MERIDIAN BIOSCIENCE INC
Form 10-K
November 29, 2017
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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, 2017.

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

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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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (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	(Do not check if a smaller reporting company)	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, 2017 was $574,070,312 based on a closing sale price of $13.80 per share on March 31, 2017. As of October 31, 2017, 42,216,567 no par value Common Shares were issued and outstanding.

Documents Incorporated by Reference

Portions of the Registrant s Annual Report to Shareholders for the fiscal year ended September 30, 2017 furnished to the Commission pursuant to Rule 14a-3(b) are incorporated by reference in Part II as specified and portions of the Registrant s Proxy Statement to be filed with the Commission for its 2018 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, the outcome of tax reform legislation, breaches of Meridian s information technology systems and natural disasters and other events could have a materially adverse effect on Meridian s results of operations and revenues. We have identified a material weakness in our internal control over financial reporting that, if 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 differences 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 dollars and shares are in thousands (both tables and text), except per share data.

This Annual Report on Form 10-K refers to trademarks such as TRU FLU®, Immuno*Card*®, Immuno*Card* STAT!®, MyTaq, SensiFAST, PREMIER® and LeadCare®, 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.

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, viral, respiratory, and parasitic 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 researchers and other diagnostic manufacturers. The Company was incorporated in Ohio in 1976. Our principal corporate offices are located near Cincinnati, Ohio, USA.

During March 2016, we acquired all of the outstanding common stock of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, Inc. (collectively, Magellan), which is now reported as part of our Diagnostics operating segment. Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of products cleared by the Food & Drug Administration (FDA) for the point-of-care testing of capillary blood to diagnose lead poisoning in children and adults. Further details of the Magellan acquisition are set forth in Note 2 of the accompanying Consolidated Financial Statements.

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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 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). These reports may also be read and copied at the SEC s public reference room at 100 F Street, N.E., Washington, DC 20549, phone number 1-800-732-0330. 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 8 of Consolidated Financial Statements

Diagnostics Segment

Overview of Products and Markets

Our primary source of revenues is clinical diagnostic products, with our Diagnostics segment providing 71% of consolidated net revenues for fiscal 2017. Third-party revenues for this segment were approximately $144,000, $145,000 and $146,000 for fiscal 2017, 2016 and 2015, respectively. As of September 30, 2017, our Diagnostics segment had approximately 420 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.

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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 (*illumi*gene brand) 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 (TRU, 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 used principally in the detection of infectious diseases caused by various bacteria, viruses, parasites and pathogens, including most notably the following general areas:

C. difficile causative agent for antibiotic-associated diarrhea from a hospital-acquired infection

Foodborne Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter jejuni* (Campy)

H. pylori stomach ulcers

Respiratory Group A *Streptococcus* (strep throat), *M. pneumoniae* (Mycoplasma) and *Bordetella pertussis* (whooping cough), among tests for other diseases

Women s Health & Sexually Transmitted Diseases (STD) Group B *Streptococcus*, *Chlamydia trachomatis*, *Neisseria gonorrhea*, Herpes Simplex Virus Type 1 & Type 2

Our clinical diagnostics products also include Magellan s LeadCare brand of tests for quantitative determination of blood lead levels.

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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We continue to invest in new product development for our molecular testing platform, and this platform now has nine commercialized tests spanning hospital acquired infections, women s health, respiratory, sexually transmitted diseases, and tropical diseases. As of September 30, 2017, our ***illumi****gene* Malaria test has been placed in nearly 150 accounts in the EMEA region (i.e., Europe, Middle East and Africa) for use as a screening test for travelers returning to Europe from endemic areas in Africa. Our efforts to develop market channels in the endemic areas of Africa continue, as we work to convince policy-makers of the advantages of a more accurate molecular test to assist in efforts to eradicate malaria.

We believe that our ***illumi****gene* system has been well-accepted in our global markets. We now have nearly 1,650 customer account placements. Of these account placements, approximately 1,375 accounts have completed evaluations and validations and are regularly purchasing product, with the balance of our account placements being in some stage of product evaluation and/or validation. Of our account placements, we have nearly 600 accounts that are regularly purchasing, evaluating and/or validating two or more assays.

Our current research and development pipeline for immunoassay products includes a new instrument that utilizes fluorescent chemistry and has colorimetric capabilities. This new platform is being branded under the Curian name. During the first half of fiscal 2018, we expect to submit a 510(k) to the FDA for one or more of our existing rapid immunoassay tests using the colorimetric capabilities of the Curian instrument. During the second half of fiscal 2018, we expect to submit a 510(k) to the FDA for our first fluorescent assay, a combination *C.difficile* common antigen (GDH) and toxin (A/B) test. Looking forward into fiscal 2019 and 2020, we expect to develop additional rapid immunoassay tests using the Curian fluorescent chemistry.

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 increasing 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) and Accountable Care Organizations (ACOs) 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, ACOs 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 for antibiotic use, symptom-relieving drugs and hospital stays.

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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. We utilize multi-year supply agreements to secure our business where we deem appropriate.

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.

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:

United States

In the U.S., 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 2017, 2016 and 2015: Cardinal Healthcare Corporation and Thermo Fisher Scientific. Our revenues from Cardinal were approximately $23,000, $20,000 and $29,000 during fiscal 2017, 2016 and 2015, respectively. Our revenues from Thermo Fisher were approximately $18,000, $20,000 and $25,000 during fiscal 2017, 2016 and 2015, respectively.

EMEA

In EMEA, our sales and distribution network consists of direct sales forces in Belgium, France, Holland and Italy, and independent distributors in other European countries, Africa and the Middle East. We have implemented a direct sales presence in Germany and the U.K. for our ***illumi****gene* products, and utilize independent distributors for our immunoassay products. We maintain a distribution center near Milan, Italy.

ROW

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

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Competition

Our major competitors in molecular diagnostics are Cepheid and Becton Dickinson, who have systems with multiple-assay menus. We also face competition in molecular diagnostics, but to a lesser degree, from companies such as Alere and Quidel, who have a limited commercial menu and tend to compete strictly on price. We believe that our molecular platform offers a number of competitive features:

Molecular assay sensitivity that is comparable to higher costing PCR;

Low capital investment with no instrument service cost;

Small footprint that is portable and does not consume much laboratory space; and

Product menu that fits with initiatives to improve clinical and economic outcomes.

Our major competitors in rapid immunoassay diagnostics are primarily Alere and Quidel. Over the last two years, companies such as BioMerieux have captured market share in our foodborne category via multi-plex panel tests. However, over the last several months, payors have raised 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.

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 Magellan business has a dedicated research and development team in Billerica, Massachusetts. Research and development expenses for the Diagnostics segment for fiscal 2017, 2016 and 2015 were approximately $13,000, $11,000 and $10,000, respectively. 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 ***illumi****gene* 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 substantially all of our own immunoassay requirements. Primers for our ***illumi****gene* 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.

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Intellectual Property, Patents and Licenses

We own or license U.S. and foreign patents, most of which are for selected products manufactured by our Diagnostics segment. These patents are used in our manufacturing processes for selected products (method patents) or may relate to the design of the test device technology format (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 ***illumi****gene* products, which represented 17%, 20% and 21% of consolidated revenues for fiscal 2017, 2016 and 2015, 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.

The patents for our *H. pylori* products, owned by us and which represented 14%, 15% and 14% of consolidated revenues for fiscal 2017, 2016 and 2015, 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, as we currently market the only FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market. 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. In order to defend against competition, our product development pipeline includes multiple new product initiatives for the detection of *H. pylori*, including drug resistance. We are unable to provide assurances that we will be successful with any competition defense strategy or that any competition defense 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 30 within MD&A for discussion regarding the FDA s inspection of our Billerica facility.

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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 Cincinnati manufacturing facility is certified to ISO 13485:2012, and our Magellan facility in Billerica, Massachusetts is certified to ISO 13485:2003.

Medical Device Tax

As more fully discussed in the accompanying MD&A, the Company was subject to the medical device tax established as part of the U.S. health care reform legislation through December 31, 2015. Upon expiration of the tax s two-year moratorium, which is currently scheduled for December 31, 2017, the Company would become subject to the tax once again. We are unable to predict any future legislative changes or developments related to this moratorium or excise tax.

Seasonal Factors and Sporadic Outbreaks

Our principal business is the sale of a broad range of clinical diagnostic test kits for common gastrointestinal, viral, upper respiratory and parasitic 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 the H1N1 influenza outbreak during fiscal 2009. 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.

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. Third-party revenues for this segment were approximately $57,000, $51,000 and $49,000 for fiscal 2017, 2016 and 2015, respectively. As of September 30, 2017, our Life Science segment had approximately 220 employees in seven countries.

