MERIDIAN BIOSCIENCE INC
Form 10-K
November 29, 2018
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS

PURSUANT TO SECTIONS 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2018.

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File No. 0-14902

MERIDIAN BIOSCIENCE, INC.

3471 River Hills Drive

Cincinnati, Ohio 45244

IRS Employer ID No. 31-0888197

Incorporated under the Laws of Ohio

Phone: (513) 271-3700

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange of which registered
Common Shares, No Par Value	The NASDAQ Stock Market LLC (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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange 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, and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S K (Section 229.405 of this Chapter) 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, a smaller reporting company or emerging growth company. See definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer | Accelerated filer

Non-accelerated filer | Smaller reporting company

Emerging growth company

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

If an emerging growth company, indicate 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 13(a) of the Exchange Act.

The aggregate market value of Common Shares held by non-affiliates as of March 31, 2018 was $592,033,599 based on a closing sale price of $14.20 per share on March 31, 2018. As of October 31, 2018, 42,402,912 no par value Common Shares were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s proxy statement to be filed with the Commission for its 2019 Annual Shareholders Meeting are incorporated by reference in Part III as specified.

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MERIDIAN BIOSCIENCE, INC.

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ON FORM 10-K

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates , anticipates , projects , plans , seeks , may , will , intends , believes , should and similar expressions or the negative versions thereof and which also may be identified by their context. All statements that address operating performance or events or developments that Meridian expects or anticipates will occur in the future, including, but not limited to, statements relating to per share diluted earnings and

revenue, are forward-looking statements. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. Specifically, Meridian s forward-looking statements are, and will be, based on management s then-current views and assumptions regarding future events and operating performance. Meridian assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian s operating results, financial condition and continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian s competition, its ability to effectively sell such products and its ability to successfully expand and effectively manage increased sales and marketing operations. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis or in protecting its intellectual property, and unexpected or costly manufacturing costs associated with the ramp up of new products could cause actual results to differ from expectations. Meridian relies on proprietary, patented and licensed technologies. As such, the Company s ability to protect its intellectual property rights, as well as the potential for intellectual property litigation, would impact its results. Ongoing

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consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers, can change expected results. Costs and difficulties in complying with laws and regulations, including those administered by the United States Food and Drug Administration, can result in unanticipated expenses and delays and interruptions to the sale of new and existing products, as can the uncertainty of regulatory approvals and the regulatory process. The international scope of Meridian s operations, including changes in the relative strength or weakness of the U.S. dollar and general economic conditions in foreign countries, can impact results and make them difficult to predict. One of Meridian s growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses will be successfully integrated into Meridian s operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention, and there may be additional risks with respect to Meridian s ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. Meridian cannot predict the outcome of goodwill impairment testing and the impact of possible goodwill impairments on Meridian s earnings and financial results. Meridian cannot predict the possible impact of U.S. health care legislation enacted in 2010 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act and any modification or repeal of any of the provisions thereof initiated by Congress or the presidential administration, and any similar initiatives in other countries on its results of operations. Efforts to reduce the U.S. federal deficit, breaches of Meridian s information technology systems, trade wars, increased tariffs, and natural disasters and other events could have a materially adverse effect on Meridian s results of operations and revenues. In the past, the Company has identified a material weakness in our internal control over financial reporting, which has been remediated, but the Company can make no assurances that a material weakness will not be identified in the future, which if identified and not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements. In addition to the factors described in this paragraph, as well as those factors identified from time to time in our filings with the Securities and Exchange Commission, Part I, Item 1A Risk Factors of this Annual Report on Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company. Readers should carefully review these forward-looking statements and risk factors and not place undue reliance on our forward-looking statements.

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PART I.

This Annual Report on Form 10-K includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties. See Forward-Looking Statements above. Factors that could cause or contribute to such risks and uncertainties include those discussed in Item 1A. Risk Factors. In addition to the risk factors discussed herein, we are also subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of these risks and uncertainties develops into actual events, our business, financial condition or results of operations could be adversely affected.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to Meridian, we, us, our, or company refer to Meridian Bioscience, Inc. and its subsidiaries.

In the discussion that follows, all dollar amounts and share amounts are in thousands (both tables and text), except per share data.

This Annual Report on Form 10-K refers to trademarks such as Alethia, Curian, Immuno*Card*®, Immuno*Card* STAT!®, LeadCare®, MyTaq, PREMIER®, and SensiFAST, which are protected under applicable intellectual property laws and are our property. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® or symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames. Our molecular diagnostic test platform, formerly known under the tradenames ***illumi****gene* and ***illumi****pro*, is being rebranded under the tradename Alethia. References to Alethia throughout this Annual Report on Form 10-K refer to our molecular diagnostic tests and instrumentation formerly marketed and sold under the ***illumi****gene* and ***illumi****pro* brands.

ITEM 1.

BUSINESS

Overview

Meridian is a fully-integrated life science company with principal businesses in: (i) the development, manufacture, sale and distribution of diagnostic test kits, primarily for certain gastrointestinal and respiratory infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents used by other diagnostic manufacturers and researchers in immunological and molecular tests for human, animal, plant and environmental applications. The Company was incorporated in Ohio in 1976. Our principal corporate offices are located near Cincinnati, Ohio, USA.

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Our website is www.meridianbioscience.com. We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements and any amendments thereto, free of charge through this website, as soon as reasonably practicable after such material has been electronically filed with or furnished to the Securities and Exchange Commission (SEC). The SEC maintains an internet site containing these filings and other information regarding Meridian at www.sec.gov. The information on our website is not and should not be considered part of this Annual Report on Form 10-K.

Reportable Segments

Our reportable segments are Diagnostics and Life Science, both of which are headquartered in Cincinnati, Ohio. Detailed information related to the reportable segments can be found in the following locations within this Annual Report on Form 10-K:

Type of Segment Information	Location within Annual Report on Form 10-K
Physical locations and activities	Item 2. Properties
Revenue by geographic region	Item 7. Management s Discussion and Analysis of Financial Condition & Results of Operations (hereafter MD&A)
Financial information	Note 9 of Consolidated Financial Statements

Diagnostics Segment

Overview of Products and Markets

Our largest source of revenues is clinical diagnostic products, with our Diagnostics segment providing 70% of consolidated net revenues for fiscal 2018. As of September 30, 2018, our Diagnostics segment had approximately 400 employees in seven countries.

Our clinical diagnostic products provide accuracy, simplicity and speed; enable early diagnosis and treatment of common, acute medical conditions; and provide for better patient outcomes at reduced costs. We target diagnostics for disease states that: (i) are conditions where rapid diagnosis impacts patient outcomes; (ii) have opportunistic demographic and disease profiles; (iii) are underserved by current diagnostic products; and/or (iv) have difficult sample handling requirements (e.g., stool). This approach has allowed us to establish significant market share in our target disease states, gastrointestinal and respiratory illnesses, and tests for elevated lead levels in blood.

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Our clinical diagnostic products span a broad menu of testing platforms and technologies, and also include transport media that store and preserve specimen samples from patient collection to laboratory testing. Our testing platforms include:

Isothermal DNA Amplification (Alethia brand, formerly *illumi*gene) high sensitivity, molecular platform that is suitable for virtually any moderately-complex laboratory, whether centralized or decentralized; provides flexibility to process from 1 to 10 tests per run in generally under one hour; and requires no batching of samples.

Rapid Immunoassay (Immuno*Card* and Immuno*Card* STAT! brands) single-use immunoassays that have fast turnaround times (generally under 20 minutes); and can reduce expensive send-outs for hospitals and outpatient clinics.

Enzyme-linked Immunoassay (PREMIER brand) batch immunoassay platform that can process up to 96 tests per run; is highly accurate and economical; and is adaptable to automation.

Anodic Stripping Voltammetry (LeadCare brand) electrical chemical sensor platform for quantitative determination of lead levels in blood.

Our clinical diagnostic products are comprised of products used principally in the detection of infectious diseases caused by various bacteria, viruses, parasites and pathogens, along with the LeadCare brand of tests for quantitative determination of blood lead levels. These products are grouped into the following product families:

Gastrointestinal Assays

Includes tests for the following, among others: *C. difficile*, Enterohemorrhagic *E. coli*, *Campylobacter jejuni* (Campy), *H. pylori,* Cryptosporidium*, giardia lamblia, and* calprotectin.

Respiratory Illness Assays

Includes tests for the following, among others: Group A *Streptococcus* (strep throat), Influenza, *M. pneumoniae* (Mycoplasma), *Bordetella pertussis* (whooping cough), and respiratory syncytial virus (RSV).

Blood Chemistry Assays

Tests for elevated lead levels in blood.

Other Assays

Includes tests for the following, among others: Group B *Streptococcus*, *Chlamydia trachomatis*, *Neisseria gonorrhea*, Herpes Simplex Virus Type 1 & Type 2, and Malaria.

Our product portfolio includes over 140 diagnostic tests and transport media, and is marketed to acute care hospitals, reference laboratories, outpatient clinics and physician office laboratories in over 70 countries around the world.

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Our current research and development pipeline for immunoassay products includes a new instrument that utilizes fluorescent chemistry, which improves workflow and test result readability. This new platform is being branded under the Curian name. During fiscal 2019, we expect to submit a 510(k) to the FDA for one or more rapid immunoassay tests for use with the Curian instrument. We expect to develop additional rapid immunoassay tests for use with the Curian instrument beyond 2019. Our current research and development pipeline for molecular products includes a combination test for the detection of *H. pylori* and the resistance of one or more antibiotics. Our congenital cytomegalovirus (CMV) test is currently awaiting FDA 510(k) clearance.

Market Trends

The global market for infectious disease tests continues to expand as new disease states are identified, new therapies become available, and worldwide standards of living and access to health care improve. More importantly, within this market, there is a continuing shift from conventional testing, which requires highly trained personnel and lengthy turnaround times for test results, to more technologically advanced testing, which can be performed by less highly trained personnel and completed in minutes or hours.

The growing global pressures to contain total health care costs have accelerated the increased use of diagnostic testing. With rapid and accurate diagnoses of infectious diseases, physicians can pinpoint appropriate therapies quickly, leading to faster recovery, shorter hospital stays and lower overall treatment cost. Integrated Delivery Networks (IDNs) in our U.S. market have the goal of increasing the efficiency of health care delivery, reducing spending and improving clinical outcomes. We believe our product portfolio positions us competitively with IDNs and health care systems that are transitioning from fee-for-service compensation models to value-based reimbursement. Our *C. difficile*, Group B *Streptococcus*, Group A *Streptococcus* and *H. pylori* products are all examples of how a highly accurate diagnostic test on the front end can mitigate or reduce down-stream costs of antibiotic use, symptom-relieving drugs and hospital stays.

We also continue to see aggregation of buying power in our U.S. market via multi-hospital group purchasing organizations and IDNs, consolidation among reference laboratories, hospital laboratories being operated by large reference laboratories, and acquisition of physician practices by hospitals, health systems and for-profit specialty health care companies.

Cost containment pressures have also affected health care systems outside the U.S., particularly in Europe, where the health care systems are generally government-run. The level of government budget deficits can have an adverse effect on the amount of government health care spend.

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Sales, Marketing and Distribution

Our Diagnostics segment s sales and distribution network consists of the following for each of the broad geographic regions we serve:

Americas

In the Americas, our sales and distribution network consists of a direct sales force complemented by independent distributors. The use of independent distributors allows our products to reach any size health care facility and also provides our customers the option to purchase our products directly from Meridian or through an authorized distributor. Two independent distributors accounted for 10% or more of consolidated revenues in fiscal 2018, 2017 and 2016: Cardinal Healthcare Corporation (Cardinal) and Thermo Fisher Scientific (Fisher). Our Diagnostics segment revenues from Cardinal were approximately $21,000, $22,000 and $20,000 during fiscal 2018, 2017 and 2016, respectively. Our Diagnostics segment revenues from Fisher were approximately $22,000, $18,000 and $20,000 during fiscal 2018, 2017 and 2016, respectively.

EMEA

In Europe, the Middle East and Africa (EMEA), our sales and distribution network consists of direct sales personnel in Belgium, France and Italy, and independent distributors in other European countries, Africa and the Middle East. We maintain a distribution center near Milan, Italy.

ROW

With the exception of Australia and China, where we utilize direct sales personnel, we utilize independent distributors throughout the rest of the world (ROW).

Competition

Our major competitors in molecular diagnostics are Cepheid (acquired by Danaher) and Becton Dickinson, which have systems with multiple-assay menus. We also face competition in molecular diagnostics, but to a lesser degree, from companies such as Abbott (Alere) and Quidel.

Our major competitors in rapid immunoassay diagnostics are primarily Abbott (Alere) and Quidel. In recent years, companies such as BioMerieux have captured market share in our gastrointestinal category via multi-plex panel tests. However, since their introduction to the market, payors have begun to raise concerns over reimbursement levels relative to clinical utility. For blood lead testing, we believe we have the only FDA-cleared, CLIA-waived point-of-care test available commercially. Other blood lead testing systems in use, marketed by our competitors, include Graphite Furnace Atomic Absorption Spectroscopy, which requires a highly-skilled technician and larger laboratory space to operate, in addition to not being portable or suitable for point-of-care use. We believe that with the breadth and depth of our product portfolio, we are well positioned for the clinical laboratory.

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Research and Development

Our Diagnostics segment s research and development organization for infectious disease products is located at our corporate headquarters in Newtown, Ohio, a suburb of Cincinnati, and has expertise in biochemistry, immunology, mycology, bacteriology, virology, parasitology, and molecular biology. Our blood-chemistry products have a dedicated research and development team in Billerica, Massachusetts. Our research and development activities are focused on new product and new technology development, new applications for our existing technologies, and improvements to existing products. Research and development efforts may occur in-house or with collaborative partners. We believe that new product development is a key source for sustaining revenue growth. The products within our Alethia molecular platform, *H. pylori* product family and blood lead testing family were developed solely in-house, or substantially so. See Operating Expenses section within MD&A on page 39.

Manufacturing

Our immunoassay and molecular assay products require the production of highly specialized reagents, primers and enzymes. We produce the vast majority of our own immunoassay requirements. Primers for our Alethia molecular assay products are purchased from outside vendors. Our blood lead testing products require the production of electrical chemical sensors, which we manufacture using critical raw materials purchased from outside vendors. We believe that we have sufficient manufacturing and sourcing capacity for anticipated growth over the next several years.

