also plan to collect the data necessary to support Conformité Européenne ("CE") Mark approval using a subset of patients from the TRANSCEND clinical trial. Until regulatory approvals have been obtained, our SurVeil DCB is not approved for commercial sale.

Our DCB product platform also includes two other products currently in development stage. The first is our paclitaxel-based Avess™ DCB for the treatment of AV fistulae. Secondly, we are developing our sirolimus-based Sundance™ DCB for the treatment of below-the-knee PAD. In fiscal 2018, we submitted an application for a first in-human study of our Avess DCB.

Specialty catheters

Often, interventional vascular procedures require one or more devices to provide appropriate access and necessary support for the physician. Our integration of proprietary low-profile balloon catheter, ultra-thin-walled catheter, and surface modification coating technologies is generating a pipeline of highly differentiated medical devices that improve on currently available minimally-invasive PAD treatments, or in some cases offer an option for complex cases. Our specialty catheters are designed for high performance in challenging vascular anatomy, providing clinicians enhanced ability to access, cross and treat increasingly complex vascular lesions.

During fiscal 2018, we received U.S. Food and Drug Administration ("FDA") clearances for our Telemark™ coronary/peripheral support microcatheter and our .018" low-profile percutaneous transluminal angioplasty ("PTA") balloon dilation catheter. Additionally, in fiscal 2017 we received FDA and CE Mark clearances for our .014" low-profile PTA balloon catheter, designed for peripheral angioplasty procedures. We are currently in discussions with potential partners to distribute these products and expect to begin to generate revenue in fiscal 2019.

Thrombectomy

Acute vascular occlusion, or the blocking of arteries by clots or plaque is another peripheral vascular condition commonly associated with PAD. Often, these clots require surgical intervention and have proven difficult to remove with currently available medical device technologies. A similar condition in the venous system, known as Venous Thromboembolism ("VTE"), includes both pulmonary embolism and deep vein thrombosis. VTE has a high prevalence in the US and high overall and in-hospital mortality rates which causes strain on the U.S. healthcare system.

We plan to leverage the Embolitech thrombectomy platform technology that we acquired in fiscal 2018 to develop products to treat these conditions more effectively as compared with existing treatment methods and devices. The Embolitech technology platform is designed to remove difficult, organized (hard) blood clots that are often difficult for existing devices, and has potential applications in the peripheral vascular market, as well as the neurology and coronary markets. The technology offers an innovative design that eliminates the need for the use of thrombolytics, reducing the likelihood of ICU time and bleeding complications that affect patient recovery and outcomes. Our goal with this technology is to reduce procedure time and eliminate the need for additional external capital equipment, thereby providing an easy-to-use, on-the-table solution for clinicians and patients.

Overview of Surmodics' Surface Modification Coating Technologies

We believe Surmodics is positioned to take advantage of the continuing trend of incorporating surface modification coating technologies, particularly in the area of device drug-delivery, into the design of more efficient and effective combination products, as well as new product applications. We have a growing proprietary technology portfolio that incorporates our market expertise and insight, as well as unique collaborative research, development and manufacturing capabilities — key ingredients to bring innovation together to benefit patients 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 their devices' performance by choosing the specific coating properties desired for particular applications. Our surface modification coating technologies also can be combined to deliver multiple surface-enhancing characteristics on the same device.

Our proprietary PhotoLink® coating technology ("PhotoLink 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 Technology 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 Technology 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 proprietary reagent portfolio for use by our customers. These reagents enable our customers to develop novel surface features for their devices, satisfying the expanding healthcare industry requirements. 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.

The PhotoLink Technology coating process is relatively simple to use and is easily integrated into the customer's manufacturing operations. 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, coatings incorporating the PhotoLink Technology are generally compatible with accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

Our Serene® hydrophilic coating platform optimizes lubricity and durability while significantly reducing particulates generation. This next-generation PhotoLink Technology-enabled coating has demonstrated excellent lubricity on a wide range of substrates, and has been used on FDA-cleared coronary, peripheral and structural heart devices.

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 drug release 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 DCB's 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.

Licensing Arrangements

We commercialize our surface modification coating 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 43.6%, 43.5% and 46.5% of our total revenue in fiscal 2018, 2017 and 2016, respectively. Greater than 91% 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 reagent chemical sales to licensees for use in their coating processes. Additionally, under the Abbott Agreement, we have provided worldwide commercialization rights, including a license under certain of our intellectual property, for the SurVeil DCB. During fiscal 2018, we recognized revenue of $4.4 million related to the Abbott Agreement, which represents a portion of the up-front license fee received under that agreement.

The licensing process for our coating technology licenses 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.

License agreement terms are generally for a specified number of years or our patent's life, 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 tied to the date on which the customer's product was first sold.

Our license agreements may include certain license fees and/or milestone payments. Substantially all our licensed coatings technology applications are nonexclusive, allowing us to license each technology to multiple customers. Moreover, even exclusive coatings technology 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 coatings 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. License fees, milestone payments, and the royalty rates are based on various factors, including the licensed product's or technology's stage of development, the perceived value of our technology to the customer's product, the size of the potential market, and whether the arrangement is exclusive or nonexclusive. Our agreements generally incorporate a minimum royalty to be paid by the licensee. Royalty payments generally commence one quarter after the customer's actual product sales occur because of the delay in reporting sales by our licensees. As such, we have historically recognized royalty revenue in the quarter that customer royalty payments are due to us. Commencing in fiscal 2019 we will adopt a new revenue recognition accounting standard that will require us to recognize and accrue sales-based royalty revenue under our coating technology licenses in the same quarter that the underlying customer product sale occurs.

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 13, 17 and 18 new licenses in fiscal 2018, 2017 and 2016, respectively.