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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 researchers and other diagnostic manufacturing companies focused on the development of immunoassay and molecular assay tests. Approximately 72% of Life Science revenues are generated from the industrial market, defined as diagnostic manufacturers and the agriculture industry. This continues to be an increasing focus of our Bioline molecular components business, which historically focused on the academic/research market that comprises the remaining 28% of Life Science revenues. We utilize direct sales teams in key countries such as the U.S., the U.K., Germany, France, Australia and Singapore. We have added distribution capabilities to our Singapore sales and business development office to increase our presence and our revenue opportunities in Asia for both molecular and immunoassay components. Additionally, 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 sales to customers in China. We utilize a network of distributors in other major countries. During fiscal 2017, 17% 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 clinical and agricultural 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.

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.

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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

Research and development expenses for our Life Science segment for each of fiscal 2017, 2016 and 2015 were approximately $3,000. The primary focus of this research and development organization is development of new molecular reagent products. See Operating Expenses section within MD&A on page 39.

Manufacturing and Government Regulation

Our Life Science U.S. facilities are ISO 9001:2008 certified and our Bioline facilities in the U.K. and Germany are ISO 13485:2012 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.

As previously noted in the Overview section, during March 2016, we acquired all of the outstanding common stock of Magellan. Details of the Magellan acquisition are set forth in Note 2 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 $59,000 or 29% of consolidated fiscal 2017 revenues, $52,000 or 26% of consolidated fiscal 2016 revenues, and $49,000 or 25% of consolidated fiscal 2015 revenues. We expect to continue to look to international markets as a source of revenue growth in the future.

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Fluctuations in foreign currency exchange rates since fiscal 2016 had an approximate $1,200 unfavorable impact on fiscal 2017 revenues; $400 within the Diagnostics segment and $800 within the Life Science segment. This compares to year-to-year currency exchange rates having an approximate $1,700 unfavorable impact on revenues in fiscal 2016; $700 within the Diagnostics segment and $1,000 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 2017, 2016 or 2015.

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 29% and 27%, respectively, of the Diagnostics segment s total revenues, or 21% and 20%, respectively, of our consolidated revenues, for fiscal 2017 and fiscal 2016. 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, viral, upper respiratory and parasitic 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 H1N1 influenza. 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 integrated delivery networks (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 makes changes that are expected to significantly impact the pharmaceutical and medical device industries. The Protecting Access to Medicare Act of 2014 will require applicable laboratories to report all private payor reimbursement rates and the volumes for each test they perform. Although a final rule has yet to be published, 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. Although to date, we have not seen any significant effect on the reimbursement rates for our products, if reimbursement amounts for diagnostic testing services are decreased 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.

In addition, as more fully discussed in the accompanying MD&A, the Company was subject to a 2.3% medical device tax established as part of the U.S. health care reform legislation through December 31, 2015. Upon expiration of the tax s two-year moratorium, which is currently scheduled for December 31, 2017, the Company would become subject to the tax once again. We are unable to predict any future legislative changes or developments related to this moratorium or 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 sales of purified antigens and reagents to two diagnostic manufacturing customers were 17% and 18% of the Life Science segment s total revenues for fiscal 2017 and fiscal 2016, respectively; and 5% of our consolidated revenues for each of fiscal 2017 and fiscal 2016. Our Life Science segment has five other significant customers who purchase antigens, antibodies and reagents, which together comprised 10% and 7% of the segment s total revenues for fiscal 2017 and fiscal 2016, 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 to increase in the near future, as we currently market the only FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market. At present, we are aware of two companies that have commenced clinical trials of *H. pylori* products in the U.S., one of which is DiaSorin Inc. (see Item 3. Legal Proceedings). 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. In order to mitigate any loss in revenues, among other things, we are researching and experimenting with new products and attempting to secure significant customers under long-term contracts. We are unable to provide assurances that we will be successful with any mitigation strategy or that any mitigation strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

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

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 29% and 26% of our net revenues for fiscal 2017 and 2016, respectively, were attributable to markets outside of the Americas. For fiscal 2017, approximately 15% 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, Euro and Singapore dollar to the U.S. dollar. We are also subject to other risks associated with international operations, including longer customer payment cycles, tariff regulations, 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. The 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.

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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.

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 recent Safety Notification related to Magellan s lead testing systems for venous blood samples, issued its Form FDA 483 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. See a more detailed discussion of this matter within MD&A on page 30.

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 make 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 ***illumi****pro-10* Incubator/Reader (instrument), a component of our ***illumi****gene* molecular system, and a separate third party manufactures our proprietary LeadCare instruments. These instruments are manufactured exclusively for Meridian according to our specifications. While other manufacturers for these types of instruments are available, we source 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 ***illumi****gene* 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%, 12% and 15% of consolidated revenues in fiscal 2017, 2016 and 2015, 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, 2017, we have approximately $55,000 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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Following its June 23, 2016 vote to leave the European Union (commonly referred to as Brexit), on March 29, 2017, the United Kingdom invoked Article 50 of the Lisbon Treaty; thus formally commencing the process of exiting the European Union. While the impact of Brexit 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 the hiring and retention of qualified staff, regulatory affairs, manufacturing and logistics. 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 collectibility 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.

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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.

Risks Related to Our Common Stock

We have identified a material weakness in our internal control over financial reporting that, if not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements.

As described in Item 9A. Controls and Procedures, we have concluded that our internal control over financial reporting was ineffective as of September 30, 2017 because a material weakness existed in our internal control over financial reporting. If we are unable to remediate our material weakness in a timely manner, 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.

ITEM 1B.

UNRESOLVED STAFF COMMENTS

None.

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ITEM 2.

PROPERTIES

Our corporate offices, Diagnostics manufacturing facility, and 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. Magellan s operations are headquartered in an approximately 32,000 square foot leased facility in Billerica, Massachusetts, in which it conducts manufacturing, research and development, sales, and administrative activities. 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; Taunton, Massachusetts; London, England; Luckenwalde, Germany; Sydney, Australia; Singapore; 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: Taunton approximately 10,000 square feet of sales and warehouse space; 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, warehouse, research and development, and manufacturing space; Singapore approximately 2,000 square feet of sales and business development space; Beijing less than 1,000 square feet of sales and business development space.

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 May 17, 2017, Meridian filed a complaint in the United States District Court for the Southern District of Ohio, Western Division (Cincinnati) naming DiaSorin Inc. (DiaSorin) as a defendant. Meridian s complaint alleges DiaSorin has breached the 2010 Co-Development and License Agreement (the Agreement) between it and Meridian relating to the co-development of certain tests and diagnostic products, pursuant to which Meridian disclosed certain trade secrets and proprietary information. The lawsuit underlying Meridian s complaint alleges

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that DiaSorin breached the Agreement and used, and is currently using, Meridian s proprietary information and therefore seeks injunctive relief and unspecified damages to protect Meridian s intellectual property and information with respect to it diagnostics products. Approximately $1,500 of expense related to this matter is included within the accompanying Consolidated Statement of Operations for fiscal 2017.

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. The complaint alleges that Meridian made false and misleading representations concerning certain lead test systems used by Magellan at or around the time of Meridian s acquisition of Magellan and subsequent thereto. The lawsuit underlying plaintiff s class action complaint seeks compensatory damages, injunctive relief and attorneys fees to all members of the proposed class. Because the litigation and related discovery are in preliminary stages, we do not have sufficient information 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 2017.

ITEM 4.

MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5.

MARKET FOR REGISTRANT S COMMON

EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Refer to Forward-Looking Statements following the Index in front of this Form 10-K and Item 1A Risk Factors on Pages 15 through 26 of this Annual Report.

Common Stock Information on the inside back cover of the Annual Report to Shareholders for fiscal 2017 and Quarterly Financial Data (Unaudited) relating to our dividends in Note 10 to the Consolidated Financial Statements are incorporated herein by reference. Except as may otherwise be prohibited by applicable law, there are no restrictions on cash dividend payments.

Following the release of results for the fiscal 2017 first quarter, the board of directors reduced the fiscal 2017 indicated annual cash dividend rate to $0.50 per share (down from $0.80 per share) in order to align it with the stated policy guidelines of the payout ratio to range between 75% and 85% of each fiscal year s net earnings. This indicated annual rate represents 75% of fiscal 2017 s non-GAAP diluted earnings per share. 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

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acquisitions. At its meeting on November 8, 2017, the board of directors announced a continuation of the $0.50 indicated annual dividend rate per share for fiscal 2018. We paid dividends of $0.575 per share in fiscal 2017, and $0.80 per share in each of fiscal 2016 and fiscal 2015.

As of September 30, 2017, there were approximately 675 holders of record and approximately 15,200 beneficial owners of our common shares.

ITEM 6.

SELECTED FINANCIAL DATA

Incorporated by reference from inside front cover of the Annual Report to Shareholders for 2017.

