

SURMODICS INC
Form 10-K
December 01, 2017

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, 2017

Commission file number 0-23837

SURMODICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(Registrant's Telephone Number, Including Area Code)

(952) 500-7000

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

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

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

| | |
|---|--|
| <input type="checkbox"/> Large accelerated filer | <input type="checkbox"/> Accelerated filer |
| <input type="checkbox"/> Non-accelerated filer (Do not check if a smaller reporting company) | <input type="checkbox"/> Smaller reporting company |
| | <input type="checkbox"/> 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, 2017 was approximately \$176 million (based upon the closing sale price of the registrant’s Common Stock on such date).

The number of shares of the registrant’s Common Stock outstanding as of November 25, 2017 was 13,098,716.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s Proxy Statement for the Registrant’s 2018 Annual Meeting of Shareholders are incorporated by reference into Part III.

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Forward-Looking Statements

Certain statements contained in this Form 10-K, or in other reports of the Company and other written and oral statements made from time to time by the Company, do not relate strictly to historical or current facts. As such, they are considered “forward-looking statements” that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation

Reform Act of 1995. Such statements can be identified by the use of terminology such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “possible,” “project,” “will” and similar words or expressions. Any statement that is not a 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 of the SurVeil® drug-coated balloon (“SurVeil DCB”), including the estimated cost associated with the TRANSCEND clinical trial, sales efforts, the impact of significant customer agreements, including its agreements with Medtronic plc (“Medtronic”), the impact of acquisitions, the Company’s whole-products solutions strategy, and our expectations related to 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 – General

Surmodics, Inc. and subsidiaries (referred to as “Surmodics,” the “Company,” “we,” “us,” “our” and other like terms) is a leading 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. Our business segments partner with many of the world’s leading and emerging medical device, diagnostic and life science companies to develop and commercialize innovative products designed to improve patient diagnosis and treatment.

In fiscal 2017, our business performance continued to be driven by growth in our core Medical Device and In Vitro Diagnostics (“IVD”) businesses, while we continued medical device product and platform development leveraging the technologies and manufacturing capabilities acquired with the fiscal 2016 acquisitions of Creagh Medical Ltd. (“Creagh Medical”) and NorMedix, Inc. (“NorMedix”) (together the “Fiscal 2016 Acquisitions”) in our Medical Device business unit.

The Company was organized as a Minnesota corporation in June 1979. We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the “Exchange Act”) on our website, www.surmodics.com, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

The information below provides an overview of the principal products, services and markets for each of our two business units. For more information regarding domestic and foreign revenue and revenue by our business units, also known as our operating segments, for each of our last three fiscal years, see Note 12 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K. The discussion of other aspects of our business including research and development (“R&D”), intellectual property, marketing and sales, future acquisition strategy, significant customers, competition, manufacturing, government regulation and our employees applies to our business in general and we describe material segment information within these sections where relevant.

Medical Device Segment

Advances in medical device technology have helped drive improved device efficacy and patient outcomes. The convergence of the pharmaceutical, biotechnology and medical device industries, often made possible by surface 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, ophthalmology, orthopedics and other large 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 and device drug delivery 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. For example, stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures, and they have diminished the need for more invasive cardiac bypass surgery. Drug-coated balloons have further transformed intravascular therapies by enhancing patient outcomes

while not leaving stents in the vascular system. Transcatheter heart valve repair or replacement via a minimally invasive catheter-based system has enabled the treatment of patients suffering from heart valve disease who are too ill to undergo open-heart surgery. Positive clinical outcomes and acceptance of these and other similar innovations by patients, physicians and insurance companies has helped certain segments of the United States (“U.S.”) medical device industry grow at a faster pace than the economy as a whole. The attractiveness of the industry has drawn intense competition among the companies participating in this area.

Our Medical Device segment provides surface modification coating technologies that impart lubricity, prohealing or biocompatibility characteristics, or drug delivery capabilities, as well as vascular device, catheter and balloon design, development and manufacturing capabilities. Historically, we have provided surface modification technologies to enhance our customers’ medical devices and delivery systems. Since fiscal 2013, with our investment in our drug-coated balloon (“DCB”) platform, we have been focused on a strategy to develop and manufacture proprietary medical device products that combine our surface modification

coatings with medical devices or delivery systems (“whole-product solutions”). This strategy does not change our focus on our core surface modification 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. Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs, and partner with them on successful commercialization.

During fiscal 2017, we continued investing in our whole-product solutions strategy and achieved meaningful strategic milestones, including the initiation of the TRANSCEND SurVeil® DCB pivotal clinical trial, as well as U.S. Food and Drug Administration (“FDA”) and Conformité Européenne (“CE Mark”) clearance for our .014” low-profile percutaneous transluminal angioplasty balloon dilation catheter (“.014” PTA balloon catheter”), designed for peripheral angioplasty procedures.

Overview of Interventional Peripheral Market and Whole-Products 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 products incorporating our proprietary catheter, balloon and surface modification coating technologies. Our whole-product solutions strategy has been built on the acquisition of state-of-the-art medical device design, development and manufacturing capabilities to complement our leadership in surface modification coating technologies to develop whole-product solutions for treatment of PAD and other vascular diseases. The Creagh Medical acquisition brought a state-of-the-art R&D and manufacturing facility offering robust extrusion, balloon-forming, top-assembly, packaging and regulatory capabilities focused on balloon catheters. The NorMedix acquisition provided ultra-thin-walled, minimally invasive catheter technologies. We have integrated our balloon catheter, ultra-thin-walled catheter and surface modification technologies to design, develop and manufacture proprietary products. We are currently seeking third-party companies to distribute our products to end users.

During fiscal 2017 we received FDA 510(k) clearance and CE Mark for our first whole-product solution, a .014” PTA balloon catheter, and expect to receive regulatory approval for several additional catheter and balloon-based products throughout calendar 2018. We are currently in discussions with potential partners to distribute our .014” PTA balloon catheter.

Surmodics is focused on the development of drug coated balloons to treat PAD. The development of the SurVeil DCB is a major step forward in our strategy to offer whole-product solutions for the medical device industry. 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. We began enrollment in the TRANSCEND SurVeil DCB pivotal clinical study in the fourth quarter of fiscal 2017, with the objective of obtaining data necessary to support regulatory approvals and reimbursement for this device in the U.S. We also plan to initiate SurVeil DCB clinical trials in Europe to support CE Mark approval. Until regulatory approvals have been obtained, our SurVeil DCB is not approved for commercial sale.

In addition to our SurVeil DCB program, we are developing other DCB's for treatment of PAD below-the-knee ("BTK") and arteriovenous ("AV") fistulae, commonly associated with hemodialysis.

Overview of Surmodics' Surface Modification and Device Drug Delivery Technologies

We believe Surmodics is positioned to take advantage of the continuing trend of incorporating surface modification and device drug delivery technologies into the design of combination products, potentially leading to more efficient and effective products as well as new product applications. We have a growing 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, us, and the healthcare industry.

Coatings for Surface Modification and Device Drug Delivery

Key differentiating characteristics of our coating platforms are their flexibility, durability and ease of use. In terms of flexibility, coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents. Additionally, the surface modification process can be tailored to provide customers with the ability to improve their devices' performance by choosing the specific coating properties desired for particular applications. Our surface modification technologies also can be combined to deliver multiple surface-enhancing characteristics on the same device.

Our proprietary PhotoLink® coating technology is a versatile, easily applied, coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. PhotoLink coatings can impart many performance enhancing characteristics, such as advanced lubricity (slippery) and hemocompatibility (preventing blood clot formation), when bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices.

PhotoLink reagents can be applied to a variety of substrates. The coating formulations are easily applied to the material surface by a variety of methods including, but not limited to, dipping, spraying, roll-coating or ink-jetting. We continue to expand our 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 coating process is relatively simple to use and is easily integrated into the customer's manufacturing process. In addition, the process does not subject the coated products to harsh chemical or temperature conditions, produces no hazardous byproducts, and does not require lengthy processing or curing time. Further, our PhotoLink coatings are generally compatible with accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

We launched our Serene® hydrophilic coating platform in fiscal 2013, which optimizes lubricity and durability while significantly reducing particulates generation. This next-generation coating has demonstrated excellent lubricity on a wide range of substrates, and has been used on FDA-cleared coronary, peripheral and structural heart devices. Serene coatings are applied using our PhotoLink process.

Our device drug delivery coating technologies allow therapeutic drugs to be incorporated within our proprietary polymer matrices to provide controlled, site-specific release of the drug into the surrounding environment. The 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 drug coated balloons and examples of longer-term drug delivery devices would include drug eluting stents. We work with companies in the medical device and biotechnology industries to develop specialized coatings that allow for the controlled release of drugs from device surfaces. We see at least three primary areas with strong future potential: (1) improving the function of a device which itself is necessary to treat the medical condition; (2) enabling site-specific drug delivery while limiting systemic exposure; and (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

Licensing Arrangements

We commercialize our surface modification and device drug delivery technologies primarily through licensing arrangements with medical device manufacturers. We believe this approach allows us to focus our resources on

further developing new technologies and expanding our licensing activities. Many of our technologies have been designed to allow manufacturers to implement them easily into their own manufacturing processes so customers can control production and quality internally without the need to send their products to a contract manufacturer.

We generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 43.5%, 46.5% and 51.3% of our total revenue in fiscal 2017, 2016 and 2015, respectively. Greater than 96% of our royalties and license fees revenue in this three-year period were generated from hydrophilic coating licenses. Revenue from these licensing arrangements typically includes license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees' product sales. We also generate revenue from reagent chemical sales to licensees for use in their coating processes.

The licensing process begins with the customer specifying a desired product feature to be created such as lubricity or drug delivery. Because each device and coating application is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating commercial development revenue. Feasibility studies can range in duration from several months to a year. After we complete a feasibility study, our customers cannot market their product until they receive regulatory approval. As further described under the caption “Government Regulation,” the regulatory approval process varies in each country and ranges from several months to four or more years. At any time prior to a customer’s commercial launch, a license agreement may be executed granting the licensee rights to use our technology. We often support our customers by providing coating assistance for parts required in animal tests and human clinical trials. Typically, we complete a technology transfer to most customers which enables those customers to apply the coating at their own facilities.

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 following 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 applications are nonexclusive, allowing us to license technology to multiple customers. Moreover, even exclusive licenses generally are limited to a specific “field of use,” allowing us the opportunity to further license technology to other customers. The royalty rate on a substantial number of the agreements has traditionally been in the 2% to 3% range, but there are certain contracts with lower or higher rates. In certain agreements, our royalty is based on an agreed-upon amount per unit. 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 currently recognize royalty revenue in the quarter customer royalty payments are due to us. Commencing in fiscal 2019 we are required to adopt a new revenue recognition accounting standard that will require us to recognize and accrue royalty revenue 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 17, 18 and 22 new licenses in fiscal 2017, 2016 and 2015, respectively.

Under our customer 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. Given the significant uncertainty inherent in product development and regulatory approval processes, the expected timing for regulatory approval and commercialization for the product classes pending regulatory approval is can vary greatly.

Our licensing agreements generally require us to keep our customers’ identities confidential, unless they approve of such disclosure. Licensed customers who allow the use of their name include: Abbott Laboratories (“Abbott”), Boston Scientific Corporation (“Boston Scientific”), Cook Medical, Cordis Corporation (a subsidiary of Cardinal Health, Inc.) (“Cordis”), Covidien PLC (a subsidiary of Medtronic), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), ev3 Inc. (a subsidiary of Medtronic), Medtronic, OrbusNeich Medical, Inc., 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 or sell components for in vitro diagnostic immunoassay and molecular tests and we manufacture and sell surface coatings to the diagnostic, biomedical research, and life science markets.

Immunoassay Diagnostics. An immunoassay is a biochemical test that measures the presence or concentration of a target molecule, or “analyte”, in a biological fluid or sample. Analyte levels are correlated to the patient’s disease state or medical condition of a patient 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 United States, Canada and Puerto Rico (and non-exclusive distributor in Japan) of DIARECT AG's line of antigens. Because of the lack of high-quality antigens from natural sources, DIARECT produces the majority of these antigens and other components using recombinant technology.

Surface Coatings for Molecular Diagnostic Applications. We offer custom coatings for molecular diagnostic applications, including DNA, RNA and protein microarrays. Our TRIDIA™ surface coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive groups. This proprietary technology immobilizes DNA and protein to adhere to testing surfaces. We offer other surface coatings that improve flow characteristics through membranes and microfluidic channels on diagnostic devices including point-of-care components.

Research and Development

Our R&D personnel work to enhance and expand our technology and product offerings in the area of 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, 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.

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In fiscal 2017, 2016 and 2015, our R&D expenses were \$31.8 million, \$18.5 million and \$16.2 million, respectively. Included in R&D expenses are the costs associated with our research, development and other revenue. We intend to continue significantly investing 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 2018 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-products solutions R&D activities are primarily focused on the peripheral vascular market, where we believe the integration of our surface modification, balloon catheter 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. We are doing this by developing or acquiring technologies and funding development activities that may include pre-clinical and clinical studies.

With the Fiscal 2016 Acquisitions and subsequent investments in our R&D infrastructure and facilities, we have strengthened our capabilities and broadened our capacity for R&D activities. Our facility in Ballinasloe, Ireland is fully equipped for R&D and manufacturing and is focused on design and manufacture of peripheral vascular devices. This facility's capabilities include balloon forming, extrusion, coating, braiding and assembly of finished products. The facility is equipped for medical device R&D and manufacturing with space for future growth. In the first quarter of fiscal 2017, we completed an expansion of R&D and manufacturing clean rooms as well as an analytical lab to support our whole-product solutions strategy. With the NorMedix acquisition, we obtained a differentiated catheter-technology platform and additional design and development expertise that have enhanced the value we offer our medical device customers and accelerated our development of proprietary medical device products. 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 over the next 5 years. Additional planned activities include initiation of surface modification experiments that improve medical device performance, as well as incorporation of our catheter technology platform into various other devices intended for the emerging peripheral vascular treatment market. We received FDA clearance and CE Mark for the .014" PTA balloon catheter in the fourth quarter of fiscal 2017 and we expect to receive regulatory clearance for several additional, newly-developed products during calendar 2018.