Intellectual Property, Patents and Licenses

We own or license U.S. and foreign patents, most of which are for select products manufactured by our Diagnostics segment. These patents are used in our manufacturing processes for select products (e.g., method patents) or may relate to the design of the test device technology format (e.g., design patents). In the absence of patent protection, we may be vulnerable to competitors who successfully replicate our production and manufacturing technologies and processes. Our employees are required to sign confidentiality and non-disclosure agreements designed to protect our proprietary products.

The patents for our Alethia products, which represented 16%, 17% and 20% of consolidated revenues for fiscal 2018, 2017 and 2016, respectively, are licensed from a third party, Eiken Chemical Co., Ltd., under a non-exclusive license agreement and expire between 2020 and 2022. These patents were issued in the U.S., European Community and other countries. The term of our license agreement runs until the last patent expires in 2022, at which point we will be free to practice the patents without any restriction or royalty obligation.

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The patents for our *H. pylori* products, owned by us and which represented approximately 16%, 15% and 16% of consolidated revenues for fiscal 2018, 2017 and 2016, respectively, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase in the near future, and such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. Our product development pipeline includes new product initiatives for the detection of *H. pylori*, and we recently entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests. We have executed multi-year supply agreements with our two largest reference laboratory customers for *H. pylori* tests to secure volume, albeit at lower selling prices. We are unable to provide assurances that we will be successful with any strategy or that any strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

Government Regulation

Our diagnostic products are regulated by the FDA as devices pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA). Under the FDCA, medical devices are classified into one of three classes (i.e., Class I, II or III). Class I and II devices are not expressly approved by the FDA, but, instead, are cleared for marketing. Class III devices generally must receive pre-market approval from the FDA as to safety and effectiveness. Our diagnostics manufacturing facilities in Cincinnati and Billerica are subject to periodic inspection by the FDA. See page 32 within MD&A for discussion regarding the FDA s inspection of our Billerica facility.

Each of the diagnostic products currently marketed by us in the United States has been cleared by the FDA pursuant to the 510(k) clearance process or is exempt from such requirements. We believe that most, but not all, products under development will be classified as Class I or II medical devices and, in the case of most of our Class I and all Class II devices, will be eligible for 510(k) clearance; however, we can make no assurances in this regard.

Sales of our diagnostic products in foreign countries are subject to foreign government regulation, which is similar to that of the FDA.

Our Diagnostics facilities are certified to ISO 13485:2016.

Seasonal Factors and Sporadic Outbreaks

Our principal business is the sale of a broad range of clinical diagnostic test kits for common gastrointestinal and respiratory infectious diseases, and elevated blood lead levels. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as foodborne illnesses or pandemics such as an influenza outbreak. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, we can make no assurance that revenues will not be impacted period over period by such factors.

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Life Science Segment

Overview of Products and Markets

Our Life Science segment focuses on the development, manufacture, sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents used by researchers, agri-bio companies and other diagnostic manufacturing companies. As of September 30, 2018, our Life Science segment had approximately 185 employees in five countries.

Most of the revenues for our Life Science segment currently come from the manufacture, sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents used by other diagnostic manufacturing companies focused on the development of immunoassay and molecular assay tests. Approximately 76% of Life Science revenues are generated from the industrial market, defined as diagnostic manufacturers. This continues to be an increasing focus for our molecular reagent products, which historically have been marketed to the academic/research customers that comprise the remaining 24% of Life Science revenues. We utilize direct sales teams in key countries such as the U.S., the U.K., France, Germany, and Australia. In order to further pursue revenue opportunities in Asia, and China in particular, during fiscal 2017 we established a wholly foreign owned enterprise (WFOE) location in Beijing, China, after having operated a representative office there since fiscal 2015. The WFOE employs a business development staff and imports product for sale to customers in China. We utilize a network of distributors in other major countries. During fiscal 2018, 18% of third-party revenues for this segment were from two diagnostic manufacturing customers.

Products such as antibodies, antigens and reagents are marketed primarily to diagnostic manufacturing customers as a source of raw materials for their immunoassay products, or as an outsourced step in their manufacturing processes. For example, we supply a number of major diagnostic manufacturers with proteins used to detect hepatitis A virus and rubella virus. These products are typically sold in bulk quantities, and may also be custom-designed for a particular manufacturer s requirements. Sales efforts are focused on multi-year supply arrangements in order to provide stability in volumes and pricing. We believe this benefits both us and our customers.

Molecular biology products such as PCR/qPCR reagents, nucleotides and competent cells are marketed to academic/research and industrial customers. These products are used in measuring DNA and RNA in human, animal, plant and environmental applications. These reagents improve the purity, yield and speed of PCR reactions. Products such as MyTaq and SensiFAST are examples of this type of PCR/qPCR reagent.

Market Trends

As certain global markets become increasingly accessible to us, most notably the Asia-Pacific region, geographic expansion continues to be a significant strategy for our Life Science segment, along with further penetration into industrial markets with our molecular component products.

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Competition

The market for bulk biomedical reagents is highly competitive. Important competitive factors include product quality, price, customer service and reputation. We face competitors, many of which have greater financial, research and development, sales and marketing, and manufacturing resources, and where sole-source supply arrangements do not exist. Customers also may choose to manufacture their biomedical reagents in-house rather than purchase from outside vendors such as Meridian.

The academic/research market is highly fragmented. Individual purchases are typically of small quantities. The breadth of product offerings, quality, price and service, including on-line capabilities and technical resources, are important factors to building customer loyalty and repeat purchases.

Research and Development

The focus of this research and development activity is development of new molecular and immunological reagent products. See Operating Expenses section within MD&A on page 39.

Manufacturing and Government Regulation

Our Life Science facilities are ISO 13485:2016 certified. Additionally, where appropriate, our Life Science facilities comply with Regulation EC 1069:2009.

Acquisitions

Acquisitions have played an important role in the growth of our businesses. Our acquisition objectives include, among other things: (i) enhancing product offerings; (ii) improving product distribution capabilities; (iii) providing access to new markets; and/or (iv) providing access to key biologicals or new technologies that lead to new products. Although we cannot provide assurance that we will consummate additional acquisitions in the future, nor can we provide assurance that any acquisitions will accomplish these objectives, we expect that the potential for acquisitions will continue to provide opportunities for revenue and earnings growth in the future.

During March 2016, we acquired all of the outstanding common stock of Magellan. Details of the Magellan acquisition are set forth in Note 3 of the accompanying Consolidated Financial Statements.

International Markets

International markets are an important source of revenues and future growth opportunities for both of our segments. For both segments combined, revenues from customers located outside of the Americas approximated $66,000 or 31% of consolidated fiscal 2018 revenues, $61,000 or 30% of consolidated fiscal 2017 revenues, and $53,000 or 27% of consolidated fiscal 2016 revenues. We expect to continue to look to key European markets and China as a source of revenue growth in the future.

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Fluctuations in foreign currency exchange rates since fiscal 2017 had an approximate $2,200 favorable impact on fiscal 2018 revenues; $1,400 within the Diagnostics segment and $800 within the Life Science segment. This compares to year-to-year currency exchange rates having an approximate $1,200 unfavorable impact on revenues in fiscal 2017; $400 within the Diagnostics segment and $800 within the Life Science segment. Due to natural hedge relationships with expenses, both cost of sales and operating expenses, the overall impact of exchange rate fluctuations on operating income was not significant during fiscal 2018, 2017 or 2016.

Environmental

We are in compliance with applicable portions of the federal and state hazardous waste regulations and have never been a party to any environmental proceeding.

ITEM 1A.

RISK FACTORS

In addition to the other information set forth in this report, you should carefully consider the following factors, which could materially affect our business, financial condition, cash flows or future results. Any one of these factors could cause our actual results to vary materially from recent results or from anticipated future results. The risks described below are not the only risks facing our company. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may materially adversely affect our business, financial condition and/or operating results.

Risks Affecting Growth and Profitability of our Business

We may be unable to develop new products and services or acquire products and services on favorable terms.

The medical diagnostic and life science industries are characterized by ongoing technological developments and changing customer requirements. As such, our results of operations and continued growth depend, in part, on our ability in a timely manner to develop or acquire rights to, and successfully introduce into the marketplace, enhancements of existing products and services, or new products and services that incorporate technological advances, meet customer requirements and/or respond to products developed by our competition. We cannot provide any assurance that we will be successful in developing or acquiring such rights to products and services on a timely basis, or that such products and services will adequately address the changing needs of the marketplace, either of which could adversely affect our results of operations.

In addition, we must regularly allocate considerable resources to research and development of new products, services and technologies. The research and development process generally takes a significant amount of time from research to product launch. This process is conducted in various stages. During each stage, there is a risk that we will not achieve our goals on a timely basis, or at all, and we may have to abandon a product in which we have invested substantial resources.

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We may be unable to successfully integrate operations or to achieve expected cost savings from acquisitions we make.

One of our growth strategies is the acquisition of companies and/or products. Although additional acquisitions of companies and products may enhance the opportunity to increase net earnings over time, such acquisitions could result in greater administrative burdens, increased exposure to the uncertainties inherent in marketing new products, financial risks of additional operating costs, and risk of asset impairments if future revenues and cash flows are deficient. The principal benefits expected to result from any acquisitions we make will not be achieved fully unless we are able to successfully integrate the operations of the acquired entities with our operations and realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses into our existing businesses. We cannot provide assurance that we will be able to identify and complete additional acquisitions on terms we consider favorable or that, if completed, will be successfully integrated into our operations. Furthermore, we cannot predict the outcome of goodwill impairment testing and the impact of goodwill impairments on the Company s earnings and financial results.

Revenues for our Diagnostics segment may be impacted by our reliance upon two key distributors in North America, seasonal factors and sporadic outbreaks, and changing diagnostic market conditions.

Key Distributors

Our Diagnostics segment s revenues from sales through two U.S. distributors were approximately 29% and 28% of the Diagnostics segment s total revenues for fiscal 2018 and fiscal 2017, respectively, or approximately 20% of each fiscal year s consolidated revenues. These parties distribute our products and other laboratory products to end-user customers. The loss of either of these distributors could negatively impact our revenues and results of operations unless suitable alternatives were timely found or lost sales to one distributor were absorbed by another distributor. Finding a suitable alternative on satisfactory terms may pose challenges in our industry s competitive environment. As an alternative, we could expand our efforts to distribute and market our products directly. This alternative, however, would require substantial investment in additional sales, marketing and logistics resources, including hiring additional sales and customer service personnel, which would significantly increase our future selling, general and administrative expenses.

In addition, buying patterns of these two distributors may fluctuate from quarter to quarter, potentially leading to uneven concentration levels on a quarterly basis.

Seasonal Factors and Sporadic Outbreaks

Our principal business is the sale of a broad range of diagnostic test kits for common gastrointestinal and respiratory infectious diseases, and elevated blood lead levels. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as foodborne illnesses or pandemics such as an influenza outbreak. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, we can make no assurance that revenues will not be negatively impacted period over period by such factors.

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Changing Diagnostic Market Conditions

Changes in the U.S. health care delivery system have resulted in consolidation among reference laboratories, hospital laboratories being operated by large reference laboratories, and the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. Consolidation in the U.S. health care industry has also led to the creation of group purchasing organizations (GPOs) and IDNs that aggregate buying power for hospital groups and put pressure on our selling prices. Due to such consolidation, we may not be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with institutional customers, GPOs and IDNs, which could adversely affect our results of operations.

We could be adversely affected by health care reform legislation.

Third-party payers for medical products and services, including state, federal and foreign governments, are increasingly concerned about escalating health care costs and can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. Following years of increasing pressure, during 2010 the U.S. government enacted comprehensive health care reform with the enactment of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which made changes that significantly impact the pharmaceutical and medical device industries. The Protecting Access to Medicare Act of 2014 requires applicable laboratories to report all private payor reimbursement rates and the volumes for each test they perform. The statute requires that Medicare establish reimbursement rates based on the weighted median of private insurance reimbursement rates effective January 1, 2017. The new Medicare rates would be subject to a maximum reduction of 10% a year for the initial three year period and a maximum of 15% a year for the subsequent three year period. There is no limit on the amount of potential rate increases. As a result, some of our customers in the United States may experience lower Medicare reimbursement rates for our products, which may adversely affect our business, financial condition and results of operations. We are seeing some effect on the reimbursement rates for our products. If reimbursement amounts for diagnostic testing services decrease further in the future, such decreases may reduce the amount that will be reimbursed to hospitals or physicians for such services and consequently, could place constraints on the levels of overall pricing, which could have a material effect on our revenues and/or results of operations.

Having been subject to the now-repealed 2.3% medical device tax originally established as part of the U.S. health care reform legislation through December 31, 2015, the Company is unable to predict any future legislative changes or developments related to this excise tax or any other excise tax.

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Additional state and federal health care reform measures may be adopted in the future, any of which could have a material adverse effect on our ability to successfully commercialize our products and on our industry in general. For example, the United States government has in the past considered, is currently considering and may in the future consider, health care policies and proposals intended to curb rising health care costs, including those that could significantly affect both private and public reimbursement for health care services. Further, state and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Future significant changes in the health care system in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether health care policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future, what effect such policies would have on our business, or the effect that ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

Efforts to reduce the U.S. federal deficit could adversely affect our results of operations.

As part of the Budget Control Act passed in August 2011 to extend the federal debt limit and reduce government spending, $1.2 trillion in automatic spending cuts (known as sequestration) were implemented in 2013. The sequestration requires a 2% cut in Medicare payments for all services, including our diagnostic tests, which, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless Congressional action is otherwise taken. Government research funding has also been reduced as a result of the sequestration. On January 2, 2013, the American Taxpayer Relief Act of 2012 also was signed into law, which, among other things, further reduces Medicare payments to providers such as hospitals, imaging centers and cancer treatment centers, and increases the statute of limitations period for the government to recover overpayments to providers from three to five years.

Such reductions in government health care spending or research funding could result in reduced demand for our products or additional pricing pressure. Further, there is ongoing uncertainty regarding the federal budget and federal spending levels, including the possible impacts of a failure to increase the debt ceiling. Any U.S. government default on its debt could have broad macroeconomic effects that could, among other things, raise our borrowing costs. Any future shutdown of the federal government or failure to enact annual appropriations could also have a material adverse impact on our business.