Under our coatings technology license agreements, 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. Our SurVeil DCB license requires us to complete certain activities in order to obtain regulatory approval for the device. Given the significant uncertainty inherent in product development and regulatory approval processes, the expected timing for regulatory approval and commercialization for the products pending regulatory approval is can vary greatly.

Our licensing agreements generally require us to keep our customers' identities confidential, unless they approve of such disclosure. Licensed customers that allow the use of their name include: Abbott Laboratories and Abbott Vascular, Inc. (together, "Abbott"), Boston Scientific Corporation ("Boston Scientific"), Cook Medical, Cordis Corporation (a subsidiary of Cardinal Health, Inc.), 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., and Spectranetics Corporation (a subsidiary of Koninklijke Philips N.V.).

IN VITRO DIAGNOSTICS SEGMENT

Our In Vitro Diagnostics ("IVD") business unit sells stabilization products, substrates, antigens and surface coatings to diagnostics customers. We manufacture and 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 patient's disease state or medical condition to diagnose the presence, absence or severity of disease. Analytes can range from large molecules such as proteins to small molecules such as hormones. Immunoassays are developed and produced using multiple components. The component's selection and optimization confer the assay quality and performance of the assay in terms of sensitivity and specificity. IVD companies select these critical biochemical and reagent components to meet the assay's diagnostic specifications. 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.

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 test's critical components 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 (false negative reductions), specificity (false positive reductions), speed (time from sample to results), convenience (ideally as few steps as possible) and cost effectiveness. Upon regulatory approval or clearance, the customer's diagnostic test can be sold in the marketplace. It may take several years after approval or clearance for the test to achieve peak market share and optimize Surmodics' revenue.

Overview of In Vitro Diagnostics Products

Protein Stabilizers. We offer a full line of stabilization products for the IVD market. These products increase sensitivity, reduce false positive and false negative results, while extending the diagnostic test's shelf life, thereby producing more consistent assay results. Our stabilization products are ready-to-use, eliminating the in-house manufacturing preparation time and cost of producing stabilization and blocking reagents.

Substrates. We also provide colorimetric and chemiluminescent substrates to the IVD market under our BioFX® trademark. A substrate is the diagnostic test kit component 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 U.S., 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.

OTHER FACTORS IMPACTING OUR OPERATIONS

Research and Development

Our R&D personnel work to enhance and expand our technology and product offerings in the area of whole-product solutions, drug delivery, surface modification, and in vitro diagnostics through internal scientific investigation and proprietary product development. These scientists and engineers also evaluate external technologies in support of our corporate development activities. Our R&D efforts are all 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, and providing technical assistance to existing and potential customers. These services, which generate our research, development and other revenue, include optimizing the relevant technologies for specific customer applications, supporting clinical trials, training customers, and 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 2018, 2017 and 2016, our R&D expenses were $41.0 million, $31.8 million and $18.5 million, respectively. R&D expenses are primarily comprised of research, development, clinical and regulatory activities necessary to design, develop and commercialize our products, as well as costs associated with our research, development and other revenue. We intend to continue investing significantly in R&D to advance our whole-product solutions, surface modification coatings, device drug delivery and in vitro diagnostic technologies and to expand uses for our technology platforms. We anticipate an increase in R&D expenses in fiscal 2019 primarily related to whole-product solutions product development, including our DCB development and clinical study activities. In addition, we continue to pursue access to products and technologies developed outside the Company 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 whole-product solutions offerings, including advancing our surface modification and device drug-delivery technologies to better meet these needs across multiple medical markets and to capture more of the final product value. Our whole-product solutions R&D activities are primarily focused on the peripheral vascular market, where we believe the integration of our surface modification, balloon catheter, thrombectomy and ultra-thin-walled catheter technologies will result in unique devices capable of producing better patient outcomes in complex, difficult-to-treat arterial disease cases. Our product pipeline continues to be bolstered through developing and acquiring medical device technologies and funding development activities, which has included pre-clinical and clinical studies.

With our fiscal 2018 acquisition of the Embolitech thrombectomy technology and significant investments in our R&D infrastructure, facilities and personnel over the past several years, we have strengthened our capabilities and broadened our capacity for R&D activities. In fiscal 2018, we completed the build-out of an R&D-focused facility which we lease in Eden Prairie, Minnesota. This accomplishment brings together the development teams focused on our DCB, catheter, and thrombectomy platform technologies, as well as our internal regulatory team in a state-of-the-art R&D facility in order to provide synergies and development efficiencies. Our facility in Ballinasloe, Ireland is focused on the design and manufacture of peripheral vascular devices. This facility's capabilities include balloon forming, extrusion, coating, braiding and assembly of finished products, with sufficient space for future growth. In 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. We have continued to develop surface modification coating and DCB chemistry technologies in our Eden Prairie, Minnesota facilities. Our proprietary, whole-product solutions integrate our surface modification coatings, catheter and balloon technologies and are being developed with a combined team from our U.S. and Irish facilities. In addition to our DCB-platform products, we are executing on our plan to develop and commercialize 12-15 medical device products by the end of fiscal 2023. Additional planned

activities include initiation of surface modification experiments that improve medical device performance, as well as incorporation of our catheter and thrombectomy technology platforms into various other devices intended for the emerging peripheral vascular treatment market. In addition to proprietary medical device product development, we work 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 in this area exceed those of our competitors.

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 2018 we launched MatrixGuard™ Diluent, an advanced signal blocker for matrix interferences.