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 15 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 2017 increased 4% to $5,726, or $0.13 per diluted share, from net earnings for the fourth quarter of fiscal 2016 of $5,491, or $0.13 per diluted share. The fiscal 2017 fourth quarter results include $762 of costs associated with the transition to our new CEO, announced October 10, 2017, and litigation costs associated with protecting certain intellectual property (collectively, CEO transition and IP defense costs) (impact on net earnings of $495, or $0.01 per diluted share). The fiscal 2016 fourth quarter results included $677 of costs associated with the restructuring of our sales and marketing leadership (impact on net earnings of $431, or $0.01 per diluted share). Consolidated revenues for the fourth quarter of fiscal 2017 totaled $49,697, an increase of 6% compared to the fourth quarter of fiscal 2016; increasing 5% on a constant-currency basis.

Showing positive signs of stabilization and a return to revenue growth in the Americas geographic region, revenues for the Diagnostics segment for the fourth quarter of fiscal 2017 increased 3% compared to the fourth quarter of fiscal 2016 (increasing 2% on a constant-currency basis), comprised of a 5% decrease in molecular assay products and a 6% increase in immunoassay and point-of-care lead testing products. With a 9% increase in its molecular components business and an 18% increase in its immunoassay components business, revenues

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for our Life Science segment increased 14% in the fourth quarter of fiscal 2017 compared to the fourth quarter of fiscal 2016. On a constant-currency basis, revenues for our Life Science Segment increased 13%.

The fourth quarter revenues reflect improvement in our immunoassay product lines, most notably in the foodborne and *H. pylori* product families, being partially offset by decreased revenues in Magellan s lead testing systems with venous blood samples. Our *C. difficile* business overall shows signs of stabilization and as a result, has also contributed to stabilization in our ***illumi****gene* molecular business. Both Life Science units performed well, reflecting the strength of new products and growth in the Asia-Pacific region.

Fiscal Year

Net earnings for fiscal 2017 decreased 33% to $21,557, or $0.51 per diluted share, from net earnings for fiscal 2016 of $32,229, or $0.76 per diluted share. Fiscal 2017 results include (i) $762 of CEO transition and IP defense costs; and (ii) a $6,628 impairment charge against Magellan goodwill (combined impact on net earnings of $7,123, or $0.17 per diluted share). Fiscal 2016 results include $677 of costs associated with the restructuring of our sales and marketing leadership and $1,481 of costs associated with our acquisition activities (combined impact on net earnings of $1,664, or $0.04 per diluted share). Consolidated revenues increased 2% to $200,771 for fiscal 2017 compared to fiscal 2016; increasing 3% on a constant-currency basis.

In fiscal 2017, revenues for the Diagnostics segment decreased 1% compared to fiscal 2016 (also 1% on a constant-currency basis). This decrease is comprised of a 13% decrease in molecular assay products and a 3% increase in immunoassay and lead testing products, including an $8,027 increase in Magellan revenues resulting from only six months of Meridian ownership during the comparable fiscal 2016 period. With an 8% increase in its molecular components business and a 15% increase in its immunoassay components business, revenues of our Life Science segment increased 12% during fiscal 2017 compared to fiscal 2016; increasing 14% on a constant-currency basis.

Magellan FDA Activities and Goodwill Impairment Charge

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. Magellan s lead testing systems are capable of processing both capillary and venous blood samples. Magellan s LeadCare Plus and LeadCare Ultra systems, which account for approximately 10% of Magellan s annual revenues, are used predominantly with venous blood samples. Magellan s LeadCare and LeadCare II systems are predominantly used with capillary blood samples.

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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As a result of these matters, we expect to experience delays in reinstating venous blood sample testing on our LeadCare products, as well as in obtaining 510(k) clearance for new Magellan products. We also expect delays in obtaining export certifications for Magellan products during the remediation period. In light of these factors and their impacts, during our 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). 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. Given all of the factors considered, we do not anticipate, at this time, any further goodwill impairment charge from the Magellan acquisition.

This impairment charge does not impact our cash flow, our dividend or our bank covenants. Our outlook for Magellan s LeadCare II testing volume continues to be healthy. In the time period since the FDA released its Safety Notification (which pertained to venous blood lead testing performed on the systems produced by Magellan), 374 new LeadCare II systems utilizing capillary blood samples have been placed in physician offices and clinics, contributing to the total number of LeadCare II placements increasing approximately 15% during fiscal 2017. These placements and ongoing placements of LeadCare II point-of-care systems and related capillary blood testing are expected to drive revenue growth in 2018 and beyond.

The matters giving rise to the FDA Safety Notification occurred at Magellan prior to Meridian s acquisition of Magellan. Meridian is committed to working diligently to strengthen Magellan s quality system and to address the observations noted in the Form FDA 483 with the highest sense of urgency. However, we can provide no assurance that our remediation efforts will be successful to a degree acceptable by the FDA within our contemplated time frame. It should be noted that the FDA has stated that all LeadCare blood lead testing systems can be used with capillary blood samples, the predominant sample type used by physicians testing at the point-of-care. We believe point-of-care lead testing is critical to addressing elevated lead levels among children and adults across the globe, as testing at the point-of-care improves compliance and facilitates patient education and intervention.

Beyond the impact of the impairment charge, revenues from LeadCare Plus and Ultra, which utilize primarily venous blood samples, have decreased approximately $200 since receipt of the May 17th field safety notice. Remediation costs in fiscal 2017 associated with the matter were approximately $500 pre-tax, resulting in a total impact of less than $0.01 on diluted earnings per share for the year. Remediation costs in fiscal 2018 are expected to be approximately $600 pre-tax, or less than $0.01 impact on diluted earnings per share. Remediation costs relate primarily to professional fees for regulatory consultants and periodic quality system audits. In the

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course of remediation, Magellan 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. In addition, at this time, we do not believe that there is any further impact on our results of operations or financial condition.

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 CEO transition and IP defense costs (fiscal 2017), the impairment charge against Magellan goodwill (fiscal 2017), sales & marketing leadership reorganization costs (fiscal 2016) and acquisition-related costs (fiscal 2016), each of which is a non-GAAP measure, as well as reconciliations to 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.

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.

	2017	2016	2015
Net Earnings -			
U.S. GAAP basis	$ 21,557	$ 32,229	$ 35,540
CEO transition and IP defense costs (1)	495		
Goodwill impairment charge (2)	6,628		
Sales & marketing leadership reorganization (1)		431	
Acquisition-related costs (1)		1,233	
Adjusted earnings	$ 28,680	$ 33,893	$ 35,540
Net Earnings per Basic Common Share -			
U.S. GAAP basis	$ 0.51	$ 0.77	$ 0.85
CEO transition and IP defense costs (1)	0.01		
Goodwill impairment charge (2)	0.16		
Sales & marketing leadership reorganization (1)		0.01	
Acquisition-related costs (1)		0.03	

Adjusted Basic EPS	$ 0.68	$ 0.81	$ 0.85
Net Earnings per Diluted Common Share -			
U.S. GAAP basis	$ 0.51	$ 0.76	$ 0.85
CEO transition and IP defense costs (1)	0.01		
Goodwill impairment charge (2)	0.16		
Sales & marketing leadership reorganization (1)		0.01	
Acquisition-related costs (1)		0.03	
Adjusted Diluted EPS (3)	$ 0.67	$ 0.80	$ 0.85

(1) These CEO transition and IP defense costs, sales & marketing leadership reorganization costs, and acquisition-related costs are net of income tax effects of $267, $246 and $248, 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, provided for each of the following:

By Reportable Segment & 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, as a result of the acquisition of Magellan, 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, Central and South 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; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents domestically and abroad, including sales, business development, and distribution facilities in Singapore and 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.

	2017	2016	2015	2017 vs. 2016 Inc (Dec)	2016 vs. 2015 Inc (Dec)
Diagnostics-					
Americas	$ 120,589	$ 123,714	$ 123,366	(3)%	%
EMEA	19,454	18,424	19,135	6%	(4)%
ROW	3,478	2,976	3,613	17%	(18)%
Total Diagnostics	143,521	145,114	146,114	(1)%	(1)%
Life Science-					
Americas	21,163	20,651	22,363	2%	(8)%
EMEA	21,550	19,406	17,845	11%	9%
ROW	14,537	10,911	8,508	33%	28%

Total Life Science	57,250	50,968	48,716	12%	5%
Consolidated	$ 200,771	$ 196,082	$ 194,830	2%	1%
% of total revenues-					
Diagnostics	71%	74%	75%		
Life Science	29%	26%	25%		
Total	100%	100%	100%		
Ex-Americas	29%	26%	25%		

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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 ***illumi****gene* platform

2) Immunoassays and lead tests on multiple technology platforms

Life Science

1) Molecular components

2) Immunoassay components

Revenues for each product platform/type, as well as its relative percentage of segment revenues, are shown below.