Revenues for our Life Science segment may be impacted by customer concentrations and buying patterns.

Our Life Science segment s revenues from two diagnostic manufacturing customers were 18% and 17% of the Life Science segment s total revenues for fiscal 2018 and fiscal 2017, respectively; and 5% of our consolidated revenues for each of fiscal 2018 and fiscal 2017. Our Life Science segment has five other significant customers, which together comprised 12% and 10% of the segment s total revenues for fiscal 2018 and fiscal 2017, respectively. Any significant alteration of buying patterns from these customers could adversely affect our period over period revenues and results of operations.

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Intense competition could adversely affect our profitability.

The markets for our products and services are characterized by substantial competition and rapid change. Hundreds of companies around the world supply diagnostic tests and immunoassay and molecular reagents. These companies range from multinational health care entities, for which diagnostics is one line of business, to small start-up companies. Many of our competitors have significantly greater financial, technical, manufacturing and marketing resources than we do. We cannot provide assurance that our products and services will be able to compete successfully with the products and services of our competitors.

We expect to face increased competition resulting from expiration of our H. pylori patents.

The patents for our *H. pylori* products, owned by us, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products, high margin products which represent approximately 16% of our total revenues, to increase in the near future, as we currently are one of only four companies that market FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market, one of which is DiaSorin Inc., with whom we recently entered a collaboration agreement to sell *H. pylori* tests. At present, we are also aware of at least one other company that has commenced clinical trials of *H. pylori* products in the U.S. Such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. Therefore, among other things, we have entered into the above-noted collaboration agreement with DiaSorin, and we are researching and experimenting with new products and working to secure significant customers under long-term contracts. We are unable to provide assurances that we will be successful with any strategy or that any strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

We depend on international revenues, and our financial results may be adversely impacted by foreign currency, regulatory or other developments affecting international markets.

We sell products and services into approximately 70 countries. Approximately 31% and 30% of our net revenues for fiscal 2018 and 2017, respectively, were attributable to markets outside of the Americas. For fiscal 2018, approximately 20% of our consolidated revenues were transacted in currencies other than the U.S. dollar. We are subject to the risks associated with fluctuations in the exchange rates for the Australian dollar, British pound, Chinese yuan and Euro. We are also subject to other risks associated with international operations, including longer customer payment cycles, trade wars, increased tariffs, requirements for export licenses, instability of foreign governments, and governmental requirements with respect to the importation and distribution of medical devices and immunodiagnostic and molecular biology reagents, all of which may vary by country.

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Risks Affecting our Manufacturing Operations

We are subject to comprehensive regulation, and our ability to earn profits may be restricted by these regulations.

Medical device diagnostics is a highly regulated industry. We cannot provide assurance that we will be able to obtain necessary governmental clearances or approvals, or timely clearances or approvals, to market future products in the United States and other countries. Costs and difficulties in complying with laws and regulations administered by the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Department of Commerce, the U.S. Drug Enforcement Agency, the Centers for Disease Control, or other regulators can result in unanticipated expenses and delays, and interruptions to the sale of new and existing products.

Regulatory approval can be a lengthy, expensive and uncertain process, making the timing and costs of approvals difficult to predict. Failure to comply with these regulations can result in delays in obtaining authorization to sell products, seizure or recall of products, suspension or revocation of authority to manufacture or sell products, and other civil or criminal sanctions.

If we or our third-party vendors fail to comply with FDA regulations relating to the manufacturing of our products or any component part, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be negatively impacted.

Our diagnostics manufacturing facilities, and the manufacturing facilities of any of our third-party diagnostic component manufacturers or critical suppliers, are required to comply with the FDA s Quality System Regulation (QSR) which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of the products we sell. The FDA may evaluate our compliance with the QSR, among other ways, through periodic announced or unannounced inspections which could disrupt our operations and interrupt our manufacturing. If in conducting an inspection of our manufacturing facilities, or the manufacturing facilities of any of our third-party component manufacturers or critical suppliers, an FDA investigator observes conditions or practices believed to violate the QSR, the investigator may document their observations on a Form FDA 483 that is issued at the conclusion of the inspection. A manufacturer that receives an FDA 483 may respond in writing and explain any corrective actions taken in response to the inspectional observations. The FDA will typically review the facility s written response and may re-inspect to determine the facility s compliance with the QSR and other applicable regulatory requirements. Failure to take adequate and timely corrective actions to remedy objectionable conditions listed on an FDA 483 could result in the FDA taking administrative or enforcement actions. Among these may be the FDA s issuance of a Warning Letter to a manufacturer, which informs it that the FDA considers the observed violations to be of regulatory significance that, if not corrected, could result in further enforcement action.

FDA enforcement actions, which include seizure, injunction and criminal prosecution, could result in total or partial suspension of a facility s production and/or distribution, product recalls, fines, suspension of the FDA s review of product applications, and/or the FDA s issuance of adverse publicity. Thus, an adverse inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse inspections could also delay FDA approval of our products and could have an adverse effect on our production, sales and profitability.

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We and any of our third-party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction, and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to our facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacture of the product, or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, which could, therefore, have a material adverse effect on our business, financial condition and results of operations.

On June 29, 2017, the FDA, in connection with its Safety Notification related to Magellan s lead testing systems for venous blood samples, issued its Form 483, Inspectional Observations, to Magellan. This was followed by the FDA issuing a Warning Letter related to the matter on October 23, 2017. While we remain committed to strengthening Magellan s quality system and ensuring that all aspects of the system are in full compliance, we can provide no assurance that our remediation efforts will be successful to a degree acceptable by the FDA.

Additionally, as set forth in Item 3. Legal Proceedings , on April 17, 2018, Magellan received a subpoena from the United States Department of Justice (DOJ) regarding its LeadCare product line. The subpoena outlines documents to be produced, and we are cooperating with the DOJ in this matter. We maintain rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements, and are working with the DOJ to promptly respond to the subpoena. However, we cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on Meridian.

See a more detailed discussion of these matters within MD&A on page 32.

Significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results.

Products and services manufactured at facilities we own or lease comprised a majority of our revenues. Our global supply of these products and services is dependent on the uninterrupted and efficient operation of these facilities. In addition, we currently rely on a small number of third-party manufacturers to produce certain of our diagnostic products and product components. The operations of our facilities or these third-party manufacturing facilities could be adversely affected by power failures, or natural or other disasters such as earthquakes, floods, tornadoes or terrorist threats. Although we carry insurance to protect against certain business interruptions at our facilities, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. Any significant interruption in the Company s or a third-party supplier s manufacturing capabilities could materially and adversely affect our operating results.

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We depend on sole-source suppliers for certain critical raw materials, components and finished products. A supply interruption could adversely affect our business.

Raw Materials and Components

Our diagnostic products are made from a wide variety of raw materials that are biological or chemical in nature, and that generally are available from multiple sources of supply. We sole-source certain raw materials and components, which makes it time consuming and costly to switch raw materials and components in FDA-cleared products. If certain suppliers fail to supply required raw materials or components, we will need to secure other sources which may require us to conduct additional development and testing and obtain regulatory approval. These activities require significant time and resources, and there is no assurance that new sources will be secured or regulatory approvals, if necessary, will be obtained.

We utilize third-party manufacturers for our instrumentation. One third party manufactures our proprietary Alethia Incubator/Reader (instrument), a component of our Alethia molecular system, and a separate third party currently assembles our proprietary LeadCare instruments. Upon commercialization in fiscal 2019, an additional third party will manufacture our Curian instrument. These instruments are manufactured exclusively for Meridian according to our specifications. While other manufacturers for these types of instruments are available, we source each instrument solely from one manufacturer to limit the costs involved in clearing the system for marketing in the United States. If these third-party manufacturers fail to supply us with instruments, we will need to secure another manufacturer, and it may take as long as 12 months to transfer instrument manufacturing. An interruption in the manufacturing of these instruments could have a material adverse effect on our operating results.

Additionally, one third party manufactures a certain reagent for use with our Alethia assays. While alternative suppliers exist, we elect to utilize this third party exclusively in order to maintain consistency in our materials, which is critical in complying with FDA regulatory requirements. An interruption in the manufacturing of these reagents could have a material adverse effect on our operating results.

Finished Products

We outsource the manufacturing for certain finished diagnostic products to third parties. A disruption in the supply of these finished products could have a material adverse effect on our business until we find another supplier or bring manufacturing in-house.

Four products manufactured exclusively for us by two separate and independent companies accounted for 11%, 11% and 12% of consolidated revenues in fiscal 2018, 2017 and 2016, respectively. Meridian owns all rights and title to the FDA 510(k) clearances for these products.

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Activities undertaken by Meridian to reduce the risk of these sole-supplier arrangements include maintaining adequate inventory levels, supplier qualification procedures, supplier audits, site visits, and frequent communication. Additionally, we have identified potential alternate suppliers.

Risks Related to Intellectual Property and Product Liability

We may be unable to protect or obtain proprietary rights that we utilize or intend to utilize.

In developing and manufacturing our products, we employ a variety of proprietary and patented technologies. In addition, we have licensed, and expect to continue to license, various complementary technologies and methods from academic institutions and public and private companies. We cannot provide assurance that the technologies that we own or license provide protection from competitive threats or from challenges to our intellectual property. In addition, we cannot provide assurances that we will be successful in obtaining and retaining licenses or proprietary or patented technologies in the future.

See Item 3. Legal Proceedings for a discussion of the status of certain litigation related to our intellectual property.

Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.

Litigation over intellectual property rights is prevalent in the diagnostic industry. As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third party may claim infringement against us. If found to infringe, we may attempt to obtain a license to such intellectual property; however, we may be unable to do so on favorable terms, or at all. Additionally, if our products are found to infringe on third-party intellectual property, we may be required to pay damages for past infringement and lose the ability to sell certain products, causing our revenues to decrease. Any substantial loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may have to limit or cease sales of our products.

The testing, manufacturing and marketing of medical diagnostic products involves an inherent risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease sales of our products. We currently carry product liability insurance at a level we believe is commercially reasonable, although there is no assurance that it will be adequate to cover claims that may arise. In certain customer contracts, we indemnify third parties for certain product liability claims related to our products. These indemnification obligations may cause us to pay significant sums of money for claims that are covered by these indemnifications. In addition, a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injury and otherwise. Any substantial underinsured loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

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Other Risks Affecting Our Business

Our business could be negatively affected if we are unable to attract, hire and retain key personnel.

Our future success depends on our continued ability to attract, hire and retain highly qualified personnel, including our executive officers and scientific, technical, sales and marketing employees, and their ability to manage growth successfully. If such key employees were to leave and we were unable to obtain adequate replacements, our operating results could be adversely affected.

Our bank credit agreements impose restrictions with respect to our operations.

Our bank credit agreements contain a number of financial covenants that require us to meet certain financial ratios and tests. If we fail to comply with the obligations in the credit agreements, we would be in default under the credit agreements. If an event of default is not cured or waived, it could result in acceleration of any indebtedness under our credit agreements, which could have a material adverse effect on our business. At September 30, 2018, we have $50,250 outstanding on a five-year term loan entered into in connection with the Magellan acquisition and no borrowings are outstanding under our $30,000 bank revolving credit facility.

We face risks related to global economic conditions.

We currently generate significant operating cash flows, which combined with access to the credit markets, provides us with discretionary funding capacity for research and development and other strategic activities. However, as an enterprise with global operations and markets, our operations and financial performance are in part dependent upon global economic conditions, and we could be negatively impacted by a global, regional or national economic crisis, including sovereign risk in the event of deterioration in the credit worthiness of or a default by local governments. We are particularly susceptible to the economic conditions in countries where government-sponsored health care systems are the primary payers for health care, including those countries within the European Union that are reducing their public expenditures in an effort to achieve cost savings. The uncertainty in global economic conditions poses a risk to the overall economy that could impact demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. As such, if global economic conditions deteriorate significantly, our business could be negatively impacted, including such areas as reduced demand for our products from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets, and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers. While to-date such factors have not had a significant negative impact on our results or operations, we continue to monitor and plan for the potential impact of these global economic factors.

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While the impact of the United Kingdom s planned separation from the European Union (commonly referred to as Brexit), a final agreement on which is expected in the very near future, remains uncertain, the resulting immediate changes in foreign currency exchange rates have had a limited overall impact due to natural hedging. However, any predicted deterioration in the United Kingdom and European economic outlook may have an adverse effect on revenue growth, but the extent of such effect cannot yet be quantified. In the longer term, it is possible that we will be directly impacted in a number of key areas including, without limitation, the hiring and retention of qualified staff, regulatory affairs, manufacturing, logistics, and increased tariffs. We are closely monitoring the Brexit developments in order to determine, quantify and proactively address changes as they become clear. Despite the Brexit developments, we do not expect macroeconomic conditions to have a significant impact on our liquidity needs, financial condition or results of operations, although no assurances can be made in this regard. We intend to continue to fund our working capital requirements and dividends from current cash flows from operating activities and cash on hand. If needed, we also have an additional source of liquidity through our $30,000 bank revolving credit facility. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets tightens for an extended period of time, and such conditions impact the collectability of our customer accounts receivable or impact credit terms with our vendors, or disrupt the supply of raw materials and services.

Breaches of our information technology systems could have a material adverse effect on our operations.

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The secure processing, maintenance and transmission of this information is critical to our operations. Like many multinational corporations, our information technology systems may be subjected to computer viruses or other malicious codes, unauthorized access attempts, and cyber- or phishing-attacks. We also store certain information with third parties that could be subject to these types of attacks. Any such breach could compromise our networks, and the information stored therein could be accessed, publicly disclosed, lost or stolen. Such attacks could result in our intellectual property and other confidential information being lost or stolen, disruption of our operations, and other negative consequences, such as increased costs for security measures or remediation costs, and diversion of management attention. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disruption of our operations, damage to our reputation, and/or cause a loss of confidence in our products and services, all of which could adversely affect our business revenues and competitive position. While we will continue to implement additional protective measures to reduce the risk of and detect cyber incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly. There can be no assurances that our protective measures will prevent attacks that could have a significant impact on our business.