Clinical Trials

Our PREVEIL first in-human early feasibility study using the SurVeil DCB completed enrollment in the second quarter of fiscal 2017. In PREVEIL, twelve-month results indicated that acute success measures of safety were achieved in all patients, as well as 100 percent freedom from clinically-driven target lesion revascularization. In July 2017, we received an investigational device exemption ("IDE") from the FDA to initiate a pivotal clinical trial of the SurVeil DCB. The randomized clinical trial, TRANSCEND, is now underway and is focused on evaluating the SurVeil DCB for treatment for PAD in the upper leg compared with the Medtronic IN.PACT® Admiral® DCB. The objective of the TRANSCEND clinical trial is to evaluate the safety and effectiveness of the SurVeil DCB device for treatment of subjects with symptomatic PAD due to stenosis of the femoral and/or popliteal arteries. If successful, the TRANSCEND clinical trial will be used to support regulatory approvals and reimbursement (U.S. and Europe). The trial will enroll up to 446 subjects at up to 60 sites in the U.S. and 18 outside the U.S. The trial's primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. All randomized subjects will be followed through 60 months post-index procedure. We initiated enrollment in the TRANSCEND clinical trial in October 2017 and we anticipate full enrollment in the study in fiscal 2019. There is no assurance that the TRANSCEND clinical trial will support regulatory approval, or that any anticipated time frame will be met. We estimate that the total cost of the TRANSCEND clinical trial will range between $32 million to $40 million from inception to completion.

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 when necessary to support regulatory approval or clearance for new product initiatives. We will generate the clinical data necessary to seek regulatory approval or clearance for our existing and emerging products. In September 2018, we submitted an application for a first in-human study of our Avess™ DCB for treatment of AV fistulae.

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. As of September 30, 2018, Surmodics owned or had exclusive rights to 54 pending U.S. patent applications and 145 foreign patent applications. Likewise, as of the same date, Surmodics owned or had exclusive rights to 139 issued U.S. patents and 167 international patents.

We have licensed our PhotoLink 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 31 issued U.S. patents, 10 pending U.S. patent applications, 41 issued international patents, and 31 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 fiscal 2020 to 2035. 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, our third-generation 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, our 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 patent life, 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,

generally tied to the date on which the customer's product was first sold. In recent years, we have successfully converted a number of our customers' products utilizing this early generation technology to our advanced generation technologies or extended the royalty-bearing term of their existing technology licenses.

In fiscal 2018, royalty revenue associated with our third and fourth-generation PhotoLink Technologies was approximately 8% and 21%, respectively of our consolidated fiscal 2018 revenue. In most license agreements covering these early-generation technologies, the royalty obligations will extend, at a reduced rate, beyond expiration of the applicable patent(s) as a result of know-how and other proprietary rights licensed under the agreements.

We also rely upon trade secrets, trademarks and other un-patented proprietary technologies. We seek to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of this information, or that others will not be able to independently develop such information. Additionally, there can be no assurance that any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to us.

Marketing and Sales

Through our whole-product solutions strategy, we utilize our design, development, manufacturing and regulatory capabilities 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. While whole-product solutions development and manufacturing capability and capacity scale-up have been a significant focus, it does not change our business model to provide world-class surface modification coating technologies to our medical device customers.

Sales professionals working within our Medical Device business work in concert with our R&D personnel to coordinate commercialization activities. Our sales professionals' specialization fosters an in-depth knowledge of the issues faced by our customers, such as industry trends, technology changes, biomaterial changes and the regulatory environment. As we complete development of our proprietary medical device products, we have begun working with third-parties to bring these products to the market.

With respect to our diagnostics products, our sales professionals sell directly to IVD kit manufacturers and we enter into supply agreements with third parties to distribute those products around the world. We also offer diagnostics products for sale through our website.

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.

Significant Customers

Revenue from Medtronic and Abbott represented approximately 16% and 11%, respectively, of our consolidated revenue for the year ended September 30, 2018. Revenue from these customers was generated from multiple products

and fields of use, including revenue from the Abbott Agreement, substantially all of which were recognized in our Medical Device segment. No other customer provided more than 6% of our consolidated revenue in fiscal 2018. Three customers in our IVD business accounted for 17%, 10% and 10%, respectively, of our IVD operating segment revenue.

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. Our PTA balloon catheter and microcatheter products compete with larger original equipment manufacturer ("OEM") suppliers, as well as some of our largest medical device customers. We provide differentiated whole-product solutions that integrate our surface modification, catheter, balloon and other proprietary technologies. We believe our whole-product solutions will be competitive on the basis of their safety and efficacy as a result of the innovative design and differentiated coating and device design technology, which will lead to demonstrated improvements in patient outcomes through reduced invasiveness compared to other devices used for comparable procedures.

Because a significant portion of our revenue depends on royalties derived from our customers' medical device product sales incorporating our surface modification coating technologies, we are also affected by competition within the markets for such devices. As we typically 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. Many of our existing and potential competitors have greater financial, technical and marketing resources than we have.

The ability for surface modification coating 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 coating 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, including drug-delivery technologies.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value-added approach to device, drug-delivery and surface modification coating technologies. 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), 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. With respect to our licensed surface modification coating technologies, 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, 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 one of our Eden Prairie, Minnesota facilities. 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. We manufacture PTA balloon catheters and microcatheters

in our Ballinasloe, Ireland facility, which offers a suite of capabilities, including balloon forming, extrusion, coating, braiding and assembly of finished products. We plan to manufacture substantially all of our whole-product solutions devices in our Ireland facility as the products are launched. Our SurVeil DCB is currently manufactured in one of our Eden Prairie, Minnesota facilities as we scale up our Irish facility for DCB manufacturing. We will maintain secondary, redundant manufacturing capacity in our U.S. facilities once full scale-up has been achieved in our Ireland facility.