	2017	2016	2015	2017 vs. 2016 Inc (Dec)	2016 vs. 2015 Inc (Dec)
Diagnostics-					
Molecular assays	$ 33,463	$ 38,302	$ 40,880	(13)%	(6)%
Immunoassays & lead tests	110,058	106,812	105,234	3%	1%
Total Diagnostics	$ 143,521	$ 145,114	$ 146,114	(1)%	(1)%
Life Science-					
Molecular components	$ 22,205	$ 20,599	$ 20,601	8%	%
Immunoassay components	35,045	30,369	28,115	15%	8%
Total Life Science	$ 57,250	$ 50,968	$ 48,716	12%	5%
% of Diagnostics revenues-					
Molecular assays	23%	26%	28%		
Immunoassays & lead tests	77%	74%	72%		
Total Diagnostics	100%	100%	100%		
% of Life Science revenues-					
Molecular components	39%	40%	42%		

Immunoassay components	61%	60%	58%
Total Life Science	100%	100%	100%

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Following is a discussion of the revenues generated by each of these product platforms/types:

Diagnostics Products

Molecular Assay Products

During fiscal 2017, revenues from our ***illumi****gene* molecular platform of products totaled $33,463, representing a 13% decrease from fiscal 2016 (also 13% in constant-currency). This decrease reflects the ongoing increased competition within the molecular-based testing market, most notably within the market for *C. difficile* testing.

We have nearly 1,650 customer account placements. Of these account placements, approximately 1,375 accounts have completed evaluations and validations and are regularly purchasing product, with the balance of our account placements being in some stage of product evaluation and/or validation. Of our account placements, we have nearly 600 accounts that are regularly purchasing, evaluating and/or validating two or more assays. Increasing the number of customers utilizing two or more assays is a key objective, as we believe broader menu utilization lessens the risk of displacement by competitors.

We continue to invest in new product development for our molecular testing platform, and this platform now has nine commercialized tests spanning hospital acquired infections, women s health, respiratory, sexually transmitted diseases, and tropical diseases. As of September 30, 2017, our ***illumi****gene* Malaria test has been placed in nearly 150 accounts in the EMEA region for use as a screening test for travelers returning to Europe from endemic areas in Africa. Our efforts to develop market channels in the endemic areas of Africa continue, as we work to convince policy-makers of the advantages of a more accurate molecular test to assist in efforts to eradicate malaria.

We believe that the diagnostic testing market, particularly in the U.S., is continuing to selectively move away from culture and immunoassay testing to molecular testing for diseases where there is a favorable cost/benefit position for the total cost of health care. During fiscal 2017 we experienced 4% growth in all ***illumi****gene* testing categories, other than the hyper-competitive *C. difficile* arena, which has stabilized in recent quarters. While this market is competitive, with molecular companies such as Cepheid and Becton Dickinson, and others such as Quidel, Nanosphere and Alere, we believe we are well-positioned. Our simple, easy-to-use, ***illumi****gene* platform, with its expanding menu, requires no expensive equipment purchase and little to no maintenance cost. We believe these features, along with its small footprint and the performance of the ***illumi****gene* assays, make ***illumi****gene* an attractive molecular platform for any size hospital or physician office laboratory that runs moderately-complex tests. We continue to invest in the development of additional assays for this platform and expect a test for congenital cytomegalovirus (CMV), a leading cause of deafness in infants, to be our next FDA-cleared test on the ***illumi****gene* platform.

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Immunoassay and Lead Testing Products

Revenues from our Diagnostics segment s immunoassay and lead testing products increased 3% in fiscal 2017, following a 1% increase in fiscal 2016. These results reflect the current fiscal year including a full twelve months of Magellan revenue, significantly offset by decreased revenue in our *H. pylori* and other immunoassay product lines.

Revenues from Magellan s sale of products to test for elevated levels of lead in blood totaled $18,061. Compared to 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 revenues increased 2%. This increase was achieved despite the effect on venous blood testing revenue of the previously-noted FDA-related activities.

During fiscal 2017, revenues from our *H. pylori* products decreased 4% (also 4% in constant-currency) to $30,948, which followed an 8% increase during fiscal 2016. In fiscal 2016, we employed bulk-buy sales programs (also referred to as stock-and-block programs) intended to increase major customer inventory levels as a defense against potential competitors upon the expiration of our patent, as further described below. We expect our *H. pylori* revenue to continue to return to low single-digit growth in fiscal 2018. This growth expectation reflects volume growth from the ongoing conversion of serology testing to our antigen tests. 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. A significant amount of the *H. pylori* product revenues are sales to reference labs, whose buying patterns may not be consistent from period to period. During fiscal 2017, we also introduced capabilities to identify resistance to Clarithromycin, the antibiotic commonly used to treat *H. pylori*. This is currently available in an Analyte Specific Reagent (ASR) format. We believe that partnering the ability to diagnose *H. pylori* and identify resistance provides a strong competitive advantage.

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, as we currently market the only FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market. 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. In order to mitigate competition, our product development pipeline includes multiple new product initiatives for the detection of *H. pylori*. We are unable to provide assurances that we will be successful with any mitigation strategy or that any mitigation strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit. See Item 3. Legal Proceedings for a discussion of the status of certain litigation related to our intellectual property.

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During fiscal 2017, revenues from our other immunoassay products (including *C. difficile*, foodborne and respiratory) decreased 7% (also 7% in constant-currency) to $58,732, following a 16% decrease in fiscal 2016. A return to growth during the second half of the fiscal year supports our belief that this portion of our business has stabilized and is positioned for future growth (5% increase during the second half of the year, following a 16% decline in the first half of the year).

Life Science Products

During fiscal 2017, revenues from our Life Science segment increased 12%, with revenues from molecular component sales increasing 8% compared to fiscal 2016 and revenues from immunoassay component sales increasing 15%. Life Science segment revenues increased 5% in fiscal 2016, with revenues from molecular component sales remaining flat compared to fiscal 2015 and revenues from immunoassay component sales increasing 8%. Our molecular components business growth was negatively impacted by the movement in currency exchange rates since fiscal 2016, with revenues increasing 12% on a constant-currency basis over fiscal 2016. During fiscal 2017, our Life Science segment continued to benefit from (i) increased revenues in the steadily-expanding tropical disease product family, with sales of such products doubling to approximately $2,200 in fiscal 2017; and (ii) increased revenue from sales into China, with such sales totaling approximately $5,900 during fiscal 2017 (approximately $1,000 in the molecular components business and $4,900 in the immunoassay components business) representing an approximate 44% increase over fiscal 2016. New products, including EPIK miRNA Select, JetSeq, and SensiFast Lyo-Ready, also contributed to the increase, with incremental year-over-year revenue growth of approximately $700.

Foreign Currency

Fluctuations in foreign currency exchange rates since fiscal 2016 had an approximate $1,200 unfavorable impact on fiscal 2017 revenues; $400 within the Diagnostics segment and $800 within the Life Science segment. This compares to year-to-year currency exchange rates having an approximate $1,700 unfavorable impact on revenues in fiscal 2016; $700 within the Diagnostics segment and $1,000 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 2017, 2016 or 2015.

Significant Customers

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 8 of the accompanying Consolidated Financial Statements.

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Medical Device Tax

On January 1, 2013, the medical device tax established as part of the U.S. health care reform legislation became effective, and as a result, the Company made its first required tax deposit near the end of January 2013. During fiscal 2017, 2016 and 2015, the Company recorded approximately $0, $500 and $1,900, respectively, of medical device tax expense, which is reflected as a component of cost of sales in the accompanying Consolidated Statements of Operations. During December 2015, the Consolidations Appropriations Act of 2016 imposed a two-year moratorium on this excise tax effective January 1, 2016. This moratorium expires December 31, 2017, and we are unable to predict any future legislative changes or developments related to this moratorium or excise tax.

Gross Profit:

	2017	2016	2015	2017 vs. 2016 Inc (Dec)	2016 vs. 2015 Inc (Dec)
Gross Profit	$ 124,833	$ 127,787	$ 121,882	(2)%	5%
Gross Profit Margin	62%	65%	63%	-3 points	+2 points

The overall gross profit margin decrease during fiscal 2017 primarily results from the combined effects of (i) mix of products sold, particularly decreased contribution from our higher margin *H. pylori* products; (ii) customer mix; (iii) operating segment mix; and (iv) decreased production levels in certain of our production facilities designed to reduce inventory levels. The overall increase in the gross profit margin from fiscal 2015 to fiscal 2016 reflects the combined effects of (i) mix of products sold, particularly the higher revenue contribution from *H. pylori* products; (ii) realization of manufacturing facility efficiencies for our ***illumi****gene* products as a result of bringing in-house certain reagent dispensing operations that were previously outsourced; (iii) manufacturing efficiencies in our Life Science segment; (iv) favorable effects of currency rates related to products where the purchase cost is denominated in Euros but the customer sales are billed in U.S. dollars; and (v) decreased medical device tax payments.

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.