Natural disasters, war and other events could adversely affect our future revenues and operating income.

Natural disasters (including pandemics), war, terrorism, labor disruptions and international conflicts, and actions taken by the United States and other governments or by our customers or suppliers in response to such events, could cause significant economic disruption and political and social instability in the United States and in areas outside of the United States in which we operate. These events could result in decreased demand for our products, adversely affect our manufacturing and distribution capabilities, or increase the costs for, or cause interruptions in, the supply of materials from our suppliers.

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Risks Related to Our Common Stock

Material weaknesses in our internal control over financial reporting could be identified, which if not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements.

During fiscal 2017, the Company identified a material weakness in internal control over financial reporting, which has been remediated. However, the Company can make no assurances that a material weakness will not be identified in the future or that, if identified, it will be properly corrected. In the event we are unable to remediate a material weakness identified in the future, we may be unable to provide holders of our securities with required financial information in a timely and reliable manner, and we may incorrectly report financial information. Either of these events could have a material adverse effect on our operations, investor, supplier and customer confidence in our reported financial information and/or the trading price of our common stock.

Additional stock issuance authorizations.

Our board of directors has the authority to issue up to 1,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions, including voting rights, of such shares without any future vote or action by the shareholders. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing a change in control of our company. Ohio corporation law contains provisions that may discourage takeover bids for our company that have not been negotiated with the board of directors. Such provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, sales of substantial amounts of shares in the public market could adversely affect the market price of our common stock and our ability to raise additional capital at a price favorable to us.

The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders and subject us to litigation.

The market price of our common stock may be subject to significant fluctuations due to numerous factors, including but not limited to the risks described in this Risk Factors section. In addition, the stock market in general, The NASDAQ Global Market and the market for diagnostics companies in particular may experience a loss of investor confidence. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, our financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class-action litigation. Class-action litigation, even if unsuccessful, could be costly to defend and divert management s attention and resources, which could further materially harm our financial condition and results of operations.

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There can be no assurance that we will continue to pay dividends.

The declaration, amount and timing of the Company s dividends are subject to capital availability and determinations by our board of directors that cash dividends are in the best interest of our stockholders and are in compliance with all respective laws and our agreements applicable to the declaration and payment of cash dividends. Our continuing ability to pay dividends will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, including acquisitions, debt service requirements, results of operations, financial condition and other factors beyond our control that our board of directors may deem relevant. A reduction in or elimination of our dividend payments, or our dividend program could have a negative effect on our stock price.

ITEM 1B.

UNRESOLVED STAFF COMMENTS

None.

ITEM 2.

PROPERTIES

Our corporate offices, infectious disease Diagnostics manufacturing facility, and infectious disease Diagnostics research and development facility are located in five buildings totaling approximately 120,000 square feet on 10 acres of land in the Village of Newtown, a suburb of Cincinnati, Ohio. These properties are owned by us. Our blood-chemistry manufacturing and research and development operations are located in an approximately 30,000 square foot leased facility in Billerica, Massachusetts. We also operate a Diagnostics sales and distribution center near Milan, Italy in an approximately 18,000 square foot building. This facility is owned by our wholly-owned Italian subsidiary, Meridian Bioscience Europe s.r.l. We also rent office space in Paris, France and Braine-l Alleud, Belgium for sales and administrative functions.

Our Life Science operations are conducted in several facilities in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; Sydney, Australia; and Beijing, China. Our facility in Memphis, Tennessee consists of two buildings totaling approximately 44,000 square feet and is owned by us. Our leased facility in Boca Raton, Florida contains approximately 7,500 square feet of manufacturing space. Following are details of our other Life Science facilities, all of which are leased: London approximately 21,000 square feet of sales, warehouse, distribution, research and development, manufacturing and administrative office space; Luckenwalde approximately 10,000 square feet of sales, warehouse and manufacturing space; Sydney approximately 5,000 square feet of sales and warehouse space; Beijing less than 1,000 square feet of sales and business development space.

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ITEM 3.

LEGAL PROCEEDINGS

We are a party to various litigation matters that we believe are in the normal course of business. Aside from the matters discussed below, the ultimate resolution of these matters is not expected to have a material adverse effect on our financial position, results of operations or cash flows, and no material provision has been made in the accompanying Consolidated Financial Statements for these matters.

On November 15, 2017, Barbara Forman filed a class action complaint in the United States District Court for the Southern District of Ohio naming Meridian, its Chief Executive Officer and Chief Financial Officer (in their capacities as such) as defendants. An amended complaint was filed on April 16, 2018 and the Company believes the essential elements of the amended complaint are the same. The complaint and the amended complaint are hereafter referred to as the Complaint . The Complaint seeks compensatory damages and attorneys fees. Meridian has filed a motion to dismiss the Complaint, to which the plaintiff responded on August 14, 2018. The motion has been fully briefed and remains pending before the court. We are unable to determine or predict the ultimate outcome or estimate the range of possible losses, if any. Accordingly, no provision for litigation losses has been included within the accompanying Consolidated Statement of Operations for fiscal 2018 or 2017.

On December 6, 2017, Michael Edelson filed a derivative complaint in the United States District Court for the Southern District of Ohio naming Meridian, its Chief Executive Officer, Chief Financial Officer and certain members of Meridian s Board of Directors and Audit Committee (in their capacities as such) as defendants. The complaint alleges that Meridian made false and misleading representations concerning certain of Magellan s lead test systems at or around the time of Meridian s acquisition of Magellan and subsequent thereto, and the complaint alleges that certain members of the Board of Directors and Audit Committee breached their fiduciary duties in their oversight of the Company s public disclosures and corporate governance matters. The complaint seeks compensatory damages, equitable relief relating to corporate governance matters and attorneys fees. The case has been stayed by agreement of the parties pending resolution of the motion to dismiss the class action described above. We are unable to determine or predict the ultimate outcome or estimate the range of possible losses, if any. Accordingly, no provision for litigation losses has been included within the accompanying Consolidated Statement of Operations for fiscal 2018 or 2017.

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Approximately $600 of expense for attorneys fees related to the above two class action matters is included within the accompanying Consolidated Statement of Operations for fiscal 2018. The Company maintains an insurance policy covering these matters, which has a $500 deductible.

On April 17, 2018, Magellan received a subpoena from the United States Department of Justice (DOJ) regarding its LeadCare product line. The subpoena outlines documents to be produced, and the Company is cooperating with the DOJ in this matter. The Company maintains rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements, and is working with the DOJ to promptly respond to the subpoena. However, the Company cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on the Company. Approximately $775 of expense for attorneys fees related to this matter is included within the accompanying Condensed Consolidated Statement of Operations for fiscal 2018.

On October 9, 2018, the Company and DiaSorin Inc. entered into a strategic collaboration to sell DiaSorin s *Helicobacter pylori* stool antigen test to detect *H. pylori* for use on its automated LIAISON platform under the Meridian brand name worldwide. The new collaboration results in the termination of all pending legal disputes between the two parties and will expand the previous agreement between DiaSorin and Meridian, which focused on the sale, by DiaSorin, of co-developed products in major countries in continental Europe.

ITEM 4.

MINE SAFETY DISCLOSURES

Not applicable.

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PART II.

ITEM 5.

MARKET FOR REGISTRANT S COMMON

EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Refer to Forward-Looking Statements following the Index in front of this Form 10-K and Item 1A Risk Factors on pages 14 through 26 of this Annual Report.

Market Information

Our common stock trades on the NASDAQ Global Select Market under the symbol VIVO.

Holders of our Common Stock

As of September 30, 2018, there were approximately 635 holders of record and approximately 13,200 beneficial owners of our common shares.

Dividends

Quarterly Financial Data (Unaudited) relating to our dividends in Note 11 of the Consolidated Financial Statements are incorporated herein by reference.

During fiscal 2018 and 2017, the indicated annual cash dividend rate was established at $0.50 per share (down from $0.80 per share in fiscal 2016). The declaration and amount of dividends will be determined by the board of directors in its discretion based upon its evaluation of earnings, cash flow requirements and future business developments and opportunities, including acquisitions. At its meeting on November 7, 2018, the board of directors announced a continuation of the $0.50 indicated annual dividend rate per share for fiscal 2019. We paid dividends of $0.50, $0.575 and $0.80 per share in fiscal 2018, 2017 and 2016, respectively. Except as may otherwise be prohibited by applicable law, there are no restrictions on cash dividend payments.

Stock Total Return Performance

The following graph shows the yearly percentage change in Meridian s cumulative total shareholder return on its common stock as measured by dividing the sum of (A) the cumulative amount of dividends, assuming dividend reinvestment, during the periods presented, and (B) the difference between Meridian s share price at the end and the beginning of the periods presented; by the share price at the beginning of the periods presented with the NASDAQ Composite Index and a Peer Group Index. The 2017 Peer Group consists of bioMerieux S.A., Bio-Rad Laboratories, Inc., GenMark Diagnostics, Inc., IDEXX Laboratories, Inc., Luminex Corporation, Myriad Genetics, Inc., Neogen Corporation, OraSure Technologies, Inc., Quidel Corporation and Trinity Biotech Plc. The 2018 Peer Group consists of bioMerieux S.A., Bio-Rad Laboratories, Inc., GenMark Diagnostics, Inc., Luminex Corporation, Myriad Genetics, Inc., OraSure Technologies, Inc., Quidel Corporation and Trinity Biotech Plc.

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ITEM 6.

SELECTED FINANCIAL DATA

Income Statement Information (Amounts in thousands, except per share data)

For the Year Ended September 30,	**2018**	**2017**	**2016**	**2015**	**2014**
Net revenues	$ 213,571	$ 200,771	$ 196,082	$ 194,830	$ 188,832
Gross profit	130,461	124,292	127,212	121,882	117,243
Operating income	31,584	37,382	51,378	56,060	52,392
Net earnings	23,849	21,557	32,229	35,540	34,743
Basic earnings per share	$ 0.56	$ 0.51	$ 0.77	$ 0.85	$ 0.84
Diluted earnings per share	$ 0.56	$ 0.51	$ 0.76	$ 0.85	$ 0.83
Cash dividends declared per share	$ 0.500	$ 0.575	$ 0.800	$ 0.800	$ 0.790
Book value per share	$ 4.14	$ 4.02	$ 3.95	$ 3.96	$ 3.87

Balance Sheet Information

As of September 30,	**2018**	**2017**	**2016**	**2015**	**2014**
Current assets	$ 139,053	$ 133,875	$ 126,791	$ 119,422	$ 108,832
Current liabilities	24,173	22,887	22,571	15,251	13,735
Total assets	251,377	249,777	252,028	183,282	176,929
Long-term debt obligations	50,180	54,647	58,360		
Shareholders equity	175,418	169,585	166,472	165,873	161,029

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ITEM 7.

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL

CONDITION AND RESULTS OF OPERATIONS

Refer to Forward-Looking Statements following the Index in front of this Form 10-K and Item 1A Risk Factors on pages 14 through 26 of this Annual Report.

In the discussion that follows, all dollar amounts are in thousands (both tables and text), except per share data.

Results of Operations:

Fourth Quarter

Net earnings for the fourth quarter of fiscal 2018 decreased 5% to $5,434, or $0.13 per diluted share, from net earnings for the fourth quarter of fiscal 2017 of $5,726, or $0.13 per diluted share. The fiscal 2018 fourth quarter results include $4,576 of costs associated with the transition to our new CEO, other restructuring costs and litigation costs (collectively, restructuring and litigation costs), along with certain one-time tax effects of the U.S. tax reform act enacted in December 2017 (combined impact on net earnings of $3,145, or $0.07 per diluted share). The fiscal 2017 fourth quarter results included $762 of restructuring and litigation costs (impact on net earnings of $495, or $0.01 per diluted share). Consolidated revenues for the fourth quarter of fiscal 2018 totaled $53,100, an increase of 7% compared to the fourth quarter of fiscal 2017, also increasing 7% on a constant-currency basis.

Revenues for the Diagnostics segment for the fourth quarter of fiscal 2018 increased 2% compared to the fourth quarter of fiscal 2017 (also 2% on a constant-currency basis), comprised of a 6% decrease in molecular assay products and a 5% increase in immunoassay and blood chemistry assay products. With a 9% increase in its molecular reagents products and a 27% increase in its immunological reagents products, revenues for our Life Science segment increased 19% in the fourth quarter of fiscal 2018 compared to the fourth quarter of fiscal 2017. On a constant-currency basis, revenues for our Life Science Segment increased 20%.

The fourth quarter revenues reflect improvement in our respiratory illness and blood chemistry assay product lines, being partially offset by decreased revenues for our gastrointestinal assays. Both Life Science product categories performed well, reflecting continued growth in the Asia-Pacific region and high volume sales to IVD manufacturer customers.

Fiscal Year

Net earnings for fiscal 2018 increased 11% to $23,849, or $0.56 per diluted share, from net earnings for fiscal 2017 of $21,557, or $0.51 per diluted share. Fiscal 2018 results include $13,051 of restructuring and litigation costs, along with certain one-time tax effects of the U.S. tax reform act enacted in December 2017 (combined impact on net earnings of $7,856, or $0.18 per diluted share). Fiscal 2017 results include $762 of restructuring and litigation costs, and a $6,628 impairment charge against Diagnostics segment goodwill (combined impact on net earnings of $7,123, or $0.17 per diluted share). Consolidated revenues increased 6% to $213,571 for fiscal 2018 compared to fiscal 2017, increasing 5% on a constant-currency basis.

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In fiscal 2018, revenues for the Diagnostics segment increased 5% compared to fiscal 2017 (4% on a constant-currency basis). This increase is comprised of relatively flat revenues for our molecular assay products and a 6% increase in immunoassay and blood chemistry assay products. With a 12% increase in its molecular reagents business and a 9% increase in its immunological reagents business, revenues of our Life Science segment increased 10% during fiscal 2018 compared to fiscal 2017, increasing 9% on a constant-currency basis.