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 order to meet our customers' needs in this area, our manufacturing facility in Eden Prairie, Minnesota is certified to ISO 13485 and ISO 9001. Our manufacturing 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 often 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 device and/or surface modification coating technologies can only be marketed in the U.S. after a pre-market notification for 510(k) clearance or a pre-market approval ("PMA") by the FDA. These processes can take anywhere from several months (e.g., for medical device products seeking regulatory approval under the 510(k) clearance process) to several years (e.g., for medical device products seeking regulatory approval under the PMA application process). With respect to our customers' products that incorporate our surface modification coating and IVD technologies, the burden of securing regulatory approval typically rests with our customers as the medical device manufacturers. With respect to our whole-product solutions, including the SurVeil DCB and any additional medical device products that we develop, 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' and our own 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 the details of our technologies without our 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, and may result in opportunities to market our whole-product solutions in other countries. 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 30, 2018, we had 338 employees. Of these employees we employ 145 outside the U.S., primarily in R&D and manufacturing operations functions. We are not a party to any collective bargaining agreements.

14

EXECUTIVE OFFICERS OF THE REGISTRANT

As of November 30, 2018, the names, ages and positions of the Company's executive officers are as follows:

Name	Age	Position
Gary R. Maharaj	55	President and Chief Executive Officer
Timothy J. Arens	51	Vice President, Corporate Development and Strategy; Interim Vice President, Finance and Chief Financial Officer
Thomas A. Greaney	52	Chief Operating Officer, Medical Devices
Charles W. Olson	54	Senior Vice President of Commercial and Business Development, Medical Devices
Bryan K. Phillips	47	Senior Vice President, Legal, Human Resources and Information Systems, General Counsel and Secretary
Teryl L.W. Sides	49	Senior Vice President and Chief Marketing Officer
Joseph J. Stich	53	Vice President and General Manager, In Vitro Diagnostics
Gregg S. Sutton	59	Vice President, Research and Development, Medical Devices

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.

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. In May 2018, Mr. Arens was named interim Vice President of Finance and Chief Financial Officer for a second time. 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.

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 2017, Mr. Greaney was promoted to Chief Operating Officer, 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.

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.

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.

Teryl L.W. Sides joined the Company in November 2018 as Senior Vice President and Chief Marketing Officer. Before joining Surmodics, Ms. Sides served as Founder and Chief Executive Officer of Projectory, a consulting firm that provides strategic marketing services to med tech clients, ranging from start-ups to global businesses, from 2011 to 2018. Prior to joining Projectory, Teri was the Vice President of Marketing and Product Development for Arizant, Inc. from 1998 to 2011.

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.

Gregg S. Sutton joined the Company in January 2016 as Vice President of Research and Development, Medical Devices. 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.

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. Two of our customers provided more than 10% of our revenue in fiscal 2018. Revenue from Medtronic and Abbott represented approximately 16% and 11%, respectively of our total revenue for the fiscal year ended September 30, 2018 and was generated from multiple products and fields of use. The loss of Medtronic, Abbott 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 coatings technologies to a diverse array of medical device companies, 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 operating results.

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 coating 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 surface modification coating technologies for use on their own products, particularly in the area of drug delivery. 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 as well as production and marketing capabilities than us. Further, even if we are successful with respect to our plan to develop 12-15 medical device products over the next five years, we will be competing with companies that may be better able to leverage existing sales forces. 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 our technologies. 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 surface modification coating 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-product 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 products that address unmet clinical needs, and partner with them on successful commercialization. If we are unable to identify and enter into arrangements with our medical device customers for the commercialization of our products, we may seek to market and sell these products through third-party distributors or via direct sales.

Successfully implementing our whole-product solutions strategy and related strategic initiatives will place substantial demands on our resources and 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 located both in the U.S. and Ireland;
- commercialization of our products, including through strategic partnerships with our medical device customers, third-party distributors, or via direct sales;
- sufficient liquidity to support substantial investments in R&D required to make our strategy successful; and
- increased marketing and sales-support activities.

There is no assurance that we will be able to successfully implement our whole-product strategy and related strategic initiatives in accordance with our expectations, which could impact our ability to realize an acceptable return on the investments we are making in connection with this strategy, and 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 poses numerous risks, including:

- an inability to integrate 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' ownership, and cause large one-time expenses or create goodwill or other intangible assets that could result in future significant asset impairment charges. 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, 2018, we had $27.0 million of goodwill and indefinite-lived intangible assets on our consolidated balance sheet related to our Medical Device and IVD segments, of which $19.0 million related to our Medical Device reporting unit. As required by the accounting guidance for non-amortizing intangible assets, we evaluate at least annually the potential impairment of the goodwill and trademark. Testing for impairment of non-amortizing intangible assets involves the determination of the fair value of our reporting units. The estimation of fair values involves a high degree of judgment and subjectivity in the assumptions used. We also evaluate other assets on our balance sheet, including strategic investments and intangible assets, whenever events or changes in circumstances indicate that their carrying value may not be recoverable. Our estimate of the fair value of the assets may be based on fair value appraisals or discounted cash flow models using various inputs. During fiscal 2017 and 2016, we recorded impairment charges on our indefinite-lived intangible assets of $0.4 million and $0.1 million, respectively, related to non-amortizing intangible assets arising from our acquisition of Creagh Medical. 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 and our agreement with Abbott provides that we are responsible for certain of these costs related to the SurVeil DCB.