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 direct 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 2016 we launched StabilBlock® Immunoassay Stabilizer, our most advanced stabilizer product.

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, six-month results indicated that acute success measures of safety were achieved in all patients, as well as 100 percent primary patency and encouraging late lumen loss at six months post-procedure. 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,

will evaluate 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. Study participants will be randomized to receive either treatment with SurVeil DCB or IN.PACT Admiral DCB. 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 have engaged a clinical research organization to assist us with the administration of the clinical trial. 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 cost of the TRANSCEND clinical trial will range between \$32 million to \$40 million over the next several years.

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.

Patents and Proprietary Rights

Patents and other forms of proprietary rights are an essential part of Surmodics' business. The Company aggressively pursues patent protection covering the proprietary technologies that we consider strategically important to our business. In addition to seeking patent protection in the U.S., we also generally file patent applications in European countries and, on a selective basis, other foreign countries. We strategically manage our patent portfolio so as to ensure that we have valid and enforceable patent rights protecting our technological innovations.

We protect our extensive portfolio of technologies through filing and maintaining patent rights covering a variety of coatings, drug delivery methods, reagents, and formulations, as well as particular clinical device applications. During fiscal 2017, Surmodics filed 4 original U.S. patent applications, as well as 9 international patent applications. As of September 30, 2017, Surmodics owned or had exclusive rights to 55 pending U.S. patent applications and 135 foreign patent applications. Likewise, as of the same date, Surmodics owned or had exclusive rights to 147 issued U.S. patents and 198 international patents.

We have licensed our PhotoLink hydrophilic technology on a non-exclusive basis to a number of our customers for use in a variety of medical device surface applications, including those described above. In particular, we have 30 issued U.S. patents, 10 pending U.S. patent applications, 34 issued international patents, and 32 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

customer's products utilizing this early generation technology to our advanced generation technologies.

The royalty revenue associated with our third-generation technology which has not yet converted, or is not in the process of converting, to our advanced generation technologies was approximately 12% of our fiscal 2017 revenue.

Approximately 21% of our total revenue in fiscal 2017 was generated from the fourth generation of our PhotoLink technology, which are protected by a family of patents that will begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration.

We also rely upon trade secrets, trademarks and other unpatented proprietary technologies. We seek to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will

prevent the unauthorized disclosure or use of this information, or that others will not be able to 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

Our aim is to use our design, development, manufacturing and commercialization 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 customer activities. Our sales professionals' specialization fosters an in-depth knowledge of the issues faced by our customers within these markets such as industry trends, technology changes, biomaterial changes and the regulatory environment. As we complete development of our whole-product solutions medical devices, we are seeking third-parties to sell these products. With respect to our diagnostics products, our sales professionals sell directly to IVD kit manufacturers and we enter into sales and marketing relationships with third parties to distribute those products around the world. We also offer those products for sale through our website. See Note 12 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for information regarding domestic and foreign revenue.

To support our marketing and sales activities, we publish technical literature on our various surface modification, drug delivery, and in vitro diagnostics technologies and products. In addition, we exhibit at major trade shows and technical meetings, advertise in selected trade journals and through our website, and conduct direct mailings to appropriate target markets.

We also offer ongoing customer service and technical support to our customers. This service and support may begin with a feasibility study, and also may include additional services such as assistance in the transfer of the technology to the customer, further optimization, process control and troubleshooting, preparation of product for clinical studies, and assistance with regulatory submissions for product approval. Some of these services are billable to customers, mainly feasibility and optimization activities.

Acquisitions

To further our strategic objectives and strengthen our existing businesses, we intend to continue to explore acquisitions and strategic collaborations to diversify and grow our business. As a result, we expect to make future acquisitions where we believe that we can broaden or enhance our technology offerings and expand our revenue sources and the markets in which we participate. Mergers and acquisitions of medical and diagnostic technology companies are inherently risky, and no assurance can be given that any of our previous or future acquisitions will be successful or will not materially adversely affect our consolidated results of operations, financial condition, or cash flows.

Significant Customers

Revenue from Medtronic represented approximately 18% of our consolidated revenue for the year ended September 30, 2017 and was generated from multiple products and fields of use, substantially all of which were recognized in our Medical Device segment. The percentage of revenue from Medtronic decreased in fiscal 2017 as our customer base was diversified with the Fiscal 2016 Acquisitions. No other customer provided more than 6% of our consolidated revenue in fiscal 2017. Two customers in our IVD business accounted for 13% 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. Upon receiving regulatory clearance for our proprietary products, we plan to seek third parties to sell these whole-product solutions products. Our core balloon and catheter capabilities compete with larger original equipment manufacturer (OEM) suppliers, as well as some of our largest medical device partners that have in-house resources to produce balloons and catheters. We provide differentiated whole-product solutions that integrate our surface modification, catheter, balloon and other proprietary technologies.

Because a significant portion of our revenue depends on 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 technologies, many of the large medical device manufacturers have developed, or are engaged in efforts to develop, internal competency in the area of surface modification and device drug delivery.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value-added approach to drug delivery and surface modification technology. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility), 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 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, recombinant autoimmune antigens and surface chemistry technologies), we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Some of our competitors have substantially more capital resources, marketing experience, R&D resources and production facilities than we do. We believe that our products compete on performance, stability (shelf life), sensitivity (lower levels detected, faster results), consistency and price. We believe that our continued competitive success will depend on our ability to gain market share, to develop or acquire new proprietary products, obtain patent or other protection for our products and successfully market our products directly or through partners.

Manufacturing

We manufacture our surface modification and drug delivery reagents, and our IVD products in our Eden Prairie, Minnesota facility. In certain limited circumstances, we also provide contract manufacturing services for our customers, including, for example, coating their medical devices that are intended for pre-clinical and clinical development (including human clinical trials), and products that are sold for commercial use by our customers. We manufacture balloon catheters 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 Irish facility by the end of fiscal 2018.

We attempt to maintain multiple sources of supply for the key raw materials used to manufacture our products. We do, however, purchase some raw materials from single sources, but we believe that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, we believe that we could manufacture such raw materials.

We follow quality management procedures in accordance with applicable regulations and guidance for the development and manufacture of materials and device, biotechnology or combination products that support clinical trials and commercialization. In an effort to better meet our customers' needs in this area, our Eden Prairie, Minnesota facility is certified to ISO 13485 and ISO 9001. Our facility in Ballinasloe, Ireland is certified to ISO 13485. Each of these facilities is registered with the U.S. FDA as a "Contract Manufacturer."

Government Regulation

The medical devices, IVD and biotechnology products incorporating our technologies are required to undergo long, expensive and uncertain regulatory review processes that are governed by the U.S. FDA and other international regulatory authorities. New medical devices utilizing our surface modification coating technologies can only be marketed in the U.S. after a 510(k) application has been cleared or a PMA application has been approved by the FDA. This process can take anywhere from several months (e.g., for medical device products seeking regulatory approval under the 510(k) approval process) to several years (e.g., for medical device products seeking regulatory approval under the PMA 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. During fiscal 2017, 2016 and 2015, Surmodics had multiple customers obtain regulatory clearance on medical devices incorporating our Serene coating platform. With respect to our whole-product solutions, including the SurVeil DCB 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' regulatory filings, we maintain various confidential Device Master Files with the FDA and provide technical information to other regulatory agencies outside the U.S. regarding the nature, chemical structure and biocompatibility of our reagents. Our licensees generally do not have direct access to these files. However, they may, with our permission, reference these files in their various regulatory submissions to these agencies. This approach allows regulatory agencies to understand in confidence the details of our technologies without us having to share this highly confidential information with our customers.

U.S. legislation allows companies, prior to obtaining FDA clearance or approval to market a medical product in the U.S., to manufacture medical products in the U.S. and export them for sale in international markets. This generally allows us to realize earned royalties sooner. However, sales of medical products outside the U.S. are subject to international requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required by the FDA.

Employees

As of November 30, 2017, we had 257 employees. Of these employees we employ 101 outside the U.S., primarily in R&D and manufacturing operations functions. We are not a party to any collective bargaining agreements.

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

EXECUTIVE OFFICERS OF THE REGISTRANT

As of December 1, 2017, the names, ages and positions of the Company's executive officers are as follows:

| Name | Age | Position |
|-----------------------|-----|---|
| Gary R. Maharaj | 54 | President and Chief Executive Officer |
| Timothy J. Arens | 50 | Vice President of Corporate Development and Strategy |
| Thomas A. Greaney | 51 | Chief Operating Officer, Medical Devices |
| Andrew D. C. LaFrence | 54 | Vice President of Finance and Information Systems and Chief Financial Officer |
| Charles W. Olson | 53 | Senior Vice President of Commercial and Business Development, Medical Devices |
| Bryan K. Phillips | 46 | Senior Vice President, Legal and Human Resources, General Counsel and Secretary |
| Joseph J. Stich | 52 | Vice President and General Manager, In Vitro Diagnostics |
| Gregg S. Sutton | 58 | Vice President of 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. Mr. Maharaj holds an M.B.A. from the University of Minnesota's Carlson School of Management, an M.S. in biomedical engineering from the University of Texas at Arlington and the University of Texas Southwestern Medical Center at Dallas, and a B.Sc. in Physics from the University of the West Indies.

Timothy J. Arens joined the Company in February 2007 as Director, Business Development and became Senior Director of Financial Planning and Analysis and General Manager, In Vitro Diagnostics in October 2010. He was promoted to Vice President of Finance and Interim Chief Financial Officer in August 2011 and in February 2013 became Vice President Corporate Development and Strategy. Prior to joining Surmodics, Mr. Arens was employed at St. Jude Medical, Inc., a medical technology company, from 2003 to 2007, in positions of increasing responsibility related to business development and strategic planning functions. Mr. Arens received a B.S. degree in Finance from the University of Wisconsin Eau Claire in 1989 and an M.B.A. degree from the University of Minnesota's Carlson School of Management in 1996.

Thomas A. Greaney joined the Company in November 2015 as Vice President of Operations and General Manager of Creagh Medical, after we acquired it. In August 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. Mr. Greaney received a B.E in Industrial Engineering in 1988 and a post grad Diploma in Quality Assurance in 1989, both from the National University of Ireland Galway.

Andrew D. C. LaFrence joined the Company in February 2013 as Vice President of Finance and Chief Financial Officer and was also named Vice President of Information Systems in August 2016. Prior to joining Surmodics, he served as Chief Financial Officer for CNS Therapeutics, which developed and marketed pharmaceuticals for site-specific drug delivery to the central nervous system, from January 2011 to January 2013. Prior to joining CNS,

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

Charles W. Olson joined the Company in July 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, Sales was added to his responsibilities. In November 2008, Mr. Olson was named Vice President of our Cardiovascular business unit,

in October 2010, he was named Senior Vice President and General Manager, Medical Device, and in August 2016 he was named Senior Vice President of Commercial and Business Development, Medical Devices. Prior to joining Surmodics, Mr. Olson was employed as General Manager at Minnesota Extrusion from 1998 to 2001 and at Lake Region Manufacturing in project management and technical sales from 1993 to 1998. Mr. Olson received a B.S. degree in Marketing from Winona State University in 1987.

Bryan K. Phillips joined the Company in July 2005 as Patent Counsel and Assistant General Counsel. In January 2006, Mr. Phillips was appointed Corporate Secretary, and he was promoted to Deputy General Counsel in October 2007. He was promoted to Vice President, General Counsel and Corporate Secretary in September 2008 and was promoted to Senior Vice President in October 2010. In August 2011, he became Senior Vice President, Legal and Human Resources, General Counsel and Secretary. Prior to joining Surmodics, Mr. Phillips served as patent counsel at Guidant Corporation's Cardiac Rhythm Management Group where he was responsible for developing and implementing intellectual property strategies and also for supporting the company's business development function. He also practiced law at the Minneapolis-based law firm of Merchant & Gould P.C. Mr. Phillips received a B.S. degree in Mechanical Engineering from the University of Kansas in 1993 and a law degree from the University of Minnesota Law School in 1999. He is admitted to the Minnesota bar and is registered to practice before the U.S. Patent and Trademark Office.

Joseph J. Stich joined the Company in March 2010 as Vice President of Marketing, Corporate Development and Strategy. In August 2011, he became Vice President, Business Operations and General Manager, In Vitro Diagnostics and in September 2013 his role was adjusted to Vice President and General Manager, In Vitro Diagnostics. Before joining Surmodics, Mr. Stich was Vice President of Corporate Development for Abraxis BioScience, LLC, a biotechnology company focused on oncology therapeutics, from 2009 to 2010. Prior to joining Abraxis, he was a Vice President for MGI Pharma, Inc., a biopharmaceutical company, from 2005 to 2009. Mr. Stich's prior experience also includes serving as President/COO of Pharmaceutical Corp. of America (a subsidiary of Publicis Healthcare Specialty Group), and positions of increasing responsibility in sales and marketing at Sanofi-Aventis Pharmaceuticals. He received a B.B.A. degree from the University of Wisconsin — Whitewater in 1988, and an M.B.A. degree from Rockhurst University in Kansas City, Missouri in 1996.

Gregg S. Sutton joined the Company in January 2016 as Vice President of Research and Development, 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. With a degree in mechanical engineering and over 50 patents granted, he has substantial experience in all aspects of medical device development, including intellectual property, design, product development, and manufacturing.