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Operating Expenses:

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2015:					
Diagnostics	$ 9,625	$ 17,943	$ 19,284	$	$ 46,852
Life Science	2,980	7,658	8,332		18,970
Total 2015 Expenses	**$ 12,605**	**$ 25,601**	**$ 27,616**	**$**	**$ 65,822**
Fiscal 2016:					
Diagnostics	$ 11,130	$ 21,200	$ 22,335	$ 2,158	$ 56,823
Life Science	2,685	8,671	8,230		19,586
Total 2016 Expenses	**$ 13,815**	**$ 29,871**	**$ 30,565**	**$ 2,158**	**$ 76,409**
Fiscal 2017:					
Diagnostics	$ 13,166	$ 22,727	$ 24,491	$ 7,390	$ 67,774
Life Science	2,514	9,374	7,789		19,677
Total 2017 Expenses	**$ 15,680**	**$ 32,101**	**$ 32,280**	**$ 7,390**	**$ 87,451**

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2015 Expenses	**$ 12,605**	**$ 25,601**	**$ 27,616**	$	**$ 65,822**
% of Revenues	6%	13%	14%	%	34%
Fiscal 2016 Increases (Decreases):					
Diagnostics	1,505	3,257	3,051	2,158	9,971
Life Science	(295)	1,013	(102)		616
2016 Expenses	**$ 13,815**	**$ 29,871**	**$ 30,565**	**$ 2,158**	**$ 76,409**
% of Revenues	7%	15%	16%	1%	39%
% Increase	10%	17%	11%	NMF	16%
Fiscal 2017 Increases (Decreases):					
Diagnostics	2,036	1,527	2,156	5,232	10,951
Life Science	(171)	703	(441)		91
2017 Expenses	**$ 15,680**	**$ 32,101**	**$ 32,280**	**$ 7,390**	**$ 87,451**
% of Revenues	8%	16%	16%	4%	44%

% Increase	13%	7%	6%	242%	14%

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Total operating expenses increased during both fiscal 2017 and fiscal 2016, resulting primarily from the combined effects of the following:

Diagnostics

Fiscal 2017 increase

- Magellan goodwill impairment charge;
- Incremental Magellan operating expenses due to six additional months of Meridian ownership in fiscal 2017;
- Increased R&D costs in connection with instrumentation development programs, with such elevated level of spending expected to continue into fiscal 2018 as the programs are completed and transitioned to clinical trials; and
- CEO transition and IP defense costs.

Fiscal 2016 increase

- Addition of Magellan s operating expenses since the March 24, 2016 date of acquisition, which represent approximately 50% of the total Diagnostics operating expense increase;
- Increased investment in Sales & Marketing activities, including new leadership and an expansion in sales territories;
- Costs incurred in connection with acquisition activities, most notably related to the acquisition of Magellan; and
- Costs incurred in connection with restructuring Sales & Marketing leadership, which relate to severance obligations for former employees.

Life Science

Fiscal 2017 increase

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

Fiscal 2016 increase

Increased investment in Sales & Marketing activities, including increased personnel, travel and marketing spending.

The amount of stock-based compensation expense reported for fiscal 2017, 2016 and 2015 was $3,381, $2,911 and $3,324, respectively. Details of the stock-based compensation activities giving rise to these expenses are set forth in Note 6 of the accompanying Consolidated Financial Statements.

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Operating Income

Operating income decreased 27% and 8% in fiscal 2017 and 2016, respectively, as a result of the factors discussed above, including the Magellan goodwill impairment charge and CEO transition and IP defense costs in fiscal 2017 and the costs associated with acquisition-related activities and sales & marketing leadership reorganization in fiscal 2016.

Other Income and Expense

Other income and expense in fiscal 2017 and fiscal 2016 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%. In fiscal 2015, other income and expense included $1,100 of foreign currency losses, which related primarily to a foreign subsidiary intercompany loan. This compares to $400 and $600 of foreign currency gains in fiscal 2017 and fiscal 2016, respectively.

Income Taxes

The effective rate for income taxes was 41%, 36% and 35% for fiscal 2017, 2016 and 2015, respectively. 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 2017, 2016 or 2015.

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 overnight repurchase agreements, 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 collectibility 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 has been recorded on the goodwill resulting from the Magellan acquisition due to certain FDA activities related to Magellan s lead testing system utilizing venous blood samples (see full description previously within this MD&A). As of September 30, 2017, our stock price was $14.30 per share, compared to our book value per share of $4.02. 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, 2017, our cash and equivalents balance is $9,846 higher than at the end of fiscal 2016. This increase results in large part from the combined net effects of (i) operating activities providing $4,132 more net cash, as discussed below; (ii) lowering the quarterly cash dividend rate resulting in $9,383 less in shareholder dividends being paid, as discussed below; and (iii) principal payments during the year being $2,250 higher during this first full fiscal year of the term loan obligation.

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Net cash provided by operating activities totaled $41,355 during fiscal 2017, an 11% increase from the $37,223 provided during fiscal 2016. While reflecting the effects of the timing of payments from customers, and to suppliers and taxing authorities, this increase also results in large part from the net effects of (i) decreased inventory levels during fiscal 2017, compared to increased levels during fiscal 2016; and (ii) decreased accrued employee compensation costs during fiscal 2017, reflecting the payment of $407 of discretionary bonuses to non-executives related to fiscal 2016 and the timing of regularly scheduled payroll payments. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and dividends during the next 12 months.

Following the release of results for the fiscal 2017 first quarter, the board of directors reduced the fiscal 2017 indicated annual cash dividend rate to $0.50 per share (down from $0.80 per share) in order to align it with the stated policy guidelines of the payout ratio to range between 75% and 85% of each fiscal year s net earnings. This indicated annual rate represents 75% of fiscal 2017 s non-GAAP diluted earnings per share.

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 4 of the accompanying Consolidated Financial Statements. In addition, we have a $30,000 revolving credit facility with a commercial bank that expires March 31, 2021. As of November 29, 2017, 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 2017, 2016 or 2015.

Our capital expenditures totaled $4,467 for fiscal 2017 and largely related to laboratory equipment, manufacturing equipment and a new business intelligence system. During fiscal 2018 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.

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Known Contractual Obligations:

Known contractual obligations and their related due dates were as follows as of September 30, 2017:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases [1]	$ 5,593	$ 1,978	$ 2,424	$ 766	$ 425
Purchase obligations [2]	21,764	18,885	2,879		
Loan principal payments [3]	54,750	4,500	50,250		
Scheduled interest payments [3]	4,581	1,487	3,094		
Uncertain income tax positions liability and interest [4]	682	682			
Total	$ 87,370	$ 27,532	$ 58,647	$ 766	$ 425

(1) Meridian and its subsidiaries are lessees of (i) office and warehouse buildings in Ohio, Massachusetts, Florida, Australia, Belgium, France, Germany, Singapore, 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 4 of the accompanying Consolidated Financial Statements.

(4) As of September 30, 2017, our liabilities for uncertain tax positions and related interest and penalties were $517 and $165, respectively. 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.

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 90% 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 $2,500 in fiscal 2018.

Off-Balance Sheet Arrangements

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

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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, Euro and Singapore dollar. 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 21% of consolidated revenues for fiscal 2017. Additionally, five of our product families accounted for 81% of our Diagnostics segment s third-party revenues during fiscal 2017, and 58% of our fiscal 2017 consolidated revenues.

Our Life Science segment s revenues from sales of purified antigens and reagents to two diagnostics manufacturing customers were 17% of the segment s total revenues for fiscal 2017, and 5% of our fiscal 2017 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.

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 5	Uncertain tax positions and state apportionment factors

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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, will be effective for the Company beginning October 1, 2018 (fiscal 2019). The Company has prepared an inventory of its existing revenue streams and a preliminary analysis of the revenue recognition criteria applying ASU 2014-09. This analysis is preliminary and our overall assessment is not yet complete. However, based on the analysis completed to date, aside from certain expanded disclosure requirements, the Company does not currently anticipate that its planned adoption of ASU 2014-09 on a modified retrospective basis will have a material impact on its financial statements.

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 2018.

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. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2018, although early adoption is permitted. The Company has assessed the impact that adoption of this guidance will have, and believes that the impact will primarily relate to the treatment of the differences between stock compensation expense recorded in the Company s financial statements and the stock compensation ultimately deducted on its tax returns. The tax effect of such differences is currently recorded in additional paid-in capital and reflected within the financing activities section of the statement of cash flows. Upon adoption of this guidance, these tax effects will be required to be recorded directly to income tax expense and reflected within the operating activities section of the statement of cash flows. While the impact of this guidance, which the Company plans to adopt on a prospective basis at the beginning of fiscal 2018, 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), based on the lapsing of a significant equity grant in November 2017, adoption is expected to increase the Company s fiscal 2018 effective tax rate by approximately one percentage point.

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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.