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 2018, research and development costs increased 29% over fiscal 2017 and were 50% of our total revenue, which had a significant impact on our overall operating results. In fiscal 2019, we expect to continue the clinical evaluation of the SurVeil DCB and will conduct additional development activities for the below-the-knee, AV fistula and other whole-product solutions products, which will result in significant expenses that will adversely affect our operating results, including our profitability, in fiscal 2019 and future periods. The agreement that we entered into with Abbott provides that we are responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and European Union regulatory clearances for the SurVeil DCB, including completion of the ongoing TRANSCEND clinical trial, which will involve significant costs. In addition to the costs of these research and development activities, 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 and failure to implement these standards might impact the effectiveness of our internal control over financial reporting or impact the reliability of our financial reporting.

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 adopted new revenue recognition guidance in the first quarter of fiscal 2019. The initial impact of the adoption of the revenue recognition guidance will be material to our fiscal 2019 consolidated financial statements due to an acceleration of minimum license fees and a one-quarter acceleration of royalty revenue pursuant to our hydrophilic license agreements, as well as requiring several additional financial statement footnote disclosures. We have also updated and enhanced our internal accounting systems, processes and our internal controls over financial reporting, all of which has required, and will continue to require, additional investments by us, and may require incremental resources and system configurations that could increase our operating costs in future periods. If we are not able to properly implement the new revenue recognition standards in a timely manner, the revenue that we recognize and the related disclosures that we provide under the new standards may not be complete or accurate, and we could fail to meet our financial reporting obligations in a timely manner, which could result in, among other things,

regulatory discipline and adversely affect our stock price. In addition, failure to implement these new standards, or other new or existing accounting standards, might result in material weaknesses or significant deficiencies in our internal control over financial reporting.

Our business includes foreign operations which exposes us to certain risks related to fluctuations in U.S. dollar and foreign currency exchange rates.

The Company reports its consolidated financial statements in U. S. dollars. In a period where the U.S. dollar is strengthening or weakening as compared with 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 and we have not hedged this foreign currency exposure. During fiscal 2018, 2017, and 2016, we recorded foreign currency exchange gains (losses) of $0.2 million, ($0.5) million, and ($0.4) million, respectively. The gains and losses were primarily related to these Euro-denominated contingent consideration liabilities. As our foreign operations expand, the effects may become material to our consolidated financial statements.

Changes in product mix and increased manufacturing costs could cause our product gross margin percentage to fluctuate or decline in the future.

Changes in our product mix and increases in manufacturing costs caused our product gross margin percentage to decline in fiscal 2018 and further changes to these items could cause our gross profit percentage to fluctuate or further decline in the future. In fiscal 2018, we experienced product cost growth from the prior year as a result of significant increases in balloon catheter sales, as well as product mix in our IVD segment, which was skewed toward lower-margin products. These factors, together with the scale-up of our manufacturing operations, particularly in Ireland, adversely affected our gross margin percentage for the last fiscal year and these factors will likely continue to affect our gross profit percentage in 2019 and beyond. However, whether this adverse mix impact will result in a decline of our gross profit percentage in any given year will depend on the extent to which they are, or are not, offset by positive impacts to product gross margin during such year.

RISKS RELATING TO OUR OPERATIONS AND RELIANCE ON THIRD PARTIES

We rely on third parties to market, distribute and sell most products incorporating our coating and device technologies, as well as our whole-product solutions.

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 years ended September 30, 2018, 2017 and 2016, we have derived 44%, 44%, and 47%, respectively, of our revenue from royalties and license fees derived from such licensing arrangements. The revenue that we derive from such arrangements is dependent on our licensees' ability to successfully develop, obtain successful regulatory approval for, manufacture (if applicable), market and sell products incorporating our technologies. In addition, in fiscal 2018, we entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for the SurVeil DCB. Abbott has the right to purchase commercial units from us and we will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott. Upon receipt of regulatory approval, we will rely on Abbott to effectively market and sell the SurVeil DCB.

Additionally, a licensee could modify their product in such a way that it no longer incorporates our technology. Many of these factors are outside of our control and the failure on the part of our licensees to successfully meet these requirements could have a material adverse effect on our business, financial condition and results of operations.

Moreover, 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 and may pursue parallel development or licensing of competing technologies 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.

Failure on the part of our licensees to successfully meet these requirements could have a material adverse effect on our business, financial condition and results of operations.

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

We sell many of our IVD products outside of the U.S. 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 U.S., 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.

Inaccuracies in these reports have resulted in, and could result in, additional overpayments or underpayments of royalties, which could have a material adverse effect on our business, financial condition and results of operations.

We currently 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 one of our Eden Prairie, Minnesota facilities. We also manufacture balloon catheter products at our facility in Ballinasloe, Ireland and catheter-based medical devices in limited quantities in one of our facilities in Eden Prairie, Minnesota. We plan to manufacture substantially all of our whole-product solutions devices in our Ireland facility. Our SurVeil DCB is currently manufactured in one of our Eden Prairie, Minnesota facilities as we scale up our Irish facility for DCB manufacturing. While we plan to maintain secondary, redundant manufacturing capacity once full scale-up has been achieved in our Ireland facility, our Ireland facility is not yet fully scaled-up. If our existing production facilities become 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 addition, 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 our surface modification coating technologies product sales. 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. For medical device products that incorporate our coating technology, most of the licenses provide us with indemnification against such claims. 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 components that 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 and our customers expect that we will securely maintain their information. 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, liability under personal privacy laws 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 un-patented 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 fiscal 2020 to 2035. 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 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 8% of our fiscal 2018 revenue.

Approximately 21% of our total revenue in fiscal 2018 was generated from our fourth-generation 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 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

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. During fiscal 2018, we continued the development of the SurVeil DCB, including investigating additional clinical applications and uses of the platform. In October 2017, we commenced enrollment of patients in TRANSCEND, the pivotal clinical trial for the SurVeil DCB.

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 obtain regulatory approval for new products or enhanced products, our ability to successfully compete 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 timing of when these products contribute to our future revenue and earnings growth.