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

ITEM 1A. RISK FACTORS.

RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

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

A significant portion of our revenue is derived from a relatively small number of customers. We have one customer that provided more than 10% of our revenue in fiscal 2017. Revenue from Medtronic represented approximately 18% of our total revenue for the fiscal year ended September 30, 2017 and was generated from multiple products and fields of use. The loss of Medtronic or any of our largest customers, or reductions in business from them, could have a material adverse effect on our business, financial condition, results of operations, and cash flow. There can be no assurance that revenue from any customer will continue at their historical levels. If we cannot broaden our customer base, we will continue to depend on a small number of customers for a significant portion of our revenue.

The long-term success of our business may suffer if we are unable to expand our licensing base.

We intend to continue pursuing a strategy of licensing our coatings technologies to a diverse array base 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 and device drug delivery technologies compete with technologies developed by a number of other companies. In addition, many medical device manufacturers have developed, or are engaged in efforts to develop, drug delivery or surface modification technologies for use on their own products. With respect to commercialization of our whole-product solutions, we expect to face competitive pricing pressures from larger OEM suppliers, as well as some of our largest medical device partners that have in-house resources that produce similar products. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own R&D efforts) have greater financial and technical resources 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 ours. Developments by competitors may render our existing and potential products uncompetitive or obsolete. Furthermore, there can be no assurance that new products or technologies developed by others, or the emergence of new industry standards, will not

render our products or technologies or licensees' products incorporating our technologies uncompetitive or obsolete. Any new technologies that make our drug delivery, surface modification or In Vitro Diagnostics technologies less competitive or obsolete would have a material adverse effect on our business, financial condition and results of operations.

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

Since fiscal 2013, with our investment in our DCB platform, we have been focused on a key growth strategy for our medical device business by expanding to offer whole-product solutions to our medical device customers. Our aim is to provide customers earlier access to highly differentiated 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

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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-products solutions strategy and related strategic initiatives will place substantial demands on our resources and management's time, 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 United States 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-products 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, including our Fiscal 2016 Acquisitions, 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, 2017, we had \$27.3 million of goodwill and indefinite-lived intangible assets on our consolidated balance sheet related to our Medical Device and IVD segments, of which \$19.3 million related to our Fiscal 2016 Acquisitions in 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 the Creagh Medical acquisition. Future impairment of the goodwill or other assets on our balance sheet could materially adversely affect our results of operations.

Research and development costs may adversely affect our operating results.

The success of our business depends on a number of factors, including our continued research and development of new technologies for future commercialization. In recent years, we have expended considerable resources researching and developing our DCB platform. In fiscal 2018, 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 2018 and future periods. Additionally, these activities are subject to risks of failure that are inherent in the development of new medical technologies or products. There can be no assurance that we will be successful in developing new technologies or products, or that any such technology will be commercialized.

We recognize revenue in accordance with various complex accounting standards, and changes in circumstances or interpretations may lead to accounting adjustments.

Our revenue recognition policies involve application of various complex accounting standards, including accounting guidance associated with revenue arrangements with multiple deliverables. Our compliance with such accounting standards often involves management's judgment regarding whether the criteria set forth in the standards have been met such that we can recognize as revenue the amounts that we receive as payment for our products or services. We base our judgments on assumptions that we believe to be reasonable under the circumstances. However, these judgments, or the assumptions underlying them, may change over time. In addition, the SEC or the Financial Accounting Standards Board ("FASB") may issue new positions or revised guidance on the treatment of complex accounting matters. Changes in circumstances or third-party guidance could cause our judgments to change with respect to our interpretations of these complex standards, and transactions recorded, including revenue recognized, for

one or more prior reporting periods, could be adversely affected.

As described below in “Part II, Item 7 Management’s Discussion and Analysis of Financial Condition and Results of Operations.”, the FASB issued new revenue recognition guidance for recognizing revenue from contracts with customers in May 2014. This accounting standard will be effective for us beginning in the first quarter of fiscal 2019. We are currently evaluating the impact that the adoption of this standard will have on our business model and consolidated results of operations, cash flows and financial position. We currently believe the impact will be material due to the risks associated with implementing the new standards and ensuring accuracy in our reporting during the transition, the 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 will also need to update and enhance our internal accounting systems, processes and our internal controls over financial reporting. This 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.

With our fiscal 2016 acquisition of Creagh Medical, 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 2017 and 2016, we recorded foreign currency exchange losses of \$0.5 million and \$0.4 million, respectively. The losses were primarily related to these Euro-denominated liabilities. As our foreign operations expand, the effects may become material to our consolidated financial statements.

We have previously identified material weaknesses in our internal control over financial reporting. While these particular material weaknesses have been remediated, if we do not maintain effective internal control over financial reporting, our operating results could require material modification and our financial reports may not be reliable.

A material weakness was identified in a prior year related to the design and operating effectiveness of our transactional and review controls related to recognition of royalty revenue. We have since remediated the material weakness by taking the steps described below in “Part II, Item 9A. Controls and Procedures.”. The Company conducted an evaluation under the supervision and with the participation of the Company’s management, including the Company’s Chief Executive Officer and Chief Financial Officer regarding the effectiveness of the design and operation of the Company’s disclosure controls and procedures pursuant to Rule 13a-15(b) of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company’s disclosure controls and procedures were effective as of September 30, 2017.

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

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 technologies.

A principal element of our business strategy is to enter into licensing arrangements with medical device and other companies that manufacture products incorporating our technologies. For the fiscal years ended September 30, 2017, 2016 and 2015, we have derived 44%, 47%, and 51%, 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.

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

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

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

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

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

We manufacture all of our Medical Device coating reagents (and provide coating manufacturing services for certain customers) and our IVD products at our Eden Prairie, Minnesota facility. We also manufacture balloon catheter products at our facility in Ballinasloe, Ireland and catheter-based medical devices in limited quantities in Plymouth, Minnesota. If our existing production facilities becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our customers, including certain of our licensees. In particular, because most of our customers use our coating reagents to manufacture their own products that generate royalty revenue for us, failure by us to supply these reagents could result in decreased royalty revenue, as well as decreased revenue from 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 license 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. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers resulting from employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, and regulatory penalties, disrupt our operations and the services that we provide to our customers, damage our reputation and cause a loss of confidence in our products and services, any of which could adversely affect our business and competitive position.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

Our success depends, in large part, on our ability to obtain and maintain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and protect our proprietary rights against infringement by third parties. We have been granted U.S. and foreign patents and have U.S. and foreign patent applications pending related to our proprietary technologies. There can be no assurance that any pending patent application will be approved, that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties,

that the patents of others will not prevent the commercialization of products incorporating our technologies, or that others will not independently develop similar technologies or design around our patents. Furthermore, because we generate a significant amount of our revenue through licensing arrangements, the loss or expiration of patent protection for our licensed technologies will result in a reduction of the revenue derived from these arrangements which may have a material adverse effect on our business, cash flow, results of operations, financial position and prospects.

We may become involved in expensive and unpredictable patent litigation or other intellectual property proceedings which could result in liability for damages, or impair our development and commercialization efforts.

Our commercial success also will depend, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property rights in the medical device and pharmaceutical industries, and intellectual property litigation may be used against us as a means of gaining a competitive advantage. Intellectual property litigation is complex, time consuming and expensive, and the outcome of such litigation is difficult to predict. If we were found to be infringing any third-party patent or other intellectual property right, we could be required to pay significant damages, alter our products or processes, obtain licenses from others, which we may not be able to do on commercially reasonable terms, if at all, or cease commercialization of our products and processes. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

Patent litigation or certain other administrative proceedings may also be necessary to enforce our patents or to determine the scope and validity of third-party proprietary rights. These activities could result in substantial cost to us, even if the eventual outcome is favorable to us. An adverse outcome of any such litigation or interference proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using our technology. Any action to defend or prosecute intellectual property would be costly and result in significant diversion of the efforts of our management and technical personnel, regardless of outcome, and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through trade secret or confidentiality agreements with our employees, consultants, potential licensees, or other parties as well as through other security measures. There can be no assurance that these agreements or any security measure will provide meaningful protection for our unpatented proprietary information. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we determine that our proprietary rights have been misappropriated, we may seek to enforce our rights which would draw upon our financial resources and divert the time and efforts of our management, and could have a material adverse effect on our business, financial condition and results of operations.

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

In our Medical Device business unit, we have licensed our PhotoLink hydrophilic technology to a number of our customers for use in a variety of medical device surface applications. We have several U.S. and international issued patents and pending international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and the anticipated expiration dates of the patent applications range from 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 12% of our fiscal 2017 revenue.

Approximately 21% of our total revenue in fiscal 2017 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 2017, we continued the development of the SurVeil DCB, including investigating additional clinical applications and uses of the platform. In October 2017, 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 for calendar 2016 and 2017, their status is unclear for 2018 and 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 United States 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. In the fiscal year ended September 30, 2017, the sale price for our common stock ranged from \$21.90 to \$31.80 per share. The market prices for securities of medical technology, drug delivery and biotechnology companies historically have been highly volatile, and the market has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies.

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ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal operations are located in Eden Prairie, a suburb of Minneapolis, Minnesota, where we own a building that has approximately 64,000 square feet of space. We also own a 30,000 square foot building in Ballinasloe, Ireland dedicated to our Medical Device operating segment. We lease a warehouse near our Eden Prairie facility through 2021 and a R&D-focused facility in Plymouth, Minnesota through May 2018. Upon termination of the Plymouth lease in May 2018, we plan to move substantially all of our U.S. Medical Device whole-product solutions R&D operations into a 36,000 square foot leased facility 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." The table below sets forth the quarterly high and low sales price ranges for our Common Stock, as reported by NASDAQ, in each of the last two fiscal years.

| Fiscal Quarter Ended: | High | Low |
|-----------------------|---------|---------|
| September 30, 2017 | \$31.80 | \$24.24 |
| June 30, 2017 | 29.26 | 22.35 |
| March 31, 2017 | 26.50 | 21.90 |
| December 31, 2016 | 30.75 | 23.45 |
| September 30, 2016 | 30.28 | 22.58 |
| June 30, 2016 | 24.23 | 18.45 |
| March 31, 2016 | 21.45 | 17.45 |
| December 31, 2015 | 24.98 | 19.64 |

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 24, 2017, there were 170 holders of record of our common stock.

To date, Surmodics has not paid or declared any cash dividends on its common stock. The declaration and payment by Surmodics of future dividends, if any, on its common stock will be at the sole discretion of the Board of Directors and will depend on Surmodics' continued earnings, financial condition, capital requirements and other factors that the Board of Directors deems relevant.

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. The share repurchase program does not have a fixed expiration date.

During the three months ended September 30, 2017, the Company repurchased 26,322 shares of its common stock in open market purchases for an average price of \$24.92 per share. 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, 2012 and assume reinvestment of dividends.

ITEM 6. SELECTED FINANCIAL DATA.

The data presented below as of September 30, 2017 and 2016 and for the fiscal years ended September 30, 2017, 2016 and 2015 is derived from our audited consolidated financial statements included elsewhere in this report. The data as of September 30, 2015, 2014 and 2013 and for the years ended September 30, 2014 and 2013 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 | | | | |
|--|---|----------|----------|----------|----------|
| | 2017 | 2016 | 2015 | 2014 | 2013 |
| | (Dollars in thousands, except per share data) | | | | |
| Statement of Operations Data: | | | | | |
| Total revenue | \$73,112 | \$71,366 | \$61,898 | \$57,439 | \$56,132 |
| Operating income from continuing operations | 7,103 | 16,859 | 19,089 | 18,576 | 18,820 |
| Income from continuing operations | 3,926 | 9,985 | 11,947 | 12,207 | 14,579 |
| (Loss) income from discontinued operations | — | — | — | (176) | 588 |
| Net income | 3,926 | 9,985 | 11,947 | 12,031 | 15,167 |
| Diluted income (loss) per share: | | | | | |
| Continuing operations | 0.29 | 0.76 | 0.90 | \$0.88 | \$0.99 |
| Discontinued operations | — | — | — | (0.01) | 0.04 |
| Net income | 0.29 | 0.76 | 0.90 | 0.87 | 1.03 |
| Balance Sheet Data: | | | | | |
| Cash, short-term and long-term investments | \$48,336 | \$46,941 | \$55,588 | \$63,374 | \$58,104 |
| Total assets | 136,593 | 132,894 | 98,710 | 104,889 | 101,923 |
| Retained earnings | 102,072 | 98,146 | 88,161 | 93,881 | 91,036 |
| Total stockholders' equity | 111,557 | 106,833 | 81,873 | 98,751 | 93,817 |
| Statement of Cash Flows Data: | | | | | |
| Net cash provided by operating activities from continuing operations | \$14,053 | \$25,166 | \$15,066 | \$18,537 | \$17,781 |

Note: Fiscal 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. In fiscal 2017, our business performance continued to be driven by growth in our core Medical Device and In Vitro Diagnostics (“IVD”) businesses, while we continued medical device product and platform development leveraging the technologies and manufacturing capabilities acquired with the Fiscal 2016 Acquisitions in our Medical Device business unit. Revenue in the Medical Device business consists of medical device and reagent product sales, royalty revenue from licenses of our surface modification coating technologies as well as contract coating and other design and development services. Our In Vitro Diagnostics business sells diagnostic technology products and coatings technologies to the diagnostic, biomedical research, and life science markets.