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, which intends to improve the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2019, although early adoption is permitted. While the Company has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements, in light of the levels of such transfer activity within the Company, adoption of this guidance is not expected to have a significant impact on the Company s consolidated results of operations, cash flows or financial position.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment*, which serves to simplify the process of testing for goodwill impairment by eliminating the Step 2 comparison of a reporting unit s *implied fair value* to its carrying amount. The guidance requires an entity to compare a reporting unit s fair value to its carrying amount, and if the carrying amount exceeds the fair value, an impairment equal to the excess carrying amount is recorded; no Step 2 implied fair value comparison is required. The Company early adopted this guidance during the third quarter of fiscal 2017, as permitted. See Note 1(h) for discussion of Magellan s goodwill impairment.

ITEM 7A.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

See Market Risk Exposure and Capital Resources under Item 7 above beginning on page 29.

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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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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Meridian Bioscience, Inc.

We have audited the accompanying consolidated balance sheets of Meridian Bioscience, Inc. (an Ohio corporation) and subsidiaries (the Company) as of September 30, 2017 and 2016, and 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, 2017. Our audits of the basic consolidated financial statements included the financial statement schedule listed in the index appearing under Schedule No. II. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

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

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of September 30, 2017, based on 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, 2017 expressed an adverse opinion.

/s/ GRANT THORNTON LLP
Cincinnati, Ohio
November 29, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Meridian Bioscience, Inc.

We have audited the internal control over financial reporting of Meridian Bioscience, Inc. (an Ohio corporation) and subsidiaries (the Company) as of September 30, 2017, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). 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 (Management s Report). Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

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

Because of 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.

A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management s assessment.

Information Technology General Controls (ITGC) intended to restrict access to certain data and applications were not adequate, resulting in inappropriate access at both the Information Technology and end user levels within an application impacting financial reporting function and controls.

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In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of September 30, 2017, 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), the consolidated financial statements of the Company as of and for the year ended September 30, 2017. The material weakness identified above was considered in determining the nature, timing, and extent of audit tests applied in our audit of the September 30, 2017 consolidated financial statements, and this report does not affect our report dated November 29, 2017, which expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio

November 29, 2017

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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,	**2017**	2016	2015
Net Revenues	**$ 200,771**	$ 196,082	$ 194,830
Cost of Sales	**75,938**	68,295	72,948
Gross Profit	**124,833**	127,787	121,882
Operating Expenses:			
Research and development	**15,680**	13,815	12,605
Selling and marketing	**32,101**	29,871	25,601
General and administrative	**32,280**	30,565	27,616
CEO transition and IP defense costs	**762**		
Goodwill impairment charge	**6,628**		
Sales and marketing leadership reorganization costs		677	
Acquisition-related costs		1,481	
Total operating expenses	**87,451**	76,409	65,822
Operating Income	**37,382**	51,378	56,060
Other Income (Expense):			
Interest income	**171**	67	23
Interest expense	**(1,642)**	(897)	
Other, net	**518**	96	(1,020)
Total other expense	**(953)**	(734)	(997)
Earnings Before Income Taxes	**36,429**	50,644	55,063
Income Tax Provision	**14,872**	18,415	19,523
Net Earnings	**$ 21,557**	$ 32,229	$ 35,540
Earnings Per Share Data:			
Basic earnings per common share	**$ 0.51**	$ 0.77	$ 0.85
Diluted earnings per common share	**$ 0.51**	$ 0.76	$ 0.85
Common shares used for basic earnings per common share	**42,188**	42,010	41,659
Effect of dilutive stock options and restricted share units	**383**	383	353
Common shares used for diluted earnings per common share	**42,571**	42,393	42,012
Dividends declared per common share	**$ 0.575**	$ 0.80	$ 0.80
Anti-dilutive Securities:			

Common share options and restricted share units	**873**	462	551

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

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2017**	2016	2015
Net Earnings	**$ 21,557**	$ 32,229	$ 35,540
Other comprehensive income (loss):			
Foreign currency translation adjustment	**1,616**	(2,732)	(2,639)
Unrealized gain (loss) on cash flow hedge	**1,544**	(729)	
Income taxes related to items of other comprehensive income	**(590)**	275	
Other comprehensive income (loss), net of tax	**2,570**	(3,186)	(2,639)
Comprehensive Income	**$ 24,127**	$ 29,043	$ 32,901

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

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CONSOLIDATED BALANCE SHEETS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	**2017**	2016
Assets		
Current Assets:		
Cash and equivalents	**$ 57,072**	$ 47,226
Accounts receivable, less allowances of $307 and $334, respectively	**29,106**	27,102
Inventories	**41,493**	45,057
Prepaid expenses and other current assets	**6,204**	7,406
Total current assets	**133,875**	126,791
Property, Plant and Equipment, at Cost:		
Land	**1,162**	1,155
Buildings and improvements	**32,207**	31,487
Machinery, equipment and furniture	**48,836**	45,085
Construction in progress	**1,895**	1,947
Subtotal	**84,100**	79,674
Less: accumulated depreciation and amortization	**53,590**	49,224
Net property, plant and equipment	**30,510**	30,450
Other Assets:		
Goodwill	**54,926**	61,982
Other intangible assets, net	**26,704**	29,855
Restricted cash	**1,000**	1,000
Deferred instrument costs, net	**1,368**	1,392
Fair value of interest rate swap	**815**	
Deferred income taxes	**158**	205
Other assets	**421**	353
Total other assets	**85,392**	94,787
Total assets	**$ 249,777**	$ 252,028

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

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CONSOLIDATED BALANCE SHEETS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	**2017**	2016
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	**$ 7,719**	$ 7,627
Accrued employee compensation costs	**4,536**	7,106
Current portion of acquisition consideration	**2,095**	
Other accrued expenses	**2,789**	2,606
Current portion of long-term debt	**4,500**	3,750
Income taxes payable	**1,248**	1,482
Total current liabilities	**22,887**	22,571
Non-Current Liabilities		
Acquisition consideration	**235**	2,383
Post-employment benefits	**2,468**	2,305
Fair value of interest rate swap		729
Long-term debt	**50,147**	54,610
Deferred income taxes	**4,455**	2,958
Total non-current liabilities	**57,305**	62,985
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, 42,207,317 and 42,106,587 issued, respectively		
Additional paid-in capital	**125,608**	122,356
Retained earnings	**46,923**	49,632
Accumulated other comprehensive loss	**(2,946)**	(5,516)
Total shareholders equity	**169,585**	166,472
Total liabilities and shareholders equity	**$ 249,777**	$ 252,028

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

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CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (dollars and shares 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, 2014	41,622	$ 111,851	$ 48,869	$ 309	$ 161,029
Cash dividends paid - $0.80 per share			(33,357)		(33,357)
Exercise of stock options	187	1,976			1,976
Conversion of restricted share units	29				
Stock compensation expense		3,324			3,324
Net earnings			35,540		35,540
Foreign currency translation adjustment				(2,639)	(2,639)
Balance at September 30, 2015	41,838	117,151	51,052	(2,330)	165,873
Cash dividends paid - $0.80 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

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

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CONSOLIDATED STATEMENTS OF CASH FLOWS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2017**	2016	2015
Cash Flows From Operating Activities			
Net earnings	**$ 21,557**	$ 32,229	$ 35,540
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	**4,342**	3,937	3,470
Amortization of intangible assets	**3,776**	2,690	1,748
Amortization of deferred instrument costs	**972**	1,091	1,391
Stock-based compensation	**3,381**	2,911	3,324
Goodwill impairment charge	**6,628**		
Deferred income taxes	**1,474**	(233)	(122)
Losses on long-lived assets		659	94
Change in current assets, net of acquisition	**3,481**	(8,115)	(6,079)
Change in current liabilities, net of acquisition	**(3,535)**	2,237	3,238
Other, net	**(721)**	(183)	205
Net cash provided by operating activities	**41,355**	37,223	42,809
Cash Flows From Investing Activities			
Purchase of property, plant and equipment	**(4,467)**	(4,004)	(4,613)
Purchase of equity method investment		(600)	
Proceeds from sale of assets			1,138
Purchase of intangibles and other assets			(151)
Acquisition of Magellan, net of cash acquired		(62,091)	
Net cash used for investing activities	**(4,467)**	(66,695)	(3,626)
Cash Flows From Financing Activities			
Dividends paid	**(24,266)**	(33,649)	(33,357)
Proceeds from term loan, net of issuance costs		59,860	
Payments on term loan	**(3,750)**	(1,500)	
Proceeds and tax benefits from exercises of stock options	**303**	2,494	2,614
Net cash provided by (used for) financing activities	**(27,713)**	27,205	(30,743)
Effect of Exchange Rate Changes on Cash and Equivalents	**671**	(480)	(1,514)
Net Increase (Decrease) in Cash and Equivalents	**9,846**	(2,747)	6,926
Cash and Equivalents at Beginning of Period	**47,226**	49,973	43,047
Cash and Equivalents at End of Period	**$ 57,072**	$ 47,226	$ 49,973

Supplemental Cash Flow Information

Cash paid for interest	**$ 1,605**	$ 879	$
Cash paid for income taxes	**$ 12,613**	$ 17,915	$ 20,168

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

(dollars and shares 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, viral, respiratory and parasitic 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 researchers and other diagnostic manufacturers.