Healthcare policy changes 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, or otherwise negatively impact pricing and reimbursement. Because a significant portion of our revenue is currently derived from royalties on products which constitute a percentage of our customer’s product’s selling price, these limitations could have an adverse effect on our revenue.

The Patient Protection and Affordable Care Act (the “ACA”) 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 until December 31, 2019, their status is unclear for subsequent years, as is the future of the ACA itself. 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. In particular, we cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. or abroad may have on our business.

Whole-product solutions medical devices and other products incorporating our technologies are subject to increasing scrutiny and regulations, including extensive approval/clearance processes and manufacturing requirements. Any adverse regulatory and/ or enforcement action (for us or our licensees) may materially affect our financial condition and business operations.

Our products and our business activities are subject to a complex regime of regulations. Additionally, certain state governments and the federal government have enacted legislation aimed at increasing transparency of industry interactions with health care providers. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we will continue to devote substantial additional time and financial resources to further develop and implement policies, systems, and processes to comply with enhanced legal and regulatory

requirements, which may also impact our business. We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal costs, exposure to litigation, and other adverse effects to our operations.

To varying degrees, the FDA and comparable agencies outside the US require us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. Our compliance with these laws and regulations takes significant time/ resources, involves stringent testing/ surveillance, involves attention to any needed product improvements (such as modifications, repairs, or replacements), and may include significant limitations of the uses of our products.

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.

Our facilities and procedures are subject to periodic inspections by the FDA to determine compliance with the FDA's requirements. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. The FDA has significantly increased its oversight of companies subject to its regulations, including medical device companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, refuse to grant pending pre-market approval applications or require certificates of non-U.S governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The FDA may also recommend prosecution to the U. S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and 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." Our common stock price 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. For instance, 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 utilized by our Corporate, Medical Device and IVD operating segments. We also own a 30,000 square foot building in Ballinasloe, Ireland dedicated to our Medical Device operating segment. We lease a warehouse through November 2021 and a 36,000 square foot facility, which will primarily be used for R&D and redundant manufacturing capacity in our Medical Device operating segment, through April 2028. Both of these properties are located near our principal operations in Eden Prairie, 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."

Our transfer agent is:

Broadridge Corporate Issuer Solutions, Inc.

P.O. Box 1342

Brentwood, NY 11717

1-877-830-4936

According to the records of our transfer agent, as of November 28, 2018, there were 180 holders of record of our 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.

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, with an additional $4.7 million utilized in fiscal 2017. The share repurchase program does not have a fixed expiration date.

The Company has an aggregate of $25.3 million available for future common stock purchases under the current 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, 2013 and assume reinvestment of dividends.

ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of September 30, 2018 and 2017 and for the years ended September 30, 2018, 2017 and 2016 is derived from our audited consolidated financial statements included elsewhere in this report. The data as of September 30, 2016, 2015 and 2014 and for the years ended September 30, 2015 and 2014 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				
	2018	2017	2016	2015	2014
	(Dollars in thousands, except per share data)				
Statement of Operations Data:					
Total revenue	$81,336	$73,112	$71,366	$61,898	$57,439
Operating (loss) income from continuing operations	(8,799)	7,103	16,859	19,089	18,576
(Loss) income from continuing operations	(4,457)	3,926	9,985	11,947	12,207
Loss from discontinued operations	—	—	—	—	(176)
Net (loss) income	(4,457)	3,926	9,985	11,947	12,031
Diluted (loss) income per share:					
Continuing operations	(0.34)	0.29	0.76	$0.90	$0.88
Discontinued operations	—	—	—	—	(0.01)
Net (loss) income	(0.34)	0.29	0.76	0.90	0.87
Balance Sheet Data:					
Cash, short-term and long-term investments	$65,020	$48,336	$46,941	$55,588	$63,374
Total assets	164,135	136,593	132,894	98,710	104,889
Retained earnings	97,615	102,072	98,146	88,161	93,881
Total stockholders' equity	108,610	111,557	106,833	81,873	98,751
Statement of Cash Flows Data:					
Net cash provided by operating activities from continuing operations	$34,052	$14,053	$25,166	$15,066	$18,537

Note: Fiscal 2018, 2017 and 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, with the mission of improving the detection and treatment of disease. Our business performance continues to be driven by growth in our Medical Device and IVD product offerings. We remain committed to developing medical device products and platforms leveraging the technologies and manufacturing capabilities in our Medical Device business unit for the treatment of peripheral vascular disease. These technologies include our DCB platform, specialty access delivery devices such as balloons and catheters, and the thrombectomy device platform technology acquired during fiscal 2018.

We operate two reportable business or segments as follows: (1) the Medical Device unit, which designs, develops and manufactures interventional medical devices, primarily balloons and catheters, including DCB's, for PAD treatment 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 IVD 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 derive our revenue from three primary sources: (1) 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; (2) royalties and license fees from licensing our proprietary surface modification coating technologies to customers; and (3) contract coating, design, 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 us and 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, medical device and diagnostic products sold to our customers.

Greater than 91% of our royalty and license fee revenue in fiscal 2018, 2017 and 2016 is associated with our hydrophilic coating technology licenses. With the execution of the SurVeil DCB license and development agreement with Abbott in February 2018, a portion of our license fee revenue, beginning in fiscal 2018, is associated with our proprietary medical device technology. 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 fiscal 2020 to 2035. Among these, our third-generation 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 hydrophilic coating technology was approximately 8% of our fiscal 2018 revenue. Approximately 21% of our total revenue in fiscal 2018 was royalty and license fee revenue generated from fourth-generation hydrophilic coating technology, which is protected by a family of patents that begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most 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 2035.