Update on Lead Testing

We offer multiple lead testing systems that are capable of processing both capillary and venous blood samples. Our LeadCare Plus and LeadCare Ultra systems, which accounted for approximately 10% of lead testing annual revenues in fiscal 2016, are used predominantly with venous blood samples. Typically, the Ultra and Plus systems are used in a reference lab setting. Our LeadCare II system is predominantly used with capillary blood samples and is typically used in a physician office setting. LeadCare II system revenue represented approximately 90% of our lead testing product revenues in fiscal 2016. The LeadCare II system is the only point-of-care system for testing lead exposure, receiving CLIA-waived status. Other methods for testing blood lead levels include Graphite Furnace Atomic Absorption Spectroscopy and Mass Spectrometry, which are typically performed in hospital and reference laboratory settings.

On May 17, 2017, the FDA issued a field safety notice advising customers to discontinue use of our lead testing systems with venous blood samples. This field safety notice was followed by product recall notices on May 25th and June 5th. Subsequent to the issuances of these field safety and product recall notices, the FDA completed an inspection of our Quality System for our lead testing manufacturing facility in Billerica, Massachusetts, and issued its Form 483, Inspectional Observations, on June 29, 2017, which was expectedly followed by a Warning Letter issued on October 23, 2017. During our 2017 third fiscal quarter, it was determined that a potential impairment of goodwill recorded in connection with the acquisition of Magellan had occurred (i.e., a triggering event). An impairment charge of $6,628, on both a pre-tax and after-tax basis, was recorded during the fiscal 2017 third quarter as set forth in Note 1(h) *Summary of Significant Accounting Policies Intangible Assets* of the accompanying Consolidated Financial Statements.

The Warning Letter requires periodic reporting on our remediation progress. To date, we have satisfied our post-Warning Letter reporting requirements with the FDA. During fiscal 2018 and 2017, we incurred approximately $1,600 in aggregate remediation costs, primarily related to regulatory consultants and studies required to reinstate our venous blood sample claim, and we expect to incur additional costs during fiscal 2019. In the course of remediation, we may encounter additional matters that warrant notifications to the FDA and/or customers regarding the use of its products. At this time, we do not believe that any such notifications would impact the ability to use the LeadCare systems with capillary blood samples.

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As set forth in Item 3. Legal Proceedings , on April 17, 2018, Magellan received a subpoena from the United States Department of Justice (DOJ) regarding its LeadCare product line. The subpoena outlines documents to be produced, and we are cooperating with the DOJ in this matter. We maintain rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements, and are working with the DOJ to promptly respond to the subpoena. However, we cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on Meridian.

USE OF NON-GAAP MEASURES

We have supplemented our reported GAAP financial information with information on net earnings, basic earnings per share and diluted earnings per share excluding the effects of: (i) restructuring and litigation costs (fiscal 2018, 2017 and 2016); (ii) the impairment charge against Diagnostics segment goodwill (fiscal 2017); (iii) acquisition-related costs (fiscal 2016); and (iv) certain one-time tax effects of the tax reform act each of which is a non-GAAP measure. We have provided in the tables below reconciliations to the net earnings, basic earnings per share and diluted earnings per share amounts reported under U.S. Generally Accepted Accounting Principles. We believe that this information is useful to those who read our financial statements and evaluate our operating results because:

1. These measures help to appropriately evaluate and compare the results of operations from period to period by removing the impacts of these non-routine items; and

2. These measures are used by our management for various purposes, including evaluating performance against incentive bonus achievement targets, comparing performance from period to period in presentations to our board of directors, and as a basis for strategic planning and forecasting.

Revenue reported on a constant-currency basis is also a non-GAAP measure and is calculated by applying current period average foreign currency exchange rates to each of the comparable periods. Management analyzes revenue on a constant-currency basis to better measure the comparability of results between periods. Because changes in foreign currency exchange rates have a non-operating impact on revenue, management believes that evaluating revenue changes on a constant-currency basis provides an additional and meaningful assessment of revenue to both management and investors.

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These non-GAAP measures may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP measures have limitations, in that they do not reflect all amounts associated with our results as determined in accordance with U.S. GAAP. Therefore, these measures should only be used to evaluate our results in conjunction with corresponding GAAP measures.

	2018	2017	2016
Net Earnings -			
U.S. GAAP basis	$ 23,849	$ 21,557	$ 32,229
Restructuring costs [1]	6,430	87	431
Litigation costs [1]	3,205	408	
Goodwill impairment charge [2]		6,628	
Acquisition-related costs [1]			1,233
One-time benefit from tax law change	(2,655)		
Repatriation transition tax	876		
Adjusted earnings	$ 31,705	$ 28,680	$ 33,893
Net Earnings per Basic Common Share -			
U.S. GAAP basis	$ 0.56	$ 0.51	$ 0.77
Restructuring costs [1]	0.15		0.01
Litigation costs [1]	0.08	0.01	
Goodwill impairment charge [2]		0.16	
Acquisition-related costs [1]			0.03
One-time benefit from tax law change	(0.06)		
Repatriation transition tax	0.02		
Adjusted Basic EPS	$ 0.75	$ 0.68	$ 0.81
Net Earnings per Diluted Common Share -			
U.S. GAAP basis	$ 0.56	$ 0.51	$ 0.76
Restructuring costs [1]	0.15		0.01
Litigation costs [1]	0.07	0.01	
Goodwill impairment charge [2]		0.16	
Acquisition-related costs [1]			0.03
One-time benefit from tax law change	(0.06)		
Repatriation transition tax	0.02		
Adjusted Diluted EPS [3]	$ 0.74	$ 0.67	$ 0.80

(1) These restructuring costs, litigation costs, and acquisition-related costs are net of income tax effects of $3,416, $267 and $494 in fiscal 2018, 2017 and 2016, respectively, which were calculated using the effective tax rates of the jurisdictions in which the costs were incurred.

(2) Since the goodwill impairment charge was not deductible for tax purposes, there are no income tax effects.

(3) Net Earnings per Diluted Common Share for fiscal 2017 does not sum to the total Adjusted Diluted EPS due to rounding.

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REVENUE OVERVIEW

Below are analyses of the Company s revenue, by reportable segment, provided for each of the following:

- By Geographic Region

- By Product Platform/Type

Revenue Overview- By Reportable Segment & Geographic Region

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations for infectious disease diagnostic products in Cincinnati, Ohio and manufacturing operations for products detecting elevated lead levels in blood in Billerica, Massachusetts (near Boston). These diagnostic test products are sold and distributed in the countries comprising North and Latin America (the Americas); Europe, Middle East and Africa (EMEA); and other countries outside of the Americas and EMEA (rest of the world, or ROW). The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; and Luckenwalde, Germany, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents domestically and abroad, including a sales and business development facility, with outsourced distribution capabilities, in Beijing, China to further pursue growing revenue opportunities in Asia.

Revenues for the Diagnostics segment, in the normal course of business, may be affected from quarter to quarter by buying patterns of major distributors, seasonality and the severity of seasonal diseases and outbreaks, and foreign currency exchange rates. Revenues for the Life Science segment, in the normal course of business, may be affected from quarter to quarter by buying patterns of major customers, and foreign currency exchange rates. We believe that the overall breadth of our product lines serves to reduce the variability in consolidated revenues due to these factors.

Revenues for each of our segments and the geographic regions therein are shown below.

	2018	2017	2016	2018 vs. 2017 Inc (Dec)	2017 vs. 2016 Inc (Dec)
Diagnostics-					
Americas	$ 126,647	$ 119,685	$ 123,187	6%	(3)%
EMEA	21,231	20,273	19,024	5%	7%
ROW	2,576	3,563	2,903	(28)%	23%
Total Diagnostics	150,454	143,521	145,114	5%	(1)%
Life Science-					
Americas	20,792	19,978	19,484	4%	3%
EMEA	24,530	21,968	20,075	12%	9%
ROW	17,795	15,304	11,409	16%	34%
Total Life Science	63,117	57,250	50,968	10%	12%

Consolidated	$ 213,571	$ 200,771	$ 196,082	6%	2%
% of total revenues-					
Diagnostics	70%	71%	74%		
Life Science	30%	29%	26%		
Total	100%	100%	100%		
Ex-Americas	31%	30%	27%		

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Revenue Overview- By Product Platform/Type

The revenues generated by each of our reportable segments result primarily from the sale of the following segment-specific categories of products:

Diagnostics

1) Molecular assays that operate on our Alethia platform (formerly branded as ***illumi****gene*)

2) Immunoassays and blood chemistry assays on multiple technology platforms

Life Science

1) Molecular reagents

2) Immunological reagents

	2018	2017	2016	2018 vs. 2017 Inc (Dec)	2017 vs. 2016 Inc (Dec)
Diagnostics-					
Molecular assays	$ 34,011	$ 33,901	$ 38,302	%	(11)%
Immunoassays & blood chemistry assays	116,443	109,620	106,812	6%	3%
Total Diagnostics	$ 150,454	$ 143,521	$ 145,114	5%	(1)%
Life Science-					
Molecular reagents	$ 24,613	$ 21,998	$ 20,506	12%	7%
Immunological reagents	38,504	35,252	30,462	9%	16%
Total Life Science	$ 63,117	$ 57,250	$ 50,968	10%	12%
% of Diagnostics revenues-					
Molecular assays	23%	24%	26%		
Immunoassays & blood chemistry assays	77%	76%	74%		
Total Diagnostics	100%	100%	100%		
% of Life Science revenues-					
Molecular reagents	39%	38%	40%		
Immunological reagents	61%	62%	60%		

Total Life Science	100%	100%	100%

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Following is a discussion of the revenues generated by these product platforms/types and/or disease states:

Diagnostics Products

Gastrointestinal Assays

During fiscal 2018, revenues from our gastrointestinal products, which include tests for *C. difficile*, *H. pylori* and certain foodborne pathogens, among others, totaled $78,803. This represents a 1% increase from fiscal 2017 and follows a 12% decrease during fiscal 2017. We continue to face pricing and volume pressures within this product category that will carry into fiscal 2019 and beyond for our current products. We have executed multi-year supply agreements with our two largest reference laboratory customers for *H. pylori* tests to secure volume, albeit at lower selling prices. We continue to believe there are ongoing benefits to be realized from our partnerships with managed care companies in promoting: (i) the health and economic benefits of a test and treat strategy; (ii) changes in policies that discourage the use of traditional serology methods and promote the utilization of active infection testing methods; and (iii) physician behavior movement away from serology-based testing and toward direct antigen testing.

Contributing to the competitive pressures being faced in this product category, the patents for our *H. pylori* products, owned by us, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase in the near future, and such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. Our product development pipeline includes new product initiatives for the detection of *H. pylori*, and we recently entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests. We are unable to provide assurances that we will be successful with any strategy or that any strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

Respiratory Illness Assays

Including tests for influenza, RSV, Group A Strep, Pertussis, and Mycoplasma pneumonia, among others, our respiratory illness product revenues increased 22% in fiscal 2018, following a 2% increase in fiscal 2017. These increased revenues reflect volume growth from a particularly strong 2017 2018 flu season, as measured by the rate of laboratory-confirmed influenza hospitalizations (published by the CDC).

Blood Chemistry Assays

Revenues from our sale of products to test for elevated levels of lead in blood increased 5% during fiscal 2018 to a total of $19,109. This follows fiscal 2017 revenues from such products increasing 2% over the twelve months ended September 30, 2016, of which the six months ended March 31, 2016 were prior to Meridian s ownership of Magellan. These increases were achieved despite the effect on venous blood testing revenue of the previously-noted FDA-related activities.

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Life Science Products

During fiscal 2018, revenues from our Life Science segment increased 10%, with revenues from molecular reagent sales increasing 12% compared to fiscal 2017 and revenues from immunological reagent sales increasing 9%. Life Science segment revenues increased 12% in fiscal 2017, with revenues from molecular reagent sales increasing 7% compared to fiscal 2016 and revenues from immunological reagent sales increasing 16%. Our Life Science segment s growth was impacted by the movement in currency exchange rates since fiscal 2017, with revenues increasing 9% on a constant-currency basis over fiscal 2017. During fiscal 2018, our Life Science segment continued to benefit from increased revenue from sales into China, with such sales totaling approximately $8,300 during fiscal 2018 representing an approximate 41% increase over fiscal 2017.

Foreign Currency

Fluctuations in foreign currency exchange rates since fiscal 2017 had an approximate $2,200 favorable impact on fiscal 2018 revenues; $1,400 within the Diagnostics segment and $800 within the Life Science segment. This compares to year-to-year currency exchange rates having an approximate $1,200 unfavorable impact on revenues in fiscal 2017; $400 within the Diagnostics segment and $800 within the Life Science segment. Due to natural hedge relationships with expenses, both cost of sales and operating expenses, the overall impact of exchange rate fluctuations on net earnings was not significant during fiscal 2018, 2017 or 2016.

Significant Customers

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 9 of the accompanying Consolidated Financial Statements.

Gross Profit:

	2018	2017	2016	2018 vs. 2017 Inc (Dec)	2017 vs. 2016 Inc (Dec)
Gross Profit	$ 130,461	$ 124,292	$ 127,212	5%	(2)%
Gross Profit Margin	61%	62%	65%	-1 point	-3 points

The overall gross profit margin decrease during fiscal 2018 primarily results from the combined effects of: (i) pricing pressure in our Diagnostics segment; (ii) mix of products sold, particularly decreased contribution from certain of our higher margin gastrointestinal assays; and (iii) operating segment mix. The overall decrease in the gross profit margin from fiscal 2016 to fiscal 2017 reflects the combined effects of: (i) mix of products sold, particularly decreased contribution from certain of our higher margin gastrointestinal assays; (ii) customer mix; (iii) operating segment mix; and (iv) decreased production levels in certain of our production facilities designed to reduce inventory levels.

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Our overall operations consist of the sale of diagnostic test kits for various disease states and in alternative test formats, as well as bioresearch reagents, bulk antigens and antibodies, PCR/qPCR reagents, nucleotides, competent cells, and proficiency panels. Product revenue mix shifts, in the normal course of business, can cause the consolidated gross profit margin to fluctuate by several points.