We operate two reportable business or segments as follows: (1) the Medical Device unit, which is comprised of manufacturing balloons and catheters used for a variety of interventional cardiology, peripheral and other applications, surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices, as well as drug delivery coating technologies to provide site-specific drug delivery from the surface of a medical device, with end markets that include coronary, peripheral, and neurovascular, and urology, among others, and (2) the In Vitro Diagnostics unit, which consists of

component products and technologies for diagnostic immunoassay as well as molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

We 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 and device drug delivery technologies to customers; the vast majority (typically in excess of 90%) of revenue in the “royalties and license fees” category is in the form of royalties; 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 96% of our royalty and license fee revenue in fiscal 2017, 2016 and 2015 is associated with our hydrophilic coating technology licenses. 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 technology was approximately 12% of our fiscal 2017 revenue. Approximately 21% of our total revenue in fiscal 2017 was royalty and license fee revenue generated from fourth-generation hydrophilic coating technologies, which are protected by a family of patents that begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. The remainder of our royalty revenues are derived from other Surmodics coatings that are protected by a number of patents that extend to at least fiscal 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. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) shipment has occurred or delivery has occurred if the terms specify destination; (3) the sales price is fixed or determinable; and (4) collectability is reasonably assured. When there are additional performance requirements, revenue is recognized when all such requirements have been satisfied. 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. Royalty revenue is recognized as our licensees report it to us, and payment is typically submitted concurrently with their reporting. For stand-alone license

agreements, up-front license fees are recognized over the term of the related licensing agreement. Minimum royalty fees are recognized in the period earned. Revenue related to a performance milestone is recognized upon the achievement of the milestone and meeting specific revenue recognition criteria.

Under revenue arrangements with multiple deliverables, we recognize each separable deliverable as it is earned. We account for revenue using a multiple attribution model in which consideration allocated to R&D activities is recognized as performed, and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive. Accordingly, in situations where a unit of accounting includes both a license and R&D activities, and when a license does not have stand-alone value, we apply a multiple attribution model in which consideration allocated to the license is recognized

ratably, consideration allocated to R&D activities is recognized as performed and milestone payments are recognized when the milestone events are achieved, when such activities and milestones are deemed substantive.

As further described in the New Accounting Pronouncements section, we will adopt a new accounting standard for recognizing revenue on October 1, 2018. We currently plan to adopt 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.

Goodwill and certain indefinite-lived intangible assets are not amortized but are subject, at a minimum, to annual tests for impairment in accordance with accounting guidance for goodwill. These tests require management to make significant judgments and estimates in evaluating whether impairment has occurred and, if so, the amount of that impairment. Evaluating goodwill and indefinite-lived intangible assets for impairment involves the determination of the fair value of our reporting units in which we have recorded goodwill. 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. 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 impairment test will be performed.

The impairment test is a quantitative analysis, whereby Surmodics compares the estimated fair value of the reporting units to which goodwill was assigned to their respective carrying values. This analysis requires the allocation of certain shared corporate assets, liabilities and expenses between the reporting units. In calculating fair value, the Company uses the income and market approaches as its primary indicators of fair value. The income approach is a valuation technique under which the Company estimates future cash flows using the reporting units' financial forecasts, discounted to their present value to estimate the fair value from the perspective of an unrelated market participant. The discount rate used is the Company's estimated weighted average cost of capital, estimated by observing similar metrics in publicly traded guideline companies, adjusted for Company-specific risk factors. The market approach establishes fair value by comparing Surmodics' reporting units to publicly traded guideline companies or by analysis of actual transactions of similar businesses or assets sold. The income approach is tailored to the circumstances of the Company's business, and the market approach is completed to ensure that the results of the income approach are reasonable and in line with comparable companies in the industry. The summation of the Company's reporting units' fair values is compared and reconciled to its market capitalization as of the date of its impairment test as a test of reasonableness.

We performed our annual impairment test of goodwill as of August 31, 2017, and 2016. Based on the results of the assessments, no goodwill impairment charges were recorded during fiscal 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.

Income tax accruals and valuation allowances. When preparing the consolidated financial statements, we are required to estimate the income tax obligations in each of the jurisdictions in which we operate. This process involves estimating the actual current tax obligations based on expected income, statutory tax rates and tax planning opportunities in the various jurisdictions. In the event there is a significant unusual or one-time item recognized in the results of operations, the tax attributable to that item would be separately calculated and recorded in the period the unusual or one-time item occurred. Tax law requires certain items to be included in our tax return at different times than the items are reflected in our results of operations. As a result, the annual effective tax rate reflected in our results of operations is different than that reported on our tax return (i.e., our cash tax rate). Some of these differences are permanent, such as expenses that are not deductible in our tax return, and some are temporary differences that will reverse over time, such as depreciation expense on capital assets. These temporary differences result in deferred tax assets

and liabilities, which are included in our consolidated balance sheets. Deferred tax assets generally represent items that can be used as a tax deduction or credit in our tax returns in future years, for which we have already recorded the expense in our consolidated statements of income. We must assess the likelihood that our deferred tax assets will be recovered from future taxable income, and to the extent we believe that recovery is not likely, we must establish a valuation allowance against those deferred tax assets. Deferred tax liabilities generally represent items for which we have already taken a deduction in our tax return, but we have not yet recognized the items as expense in our results of operations.

Significant judgment is required in evaluating our tax positions, and in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our deferred tax assets. We had total deferred tax assets in excess of total deferred tax liabilities of \$4.0 million and \$5.0 million, respectively, as of September 30, 2017 and 2016, including valuation allowances of \$4.5 million and \$3.8 million, respectively, as of September 30, 2017 and 2016. The valuation allowances related to three items as of September 30, 2017 and 2016. 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, 2017 and 2016, 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 and in fiscal 2016, have been offset by a valuation allowance as it is not more likely than not that the tax assets will be realized in future periods, due to Creagh Medical's history of taxable losses. Accordingly, the allocation of the purchase price of Creagh Medical to the acquired deferred tax assets related to the net operating loss carryforwards was also offset by a valuation allowance. 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 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. The total gross amount of unrecognized tax benefits as of September 30, 2017, 2016 and 2015 was \$1.5 million, \$1.5 million and \$1.2 million, respectively, excluding accrued interest and penalties. Of these unrecognized tax benefits, \$1.2 million, \$1.2 million and \$0.9 million would affect our effective tax rate for fiscal 2017, 2016 and 2015, respectively. Interest and penalties recorded for uncertain tax positions are included in our income tax provision. As of September 30, 2017, 2016 and 2015, \$0.5 million of interest and penalties were accrued at each fiscal year-end, excluding the tax benefits of deductible interest. The Internal Revenue Service ("IRS") commenced an examination of our fiscal 2016 U.S. federal income tax return in the fourth quarter of fiscal 2017. The examination has not been completed. The IRS completed an examination of our U.S. income tax return for fiscal 2012 in fiscal 2014 with an insignificant payment made associated with a timing adjustment. U.S. income tax returns for years prior to fiscal 2013 are no longer subject to examination by federal tax authorities. For tax returns for state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2007. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2012. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to the respective acquisition dates, pursuant to the terms of the related purchase agreements.

In the event that we have determined not to file tax returns with a particular state or local jurisdiction, all years remain subject to examination by the tax authorities. The ultimate outcome of tax matters may differ from our estimates and assumptions. Unfavorable settlement of any particular issue would require the use of cash and could result in increased income tax expense. Favorable resolution could result in reduced income tax expense. Within the next 12 months, we do not expect that our unrecognized tax benefits will change significantly. See Note 8 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for further information regarding changes in unrecognized tax benefits during fiscal 2017, 2016 and 2015.

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

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

Contingent consideration liabilities are remeasured to their fair value each reporting period using projected revenue, discount rates, probabilities of payment, and projected payment dates. Increases or decreases in the fair value of the contingent consideration liability can result from changes in the timing and amount of revenue estimates or in the timing or likelihood of achieving value-enhancing milestones, and changes in discount periods and rates. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model. See further discussion of contingent consideration obligations to former Creagh Medical and NorMedix shareholders, including fair value adjustments recorded in fiscal 2017 and 2016 related to these liabilities, below under “Contingent consideration (gain) accretion expense” in this Item 7 and in Note 3, “Business Combinations,” to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

Results of Operations

Years Ended September 30, 2017, 2016 and 2015

Revenue. Fiscal 2017 revenue was \$73.1 million, a \$1.7 million, or 2% increase from fiscal 2016 revenue of \$71.4 million. Fiscal 2016 revenue was \$71.4 million, a \$9.5 million, or 15% increase from fiscal 2015 revenue of \$61.9 million. Fiscal 2016 revenue included \$4.1 million from our Fiscal 2016 Acquisitions consummated in the first two quarters of fiscal 2016. The table below provides a summary of each operating segment’s annual revenue for the three-year period ended September 30, 2017.

| (dollars in thousands) | For the Year Ended | | | Increase/(Decrease) | | Increase/(Decrease) | |
|------------------------|--------------------|--------------------|--------------------|---------------------|-----|---------------------|------|
| | September 30, 2017 | September 30, 2016 | September 30, 2015 | 2017 vs. 2016 | | 2016 vs. 2015 | |
| Revenue | | | | | | | |
| Medical Device | \$53,983 | \$53,202 | \$45,944 | \$ 781 | 1 % | \$ 7,258 | 16 % |
| In Vitro Diagnostics | 19,129 | 18,164 | 15,954 | 965 | 5 % | 2,210 | 14 % |
| Total Revenue | \$73,112 | \$71,366 | \$61,898 | \$ 1,746 | 2 % | \$ 9,468 | 15 % |

Medical Device. 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 by \$0.4 million from reagents sales and \$0.4 million from balloon catheters and other medical device sales. 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. 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.

During fiscal 2017, 2016 and 2015, \$8.4 million, \$12.1 million, and \$11.0 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). While we believe we will retain a majority of this royalty revenue, there is a royalty rate step down for licensed customers at the time these patents expire, which resulted in a \$3.7 million decrease in royalty revenue in fiscal 2017. We are actively seeking to convert customers using this generation of PhotoLink coatings to our Serene coating technologies. We expect an additional decline of \$2.5 million to \$3.5 million in hydrophilic coating royalties in fiscal 2018 as the result of these patent expirations.

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Revenue in Medical Device was \$53.2 million in fiscal 2016, a 16% increase from \$45.9 million in fiscal 2015. The increase in fiscal 2016 revenue was a result of growth in each of our revenue categories, driven primarily by increased demand for reagents as well as incremental product and research, development and other revenue from our Fiscal 2016 Acquisitions. Product revenue increased by \$1.5 million from reagents sales and \$2.4 million from our Fiscal 2016 Acquisitions. Royalty and licensing revenue improved by \$1.4 million, primarily due to the aforementioned fiscal 2016 royalty revenue items. Further, we realized a \$3.1 million increase in other hydrophilic royalties, which was offset by \$2.1 million decline in hydrophilic royalties as a result of the aforementioned patent expirations. The increase in research, development and other revenue of \$1.9 million was primarily due to incremental revenue from the Fiscal 2016 Acquisitions. There were limited product price increases in fiscal 2017, 2016 and 2015.

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

In Vitro Diagnostics revenue was \$18.2 million in fiscal 2016, a 14% increase from \$16.0 million in fiscal 2015. The increase in 2016 revenue was the result of unit volume increases in substantially all product lines. There were limited product price increases in fiscal 2017, 2016 and 2015.

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

| | For the Year Ended September 30, | | 2016 | | 2015 | |
|--|----------------------------------|---------|----------|---------|---------|---------|
| | 2017 | % Total | 2016 | % Total | 2015 | % Total |
| (dollars in thousands) | Amount | Revenue | Amount | Revenue | Amount | Revenue |
| Product costs | \$11,422 | 16 % | \$10,908 | 15 % | \$8,619 | 14 % |
| Research and development | 31,817 | 44 % | 18,498 | 26 % | 16,165 | 26 % |
| Selling, general and administrative | 20,478 | 28 % | 18,000 | 25 % | 14,906 | 24 % |
| Acquisition transaction, integration and other costs | — | — | 3,187 | 4 % | — | — |
| Acquired intangible asset amortization | 2,419 | 3 % | 2,422 | 1 % | 619 | 1 % |
| Contingent consideration (gain) expense | (127) | 0 % | 1,492 | — | — | — |
| Claim settlement | — | — | — | — | 2,500 | — |

Product costs. Product gross margins (defined as product sales less related product costs) were 65% of product sales in fiscal 2017, 2016 and 2015. The increase in product costs was largely the result of increased product sales, driven by increased demand for our IVD products and, to a lesser extent, increases in reagent and medical device product sales. We expect product gross margins to decrease slightly in fiscal 2018 as we engage in larger-scale manufacturing of our whole-product solutions products in our Irish facility. It will take at least two years to optimize the manufacturing and supply chain infrastructure at this facility as we execute our whole-product solutions strategy.

Research and development expenses. The fiscal 2017 increase in R&D expense of \$13.3 million, or 72%, as compared with fiscal 2016 was primarily the result of additional internal R&D expense related to development of our whole-products solutions products, including our DCB development and clinical study activities. Internal R&D costs include employee costs, professional consulting fees, supplies, materials, facilities and overhead related to the design, development, testing and pursuit of regulatory approval for our products. Additionally, in fiscal 2017, we recognized impairment charges totaling \$0.3 million related to in process R&D intangible assets acquired with the Creagh Medical acquisition. The fiscal 2016 increase from fiscal 2015 of \$2.3 million, or 14%, was primarily the result of

\$1.8 million from our Fiscal 2016 Acquisitions and increased costs from our DCB development activities. We anticipate R&D expenses will range between 55% and 60% of fiscal 2018 revenue as we have begun enrollment in our TRANSCEND clinical trial for the SurVeil DCB and continue to invest in proprietary product development to execute our whole-products strategy.