(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, Euro and Singapore dollar 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 overnight repurchase agreements and 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, 2017		September 30, 2016	
	Cash and Equivalents	**Other**	Cash and Equivalents	Other
Overnight repurchase agreements	**$**	**$**	$ 9,988	$
Institutional money market funds	**20,104**		10,020	
Cash on hand				
Restricted		**1,000**		1,000
Unrestricted	**36,968**		27,218	
Total	**$ 57,072**	**$ 1,000**	$ 47,226	$ 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. ***illumi****gene* instruments are carried in inventory until customer placement, at which time they are transferred to deferred ***illumi****gene* instrument costs, unless sold outright. Similarly, Magellan s blood lead testing instruments are carried in inventory until they are sold outright or placed with a customer under Magellan s 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 $2,059 and $2,680 at September 30, 2017 and 2016, 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. At September 30, 2017, we had six reporting units, four of which contained goodwill (Americas Diagnostics, Bioline (molecular components), Life Science-U.S. (immunoassay components) and Magellan). We review our reporting unit structure each year as part of our annual goodwill impairment test, or more frequently in the event of changes in our structure. 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 2017, we performed quantitative assessments as of June 30, 2017 for each of our Americas Diagnostics, Bioline and Life Science-U.S. reporting units, 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 values of each reporting unit exceeded their carrying values; 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. Magellan s lead testing systems are capable of processing both capillary and venous blood samples. Magellan s LeadCare Plus and LeadCare Ultra systems, which account for approximately 10% of Magellan s annual revenues, are used predominantly with venous blood samples. Magellan s LeadCare and LeadCare II systems are predominantly used with capillary blood samples.

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.

As a result of these matters, we expect to experience delays in reinstating venous blood sample testing on our LeadCare products, as well as in obtaining 510(k) clearance for new Magellan products. We also expect delays in obtaining export certifications for Magellan products during the remediation period. In light of these factors and their impacts, during our third fiscal quarter, it was determined that a potential

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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 2016 or 2015.

During fiscal 2017, goodwill decreased $7,056, reflecting (i) a $767 acquisition measurement period adjustment downward related to Magellan (Diagnostics operating segment; see Note 2); (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 s Bioline Group. The increase of $39,633 in fiscal 2016 reflects the addition of $41,358 from the acquisition of Magellan and a $1,725 decrease from the currency translation adjustments related to the Bioline Group.

A summary of Meridian s acquired intangible assets subject to amortization, as of September 30, 2017 and 2016 is as follows:

	2017		2016	
As of September 30,	**Gross Carrying Value**	**Accum. Amort.**	Gross Carrying Value	Accum. Amort.
Manufacturing technologies, core products and cell lines	**$ 22,332**	**$ 12,807**	$ 21,921	$ 11,540
Trade names, licenses and patents	**8,689**	**4,398**	9,037	3,947
Customer lists, customer relationships and supply agreements	**24,562**	**11,854**	24,385	10,511
Non-compete agreements	**720**	**540**	680	170
	$ 56,303	**$ 29,599**	$ 56,023	$ 26,168

The actual aggregate amortization expense for these intangible assets for fiscal 2017, 2016 and 2015 was $3,776, $2,690 and $1,748, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2018 - $3,561, fiscal 2019 - $3,340, fiscal 2020 - $3,176, fiscal 2021 - $2,561 and fiscal 2022 - $2,182.

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 2017, 2016 or 2015.

(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 $787 in fiscal 2017.

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 $4,190 at September 30, 2017 and $4,178 at September 30, 2016, and have been netted against accounts receivable.

Revenue for our Diagnostics segment includes revenue for our ***illumi****gene* 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 ***illumi****gene* 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 ***illumi****gene* 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 collectibility. 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 5.

(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 6(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, will be effective for the Company beginning October 1, 2018 (fiscal 2019). The Company has prepared an inventory of its existing revenue streams and a preliminary analysis of the revenue recognition criteria applying ASU 2014-09. This analysis is preliminary and our overall assessment is not yet complete. However, based on the analysis completed to date, aside from certain expanded disclosure requirements, the Company does not currently anticipate that its planned adoption of ASU 2014-09 on a modified retrospective basis will have a material impact on its financial statements.

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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 2018.

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. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2018, although early adoption is permitted. The Company has assessed the impact that adoption of this guidance will have, and believes that the impact will primarily relate to the treatment of the differences between stock compensation expense recorded in the Company s financial statements and the stock compensation ultimately deducted on its tax returns. The tax effect of such differences is currently recorded in additional paid-in capital and reflected within the financing activities section of the statement of cash flows. Upon adoption of this guidance, these tax effects will be required to be recorded directly to income tax expense and reflected within the operating activities section of the statement of cash flows. While the impact of this guidance, which the Company plans to adopt on a prospective basis at the beginning of fiscal 2018, 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), based on the lapsing of a significant equity grant in November 2017, adoption is expected to increase the Company s fiscal 2018 effective tax rate by approximately one percentage point.

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.

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In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, which intends to improve the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2019, although early adoption is permitted. While the Company has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements, in light of the levels of such transfer activity within the Company, adoption of this guidance is not expected to have a significant impact on the Company s consolidated results of operations, cash flows or financial position.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment*, which serves to simplify the process of testing for goodwill impairment by eliminating the Step 2 comparison of a reporting unit s *implied fair value* to its carrying amount. The guidance requires an entity to compare a reporting unit s fair value to its carrying amount, and if the carrying amount exceeds the fair value, an impairment equal to the excess carrying amount is recorded; no Step 2 implied fair value comparison is required. The Company early adopted this guidance during the third quarter of fiscal 2017, as permitted. See Note 1(h) for discussion of Magellan s goodwill impairment.

(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.

(2) 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, Inc. (collectively, Magellan), for $67,874, utilizing the proceeds from a new $60,000 five-year term loan and cash and equivalents on hand. An amount of the acquisition consideration totaling $2,330 remains payable to the sellers, pending the realization of tax benefits for certain net operating loss carryforwards in future tax returns, which is expected to be paid in fiscal 2018 and fiscal 2019 upon filing of our U.S. tax returns. Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of FDA-cleared products for the point-of-care testing of blood to diagnose lead poisoning in children and adults.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of $40,591 was originally recorded in connection with this acquisition, none of which is deductible for tax purposes. As of June 30, 2017, the goodwill recorded in connection with the acquisition was written down to $33,963 (see Note 1(h) for a discussion of the $6,628 impairment write-down). This goodwill results largely from the addition of Magellan s complementary customer base and distribution channels, industry reputation in the U.S. as a leader in lead testing, and management talent and workforce. Our fiscal 2016 Consolidated Statement of Operations includes $1,105 of acquisition-related costs related to the Magellan acquisition, which are reflected as Operating Expenses.

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The Magellan results of operations, which are included in our fiscal 2017 and fiscal 2016 Consolidated Statements of Operations and reported as part of the Diagnostics operating segment, include:

(i) $0 and $181 of cost of sales in fiscal 2017 and fiscal 2016, respectively, related to the roll-out of fair value inventory adjustments for sales of products that were in Magellan s inventory on the date of acquisition and, therefore, were valued at fair value, rather than manufactured cost, in the opening balance sheet; and

(ii) $2,736 and $1,311 of general and administrative expenses in fiscal 2017 and fiscal 2016, respectively, related to the amortization of specific identifiable intangible assets recorded on the opening balance sheet including customer relationships, technology, non-compete agreements and trade names.