Operating Expenses -

Segment Detail

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2016:					
Diagnostics	$ 11,412	$ 21,339	$ 21,483	$	$ 54,234
Life Science	2,779	8,717	7,946		19,442
Unallocated expenses				2,158	2,158
Total 2016 Expenses	**$ 14,191**	**$ 30,056**	**$ 29,429**	**$ 2,158**	**$ 75,834**
Fiscal 2017:					
Diagnostics	$ 13,433	$ 22,942	$ 23,603	$	$ 59,978
Life Science	2,603	9,446	7,493		19,542
Unallocated expenses				7,390	7,390
Total 2017 Expenses	**$ 16,036**	**$ 32,388**	**$ 31,096**	**$ 7,390**	**$ 86,910**
Fiscal 2018:					
Diagnostics	$ 13,772	$ 24,990	$ 26,257	$	$ 65,019
Life Science	3,098	9,478	8,231		20,807
Unallocated expenses				13,051	13,051
Total 2018 Expenses	**$ 16,870**	**$ 34,468**	**$ 34,488**	**$ 13,051**	**$ 98,877**

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Operating Expenses -

Comparisons to Prior Year

Periods

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2016 Expenses	**$ 14,191**	**$ 30,056**	**$ 29,429**	**$ 2,158**	**$ 75,834**
% of Revenues	7%	15%	15%	1%	39%
Fiscal 2017 Increases (Decreases):					
Diagnostics	2,021	1,603	2,120		5,744
Life Science	(176)	729	(453)		100
Restructuring costs				(543)	(543)
Litigation costs				628	628
Goodwill impairment charge				6,628	6,628
Acquisition-related costs				(1,481)	(1,481)
2017 Expenses	**$ 16,036**	**$ 32,388**	**$ 31,096**	**$ 7,390**	**$ 86,910**
% of Revenues	8%	16%	15%	4%	43%
% Increase	13%	8%	6%	242%	15%
Fiscal 2018 Increases (Decreases):					
Diagnostics	339	2,048	2,654		5,041
Life Science	495	32	738		1,265
Restructuring costs				8,572	8,572
Litigation costs				3,717	3,717
Goodwill impairment charge				(6,628)	(6,628)
2018 Expenses	**$ 16,870**	**$ 34,468**	**$ 34,488**	**$ 13,051**	**$ 98,877**
% of Revenues	8%	16%	16%	6%	46%
% Increase	5%	6%	11%	77%	14%

Total operating expenses increased during both fiscal 2018 and fiscal 2017, resulting primarily from the combined effects of the following:

Diagnostics

Fiscal 2018 increase

Increased Selling & Marketing costs, reflecting increased commission and bonus payments made in connection with the increased revenue levels, along with costs associated with the new

branding strategy; and

Increased General & Administrative costs due in large part to the cash incentive compensation resulting from the revenue and net earnings results achieved, along with increased Quality System remediation costs related to Magellan.

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Fiscal 2017 increase

Incremental Magellan operating expenses due to six additional months of Meridian ownership in fiscal 2017; and

Increased Research & Development costs in connection with instrumentation development programs.

Life Science

Fiscal 2018 increase

Increased Research & Development costs related to new molecular reagent products; and

Increased General & Administrative costs due in large part to the cash incentive compensation resulting from the revenue and net earnings results achieved.

Fiscal 2017 increase

Increased investment in Sales & Marketing activities, including costs associated with the WFOE established in Beijing, China during fiscal 2017.

Other

Fiscal 2018 and fiscal 2017 activity

Restructuring costs (reflected within Other in the above tables) totaled $8,706 and $134 in fiscal 2018 and fiscal 2017, respectively. These costs reflect: (i) compensation and benefits for our previous Executive Chairman and CEO throughout fiscal 2018, the period during which we also have the compensation and benefits of a new CEO; and (ii) the costs of terminations and related expenses incurred in connection with realigning our business structure.

Litigation costs (reflected within Other in the above tables) totaled $4,345 and $628 in fiscal 2018 and fiscal 2017, respectively, and relate to the matters discussed in Item 3. Legal Proceedings .

A goodwill impairment charge totaling $6,628 was recorded in fiscal 2017, with no such additional charges occurring in fiscal 2018.

Costs were incurred in fiscal 2016 in connection with: (i) acquisition activities, most notably related to the acquisition of Magellan; and (ii) restructuring Sales & Marketing leadership, primarily related to severance obligations for former employees.

Operating Income

Operating income decreased 15% and 27% in fiscal 2018 and 2017, respectively, as a result of the factors discussed above, including the restructuring and litigation costs in fiscal 2018 and the Magellan goodwill impairment charge and restructuring and litigation costs in fiscal 2017.

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Other Income and Expense

Other income and expense in fiscal 2018 and fiscal 2017 includes interest costs on the term loan used to fund the acquisition of Magellan. The effective interest rate on this term loan is 2.76%.

Income Taxes

The effective rate for income taxes was 21%, 41% and 36% for fiscal 2018, 2017 and 2016, respectively. The lower fiscal 2018 taxes primarily result from the combined net impact of the following effects of the recently-enacted tax reform act (see Note 6 *Income Taxes* of the accompanying Consolidated Financial Statements):

- Application of an approximate 24.5% blended federal rate due to the lowering of the applicable federal rate from 35% to 21%;
- Recognizing a one-time $2,655 tax benefit including the re-measurement of deferred tax balances at the lower rate; and
- Recording a one-time $876 tax expense related to the estimated repatriation transition tax on foreign earnings.

The increased fiscal 2017 rate results primarily from the non-deductibility of the Magellan goodwill impairment charge. Excluding the effects of the Magellan goodwill impairment charge, the effective tax rate was 35% for fiscal 2017.

Impact of Inflation

To the extent feasible, we have consistently followed the practice of adjusting our prices to reflect the impact of inflation on salaries and fringe benefits for employees and the cost of purchased materials and services. Inflation and changing prices did not have a material adverse impact on our gross margin, revenues or operating income in fiscal 2018, 2017 or 2016.

Liquidity and Capital Resources:

Liquidity

Our cash flow and financing requirements are determined by analyses of operating and capital spending budgets, debt service, consideration of acquisition plans, and consideration of common share dividends. We have historically maintained a credit facility to augment working capital requirements and to respond quickly to acquisition opportunities.

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We have an investment policy that guides the holdings of our investment portfolio, which presently consists of bank savings accounts and institutional money market mutual funds. Our objectives in managing the investment portfolio are to: (i) preserve capital; (ii) provide sufficient liquidity to meet working capital requirements and fund strategic objectives such as acquisitions; and (iii) capture a market rate of return commensurate with market conditions and our policy s investment eligibility criteria. As we look forward, we will continue to manage the holdings of our investment portfolio with preservation of capital being the primary objective.

Considering the various worldwide geo-political and geo-economic conditions (including Brexit, as more fully discussed within the Risk Factors section of Part 1A), we do not expect macroeconomic conditions to have a significant impact on our liquidity needs, financial condition or results of operations, although no assurances can be made in this regard. We intend to continue to fund our working capital requirements and dividends from current cash flows from operating activities and cash on hand. If needed, we also have an additional source of liquidity through our $30,000 bank revolving credit facility. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets tightens for an extended period of time, and such conditions impact the collectability of our customer accounts receivable, impact credit terms with our vendors, or disrupt the supply of raw materials and services.

Fluctuations in overall stock market valuations may raise questions as to the potential impairment of goodwill and other long-lived assets. Our annual goodwill impairment review takes place as of June 30th each year, and is performed at the reporting unit level. While these annual reviews to-date have not resulted in the recording of any impairments, a $6,628 impairment charge was recorded in fiscal 2017 on the goodwill resulting from the Magellan acquisition due to certain FDA activities related to our lead testing system utilizing venous blood samples (see full description previously within this MD&A). As of September 30, 2018, our stock price was $14.90 per share, compared to our book value per share of $4.14. This relationship, stock price trading at a 3.6x multiple of book value, is an indicator that the fluctuation in overall stock market valuations and its impact on our stock price has not been a triggering event for further impairment of our goodwill and other long-lived assets.

As of September 30, 2018, our cash and equivalents balance is $59,763 or $2,691 higher than at the end of fiscal 2017. This increase results in large part from the cash flows from operating activities being more than sufficient to cover capital expenditures, shareholder dividends and debt service. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and shareholder dividends during the next 12 months.

The indicated annual cash dividend rate for fiscal 2018 was established at $0.50 per share. Consistent with this annual indicated dividend rate, a cash dividend of $0.125 was declared for each of the quarters of fiscal 2018.

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Capital Resources

In connection with the acquisition of Magellan, the Company entered into a $60,000 five-year term loan and related interest rate swap agreement with a commercial bank, the details of which are set forth in Note 5 of the accompanying Consolidated Financial Statements. In addition, we have a $30,000 revolving credit facility (discussed above) with a commercial bank that expires March 31, 2021. As of November 22, 2018, there were no borrowings outstanding on this facility and we had 100% borrowing capacity available to us. We have had no borrowings outstanding under this revolving credit facility during fiscal 2018, 2017 or 2016.

Our capital expenditures totaled $4,201 for fiscal 2018 and were largely related to laboratory equipment, manufacturing equipment and a new business intelligence system. During fiscal 2019 our capital expenditures are estimated to range between approximately $4,000 to $5,000, with the actual amount dependent upon actual operating results and the phasing of certain projects. Such expenditures may be funded with cash and equivalents on hand, operating cash flows and/or availability under the $30,000 revolving credit facility discussed above.

Known Contractual Obligations:

Known contractual obligations and their related due dates were as follows as of September 30, 2018:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases [1]	$ 7,914	$ 1,866	$ 4,139	$ 1,480	$ 429
Purchase obligations [2]	11,398	11,271	117	10	
Loan principal payments [3]	50,250	5,250	45,000		
Scheduled interest payments [3]	3,094	1,358	1,736		
Uncertain income tax positions liability and interest [4]	423	423			
Total	$ 73,079	$ 20,168	$ 50,992	$ 1,490	$ 429

(1) Meridian and its subsidiaries are lessees of: (i) office and warehouse buildings in Ohio, Massachusetts, Florida, Australia, Belgium, France, Germany, China and the U.K.; (ii) automobiles for use by the diagnostic direct sales forces in the U.S. and Europe; and (iii) certain office equipment such as facsimile and copier machines across all business units, under operating lease agreements that expire at various dates.

(2) Purchase obligations relate primarily to outstanding purchase orders for inventory, including instruments, service items, and research and development activities. These contractual commitments are not in excess of expected production requirements over the next twelve months.

(3) These principal and interest payments relate to the $60,000 five-year term loan with a commercial bank entered into in connection with the acquisition of Magellan, and reflect the impact of an interest rate swap agreement with the commercial bank, which effectively converts the variable interest rate on the term loan to a fixed rate of 2.76%. The details of the loan and the interest rate swap are set forth in Note 5 of the accompanying Consolidated Financial Statements.

(4) Due to inherent uncertainties in the timing of settlement of tax positions, we are unable to estimate the timing of the effective settlement of these obligations.

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Other Commitments and Off-Balance Sheet Arrangements:

License Agreements

Meridian has entered into various license agreements that require payment of royalties based on a specified percentage of sales of related products. Approximately 86% of our royalty expenses relate to our Diagnostics operating segment, where the royalty rates range from 4% to 8%. Meridian expects that payments under these agreements will amount to approximately $2,700 in fiscal 2019.

Off-Balance Sheet Arrangements

We do not utilize special-purpose financing vehicles or have undisclosed off-balance sheet arrangements.

Market Risk Exposure:

Foreign Currency Risk

We have market risk exposure related to foreign currency transactions from our operations outside the United States, as well as certain suppliers to our domestic businesses located outside the United States. The foreign currencies where we have market risk exposure are the Australian dollar, British pound, Chinese yuan and Euro. Assessing foreign currency exposures is a component of our overall ongoing risk management process, with such currency risks managed as we deem appropriate.

Concentration of Customers/Products Risk

Our Diagnostics segment s revenues from sales through two U.S. distributors were 29% of the segment s total revenues or 20% of consolidated revenues for fiscal 2018. Additionally, our three major product families gastrointestinal, respiratory illnesses and blood chemistry accounted for 84% of our Diagnostics segment s third-party revenues during fiscal 2018, and 59% of our fiscal 2018 consolidated revenues.

Our Life Science segment s revenues from sales of purified antigens and reagents to two diagnostics manufacturing customers were 18% of the segment s total revenues for fiscal 2018, and 5% of our fiscal 2018 consolidated revenues.

Critical Accounting Policies:

The consolidated financial statements included in this Annual Report on Form 10-K have been prepared in accordance with accounting principles generally accepted in the United States. Such accounting principles require management to make judgments about estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Listed below are the accounting policies management believes to be critical to understanding the accompanying Consolidated Financial Statements, along with reference to location of the policy discussion within the accompanying financial statements. The listed policies are considered critical due to the fact that application of such polices requires the use of significant estimates and assumptions, and the carrying values of related assets and liabilities are material.

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Accounting Policy	Location Within Consolidated Financial Statements	Examples of Key Estimate Assumptions
Inventories	Note 1(f)	Slow-moving, excess & obsolete inventories
Intangible Assets	Note 1(h)	Triggering events and impairment conditions
Revenue Recognition	Note 1(i)	Distributor price adjustments and fee accruals
Income Taxes	Note 1(k) and Note 6	Uncertain tax positions and state apportionment factors

Recent Accounting Pronouncements:

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which supersedes and replaces nearly all currently-existing U.S. GAAP revenue recognition guidance including related disclosure requirements. This guidance, including any clarification guidance thereon, is effective for the Company beginning October 1, 2018 (fiscal 2019). The Company anticipates that adoption of ASU 2014-09 on a modified retrospective basis will result in the recording of an immaterial adjustment to retained earnings of approximately $150 and expanding certain disclosures, as required.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which amends the accounting guidance related to leases. These changes, which are designed to increase transparency and comparability among organizations for both lessees and lessors, include, among other things, requiring recognition of lease assets and liabilities on the balance sheet and disclosing key information about leasing arrangements. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2020, although early adoption is permitted. The Company expects to begin its assessment of the impact that adoption of this guidance will have on its financial statements in fiscal 2019.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends the accounting for share-based payment transactions. These changes, which are designed for simplification, involve several aspects of the accounting for share-based transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this guidance in the first quarter of fiscal 2018, and as a result recorded $160 to the income tax provision, which under previous guidance would have been recorded in additional paid-in capital. While the future effect of this guidance is dependent on numerous factors (e.g., the market price of the Company s common stock on the equity award grant date, the exercise/lapse dates of equity awards, and the market price of the Company s common stock on such exercise/lapse dates), the effect is not expected to be material. During fiscal 2018, our tax provision included a $180 charge for application of ASU 2016-09.