Selling, general and administrative expenses. Selling, general and administrative (“SG&A”) expenses increased by \$2.5 million or 14%, compared with fiscal 2016, primarily as the result of infrastructure investments to support our whole-products solutions strategy, as well as a \$1.2 million increase in professional services costs associated with accounting, audit and legal services. The fiscal 2016 increase of \$3.1 million or 21%, compared with fiscal 2015 was primarily the result of \$1.4 million of higher stock-based compensation expense as the result of favorable trends in revenue, including the impact of the Fiscal 2016 Acquisitions, and increased compensation under our incentive plans as a result of favorable operating results. Additionally, fiscal 2016 SG&A expenses included \$1.7 million attributable to fiscal 2016 acquisitions. We expect SG&A expenses as a percent of fiscal 2018 revenue to increase slightly from fiscal 2017.

Acquisition transaction, integration and other costs. In fiscal 2016, we incurred \$3.2 million in acquisition transaction, integration and other costs related to our Fiscal 2016 Acquisitions. No acquisitions were completed in fiscal 2017 or 2015.

Acquisition related intangible asset amortization. We acquired certain intangible assets in our Fiscal 2016 Acquisitions and previous acquisitions which are being amortized over periods ranging from four to 14 years. Amortization expense on acquired intangible assets was \$2.4 million in both fiscal 2017 and fiscal 2016. The increase in amortization expense of \$1.8 million from fiscal 2015 to 2016 was the result of the intangible assets acquired with our Fiscal 2016 Acquisitions.

Contingent consideration (gain) accretion expense. In fiscal 2017 and 2016, we recorded \$(0.1) million and \$1.5 million, respectively, of net contingent consideration (gains) expense from changes in the estimated fair value of our contingent consideration obligations stemming from the Fiscal 2016 Acquisitions. In fiscal 2017 and 2016, (gains) losses on contingent consideration fair value adjustments totaling \$(2.3) million and \$0.1 million, respectively, resulted from changes in the amount and expected timing of revenue milestones as well as the probability and timing of achieving non-revenue milestones. Offsetting these gains was expense for the passage of time (i.e. accretion), which aggregated \$2.2 million and \$1.4 million, respectively, for fiscal 2017 and 2016. In fiscal 2018 and 2019, if there are changes in the amount, probability or timing of achievement of contingent consideration milestones, there may be material adjustments in the consolidated statements of income to reflect changes in the fair value of contingent consideration liabilities.

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

| | Year Ended September 30, | | |
|---|-----------------------------|-------|----------|
| (dollars in thousands) | 2017 | 2016 | 2015 |
| Investment income, net | \$390 | \$63 | \$156 |
| Gains on sales of strategic investments, contingent | | | |
| consideration milestone payments and other | 44 | 507 | 496 |
| Foreign exchange loss | (504) | (481) | — |
| Impairment loss on strategic investment | — | — | (1,500) |
| Other (loss) income | \$(70) | \$89 | \$(848) |

Other (loss) income has fluctuated between the fiscal years as a result of gains from available-for-sale securities and strategic investments as well as other-than-temporary impairment losses from strategic investments. The increase in investment income in fiscal 2017 as compared with fiscal 2016 is primarily the result of higher interest rates realized on debt investments. In addition, investment income in fiscal 2016 and 2015 was impacted by lower investment balances as we adjusted our investment portfolio toward a liquid, short-term portfolio as we contemplated strategic acquisitions. We recognized and realized investment losses of less than \$0.1 million in fiscal 2017 and 2016, while we recognized investment gains of \$0.1 million in fiscal 2015. Fiscal 2016 included consideration received from the sale of our ownership interest in a strategic investment of \$0.5 million. Fiscal 2015 included an other-than-temporary impairment loss of \$1.5 million related to our investment in CeloNova, partially offset by a gain of \$0.5 million associated with the sale of our investment in Intersect ENT. Fiscal 2017 and 2016 both included \$0.5 million of foreign currency losses related to Euro-denominated contingent consideration liabilities arising from the Creagh Medical acquisition. These losses reflect the strengthening of the Euro as compared with the U.S. dollar in each respective period.

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

| | Year Ended September 30, | | |
|--|--------------------------|--------|--------|
| | 2017 | 2016 | 2015 |
| Statutory U.S. federal income tax rate | 35.0 % | 35.0 % | 35.0 % |
| State income taxes, net of federal benefit | 0.3 | 0.8 | 0.6 |
| Subsidiary capital gain | — | 15.5 | — |
| Foreign rate differential | 13.5 | 3.7 | — |
| Valuation allowance change | 7.2 | (14.8) | (1.6) |
| Federal and foreign research and development tax credits | (10.0) | (3.4) | (0.4) |
| Stock based compensation | 4.7 | (3.6) | — |
| Manufacturing deduction | (4.4) | (1.6) | — |
| Transaction costs | — | 4.5 | — |
| Contingent consideration (gain) expense | (0.6) | 3.1 | — |
| Other | (1.5) | 1.9 | 0.3 |
| Effective tax rate | 44.2 % | 41.1 % | 33.9 % |

The difference between the 35.0% U.S. federal statutory tax rate and our effective tax rate reflects the impact of various differences between amounts recorded in our consolidated financial statements and our tax return. The income tax provision was \$3.1 million, \$7.0 million and \$6.3 million, respectively, for fiscal 2017, 2016 and 2015 resulting in effective tax rates of 44.2%, 41.1% and 34.5%, respectively. The variability in our fiscal 2017 effective tax rate from the U.S. federal statutory rate is primarily the result of operating losses in Ireland, where the 12.5% statutory rate tax benefits are offset by a full valuation allowance, non-deductible amortization expense, contingent consideration gains and accretion expense associated with the Fiscal 2016 Acquisitions, and foreign currency losses associated with our Creagh Medical Euro-denominated contingent consideration obligations. Also, in fiscal 2017, U.S. federal income tax expense was reduced by an increase in the U.S. federal research and development tax credit resulting from our increased R&D activities. Additionally, we recognized \$0.2 million and \$(0.6) million of net excess tax expense (benefit) realized from share options expired, forfeited, vested or exercised during fiscal 2017 and 2016, respectively. Prior to fiscal 2016, under accounting guidance then in effect, excess tax expense (benefits) were recorded within additional paid-in capital on the consolidated balance sheets.

In fiscal 2016, the effective tax rate was negatively affected by non-deductible transaction costs, contingent consideration accretion expense and acquisition-related amortization expense associated with our Fiscal 2016 Acquisitions. We have historically recorded other-than-temporary impairment losses with no income tax effect as it has not been more likely than not that we would generate sufficient capital gains to realize these benefits. Consequently, other-than-temporary impairments and capital gains, which are both discussed in detail under the caption Other (loss) income, are recorded without any income tax expense or benefit. During the fourth quarter of fiscal 2016, we utilized \$7.5 million of previously generated capital losses by accelerating built-in gains in our IVD subsidiary. This resulted in an increase in our tax basis in IVD and a \$2.6 million reduction in both deferred tax assets and the valuation allowance during fiscal 2016.

We recorded \$0.2 million of retroactive 2015 U.S. research and development tax credit discrete benefits for the period from January 1, 2015 to September 30, 2015 in fiscal 2016 resulting from the December 2015 signing of the Protecting Americans from Tax Hikes Act (“PATH Act”) of 2015. This reduced our fiscal 2016 effective rate by 1.3% in fiscal 2016. The PATH Act made the research and development tax credit permanent. Accordingly, the tax benefits associated with the credit for fiscal 2017 and 2016 have also been included as a benefit and have reduced the effective

rate by 8.2% and 2.1% in the respective fiscal years.

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

Segment Operating Results

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

| (dollars in thousands) | For the Year Ended | | | Increase/(Decrease) | | Increase/(Decrease) | |
|--------------------------------|--------------------|--------------------|--------------------|---------------------|--------|---------------------|--------|
| | September 30, 2017 | September 30, 2016 | September 30, 2015 | 2017 vs. 2016 | | 2016 vs. 2015 | |
| Operating income (loss) | | | | | | | |
| Medical Device | \$6,902 | \$16,975 | \$21,192 | \$ (10,073) | (59)% | \$ (4,217) | (20)% |
| In Vitro Diagnostics | 8,293 | 7,115 | 4,484 | 1,178 | 17 % | 2,631 | 59 % |
| Total segment operating income | 15,195 | 24,090 | 25,676 | (8,895) | (37)% | (1,586) | (6)% |
| Corporate | (8,092) | (7,231) | (6,587) | (861) | 12 % | (644) | 10 % |
| Total operating income | \$7,103 | \$16,859 | \$19,089 | \$ (9,756) | (58)% | \$ (2,230) | (12)% |

Medical Device. The 59% decrease in Medical Device operating income in fiscal 2017, as compared with fiscal 2016, was primarily the result of \$13.2 million in higher R&D expenses and a \$1.4 million decrease in royalty and license fee revenue, partially offset by incremental product gross margin of \$0.4 million from increased segment product sales and \$1.4 million from increased research, development and other revenue. As previously discussed, fiscal 2016 revenue was positively impacted by two fiscal 2016 royalty revenue items, which resulted in \$1.5 million of incremental net revenue. Fiscal 2017 benefited from a \$1.1 million license fee arising from a customer's acquisition and our sale of related jointly-owned intellectual property to the acquirer. Operating expenses, excluding product costs, increased as R&D expense increased by \$13.2 million in fiscal 2017 as we accelerated investment in our whole-product solutions product development, including our DCB program. Further, SG&A expenses increased \$2.5 million due to investment in infrastructure necessary to support our whole-products solutions strategy, as well as \$1.2 million of incremental professional fees related to accounting, audit and legal services. The net decrease in current-year operating income resulting from these items was partially offset by a net gain on the contingent consideration obligations of \$0.1 million in fiscal 2017, as compared with a net expense of \$1.5 million in fiscal 2016.

Operating income decreased by 20% in fiscal 2016 from fiscal 2015. The decrease was primarily the result of \$10.0 million in higher non-product operating expenses, partially offset by \$2.2 million of incremental product gross margin stemming from a \$7.3 million increase in revenue. Revenue for fiscal 2016 includes increased royalty and licensing revenue of \$1.4 million. This increase included the two previously discussed royalty revenue items. Royalty revenue also reflected a decline of \$2.1 million as the result of expiration patents protecting the third generation of our Photolink hydrophilic technology. The remaining increase in revenue in fiscal 2016 was generated by increased product sales of \$3.9 million and research, development and other revenue of \$1.9 million. Our Fiscal 2016 Acquisitions accounted for \$4.1 million of the increases in these two revenue categories. Operating expenses, excluding product costs, increased as a result of transaction, integration, amortization, and contingent consideration accretion expenses totaling \$6.5 million in fiscal 2016 associated with the Fiscal 2016 Acquisitions. Additionally, the Medical Device segment incurred \$3.5 million in higher SG&A and R&D expenses as a result of our Fiscal 2016 Acquisitions.

In Vitro Diagnostics. Operating income in our IVD segment increased by 17% in fiscal 2017 as compared with fiscal 2016 resulting from higher product gross margins as product sales increased by \$1.0 million, partially offset by a related product cost increase of \$0.1 million, as well as lower SG&A costs and acquired intangible amortization expense. Fiscal 2017 operating income benefited from increased demand in most product categories, offsetting a revenue decline from a significant microarray customer that was acquired by one of its competitors. Product gross margins increased from 64.3% in fiscal 2016 to 65.4% in 2017 due to favorable product mix. Operating income benefited from increased operating leverage from higher revenue.

Operating income increased by 59% in fiscal 2016 compared with fiscal 2015 resulting from higher product gross margins as product sales increased by \$2.2 million, partially offset by a related product cost increase of \$0.7 million, as well as lower SG&A costs. Fiscal 2016 operating income benefited from increased demand across all product categories. Product gross margins were 64.3% and 63.7% in fiscal 2016 and 2015, respectively. Direct SG&A expenses decreased by \$0.7 million in fiscal 2016 compared with fiscal 2015 as a result of lower legal expenses from the settlement of a legal matter in the fourth quarter of fiscal 2015.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive, corporate accounting, legal, human resources and Board of Directors related fees and expenses that have not been fully allocated to the Medical Device and In Vitro Diagnostics segments. Corporate also includes expenses, such as litigation, which if not specific to a segment are not allocated to our operating segments. The unallocated Corporate expense operating loss was \$8.1 million, \$7.2 million and \$6.6 million in fiscal 2017, 2016 and 2015, respectively. The \$0.9 million, or 12% increase in corporate expenses in fiscal 2017 as compared with fiscal 2016 was due to increased professional services related to accounting, audit and legal services.

The \$0.6 million, or 10% increase in corporate expenses in fiscal 2016 as compared with fiscal 2015 was due to a \$0.9 million increase in stock-based compensation expense, offset by reductions in other corporate expenses.

Liquidity and Capital Resources

As of September 30, 2017, we had working capital of \$51.1 million, a \$2.7 million increase from \$48.4 million as of September 30, 2016. Working capital is defined by us as current assets minus current liabilities. The increase from the prior-year end is a result of a reduction in accrued compensation and amounts due to customers, as well as strong fourth quarter revenue, resulting in an increase in accounts receivable. Our cash and cash equivalents and available-for-sale investments totaled \$48.3 million as of September 30, 2017, an increase of \$1.6 million from \$46.9 million as of September 30, 2016, principally associated with cash flow from operating activities of \$14.1 million offset by \$6.4 million of plant and equipment expenditures, \$4.7 million paid to repurchase our common stock and \$2.2 million of cash payments for taxes related to net share settlement of equity awards.