Critical Accounting Policies and Significant Estimates

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 and such differences 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. We license technology to third parties and collect royalties based on the greater of the contractual percentage of a customer's sales of products incorporating our licensed technologies or minimum contractual royalties. The financial information included in this Form 10-K includes royalty revenue recognized as our licensees reported it to us, typically submitted concurrently with their royalty payments. For stand-alone license agreements, up-front license fees are recognized over the term of the related licensing agreement. Minimum royalty

fees were recognized in the period earned. Revenue related to a performance milestone was recognized upon the achievement of the milestone and meeting specific revenue recognition criteria.

We license technology to third parties and, at times, these arrangements include multiple deliverables that required us to determine the appropriate unit(s) of account and allocate the consideration received to each of the unit(s) of account identified. The deliverables may include license(s) to Surmodics' technology, research, development and clinical activities, and product sales. Under revenue arrangements with multiple deliverables, we recognized each separable deliverable as it was earned. When appropriate, we accounted for revenue using a multiple attribution model in which consideration allocated to R&D and clinical activities was recognized as performed, and milestone payments were recognized when the milestone events were achieved, when such activities and milestones were deemed substantive. Accordingly, in situations where a unit of accounting included both a license and R&D and

clinical activities, and when a license did not have stand-alone value and R&D and clinical activities had a readily determinable standalone selling price, we applied a multiple attribution model in which consideration allocated to the license was recognized ratably, consideration allocated to R&D and clinical activities was recognized as performed and milestone payments were recognized when the milestone events were achieved, when such activities and milestones were deemed substantive. In situations where a license did not have standalone value and R&D and clinical activities did not have readily determinable standalone selling prices, consideration was recognized over the period the R&D and clinical activities were performed, on a proportional performance basis if the license granted a customer exclusive rights to a technology for substantially all of its estimated useful life.

Revenue associated with the upfront payment received under our license and development agreement with Abbott is recognized as the clinical and regulatory activities are performed on a proportional performance basis based on actual costs incurred relative to the expected total cost of the underlying activities, most notably the completion of the TRANSCEND clinical trial. A significant component of the cost of this trial is the cost of our outsourced clinical trial clinical research organization (“CRO”) consultants, which are estimated based on executed statements of work, project budgets, and patient enrollment timing, among other things. Costs related to the clinical and regulatory activities are expensed in the period incurred. A significant change to the Company’s estimate of the costs to complete the TRANSCEND clinical trial could have a material effect on the Company’s results of operations. The total expected cost of the trial is a significant management estimate and is reviewed and assessed each reporting period. The current portion of deferred revenue on the consolidated balance sheet represents the amount of deferred revenue that is expected to be recognized over the next year, based on estimated costs to be incurred. The estimate of future revenue from the Abbott agreement will continue to be monitored and adjusted based on estimates in effect each period-end.

As further described in the New Accounting Pronouncements section, we adopted a new accounting standard for recognizing revenue on October 1, 2018. We adopted the standard using the modified retrospective approach and expect the impact will be material to the consolidated financial statements due to an anticipated one-quarter acceleration of minimum license fees and royalty revenue earned under our hydrophilic coatings license agreements.

Customer advances are accounted for as a liability until all criteria for revenue recognition have been met.

Goodwill and other indefinite-lived intangible assets. We record all assets and liabilities acquired in purchase acquisitions, including goodwill and other intangible assets, at fair value as required by accounting guidance for business combinations. The initial recognition of goodwill and other intangible assets 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.

On an ongoing basis, goodwill and certain indefinite-lived intangible assets are not amortized but are subject, at a minimum, to annual tests for impairment at the reporting unit level. A reporting unit is an operating segment, or component thereof, for which discrete financial information is available and reviewed by management on a regular basis. Management has determined that our reporting units are comprised of our Medical Device and IVD business units.

Goodwill in our reporting units is evaluated for impairment in two ways. First, an assessment of qualitative factors is performed to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing an impairment test, as described below, becomes unnecessary. If events or circumstances occur that would indicate that the carrying amount may be impaired, or if the Company otherwise determines it necessary, the quantitative impairment test would be performed.

These tests require management to make significant judgments and estimates, most of which are based each reporting unit’s projected future cash flows. Our estimates associated with the annual test of goodwill and indefinite-lived

intangible assets are considered critical due to the amount of these assets recorded on our consolidated balance sheets and the judgment required in determining fair value, including projected future cash flows and, in the case of a quantitative test and impairment measurement, applicable discount rates.

We performed our annual impairment test of goodwill and indefinite-lived intangible assets annually in the fourth quarter of our fiscal year. Based on the results of the assessments, no goodwill impairment charges were recorded during fiscal 2018, 2017 or 2016. During fiscal 2017 and 2016, we recorded impairment charges on our indefinite-lived intangible assets of $0.4 million and $0.1 million, respectively, as a result of decreases in future revenue estimates associated with these assets. No impairment charges were recorded in fiscal 2018 related to indefinite-lived intangible assets.

Income tax accruals and valuation allowances. 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 $6.3 million and $4.0 million, respectively, as of September 30, 2018 and 2017, including valuation allowances of $4.5 million for both fiscal 2018 and 2017. The valuation allowances principally related to three items as of September 30, 2018 and 2017. First, financial statement other-than-temporary losses on strategic investments that were unrealized for tax purposes as we did not foresee future offsetting taxable capital gains. Therefore, as of September 30, 2018 and 2017, a valuation allowance has been recorded for all 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 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. Third, deferred tax assets related to state R&D tax credit carryforwards have been offset by valuation allowances to the extent they are not expected to be utilized in future years.