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In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The update addresses certain specific cash flows and their treatment, with the objective being to reduce the existing diversity in how the items are presented and classified within the statement of cash flows. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2019, although early adoption is permitted. Adoption of this guidance is not expected to have a significant impact on the Company s statement of cash flows.

ITEM 7A.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

See Market Risk Exposure and Capital Resources under Item 7 above beginning on page 31.

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ITEM 8.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

All other supplemental schedules are omitted due to the absence of conditions under which they are required or because the information is shown in the Consolidated Financial Statements or Notes thereto.

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Management s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f).

The Company s 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 the assets of the Company; (ii) 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 (iii) 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 its inherent limitations, internal control over financial reporting can only provide reasonable assurance and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2018, based on the framework and criteria in the 2013 *Internal Control Integrated Framework,* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management s evaluation and those criteria, the Company concluded that its system of internal control over financial reporting was effective as of September 30, 2018.

The Company s independent registered public accounting firm has issued an attestation report on the registrant s internal control over financial reporting.

/s/ Jack Kenny
Jack Kenny
Chief Executive Officer
November 29, 2018

/s/ Melissa A. Lueke
Melissa A. Lueke
Executive Vice President and
Chief Financial Officer
November 29, 2018

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Meridian Bioscience, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Meridian Bioscience, Inc. (an Ohio corporation) and subsidiaries (the Company) as of September 30, 2018 and 2017, the related consolidated statements of operations, comprehensive income, shareholders equity, and cash flows for each of the three years in the period ended September 30, 2018, and the related notes and financial statement schedule listed in the index appearing under Schedule No. II (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company s internal control over financial reporting as of September 30, 2018, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated November 29, 2018 expressed an unqualified opinion.

Basis for opinion

These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the Company s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company s auditor since 2005.

Cincinnati, Ohio
November 29, 2018

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Meridian Bioscience, Inc.

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of Meridian Bioscience, Inc. (an Ohio corporation) and subsidiaries (the Company) as of September 30, 2018, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2018, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements of the Company as of and for the year ended September 30, 2018, and our report dated November 29, 2018 expressed an unqualified opinion on those financial statements.

Basis for opinion

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and limitations of internal control over financial reporting

A 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 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.

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Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio
November 29, 2018

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CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2018**	2017	2016
Net Revenues	**$ 213,571**	$ 200,771	$ 196,082
Cost of Sales	**83,110**	76,479	68,870
Gross Profit	**130,461**	124,292	127,212
Operating Expenses:			
Research and development	**16,870**	16,036	14,191
Selling and marketing	**34,468**	32,388	30,056
General and administrative	**34,488**	31,096	29,429
Restructuring costs	**8,706**	134	677
Litigations costs	**4,345**	628	
Goodwill impairment charge		6,628	
Acquisition-related costs			1,481
Total operating expenses	**98,877**	86,910	75,834
Operating Income	**31,584**	37,382	51,378
Other Income (Expense):			
Interest income	**418**	171	67
Interest expense	**(1,520)**	(1,642)	(897)
Other, net	**(102)**	518	96
Total other expense	**(1,204)**	(953)	(734)
Earnings Before Income Taxes	**30,380**	36,429	50,644
Income Tax Provision	**6,531**	14,872	18,415
Net Earnings	**$ 23,849**	$ 21,557	$ 32,229
Earnings Per Share Data:			
Basic earnings per common share	**$ 0.56**	$ 0.51	$ 0.77
Diluted earnings per common share	**$ 0.56**	$ 0.51	$ 0.76
Common shares used for basic earnings per common share	**42,325**	42,188	42,010
Effect of dilutive stock options and restricted share units	**429**	383	383
Common shares used for diluted earnings per common share	**42,754**	42,571	42,393
Dividends declared per common share	**$ 0.500**	$ 0.575	$ 0.800
Anti-dilutive Securities:			

Common share options and restricted share units	**1,007**	873	462

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

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (dollar amounts in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2018**	2017	2016
Net Earnings	**$ 23,849**	$ 21,557	$ 32,229
Other comprehensive income (loss):			
Foreign currency translation adjustment	**(1,075)**	1,616	(2,732)
Unrealized gain (loss) on cash flow hedge	**907**	1,544	(729)
Income taxes related to items of other comprehensive income	**(263)**	(590)	275
Other comprehensive income (loss), net of tax	**(431)**	2,570	(3,186)
Comprehensive Income	**$ 23,418**	$ 24,127	$ 29,043

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

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CONSOLIDATED STATEMENTS OF CASH FLOWS (dollar amounts in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2018**	2017	2016
Cash Flows From Operating Activities			
Net earnings	**$ 23,849**	$ 21,557	$ 32,229
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	**4,491**	4,342	3,937
Amortization of intangible assets	**3,433**	3,776	2,690
Amortization of deferred instrument costs	**764**	972	1,091
Stock-based compensation	**3,402**	3,381	2,911
Goodwill impairment charge		6,628	
Deferred income taxes	**(300)**	1,474	(233)
Losses on long-lived assets			659
Change in:			
Accounts receivable	**(4,447)**	(1,211)	119
Inventories	**(1,142)**	3,467	(8,225)
Prepaid expenses and other current assets	**323**	1,225	(9)
Accounts payable and accrued expenses	**4,124**	(3,151)	1,773
Income taxes payable	**(524)**	(384)	464
Other, net	**810**	(721)	(183)
Net cash provided by operating activities	**34,783**	41,355	37,223
Cash Flows From Investing Activities			
Purchase of property, plant and equipment	**(4,201)**	(4,467)	(4,004)
Purchase of equity method investment			(600)
Acquisition of Magellan, net of cash acquired			(62,091)
Net cash used for investing activities	**(4,201)**	(4,467)	(66,695)
Cash Flows From Financing Activities			
Dividends paid	**(21,170)**	(24,266)	(33,649)
Proceeds from term loan, net of issuance costs			59,860
Payments on term loan	**(4,500)**	(3,750)	(1,500)
Proceeds and tax benefits from exercises of stock options	**187**	303	2,494
Payment of acquisition consideration	**(2,110)**		
Net cash provided by (used for) financing activities	**(27,593)**	(27,713)	27,205
Effect of Exchange Rate Changes on Cash and Equivalents	**(298)**	671	(480)
Net Increase (Decrease) in Cash and Equivalents	**2,691**	9,846	(2,747)
Cash and Equivalents at Beginning of Period	**57,072**	47,226	49,973

Cash and Equivalents at End of Period	**$ 59,763**	$ 57,072	$ 47,226
Supplemental Cash Flow Information			
Cash paid for interest	**$ 1,487**	$ 1,605	$ 879
Cash paid for income taxes	**$ 6,555**	$ 12,613	$ 17,915

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

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CONSOLIDATED BALANCE SHEETS (dollar amounts in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	**2018**	2017
Assets		
Current Assets:		
Cash and equivalents	**$ 59,763**	$ 57,072
Accounts receivable, less allowances of $310 and $307, respectively	**32,336**	29,106
Inventories	**41,993**	41,493
Prepaid expenses and other current assets	**4,961**	6,204
Total current assets	**139,053**	133,875
Property, Plant and Equipment, at Cost:		
Land	**1,160**	1,162
Buildings and improvements	**32,444**	32,207
Machinery, equipment and furniture	**50,606**	48,836
Construction in progress	**1,631**	1,895
Subtotal	**85,841**	84,100
Less: accumulated depreciation and amortization	**55,846**	53,590
Net property, plant and equipment	**29,995**	30,510
Other Assets:		
Goodwill	**54,637**	54,926
Other intangible assets, net	**23,113**	26,704
Restricted cash	**1,000**	1,000
Deferred instrument costs, net	**1,239**	1,368
Fair value of interest rate swap	**1,722**	815
Deferred income taxes	**130**	158
Other assets	**488**	421
Total other assets	**82,329**	85,392
Total assets	**$ 251,377**	$ 249,777

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

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CONSOLIDATED BALANCE SHEETS (dollar amounts in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	**2018**	2017
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	**$ 6,260**	$ 7,719
Accrued employee compensation costs	**7,263**	4,536
Current portion of acquisition consideration		2,095
Other accrued expenses	**5,065**	2,789
Current portion of long-term debt	**5,250**	4,500
Income taxes payable	**335**	1,248
Total current liabilities	**24,173**	22,887
Non-Current Liabilities		
Acquisition consideration		235
Post-employment benefits	**2,646**	2,468
Long-term debt	**44,930**	50,147
Long-term income taxes payable	**441**	
Deferred income taxes	**3,769**	4,455
Total non-current liabilities	**51,786**	57,305
Commitments and Contingencies		
Shareholders Equity:		
Preferred stock, no par value; 1,000,000 shares authorized; none issued		
Common shares, no par value; 71,000,000 shares authorized, 42,399,962 and 42,207,317 issued, respectively		
Additional paid-in capital	**129,193**	125,608
Retained earnings	**49,602**	46,923
Accumulated other comprehensive loss	**(3,377)**	(2,946)
Total shareholders equity	**175,418**	169,585
Total liabilities and shareholders equity	**$ 251,377**	$ 249,777

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

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CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (dollar and share amounts in thousands, except per share data)

Meridian Bioscience, Inc. and Subsidiaries

	Common Shares Issued	Additional Paid-in Capital	Retained Earnings	Accum Other Comp Income (Loss)	Total
Balance at September 30, 2015	41,838	$ 117,151	$ 51,052	$ (2,330)	$ 165,873
Cash dividends paid - $0.800 per share			(33,649)		(33,649)
Exercise of stock options	152	2,294			2,294
Conversion of restricted share units	117				
Stock compensation expense		2,911			2,911
Net earnings			32,229		32,229
Foreign currency translation adjustment				(2,732)	(2,732)
Hedging activity, net of tax				(454)	(454)
Balance at September 30, 2016	42,107	122,356	49,632	(5,516)	166,472
Cash dividends paid - $0.575 per share			(24,266)		(24,266)
Exercise of stock options	18	(129)			(129)
Conversion of restricted share units	82				
Stock compensation expense		3,381			3,381
Net earnings			21,557		21,557
Foreign currency translation adjustment				1,616	1,616
Hedging activity, net of tax				954	954
Balance at September 30, 2017	42,207	125,608	46,923	(2,946)	169,585
Cash dividends paid - $0.500 per share			(21,170)		(21,170)
Exercise of stock options	13	183			183
Conversion of restricted share units	180				
Stock compensation expense		3,402			3,402
Net earnings			23,849		23,849
Foreign currency translation adjustment				(1,075)	(1,075)
Hedging activity, net of tax				644	644
Balance at September 30, 2018	42,400	$ 129,193	$ 49,602	$ (3,377)	$ 175,418

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Meridian Bioscience, Inc. and Subsidiaries

(dollar and share amounts in thousands, except per share data)

(1) Summary of Significant Accounting Policies

(a) Nature of Business - Meridian is a fully-integrated life science company whose principal businesses are: (i) the development, manufacture and distribution of clinical diagnostic test kits primarily for certain gastrointestinal and respiratory infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents used by other diagnostic manufacturers and researchers.

(b) Principles of Consolidation - The consolidated financial statements include the accounts of Meridian Bioscience, Inc. and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Unless the context requires otherwise, references to Meridian, we, us, our or our company re Meridian Bioscience, Inc. and its subsidiaries.

(c) Use of Estimates - The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(d) Foreign Currency Translation - Assets and liabilities of foreign operations are translated using year-end exchange rates with gains or losses resulting from translation included as a separate component of accumulated other comprehensive income or loss. Revenues and expenses are translated using exchange rates prevailing during the year. We also recognize foreign currency transaction gains and losses on certain assets and liabilities that are denominated in the Australian dollar, British pound, Chinese yuan and Euro currencies. These gains and losses are included in other income and expense in the accompanying Consolidated Statements of Operations.

(e) Cash, Cash Equivalents and Investments - The primary objectives of our investment activities are to preserve capital and provide sufficient liquidity to meet operating requirements and fund strategic initiatives such as acquisitions. We maintain a written investment policy that governs the management of our investments in fixed income securities. This policy, among other things, provides that we may purchase only high credit-quality securities that have short-term ratings of at least A-2, P-2 and F-2, and long-term ratings of at least A, Baa1 and A, by Standard & Poor s, Moody s and Fitch, respectively, at the time of purchase. We consider short-term investments with original maturities of 90 days or less to be cash equivalents, including institutional money market funds. At times our investments of cash and equivalents with various high credit quality financial institutions may be in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit.

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Our investment portfolio includes the following components:

	September 30, 2018		September 30, 2017	
	Cash and Equivalents	**Other**	Cash and Equivalents	Other
Institutional money market funds	**$ 20,421**	**$**	$ 20,104	$
Cash on hand				
Restricted		**1,000**		1,000
Unrestricted	**39,342**		36,968	
Total	**$ 59,763**	**$ 1,000**	$ 57,072	$ 1,000

(f) **Inventories** - Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out (FIFO) basis. Alethia instruments are carried in inventory until customer placement, at which time they are transferred to deferred instrument costs, unless sold outright. Similarly, blood lead testing instruments are carried in inventory until they are sold outright or placed with a customer under the customer reagent rental program, at which time they are transferred to property, plant and equipment.

We establish reserves against cost for excess and obsolete materials, finished goods whose shelf life may expire before sale to customers, and other identified exposures. Such reserves were $1,971 and $2,059 at September 30, 2018 and 2017, respectively. We estimate these reserves based on assumptions about future demand and market conditions. If actual demand and market conditions were to be less favorable than such estimates, additional inventory write-downs would be required and recorded in the period known. Such adjustments would negatively affect gross profit margin and overall results of operations.

(g) **Property, Plant and Equipment** - Property, plant and equipment are stated at cost. Upon retirement or other disposition, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in earnings. Maintenance and repairs are expensed as incurred. Depreciation is computed on the straight-line method in amounts sufficient to write-off the cost over the estimated useful lives, generally as follows:

Buildings and improvements - 18 to 40 years

Leasehold improvements - life of the lease

Machinery, equipment and furniture - 3 to 10 years

Computer equipment and software - 3 to 5 years

Instruments under customer reagent rental arrangements - 5 years

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(h) Intangible Assets - Goodwill is subject to an annual impairment review (or more frequently if impairment indicators arise) at the reporting unit level, which we perform annually as of June 30, the end of our third fiscal quarter. A reporting unit is generally an operating segment or one level below an operating segment that constitutes a business for which discrete financial information is available and regularly reviewed by segment management. Following the fiscal 2018 restructuring and consolidation of separately-run businesses into two integrated global business units (see Note 2), at September 30, 2018, we had two reporting units (Diagnostics and Life Science), both of which contained goodwill. We review our reporting unit structure annually, or more frequently if facts and circumstances warrant. Goodwill is considered impaired if the carrying value of the reporting unit exceeds its fair value. We have no intangible assets with indefinite lives other than goodwill.