The Company's investment policy prohibits ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Throughout 2017 and 2016, the Company made investments in short-term available for sale securities, resulting in an ending balance as of September 30, 2017 and 2016 of \$31.8 million and \$22.0 million, respectively. Our investment policy requires that for investments with a duration of greater than one year, no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity. Management plans to continue to direct its investment advisors to manage the Company's securities investments primarily for the safety of principal for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

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

The Credit Agreement contains affirmative and negative covenants customary for a transaction of this type which, among other things, require the Company to meet certain financial tests. The Credit Agreement also contains covenants which, among other things, limit the Company's ability to: incur unfinanced capital expenditures in an amount greater than \$10.0 million in the aggregate during any fiscal year; incur additional debt; make certain investments; create or permit certain liens; create or permit restrictions on the ability of subsidiaries to pay dividends or make other distributions; consolidate or merge; and engage in other activities customarily restricted in such agreements, in each case subject to exceptions permitted by the Credit Agreement. The Credit Agreement also contains customary events of default, the occurrence of which would permit the Bank to terminate its commitment and accelerate the loans. While we have been in compliance with the Credit Agreement's covenants since inception, there is no assurance that we will continue to be in compliance and our future ability to access funds under our credit facility may be limited. As of September 30, 2017, we had no borrowings outstanding under the line of credit.

We also have entered into a three-year \$5.0 million multicurrency overdraft facility in Ireland.

We believe that our existing cash, cash equivalents and investments, will provide liquidity sufficient to fund our operations and planned capital expenditures in the next twelve months. There can be no assurance, however, that our

business will continue to generate cash flows at current levels. Additionally, disruptions in financial markets or an increase in interest rates may negatively impact our ability to access capital in a timely manner and on attractive terms. In the event Creagh Medical begins to generate taxable income in future years, repatriation of its earnings may result in substantial U.S. tax cost. Our current plans do not foresee a need to repatriate funds as we have designated these funds as permanently reinvested in order to fund our operations or meet currently anticipated liquidity and capital investment needs.

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The following table depicts our cash flows provided by operating activities from continuing operations for fiscal 2017, 2016 and 2015:

| | For the Years Ended | | |
|--|---------------------|----------|----------|
| | September 30, | | |
| | 2017 | 2016 | 2015 |
| (dollars in thousands) | | | |
| Net income | \$3,926 | \$9,985 | \$11,947 |
| Depreciation and amortization | 5,555 | 4,873 | 2,805 |
| Stock-based compensation | 3,472 | 3,844 | 2,381 |
| Contingent consideration (gain) expense | (127) | 1,492 | — |
| Unrealized foreign exchange loss | 474 | 444 | — |
| Deferred taxes | 1,000 | 261 | 93 |
| Impairment losses on intangible assets | 427 | — | — |
| Impairment loss on strategic investment | — | — | 1,500 |
| Net other operating activities | 171 | (567) | (963) |
| Net change in other operating assets and liabilities | (845) | 4,834 | (2,697) |
| Net cash provided by operating activities from continuing operations | \$14,053 | \$25,166 | \$15,066 |

Operating Activities. We generated cash flows from operating activities from continuing operations of \$14.1 million, \$25.2 million and \$15.1 million in fiscal 2017, 2016 and 2015, respectively. Operating cash flow is primarily generated by net income as adjusted for non-cash expenses (benefits) for depreciation and amortization, contingent consideration gain, unrealized foreign exchange loss, stock-based compensation and deferred taxes. Deferred tax asset reductions during fiscal 2017 were primarily related to changes in tax depreciation methods for certain long-lived assets and positively impacted cash flows by \$1.0 million, as compared with \$0.3 million in the prior-year period. Net expense from changes in the fair value of our contingent consideration obligations, including accretion expense, gains on fair value adjustments, and the effects of foreign currency exchange rate losses, declined by \$1.6 million from fiscal 2016 to fiscal 2017 as a result of previously discussed gains from reductions in the estimated fair value of these liabilities.

Net changes in operating assets and liabilities in fiscal 2017 had a negative impact on cash flows of (\$0.8) million as compared with a positive impact of \$4.8 million in fiscal 2016. Significant changes in operating assets and liabilities during these periods included:

• Cash (used) provided by accounts receivable was (\$0.5) million in fiscal 2017, compared with \$0.9 million in fiscal 2016, which benefited from a \$2.4 million customer payment due in the fourth quarter of fiscal 2015 and paid in the first quarter of fiscal 2016. Fiscal 2017 cash flows were negatively impacted by increased accounts receivable balances as product sales increased during the fiscal 2017 fourth quarter as compared with same fiscal 2016 period.

• Cash used for prepaids and other current assets totaled (\$0.6) million in fiscal 2017 as compared with cash provided of \$0.4 million in fiscal 2016. The change was primarily driven by \$0.7 million of increased research and development tax credit assets and other reimbursable R&D expenses included in prepaids and other current assets as of September 30, 2017 as compared with the prior year-end.

• Cash provided by overpaid customer royalties and license fees totaled \$0.1 million during fiscal 2017, as compared with \$1.7 million in fiscal 2016. These overpayments primarily relate to the previously disclosed patent expirations.

The reduction in these amounts reflects improved customer royalty reporting and settlements of customer overpayments.

Cash used for payments of accrued incentive compensation increased by (\$0.5) million from fiscal 2016 to (\$1.3) million during fiscal 2017 as the result of incentive compensation payments related to the improved achievement of performance objectives in fiscal 2016 versus fiscal 2015. Reductions in accrued compensation from fiscal 2016 to fiscal 2017 were offset by increased accrued professional fees, including clinical trial expenses, in fiscal 2017 as compared with the prior year.

Investing Activities. We used cash in investing activities from continuing operations of (\$16.2) million and (\$55.5) million in fiscal 2017 and 2016, respectively, and we generated cash flows from investing activities from continuing operations of \$16.7 million in fiscal 2015. We invested \$6.4 million, \$8.2 million and \$1.9 million in property and equipment in fiscal 2017, 2016 and 2015, respectively. Fiscal 2017 capital expenditures were primarily related to investments in property and equipment to facilitate our whole-products strategy, including the expansion of R&D and manufacturing clean rooms as well as an analytical lab in our Irish

facility. Fiscal 2016 capital expenditures included our purchase of the Irish facility for \$2.8 million and our acquisitions of Creagh Medical and NorMedix for \$25.9 million of net cash. We purchased available-for-sale securities totaling \$9.8 million and \$22.0 million, net of sales proceeds, in fiscal 2017 and 2016, respectively. In fiscal 2016 we received \$0.5 million upon the sale of a strategic investment. In fiscal 2015, we received cash proceeds aggregating \$18.3 million net, from sales of available-for-sale securities as we adjusted our investment portfolio toward a liquid, short-term portfolio as we contemplated strategic acquisitions. In addition, we received cash proceeds of \$0.5 million from our sale of Intersect ENT shares in fiscal 2015.

Financing Activities. We used cash flows from financing activities from continuing operations of (\$6.5) million, (\$0.2) million and (\$19.7) million in fiscal 2017, 2016 and 2015, respectively. The primary financing activities in fiscal 2017 were the repurchase of common stock under our stock repurchase authorization for \$4.7 million and \$2.2 million to purchase common stock to pay employee taxes resulting from both stock option exercise and issuance of common shares associated with our 2014-2016 performance share program. The primary financing activities in fiscal 2016 related to the payment of contingent consideration required by the terms of a prior-year acquisition in our IVD segment and payments of \$0.4 million to purchase common stock to pay employee taxes resulting primarily from the issuance of common shares associated with our fiscal 2013-2015 performance share program. The primary financing activity in fiscal 2015 was related to the repurchase of common stock of \$20.0 million and payments of \$0.8 million to purchase common stock to pay employee taxes resulting primarily from the issuance of common shares associated with our fiscal 2012-2014 performance share program. We also generated \$0.4 million, \$0.5 million and \$0.7 million in fiscal 2017, 2016 and 2015, respectively, from the sale of common stock pursuant to our stock-based compensation arrangements.

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

On November 5, 2014, the Company's Board of Directors authorized it to repurchase up to \$30.0 million ("fiscal 2015 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. An aggregate of \$5.3 million remains outstanding under this authorization. This share repurchase program does not have a fixed expiration date.

During fiscal 2017, we paid \$4.7 million to repurchase 196,190 common shares in open market purchases at an average price of \$23.97 per share. During fiscal 2015, the Company entered into an accelerated share repurchase program ("ASR") with Wells Fargo Bank, National Association. In the aggregate, the Company purchased 847,864 shares under the ASR program for an average price of \$23.59 per share. Based on the facts associated with the agreement, the forward contract was indexed to the Company's common stock and met the U.S. GAAP requirements to be classified as permanent equity. The contract was completed July 8, 2015.

As of December 2, 2017, the Company has an aggregate of \$25.3 million available for future common stock purchases under the current authorization.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to us. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Medtronic is our largest customer at approximately 18% of total consolidated revenue for fiscal 2017. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 4% of our total revenue. No other individual customer using licensed technology constitutes more than 10% of our total revenue.

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

Off-Balance Sheet Arrangements and Contractual Obligations. As of September 30, 2017, we did not have any off-balance sheet arrangements.

Presented below is a summary of contractual obligations as of September 30, 2017 and payments due under these arrangements by period (in thousands). See Note 11 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K for additional information regarding the below obligations.

| (dollars in thousands) | Total | Less | 1-3 | 4-5 | More |
|---------------------------------------|----------|---------|----------|---------|---------|
| | | than | Years | Years | than |
| | | 1 Year | Years | Years | 5 |
| | | Years | | | Years |
| Operating leases (1) | \$273 | \$114 | \$147 | \$12 | \$— |
| Contingent consideration (2) | 18,870 | 1,750 | 17,120 | — | — |
| Minimum annual royalty obligation (3) | 2,360 | 236 | 472 | 472 | 1,180 |
| Clinical trial CRO obligations (4) | 23,208 | 4,218 | 12,344 | 3,883 | 2,763 |
| Total | \$44,711 | \$6,319 | \$30,082 | \$4,367 | \$3,943 |

(1) Operating lease obligations do not reflect contractual obligations for the lease of an R&D facility in Eden Prairie, Minnesota, which we executed in November 2018. This lease requires escalating annual payments of approximately \$0.4 million over a ten-year term.

(2) In connection with the acquisition of Creagh Medical, we are contingently liable for milestone payments aggregating up to €12.0 million (approximately \$14.2 million as of September 30, 2017) to be paid in the quarter ending December 31, 2018. The contingent consideration related to the Creagh Medical acquisition is denominated in Euros and not hedged. In connection with the acquisition of NorMedix, we are contingently liable for milestone payments aggregating up to \$7.0 million, which are payable as earned. While it is not certain if and/or when these payments will be made, the maturity dates included in this table reflect our best estimates. See Note 3 to the consolidated financial statements in “Item 8. Financial Statements and Supplementary Data” in this Annual Report on Form 10-K for additional information regarding the Fiscal 2016 Acquisitions and the related contingent consideration liabilities.

(3) Minimum annual royalty obligation relates to payments associated with an in-bound license agreement whereby we pay, at a minimum, €200,000 euros (equivalent to approximately \$236,000 as of September 30, 2017) to gain access to polymer technology which is utilized in a drug delivery customer license. The agreement includes an early termination clause. However, the future obligations above are presented through September 2027, the remaining term of the agreement, as it is not currently more likely than not that the agreement will be terminated early.

(4) Clinical trial clinical research organization (“CRO”) obligations represent contractual periodic payments for services performed and milestone payments to third-party CROs for clinical trials. The timing of payments and recognition of expenses under these contracts is dependent on enrollment in our ongoing clinical trials and may be different from the amounts presented, which are estimated based on projected enrollment rates. The aggregate future contractual obligation under this arrangement is \$23.2 million as of September 30, 2017.

As of September 30, 2017, our gross liability, including interest and penalties, for uncertain tax positions was \$1.5 million. We are not able to reasonably estimate the amount by which the liability will increase or decrease over an extended period of time or whether a cash settlement of the liability will be required. Therefore, these amounts have been excluded from the schedule of contractual obligations above.

In addition, we may be required to pay stock consideration of up to 480,059 of our common shares related to another business acquisition, contingent on future achievement of certain development objectives of the acquired business. The timing and amount is uncertain, thus we are not able to reasonably estimate whether settlement of the contingent liability will be required. Therefore, this amount has been excluded from the schedule of contractual obligations above.

New Accounting Pronouncements

Accounting Standards to be Adopted

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (ASC Topic 606). Principles of this guidance require entities to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration an entity expects to be entitled to in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This accounting standard will be effective for us beginning in the first quarter of fiscal year 2019 (October 1, 2018) using one of two prescribed retrospective methods. We are currently evaluating the impact that the adoption of this standard will have on our business model and consolidated results of operations, cash flows and financial position. We currently

plan to adopt 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 its hydrophilic license agreements, as well as several additional required financial statement footnote disclosures. Under the modified retrospective approach, we will apply the new revenue standard to all new revenue contracts initiated on or after the effective date, and, for contracts which have remaining obligations as of the effective date, we will enter an adjustment to the opening balance of retained earnings.

In February 2016, the FASB issued ASU No. 2016-02, Leases (ASC Topic 842). The new guidance primarily affects lessee accounting, while accounting by lessors will not be significantly impacted by the update. The update maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for us beginning the first quarter of fiscal year 2020 (October 1, 2019) using a modified retrospective approach. Based on lease contracts in place as of December 1, 2017, we believe the impact will be material due to the right-of-use assets and lease liabilities that will be recorded on our consolidated balance sheets upon adoption of the standard.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (ASU Topic 326), Measurement of Credit Losses on Financial Statements. This accounting standard requires a financial asset (or a group of financial assets) measured at an amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The accounting standard will be effective for us beginning in the first quarter of fiscal 2020 (October 1, 2019), and early adoption is permitted. We currently are evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position. Based on a preliminary assessment, we currently estimate the impact will not be material as we historically have not had significant collectability concerns with our customers.