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. We regularly monitor our uncertain tax positions and adjust the related liabilities to reflect completion of tax audits, expiration of an applicable statute of limitations, changes in tax laws or interpretations, and changes in our business that result in uncertainties that previously did not meet the recognition criteria. See Note 9, "Income taxes," 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 income taxes and their effect on the consolidated financial statements for fiscal 2018, 2017 and 2016.

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 as 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 their fair value each reporting period using projected revenue, discount rates, and probabilities of milestone achievement. 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 strategic 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 consideration obligations to former Creagh Medical and NorMedix shareholders, including fair value adjustments recorded in fiscal 2018, 2017 and 2016 related to these liabilities, below under "Contingent consideration expense (gain)" in this Item 7 and in Note 5, "Fair Value Measurements," to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

32

Results of Operations

Years Ended September 30, 2018, 2017 and 2016

Revenue. Fiscal 2018 revenue was $81.3 million, an $8.2 million, or 11% increase from fiscal 2017 revenue of $73.1 million. Fiscal 2017 revenue was $73.1 million, a $1.7 million, or 2% increase from fiscal 2016 revenue of $71.4 million. The table below provides a summary of each operating segment's annual revenue for each of the three years ended September 30, 2018, 2017 and 2016.

	For the Year Ended September 30,			Increase/(Decrease)		Increase/(Decrease)	
(dollars in thousands)	2018	2017	2016	2018 vs. 2017		2017 vs. 2016	
Revenue							
Medical Device	$60,513	$53,983	$53,202	$ 6,530	12 %	$ 781	1 %
In Vitro Diagnostics	20,823	19,129	18,164	1,694	9 %	965	5 %
Total Revenue	$81,336	$73,112	$71,366	$ 8,224	11 %	$ 1,746	2 %

Medical Device. Revenue in Medical Device was $60.5 million in fiscal 2018, a 12% increase from $53.9 million in fiscal 2017. The increase in fiscal 2018 revenue was a result of growth in product sales and royalty and license fee revenue, partially offset by a reduction in research, development and other revenue. Product revenue increased by $3.4 million, largely driven by increased sales of balloon catheters, as well as growth in demand for our chemical reagents. Royalty and license fee revenue increased $3.7 million in fiscal 2018, as compared with the prior-year, despite facing headwinds from the one-time $1.1 million license fee recognized in fiscal 2017, along with the effects of the prior-year expiration of patents covering our third-generation PhotoLink technology which reduced royalty revenue by $2.2 million in fiscal 2018. Driving the increase in royalty and license fee revenue from the prior year was $4.4 million of license fee revenue from our SurVeil DCB license and development agreement with Abbott, as well as increases in royalties from licenses of our advanced-generation coatings. These revenue increases were partly offset by a $0.6 million decrease in research, development and other revenue as we experienced delays in customer research and development programs.

During fiscal 2018, 2017 and 2016, $6.3 million, $8.4 million, and $12.1 million, respectively, of Medical Device royalty revenue was generated from our third-generation 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). There was a royalty rate step down for licensed customers at the time these patents expired, which resulted in decreases in royalty revenue from licenses of our third-generation coating technology, as compared with the prior years. While we have continued to earn royalty revenue from licenses of our third-generation PhotoLink technology, we are actively seeking to convert customers using this generation of PhotoLink coatings to our Serene coating technologies.

Revenue in Medical Device was $53.9 million in fiscal 2017, a 1% increase from $53.2 million in fiscal 2016. The increase in fiscal 2017 revenue was a result of growth in product sales and research, development and other revenue, partially offset by a reduction in royalty and license fee revenue. Increases in product sales were driven primarily by increased demand for reagents as well as balloon catheter sales. Product revenue increased due to increases in reagent sales and sales of balloon catheters and other medical devices. The increase in research, development and other revenue of $1.4 million was primarily due to an increase in demand from new and existing customers for our coating and feasibility services. Royalty and licensing revenue declined by $1.4 million, as compared with fiscal 2016. The decrease in royalty revenue was primarily attributable to two prior-year royalty revenue items which positively impacted fiscal 2016 revenue by a net of $1.5 million, as well as the effect of previously disclosed patent expirations

of patents covering our third-generation PhotoLink hydrophilic technology. The prior-year royalty revenue items consisted of a $2.9 million catch-up payment for previously unreported royalties owed to the Company by one customer for the period from fiscal 2009 through fiscal 2016, partly offset by 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 related to years prior to fiscal 2016. In addition, in fiscal 2017 we realized a $1.1 million license fee related to a customer's acquisition and our sale of related jointly-owned intellectual property to the acquirer. Royalty revenue associated with our third-generation hydrophilic coatings decreased $3.7 million from fiscal 2016 to fiscal 2017 as a result of the previously disclosed patent expirations, partially offset by a $1.3 million increase from other hydrophilic royalties over the same time period.

In Vitro Diagnostics. In Vitro Diagnostics revenue was $20.8 million in fiscal 2018, a 9% increase from $19.1 million in fiscal 2017. Revenue growth in fiscal 2018 was driven by sales volume increases in our microarray slides, distributed antigen products and BioFX-branded products.

In Vitro Diagnostics revenue was $19.1 million in fiscal 2017, a 5% increase from $18.2 million in fiscal 2016. The increase in fiscal 2017 revenue reflected strong growth in stabilization, substrate, and antigen product sales which was more than offset by a revenue decline from a significant microarray customer that was acquired by one of its competitors.

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

	For the Year Ended September 30,								
	2018			2017			2016		
(dollars in thousands)	Amount	% Total Revenue		Amount	% Total Revenue		Amount	% Total Revenue	
Product costs	$13,997	17	%	$11,422	16	%	$10,908	15	%
Research and development	40,973	50	%						