During fiscal 2018, we performed quantitative assessments as of June 30, 2018 for each of our Diagnostics and Life Science reporting units. As part of this assessment, fair value, as determined through a valuation performed by a third party, was calculated via both market (comparable company) and income (discounted cash flows) approaches. Based upon these approaches, the fair value of each reporting unit exceeded its carrying value; therefore, each of the Diagnostics and Life Science reporting units satisfied the quantitative assessment for fiscal 2018.

Similarly, during fiscal 2017, we performed quantitative assessments as of June 30, 2017 for each of our Americas Diagnostics, Bioline and Life Science-U.S. reporting units that existed at that time, noting the separate Magellan discussion below. As part of this assessment, fair value, as determined through a valuation performed by a third party, was calculated via both market (comparable company) and income (discounted cash flows) approaches. Based upon these approaches, the fair value of each reporting unit exceeded its carrying value; therefore, each of the Americas Diagnostics, Bioline and Life Science-U.S. reporting units satisfied the quantitative assessment for fiscal 2017.

During the quarter ended June 30, 2017, the events described below occurred, indicating that impairment of the goodwill recorded as part of the Magellan acquisition had occurred.

On May 17, 2017, the FDA issued a field safety notice advising customers to discontinue use of Magellan s lead testing systems with venous blood samples. This field safety notice was followed by product recall notices on May 25th and June 5th. Subsequent to the issuances of these field safety and product recall notices, the FDA completed an inspection of Magellan s quality system, and issued its Form 483, Inspectional Observations, on June 29, 2017, which was expectedly followed by a Warning Letter issued on October 23, 2017. The Warning Letter requires periodic reporting on our remediation progress.

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In light of these factors and their impacts, during the third quarter of fiscal 2017, it was determined that a potential impairment of goodwill recorded in connection with the acquisition of Magellan had occurred (i.e., a triggering event). With the assistance of an independent valuation firm, Magellan s fair value was calculated via both market (comparable company) and income (discounted cash flows) approaches. Based upon these approaches, it was determined that the carrying value of the Magellan reporting unit did, in fact, exceed its fair value. As a result, an impairment charge of $6,628, on both a pre-tax and after-tax basis, was recorded during the third quarter and is reflected as a separate operating expense line item within the accompanying Consolidated Statement of Operations for the year ended September 30, 2017. This quantitative assessment as of May 31, 2017 was supplemented by a qualitative assessment of Magellan s goodwill as of June 30, 2017, with such assessment indicating that no additional impairment existed.

No impairments were indicated or recorded from the analyses performed for fiscal 2018 or 2016.

During fiscal 2018, goodwill decreased $289, resulting solely from currency translation adjustments on the goodwill of the Life Science reporting unit. The decrease of $7,056 in fiscal 2017 reflects: (i) a $767 acquisition measurement period adjustment downward related to Magellan (Diagnostics segment; see Note 3); (ii) the $6,628 impairment charge related to Magellan; and (iii) a $339 increase from the currency translation adjustment on the goodwill of the Life Science segment.

A summary of Meridian s acquired intangible assets subject to amortization, as of September 30, 2018 and 2017 is as follows.

	2018		2017	
As of September 30,	**Gross Carrying Value**	**Accum. Amort.**	Gross Carrying Value	Accum. Amort.
Manufacturing technologies, core products and cell lines	**$ 22,297**	**$ 13,974**	$ 22,332	$ 12,807
Tradenames, licenses and patents	**8,647**	**5,267**	8,689	4,398
Customer lists, customer relationships and supply agreements	**24,461**	**13,051**	24,562	11,854
Non-compete agreements	**720**	**720**	720	540
	$ 56,125	**$ 33,012**	$ 56,303	$ 29,599

The actual aggregate amortization expense for these intangible assets for fiscal 2018, 2017 and 2016 was $3,433, $3,776 and $2,690, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2019 - $3,328, fiscal 2020 - $3,165, fiscal 2021 - $2,560, fiscal 2022 - $2,182 and fiscal 2023 - $2,170.

Long-lived assets, excluding goodwill, are reviewed for impairment when events or circumstances indicate that such assets may not be recoverable at their carrying value. Whether an event or circumstance triggers an impairment is determined by comparing an estimate of the asset s future undiscounted cash flows to its carrying value. If impairment has occurred, it is measured by a fair-value based calculation.

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Our ability to recover the carrying value of our intangible assets, both identifiable intangibles and goodwill, is dependent upon the future cash flows of the related acquired businesses and assets. We make judgments and assumptions regarding future cash flows, including sales levels, gross profit margins, operating expense levels, working capital levels, and capital expenditures. With respect to identifiable intangibles and fixed assets, we also make judgments and assumptions regarding useful lives.

We consider the following factors in evaluating events and circumstances for possible impairment: (i) significant under-performance relative to historical or projected operating results; (ii) negative industry trends; (iii) sales levels of specific groups of products (related to specific identifiable intangibles); (iv) changes in overall business strategies; and (v) other factors.

If actual cash flows are less favorable than projections, this could trigger impairment of intangible assets and other long-lived assets. If impairment were to occur, this would negatively affect overall results of operations. Aside from the Magellan matter noted above, no triggering events have been identified by the Company for fiscal 2018, 2017 or 2016.

(i) Revenue Recognition and Accounts Receivable - Revenue is generally recognized from sales when product is shipped and title has passed to the customer. Revenue is reduced in the period of sale for fees paid to distributors, which are inseparable from the distributor s purchase of our product and for which we receive no goods or services in return. Such fees totaled $1,453, $787, and $339 in fiscal 2018, 2017 and 2016, respectively. Revenue for the Diagnostics segment is reduced at the date of sale for product price adjustments due to certain distributors under local contracts. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Such accruals were $4,303 at September 30, 2018 and $4,190 at September 30, 2017, and have been netted against accounts receivable.

Revenue for our Diagnostics segment includes revenue for our Alethia molecular test system. This system includes an instrument, instrument accessories and test kits. In markets where the test system is sold via multiple deliverable arrangements, the cost of the instrument and instrument accessories is deferred upon placement at a customer and amortized on a straight-line basis into cost of sales over the expected utilization period, generally three years.

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We evaluate whether each deliverable in the arrangement is a separate unit of accounting. The significant deliverables are an instrument, instrument accessories (e.g., printer) and test kits. An instrument and instrument accessories are delivered to the customer prior to the start of the customer utilization period in order to accommodate customer set-up and installation. There is *de minimis* consideration received from the customer at the time of instrument placement. We have determined that the instrument and instrument accessories are not a separate unit of accounting because such equipment can only be used to process and read the results from our Alethia diagnostic tests (i.e., our instrument and test kits function together to deliver a diagnostic test result), and therefore the instrument and instrument accessories do not have standalone value to the customer. Consequently, there is no revenue allocated to the placement of the instrument and instrument accessories. Test kits are delivered to the customer over the utilization period of the instrument, which we estimate has a useful life of three years. Our average customer contract period, including estimated renewals, is at least equal to the estimated three-year utilization period. Revenue for the sale of test kits is recognized upon shipment and transfer of title to the customers.

In markets where the test system is not sold via multiple deliverable arrangements, the cost of the instrument and instrument accessories is charged to cost of sales at the time of shipment and transfer of title to the customer. Revenue for the sales of instruments, instrument accessories and test kits is recognized upon shipment and transfer of title to the customers. In these markets, our Alethia molecular test system is sold to independent distributors who inventory the instruments, instrument accessories and test kits for resale to end-users.

Our products are generally not subject to a customer right of return except for product recall events under the rules and regulations of the Food and Drug Administration or equivalent agencies outside the United States. In this circumstance, the costs to replace affected products would be accrued at the time a loss was probable and estimable.

Trade accounts receivable are recorded in the accompanying Consolidated Balance Sheets at invoiced amounts less provisions for distributor price adjustments under local contracts and doubtful accounts. The allowance for doubtful accounts represents our estimate of probable credit losses and is based on historical write-off experience and known conditions that would likely lead to non-payment. The allowance for doubtful accounts and related metrics, such as days sales outstanding, are reviewed monthly. Accounts with past due balances over 90 days are reviewed individually for collectability. Customer invoices are charged off against the allowance when we believe it is probable that the invoices will not be paid.

(j) Research and Development Costs - Research and development costs are charged to expense as incurred. Research and development costs include, among other things, salaries and wages for research scientists, materials and supplies used in the development of new products, costs for development of instrumentation equipment, costs for clinical trials, and costs for facilities and equipment.

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(k) Income Taxes - The provision for income taxes includes federal, foreign, state and local income taxes currently payable and those deferred because of temporary differences between income for financial reporting and income for tax purposes. We prepare estimates of permanent and temporary differences between income for financial reporting purposes and income for tax purposes. These differences are adjusted to actual upon filing of our tax returns, typically occurring in the third and fourth quarters of the current fiscal year for the preceding fiscal year s estimates.

We account for uncertain tax positions using a benefit recognition model with a two-step approach: (i) a more-likely-than-not recognition criterion; and (ii) a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being ultimately realized upon ultimate settlement. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. We recognize accrued interest related to unrecognized tax benefits as a portion of our income tax provision in the Consolidated Statements of Operations. See Note 6.

(l) Stock-Based Compensation - We recognize compensation expense for all share-based awards made to employees, based upon the fair value of the share-based award on the date of the grant. See Note 7(b).

(m) Comprehensive Income (Loss) - Comprehensive income (loss) represents the net change in shareholders equity during a period from sources other than transactions with shareholders. As reflected in the accompanying Consolidated Statements of Comprehensive Income, our comprehensive income is comprised of net earnings, foreign currency translation, unrealized losses on our cash flow hedge, and the income taxes thereon.

(n) Shipping and Handling Costs - Shipping and handling costs invoiced to customers are included in net revenues. Costs to distribute products to customers, including freight costs, warehousing costs, and other shipping and handling activities are included in cost of sales.

(o) Non-Income Government-Assessed Taxes - We classify all non-income, government-assessed taxes (sales, use and value-added) collected from customers and remitted by us to appropriate revenue authorities, on a net basis (excluded from net revenues) in the accompanying Consolidated Statements of Operations.

(p) Recent Accounting Pronouncements - In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which supersedes and replaces nearly all currently-existing U.S. GAAP revenue recognition guidance including related disclosure requirements. This guidance, including any clarification guidance thereon, is effective for the Company beginning October 1, 2018 (fiscal 2019). The Company anticipates that adoption of ASU 2014-09 on a modified retrospective basis will result in the recording of an immaterial adjustment to retained earnings of approximately $150 and expanding certain disclosures, as required.

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In February 2016, the FASB issued ASU 2016-02, *Leases*, which amends the accounting guidance related to leases. These changes, which are designed to increase transparency and comparability among organizations for both lessees and lessors, include, among other things, requiring recognition of lease assets and liabilities on the balance sheet and disclosing key information about leasing arrangements. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2020, although early adoption is permitted. The Company expects to begin its assessment of the impact that adoption of this guidance will have on its financial statements in fiscal 2019.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends the accounting for share-based payment transactions. These changes, which are designed for simplification, involve several aspects of the accounting for share-based transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this guidance in the first quarter of fiscal 2018, and as a result recorded $160 to the income tax provision, which under previous guidance would have been recorded in additional paid-in capital. While the future effect of this guidance is dependent on numerous factors (e.g., the market price of the Company s common stock on the equity award grant date, the exercise/lapse dates of equity awards, and the market price of the Company s common stock on such exercise/lapse dates), the effect is not expected to be material. During fiscal 2018, our tax provision included a $180 charge for application of ASU 2016-09.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The update addresses certain specific cash flows and their treatment, with the objective being to reduce the existing diversity in how the items are presented and classified within the statement of cash flows. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2019, although early adoption is permitted. Adoption of this guidance is not expected to have a significant impact on the Company s statement of cash flows.

(q) Reclassifications - Certain reclassifications have been made to the prior fiscal year financial statements to conform to the current year presentation. Such reclassifications had no impact on net earnings or shareholders equity.

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(2) Restructuring

During the second quarter of fiscal 2018, the Company began implementation of a plan to realign its business structure into two business units, Diagnostics and Life Science, supported by a global corporate team. As part of this plan, certain functions and locations within both business units have been streamlined, including: (i) the elimination of certain executive management and commercial sales positions; (ii) the closing of Life Science locations in Taunton, Massachusetts and Singapore, the operations of which were transferred to locations in Memphis, Tennessee and London, England, respectively; and (iii) the transfer of certain functions performed in the Billerica, Massachusetts Diagnostics facility to the corporate headquarters in Cincinnati, Ohio.

A summary of the restructuring costs recorded in fiscal 2018 is as follows:

	Fiscal 2018 Restructuring Costs
Severance, other termination benefits and related costs	$ 5,012
Lease and other contract termination fees	353
Loss on fixed asset disposals and inventory scrap	225
Other	742
Total	$ 6,332

The above table does not include $2,374 of CEO transition costs, which primarily represents the compensation and benefits for our previous Executive Chairman and CEO, Mr. John A. Kraeutler, throughout fiscal 2018, the period during which we also have the compensation and benefits our new CEO, Mr. Jack Kenny, who began employment at the beginning of fiscal 2018. These CEO transition costs and the restructuring costs set forth in the table above comprise the $8,706 of restructuring costs set forth in the accompanying Consolidated Statement of Operations.

At September 30, 2018, the accrued liability associated with the restructuring costs noted above consisted of the following:

	Balance as of September 30, 2018
Severance, other termination benefits and related costs	$ 987
Lease and other contract termination fees	33
Other	6
Total accrued liability balance	$ 1,026

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(3) Magellan Acquisition

On March 24, 2016, we acquired all of the outstanding common stock of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, I