Accounting Standards Adopted

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new guidance clarifies requirements for presentation and classification of the following items within the statement of cash flows: debt prepayments, settlement of zero coupon debt instruments, contingent consideration payments, insurance proceeds, securitization transactions and distributions from equity method investees. The update also addresses classification of transactions that have characteristics of more than one class of cash flows. We early-adopted this accounting standard in the fourth quarter of fiscal 2017 with no material impact on our consolidated statement of cash flows. Under the guidance, if and when our contingent consideration liabilities are paid, a portion of the payment will be classified as cash flows from operations, with the remainder classified as cash flows from financing activities.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The new guidance removes Step 2 of the goodwill impairment test, which required a hypothetical purchase price allocation. A goodwill impairment will now be defined as the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. We early-adopted this accounting standard in the fourth quarter of fiscal 2017 with no impact on our consolidated financial statements, as we have not been required to complete Step 2 of the goodwill impairment test.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of commercial paper instruments and corporate bonds with varying maturity dates, all of which are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. Surmodics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. As of September 30, 2017, the Company did not have any outstanding borrowings on its credit facility and owned no interest-bearing securities with more than ten months remaining till maturity, and therefore a one percentage point increase in interest rates would not have a material impact on the results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial

instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements, corporate bonds and commercial paper instruments.

Management believes that a change in raw material prices would not have a material impact on future earnings or cash flows because our inventory exposure is not material.

With the Creagh Medical acquisition in November 2015, we are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening as compared with the Euro, our revenue and expenses denominated in Euro's are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. During fiscal 2017 and fiscal 2016, we recognized \$0.5 million and \$0.4 million, respectively, in foreign currency losses which were primarily related to this Euro-denominated obligation. Prior to this acquisition, our international operations consisted primarily of sales of reagent and stabilization chemicals and changes in foreign currencies relative to the U.S. Dollar did not have a significant effect on our operations. All sales transactions are denominated in U.S. dollars or Euros. We generate royalty revenue from customers' product sales in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in U.S. Dollars or Euros. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The consolidated balance sheets as of September 30, 2017 and 2016 and the consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2017, together with Report of Independent Registered Public Accounting Firm and related notes (including selected unaudited quarterly financial data) begin on page F-1 of this Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

1. Disclosure Controls and Procedures.

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected.

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of September 30, 2017, the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, the Certifying Officers concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective as of September 30, 2017, as designed and implemented to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

2. Internal Control over Financial Reporting.

a. Management's Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our consolidated financial statements.

Management evaluated the design and operating effectiveness of the Company's internal control over financial reporting based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation, management concluded that internal control over financial reporting was effective as of September 30, 2017.

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

A material weakness in the Company's internal control over financial reporting was reported in "Item 9A. Controls and Procedures" of the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2016 because the Company did not have effective transactional and review controls related to royalty revenue recognition. The ineffectiveness of these internal controls did not result in a restatement of previously issued interim or annual consolidated financial statements. This material weakness has been remediated as of September 30, 2017. Accordingly, management concluded that the Company's internal control over financial reporting and our internal control over financial reporting was effective as of September 30, 2017.

The Company's independent registered public accounting firm, Deloitte & Touche LLP, who audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the effectiveness of management's internal control over financial reporting as of September 30, 2017. This report states that internal control over financial reporting was effective and appears on page F-1 of this Annual Report on Form 10-K.

b. Changes in Internal Controls Over Financial Reporting.

Except for the changes described below, that existed as of September 30, 2016, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended September 30, 2017 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

During fiscal 2016 and in the first quarter of fiscal 2017, the Company's management designed and implemented certain changes in processes and controls for the purpose of remediating the material weakness described above that existed as of September 30, 2016, and enhancing the Company's internal control over financial reporting as follows:

- Enhanced the evaluation and analysis of royalties reported and/or paid by customers to determine the proper amount of revenue to be recognized based on terms of the relevant license agreement, including comparison of amounts reported by customers to management's expectations.

- Established quarterly meetings of a cross-functional team from our Medical Device business development, accounting and legal departments to review and evaluate license agreements and royalty revenue in order to identify circumstances that could impact royalty revenue recognition with an emphasis on the review of the analysis generated from the preceding control, new or amended licenses, licenses impacted by expired or expiring patents, non-routine royalty revenue as well as the status of current customer inquiries related to reported and unpaid royalty revenue.

- Augmented proactive communications with customers and internal departments related to patent expirations, license terms and license utilization.

- Established a process for ongoing monitoring, review and conclusion of customer investigations or inquiries. These matters are identified from a review of customer license agreements, customer utilization of the Company's technology, royalty revenue reporting and discussions with customers, among other things.

Based on the observed operating effectiveness of the above controls, management has concluded that, as of September 30, 2017, the material weakness has been remediated.

The foregoing has been approved by our management, including our Chief Executive Officer and Chief Financial Officer, who have been involved with the reassessment and analysis of our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by Item 10 relating to directors, our audit committee, the nature of changes, if any, to procedures by which our shareholders may recommend nominees for directors, our code of ethics and compliance with Section 16(a) of the Exchange Act is incorporated herein by reference to the sections entitled “Election of Directors,” “Section 16(a) Beneficial Ownership Reporting Compliance,” “Corporate Governance — Code of Ethics and Business Conduct,” “Corporate Governance — Corporate Governance and Nominating Committee; Procedures and Policy” and “Audit Committee Report,” which will appear in the Company’s Proxy Statement for its 2018 Annual Meeting of Shareholders. The information required by Item 10 relating to executive officers appears in Part I of this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 is incorporated herein by reference to the sections entitled “Executive Compensation and Other Information,” “Compensation Discussion and Analysis,” “Director Compensation During Fiscal 2017” and “Organization and Compensation Committee Report,” which will appear in the Company’s Proxy Statement for its 2018 Annual Meeting of Shareholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by Item 12 is incorporated herein by reference to the sections entitled “Principal Shareholders,” and “Management Shareholdings” which will appear in the Company’s Proxy Statement for its 2018 Annual Meeting of Shareholders.

Equity Compensation Plan Information

The following table provides information related to the Company’s equity compensation plans in effect as of September 30, 2017:

| Plan Category | (a) Warrants and Rights | (b) Weighted-Average Exercise Price of Outstanding Options, | (c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) | |
|-------------------------------|----------------------------|--|---|-----|
| | | | (1) | (2) |
| Equity compensation plans | | | | |
| approved by shareholders | 1,302,465 | (1) \$ 16.57 | (1) 888,546 | (2) |
| Equity compensation plans not | | | | |
| approved by shareholders | — | N/A | — | |
| Total | 1,302,465 | \$ 16.57 | 888,546 | |

(1) Excludes shares that may be issued under the Company's amended and restated 1999 Employee Stock Purchase Plan, but includes amounts reserved for previously-granted restricted stock and performance share awards under the 2009 Equity Incentive Plan.

(2) Includes 888,546 shares available for future issuance under the 2009 Equity Incentive Plan. Excludes 205,734 shares available under the amended and restated 1999 Employee Stock Purchase Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by Item 13 is incorporated herein by reference to the sections entitled "Corporate Governance — Related Person Transaction Approval Policy" and "Corporate Governance — Majority of Independent Directors; Committees of Independent Directors," which will appear in the Company's Proxy Statement for its 2018 Annual Meeting of Shareholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by Item 14 is incorporated herein by reference to the section entitled "Audit Committee Report," which will appear in the Company's Proxy Statement for its 2018 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) 1. Financial Statements

The following statements are included in this report on the pages indicated:

| | |
|--|-----------------|
| <u>Report of Independent Registered Public Accounting Firm</u> | Page (s) F-2 |
| <u>Consolidated Balance Sheets</u> | F-3 |
| <u>Consolidated Statements of Income</u> | F-4 |
| <u>Consolidated Statements of Comprehensive Income</u> | F-5 |
| <u>Consolidated Statements of Stockholders' Equity</u> | F-6 |
| | F-7 to |
| <u>Consolidated Statements of Cash Flows</u> | F-8 |
| | F-9 to |
| <u>Notes to Consolidated Financial Statements</u> | F-35 |

2. Financial Statement Schedule. See Schedule II — “Valuation and Qualifying Accounts” in this section of this Form 10-K. All other schedules are omitted because they are inapplicable, not required, or the information is in the consolidated financial statements or related notes.

3. Listing of Exhibits. The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index following the signature page.

Surmodics, Inc.

Valuation and Qualifying Accounts

(In thousands)

| Description | Balance at Beginning of Period | Additions | | Balance at End of Period |
|---------------------------------|--|---|--------------------------------|-----------------------------------|
| | | Charged (Credited) to Expenses | Deductions From Reserves | |
| Year Ended September 30, 2015: | | | | |
| Allowance for doubtful accounts | \$ 42 | \$ — | \$ 32 | (a) \$ 10 |

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Year Ended September 30, 2016:

| | | | | |
|---------------------------------|-------|------|------|-----------|
| Allowance for doubtful accounts | \$ 10 | \$ 9 | \$ — | (a) \$ 19 |
|---------------------------------|-------|------|------|-----------|

Year Ended September 30, 2017:

| | | | | |
|---------------------------------|-------|--------|-------|------------|
| Allowance for doubtful accounts | \$ 19 | \$ 222 | \$ 11 | (a) \$ 230 |
|---------------------------------|-------|--------|-------|------------|

(a)Uncollectible accounts written off and adjustments to the allowance.

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-K

For the Fiscal Year Ended September 30, 2017

SURMODICS, INC.

Exhibit

- 2.1 Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. — incorporated by reference to Exhibit 2.1 to the Company's on Form 8-K filed on January 24, 2005, SEC File No. 0-23837.
- 2.2 Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company's 8-K dated November 27, 2015, SEC File No. 0-23837.
- 2.3 Put and Call Option Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.2 to the Company's 8-K filed on, SEC File No. 0-23837.
- 2.4 Stock Purchase Agreement, dated January 8, 2016, among Surmodics, Inc. and the shareholders of NorMedix, Inc. and Gregg Sutton as Seller's Agent — incorporated by reference to Exhibit 2.1 to the Company's Form 8-K filed on January 13, 2016, SEC File No. 0-23837.
- 3.1 Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2016, SEC File No. 0-23837.
- 3.2 Restated Bylaws of Surmodics, Inc., as amended December 18, 2015 — incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed on December 23, 2015.
- 10.1* 2003 Equity Incentive Plan (as amended and restated December 13, 2005) (adopted December 13, 2005 by the board of directors and approved by the shareholders on January 30, 2006) — incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 3, 2006, SEC File No. 0-23837.
- 10.2* Form of Surmodics, Inc. 2003 Equity Incentive Plan Non-qualified Stock Option Agreement — incorporated by reference to Exhibit 99.1 to the Company's Form 8-K/A filed on March 20, 2006, SEC File No. 0-23837.
- 10.3* Form of Surmodics, Inc. 2003 Equity Incentive Plan Incentive Stock Option Agreement — incorporated by reference to Exhibit 99.2 to the Company's 8-K filed on March 20, 2006, SEC File No. 0-23837.
- 10.4* Form of Surmodics, Inc. 2003 Equity Incentive Plan Restricted Stock Agreement — incorporated by reference to Exhibit 99.3 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
- 10.5* Form of Surmodics, Inc. 2003 Equity Incentive Plan Performance Share Award Agreement — incorporated by reference to Exhibit 99.4 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
- 10.6*

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Form of Surmodics, Inc. 2003 Equity Incentive Plan Performance Unit Award (cash settled) Agreement — incorporated by reference to Exhibit 99.5 to the Company’s Form 8-K filed on March 20, 2006, SEC File No. 0-23837.

- 10.7* Form of Surmodics, Inc. 2003 Equity Incentive Plan Restricted Stock Unit Agreement — incorporated by reference to Exhibit 99.6 to the Company’s Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
- 10.8* Form of Surmodics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (cash settled) Agreement — incorporated by reference to Exhibit 99.7 to the Company’s Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
- 10.9* Form of Surmodics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (stock settled) Agreement — incorporated by reference to Exhibit 99.8 to the Company’s Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
- 10.10* Form of Incentive Stock Option Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company’s Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
- 10.11* Form of Non-Statutory Stock Option Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
- 10.12* Form of Performance Share Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company’s Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
- 10.13* Form of Restricted Stock Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.5 to the Company’s Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
- 10.14* Form of Restricted Stock Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.5 to the Company’s Quarterly Report on Form 10-Q filed on February 4, 2015, SEC File No. 0-23837.
- 10.15* Surmodics, Inc. 2009 Equity Incentive Plan (as amended and restated on February 17, 2016) — incorporated by reference to Appendix B to the Company’s Definitive Proxy Statement for the annual meeting of shareholders held on February 17, 2016 filed on January 8, 2016, SEC File No. 0-23837.
- 10.16* Surmodics, Inc. 1999 Employee Stock Purchase Plan (as amended and restated on February 17, 2016) — incorporated by reference to Appendix D to the Company’s Definitive Proxy Statement for the annual meeting of shareholders held on February 17, 2016 filed on January 8, 2016, SEC File No. 0-23837.
- 10.17** The Company’s Board Compensation Policy, Amended and Restated as of July 18, 2017.
- 10.18* Severance Agreement by and between Gary R. Maharaj and Surmodics, Inc. dated as of December 14, 2010 — incorporated by reference to Exhibit 10.2 to the Company’s Form 10-Q filed on February 4, 2011, SEC File No. 0-23837.
- 10.19* Change of Control Agreement with Charles W. Olson dated February 9, 2012 — incorporated by reference to Exhibit 10.2 to the Company’s Form 8-K filed on February 10, 2012, SEC File No. 0-23837.

- 10.20* Amendment to Change of Control Agreement with Charles W. Olson dated February 9, 2012 — incorporated by reference to Exhibit 10.1 to the Company’s Form 8 K filed on February 13, 2015, SEC File No. 0 23837.
- 10.21* Change of Control Agreement with Bryan K. Phillips dated February 9, 2012 — incorporated by reference to Exhibit 10.3 to the Company’s Form 8 K filed on February 10, 2012, SEC File No. 0 23837.
- 10.22* Amendment to Change of Control Agreement with Bryan K. Phillips dated February 9, 2015 — incorporated by reference to Exhibit 10.3 to the Company’s Form 8 K filed on February 13, 2015, SEC File No. 0 23837.
- 10.23* Change of Control Agreement with Joseph J. Stich dated February 9, 2012 — incorporated by reference to Exhibit 10.4 to the Company’s Form 8 K filed on February 10, 2012, SEC File No. 0 23837.
- 10.24* Amendment to Change of Control Agreement with Joseph J. Stich dated February 9, 2015 — incorporated by reference to Exhibit 10.4 to the Company’s Form 8 K filed on February 13, 2015, SEC File No. 0 23837.
- 10.25* Change of Control Agreement by and between Andrew D.C. LaFrence and Surmodics, Inc. dated as of December 17, 2012 — incorporated by reference to Exhibit 10.2 to the Company’s Form 8 K filed on December 21, 2012, SEC File No. 0 23837.

- 10.26* Amendment to Change of Control Agreement by and between Andrew D.C. LaFrence and Surmodics, Inc. dated as of February 9, 2015 — incorporated by reference to Exhibit 10.2 to the Company’s Form 8 K filed on February 13, 2015,
SEC File No. 0 23837.
- 10.27* Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2014, SEC File No. 0 23837.
- 10.28* Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Quarterly Report on Form 10-Q filed on February 4, 2015, SEC File No. 0 23837.
- 10.29* Form of Deferred Stock Unit Master Agreement (Quarterly Awards) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company’s Quarterly Report on Form 10-Q filed on February 8, 2013, SEC File No. 0 23837.
- 10.30* Form of Deferred Stock Unit Master Agreement (Quarterly Awards) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company’s Quarterly Report on Form 10-Q filed on February 4, 2015, SEC File No. 0 23837.
- 10.31* Form of Restricted Stock Unit Award Agreement (Employee) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 22, 2016, SEC File No. 0 23837.
- 10.32 Amended and Restated Credit Agreement dated November 2, 2016, by and between Surmodics, Inc., and Wells Fargo Bank, National Association — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on November 7, 2016, SEC File No. 0 23837.
- 10.33 Amended and Restated Revolving Line of Credit Note dated November 2, 2016 — incorporated by reference to Exhibit 10.2 to the Company’s Form 8-K filed on November 7, 2016, SEC File No. 0 23837.
- 10.34 Letter Amendment to Amended and Restated Credit Agreement dated November 2, 2016 by and between Surmodics, Inc. and Wells Fargo Bank, National Association – incorporated by reference into the Company’s Quarterly Report on Form 10-Q filed on August 3, 2017. SEC File No. 0-23837.
- 10.35* Omnibus Amendment to Certain Equity Agreements with Non-Employee Directors under the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2014, SEC File No. 0 23837.

| | |
|----------------|---|
| <u>10.36</u> * | <u>Form of Non-Statutory Stock Option Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2014, SEC File No. 0 23837.</u> |
| 21 | <u>Subsidiaries of the Registrant.</u> ** |
| 23 | <u>Consent of Deloitte & Touche LLP.</u> ** |
| 24 | <u>Power of Attorney (included on signature page of this Form 10-K).</u> ** |
| 31.1 | <u>Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> ** |
| 31.2 | <u>Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u> ** |
| 32.1 | <u>Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u> ** |
| 32.2 | <u>Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u> ** |
| 101.INS** | XBRL Instance Document |
| 47 | |

101.SCH** XBRL Taxonomy Extension Schema Document

101.CAL** XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF** XBRL Taxonomy Extension Definition Linkbase Document

101.LAB** XBRL Taxonomy Extension Label Linkbase Document

101.PRE** XBRL Taxonomy Extension Presentation Linkbase Document

*Management contract or compensatory plan or arrangement

** Filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SURMODICS, INC.

By: /s/ Gary R. Maharaj
 Gary R. Maharaj
 President and Chief Executive Officer

Dated: December 1, 2017

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant, in the capacities, and on the dates indicated.

(Power of Attorney)

Each person whose signature appears below authorizes GARY R. MAHARAJ or ANDREW D. C. LAFRENCE, and constitutes and appoints said persons as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, authorizing said persons and granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

| Signature | Title | Date |
|--------------------------|---|------------------|
| /s/ Gary R. Maharaj | President and Chief Executive | December 1, 2017 |
| Gary R. Maharaj | Officer (principal executive officer) and Director | |
| /s/ Andrew D.C. LaFrence | Vice President of Finance and Information Systems and Chief Financial Officer | December 1, 2017 |
| Andrew D.C. LaFrence | (principal financial officer and principal accounting officer) | |
| /s/ Susan E. Knight | Chairman of the Board of Directors | December 1, 2017 |
| Susan E. Knight | | |
| /s/ José H. Bedoya | Director | |

| | | |
|--------------------------------|----------|---------------------|
| José H. Bedoya | | December 1, 2017 |
| /s/ David R. Dantzker, M.D. | Director | December 1, 2017 |
| David R. Dantzker, M.D. | | |
| /s/ Ronald B. Kalich | Director | December 1, 2017 |
| Ronald B. Kalich | | |
| /s/ Shawn T McCormick | Director | December 1, 2017 |
| Shawn T McCormick | | |
| /s/ Lisa Wipperman Heine | Director | December 1, 2017 |

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Surmodics, Inc.

Eden Prairie, Minnesota

We have audited the internal control over financial reporting of Surmodics, Inc. and subsidiaries (the "Company") as of September 30, 2017, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2017, based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended September

30, 2017 of the Company and our report dated December 1, 2017 which expressed an unqualified opinion on those consolidated financial statements and financial statement schedules.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota

December 1, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Surmodics, Inc.

Eden Prairie, Minnesota

We have audited the accompanying consolidated balance sheets of Surmodics, Inc. and subsidiaries (the "Company") as of September 30, 2017 and 2016, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2017. Our audits also included the financial statement schedule listed in the Index at Item 15. The consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Surmodics, Inc. and subsidiaries as of September 30, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2017, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 30, 2017, based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 1, 2017 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota

December 1, 2017

Surmodics, Inc. and Subsidiaries

Consolidated Balance Sheets

As of September 30

| | 2017 | 2016 |
|---|------------------------------------|-------------------|
| | (In thousands, except share and | |
| | per share data) | |
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 16,534 | \$ 24,987 |
| Available-for-sale securities | 31,802 | 21,954 |
| Accounts receivable, net of allowance for doubtful accounts of \$230 and \$19 as of | | |
| September 30, 2017 and 2016, respectively | 7,211 | 6,869 |
| Inventories | 3,516 | 3,579 |
| Income tax receivable | 599 | 697 |
| Prepays and other | 1,221 | 472 |
| Total Current Assets | 60,883 | 58,558 |
| Property and equipment, net | 22,942 | 19,601 |
| Deferred income taxes | 4,027 | 5,027 |
| Intangible assets, net | 20,562 | 22,525 |
| Goodwill | 27,282 | 26,555 |
| Other assets | 897 | 628 |
| Total Assets | \$ 136,593 | \$ 132,894 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 2,396 | \$ 1,622 |
| Accrued liabilities: | | |
| Compensation | 3,822 | 5,418 |
| Accrued other | 1,835 | 2,170 |
| Contingent consideration | 1,750 | 925 |
| Total Current Liabilities | 9,803 | 10,135 |
| Contingent consideration, less current portion | 13,114 | 13,592 |
| Other long-term liabilities | 2,119 | 2,334 |
| Total Liabilities | 25,036 | 26,061 |
| Commitments and Contingencies (Note 11) | | |
| Stockholders' Equity: | | |
| Series A preferred stock — \$.05 par value, 450,000 shares authorized; no shares | | |
| issued and outstanding | — | — |
| Common stock — \$.05 par value, 45,000,000 shares authorized; 13,094,988 and | 655 | 660 |

13,208,443 shares issued and outstanding, as of September 30, 2017 and 2016,

respectively

| | | |
|--|-----------|-----------|
| Additional paid-in capital | 5,413 | 6,754 |
| Accumulated other comprehensive income | 3,417 | 1,273 |
| Retained earnings | 102,072 | 98,146 |
| Total Stockholders' Equity | 111,557 | 106,833 |
| Total Liabilities and Stockholders' Equity | \$136,593 | \$132,894 |

The accompanying notes are an integral part of these consolidated financial statements.

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Surmodics, Inc. and Subsidiaries

Consolidated Statements of Income

For the Years Ended September 30

| | 2017 | 2016 | 2015 |
|--|-----------------------|----------|----------|
| | (In thousands, except | | |
| | per share data) | | |
| Revenue: | | | |
| Product sales | \$32,790 | \$30,999 | \$24,925 |
| Royalties and license fees | 31,787 | 33,203 | 31,763 |
| Research, development and other | 8,535 | 7,164 | 5,210 |
| Total revenue | 73,112 | 71,366 | 61,898 |
| Operating costs and expenses: | | | |
| Product costs | 11,422 | 10,908 | 8,619 |
| Research and development | 31,817 | 18,498 | 16,165 |
| Selling, general and administrative | 20,478 | 18,000 | 14,906 |
| Acquisition transaction, integration and other costs | — | 3,187 | — |
| Acquired intangible asset amortization | 2,419 | 2,422 | 619 |
| Contingent consideration accretion (gain) expense | (127) | 1,492 | — |
| Claim settlement | — | — | 2,500 |
| Total operating costs and expenses | 66,009 | 54,507 | 42,809 |
| Operating income | 7,103 | 16,859 | 19,089 |
| Other (loss) income: | | | |
| Investment income, net | 390 | 63 | 156 |
| Foreign exchange loss | (504) | (481) | — |
| Impairment loss on strategic investment | — | — | (1,500) |
| Gains on strategic investments and other | 44 | 507 | 496 |
| Other (loss) income | (70) | 89 | (848) |
| Income before income taxes | 7,033 | 16,948 | 18,241 |
| Income tax provision | (3,107) | (6,963) | (6,294) |
| Net income | \$3,926 | \$9,985 | \$11,947 |
| Basic net income per share: | \$0.30 | \$0.77 | \$0.92 |
| Diluted net income per share: | \$0.29 | \$0.76 | \$0.90 |
| Weighted average number of shares outstanding: | | | |
| Basic | 13,153 | 12,998 | 13,029 |
| Diluted | 13,389 | 13,219 | 13,289 |

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Comprehensive Income

For the Years Ended September 30

| | 2017 | 2016 | 2015 |
|--|----------------|----------|----------|
| | (In thousands) | | |
| Net income | \$3,926 | \$9,985 | \$11,947 |
| Other comprehensive income (loss): | | | |
| Unrealized holding gains (losses) on available-for-sale securities, net of tax | 49 | (68) | (1,208) |
| Reclassification adjustment for realized gain included in net income, net of tax | — | — | (315) |
| Foreign currency translation adjustments | 2,095 | 1,336 | — |
| Other comprehensive income (loss) | 2,144 | 1,268 | (1,523) |
| Comprehensive income | \$6,070 | \$11,253 | \$10,424 |

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity

For the Years Ended September 30

| | Common Shares | Stock Amount | Additional Paid-In Capital | Accumulated Other Comprehensive Income | Retained Earnings | Total Stockholders' Equity |
|--|------------------|-----------------|----------------------------------|---|----------------------|----------------------------------|
| | (In thousands) | | | | | |
| Balance at September 30, 2014 | 13,607 | \$ 680 | \$ 2,662 | \$ 1,528 | \$ 93,881 | \$ 98,751 |
| Net income | — | — | — | — | 11,947 | 11,947 |
| Other comprehensive loss, net of tax | — | — | — | (1,523) | — | (1,523) |
| Issuance of common stock | 139 | 7 | 272 | — | — | 279 |
| Common stock repurchased | (848) | (42) | (2,485) | — | (17,473) | (20,000) |
| Common stock options exercised, net | 47 | 2 | 429 | — | — | 431 |
| Purchase of common stock to pay employee taxes | — | — | (631) | — | (194) | (825) |
| Excess tax benefit from stock-based compensation plans | — | — | 432 | — | — | 432 |
| Stock-based compensation | — | — | 2,381 | — | — | 2,381 |
| Balance at September 30, 2015 | 12,945 | 647 | 3,060 | 5 | 88,161 | 91,873 |
| Net income | — | — | — | — | 9,985 | 9,985 |
| Other comprehensive income, net of tax | — | — | — | 1,268 | — | 1,268 |
| Issuance of common stock | 74 | 4 | 266 | — | — | 270 |
| Common stock options exercised, net | 196 | 10 | 1,536 | — | — | 1,546 |
| Purchase of common stock to pay employee taxes | (7) | (1) | (1,952) | — | — | (1,953) |
| Stock-based compensation | — | — | 3,844 | — | — | 3,844 |
| Balance at September 30, 2016 | 13,208 | 660 | 6,754 | 1,273 | 98,146 | 106,833 |
| Net income | — | — | — | — | 3,926 | 3,926 |
| Other comprehensive income, net of tax | — | — | — | 2,144 | — | 2,144 |
| Issuance of common stock | 99 | 5 | 343 | — | — | 348 |
| Common stock options exercised, net | 7 | 1 | 95 | — | — | 96 |
| Common stock repurchased | (196) | (10) | (4,692) | — | — | (4,702) |
| Purchase of common stock to pay employee taxes | (23) | (1) | (559) | — | — | (560) |