The results of Magellan included in the Company s accompanying consolidated results are as follows, reflecting the items noted above, including the $6,628 goodwill impairment charge, and excluding interest expense on the debt secured by Meridian in connection with the transaction:

	2017	2016	2,015
Net Revenues	**$ 18,061**	$ 10,034	$
Net Earnings	**$ (5,916)**	$ 848	$

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The recognized amounts of identifiable assets acquired and liabilities assumed in the acquisition of Magellan are as follows:

	March 24, 2016 (as initially reported)	Measurement Period Adjustments	March 24, 2016 (as adjusted)
Fair value of assets acquired -			
Cash and equivalents	$ 3,400	$	$ 3,400
Accounts receivable	1,700		1,700
Inventories	1,400		1,400
Other current assets	300		300
Property, plant and equipment	2,800	(200)	2,600
Goodwill	42,800	(2,200)	40,600
Other intangible assets (estimated useful life):			
Customer relationships (15 years)	12,600	300	12,900
Technology (10 years)	10,600	300	10,900
Non-compete agreements (2 years)	700		700
Trade names (approximate 9 year weighted average)	3,700	(700)	3,000
	80,000	(2,500)	77,500
Fair value of liabilities assumed -			
Accounts payable and accrued expenses	1,600	100	1,700
Deferred income tax liabilities	10,600	(2,700)	7,900
Total consideration paid (including $2,400 accrued to be paid)	$ 67,800	$ 100	$ 67,900

The consolidated pro forma results of the combined entities of Meridian and Magellan, had the acquisition date been October 1, 2015, are as follows for the periods indicated:

	(UNAUDITED) Fiscal Year Ended September 30,	
	2017	2016
Net Revenues	**$ 200,771**	**$ 203,720**
Net Earnings	**$ 21,557**	**$ 32,226**

These pro forma amounts have been calculated by including the results of Magellan, and adjusting the combined results to give effect to the following, as if the acquisition had been consummated on October 1, 2015, together with the consequential tax effects thereon:

(i) remove the effect of transaction costs incurred by the Company ($1,105 in fiscal 2016);

(ii) reflect the additional depreciation and amortization that would have been charged in connection with the fair value adjustments to inventory, property, plant and equipment, and identifiable intangible assets ($1,412 in fiscal 2016);

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(iii) reflect the additional stock compensation expense related to equity-based awards granted under the Company s 2012 Stock Incentive Plan to certain Magellan employees in accordance with executed employee agreements, and to certain Meridian employees to reward them for their efforts in connection with the transaction ($95 in fiscal 2016); and

(iv) reflect the additional interest expense that would have been incurred on the Company s $60,000 term note ($789 in fiscal 2016).

(3) Inventories

Inventories are comprised of the following:

As of September 30,	**2017**	2016
Raw materials	**$ 6,575**	$ 7,639
Work-in-process	**11,559**	13,146
Finished goods - instruments	**1,460**	2,378
Finished goods - kits and reagents	**21,899**	21,894
Total	**$ 41,493**	$ 45,057

(4) Bank Credit Arrangements

In connection with the acquisition of Magellan (see Note 2), on March 22, 2016 the Company entered into a $60,000 five-year term loan with a commercial bank. The term loan requires quarterly principal and interest payments, with interest at a variable rate tied to LIBOR, and a balloon principal payment due March 31, 2021. The required principal payments on the term loan for each of the remaining fiscal years are as follows: fiscal 2018 - $4,500, fiscal 2019 - $5,250, fiscal 2020 - $6,000, and fiscal 2021 - $39,000. In light of the term loan s interest being determined on a variable rate basis, the fair value of the term loan at September 30, 2017 approximates the current carrying value reflected in the accompanying Consolidated Balance Sheet.

In order to limit exposure to volatility in the LIBOR interest rate, the Company and the commercial bank also entered into an interest rate swap that effectively converts the variable interest rate on the term loan to a fixed rate of 2.76%. With an initial notional balance of $60,000, the interest rate swap was established with critical terms identical to those of the term loan, including (i) notional reduction amounts and dates; (ii) LIBOR settlement rates; (iii) rate reset dates; and (iv) term/maturity. Due to this, the interest swap has been designated as an effective cash flow hedge, with changes in fair value reflected as a separate component of other comprehensive income in the accompanying Consolidated Statements of Comprehensive Income. At September 30, 2017 and 2016, the fair value of the interest rate swap was an asset of $815 and a liability of $729, respectively, and is reflected as a non-current asset and non-current liability, respectively, in the accompanying Consolidated Balance Sheets. This fair value was determined by reference to a third party valuation, and is considered a Level 2 input within the fair value hierarchy of valuation techniques.

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In addition, the Company maintains a $30,000 revolving credit facility with a commercial bank, which expires March 31, 2021. There were no borrowings outstanding on this revolving credit facility at September 30, 2017 or September 30, 2016.

The term loan and revolving credit facility are collateralized by the business assets of the Company s U.S. subsidiaries and require compliance with financial covenants that limit the amount of debt obligations and require a minimum level of coverage of fixed charges, as defined in the borrowing agreement. As of September 30, 2017, the Company is in compliance with all covenants. The Company is also required to maintain a cash compensating balance with the bank in the amount of $1,000, and is in compliance with this requirement.

(5) Income Taxes

(a) Earnings before income taxes, and the related provision for income taxes for the years ended September 30, 2017, 2016 and 2015 were as follows:

Year Ended September 30,	**2017**	2016	2015
Domestic	**$ 31,885**	$ 44,795	$ 50,653
Foreign	**4,544**	5,849	4,410
Total earnings before income taxes	**$ 36,429**	$ 50,644	$ 55,063
Provision (credit) for income taxes -			
Federal -			
Current	**$ 11,262**	$ 16,178	$ 16,152
Temporary differences			
Fixed asset basis differences and depreciation	**(181)**	(45)	50
Intangible asset basis differences and amortization	**(1,158)**	(744)	(421)
Currently non-deductible expenses and reserves	**884**	(694)	217
Stock-based compensation	**(635)**	129	126
Net operating loss carryforwards utilized	**1,831**		
Tax credit carryforwards utilized	**67**	41	250
Other, net	**99**	181	19
Subtotal	**12,169**	15,046	16,393
State and local	**1,900**	2,421	2,236
Foreign	**803**	948	894
Total income tax provision	**$ 14,872**	$ 18,415	$ 19,523

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(b) The following is a reconciliation between the statutory U.S. income tax rate and the effective rate derived by dividing the provision for income taxes by earnings before income taxes:

Year Ended September 30,	**2017**		2016		2015	
Computed income taxes at statutory rate	**$ 12,750**	**35.0%**	$ 17,719	35.0%	$ 19,264	35.0%
Increase (decrease) in taxes resulting from -						
State and local income taxes	**1,093**	**3.0**	1,329	2.6	1,365	2.5
Foreign tax rate differences	**(281)**	**(0.8)**	(337)	(0.7)	(217)	(0.4)
Qualified domestic production incentives	**(1,012)**	**(2.8)**	(1,290)	(2.5)	(1,197)	(2.2)
Acquisition-related costs			215	0.4		
Uncertain tax position activity	**134**	**0.4**	122	0.2	(25)	
Goodwill impairment charge	**2,320**	**6.4**				
Valuation allowance			327	0.7	7	
Other, net	**(132)**	**(0.4)**	330	0.7	326	0.6
	$ 14,872	**40.8%**	$ 18,415	36.4%	$ 19,523	35.5%

(c) The components of net deferred tax liabilities were as follows:

As of September 30,	**2017**	2016
Deferred tax assets -		
Valuation reserves and non-deductible expenses	**$ 1,762**	$ 2,366
Stock compensation expense not deductible	**3,367**	3,110
Net operating loss and tax credit carryforwards	**743**	2,190
Basis difference in equity-method investee	**302**	302
Inventory basis differences	**1,269**	1,620
Other	**(289)**	297
Subtotal	**7,154**	9,885
Less valuation allowance	**(342)**	(342)
Deferred tax assets	**6,812**	9,543
Deferred tax liabilities -		
Fixed asset basis differences and depreciation	**(1,325)**	(1,526)
Intangible asset basis differences and amortization	**(9,784)**	(10,770)
Deferred tax liabilities	**(11,109)**	(12,296)
Net deferred tax liabilities	**$ (4,297)**	$ (2,753)

For income tax purposes, we have recorded deferred tax assets related to operating loss and tax credit carryforwards in both U.S. and foreign jurisdictions totaling $546 and $197, respectively, as of September 30, 2017. At September 30, 2016, such deferred tax assets totaled $1,945 and $245, respectively. The operating loss carryforwards in foreign

jurisdictions have no expiration date. The operating loss carryforwards in the U.S. expire between 2023 and 2036 at the federal level, and between 2028 and 2036 at the state level. The aggregate amount of federal, state and foreign operating loss carryforwards total $552, $2,731 and $697, respectively, at September 30, 2017, and the AMT tax credit carryforward totals $133. The use of the federal and state losses and credits is limited by the change of ownership provisions of the Internal Revenue Code.

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The realization of deferred tax assets is dependent upon the generation of future taxable income in the applicable jurisdictions. We have considered the levels of currently anticipated pre-tax income in U.S. and foreign jurisdictions in assessing the required level of the deferred tax asset valuation allowance including the characterization of the income as ordinary or capital. Taking into consideration historical and current operating results, and other factors, we believe that it is more likely than not that the net deferred tax asset of $6,812 will be realized. The amount of the net deferred tax asset considered realizable, however, could be reduced in future years if estimates of future taxable income are reduced.

Undistributed earnings reinvested indefinitely in our non-U.S. operations were approximately $12,500 and $10,000 at September 30, 2017 and September 30, 2016, respectively. U.S. deferred tax liabilities of approximately $2,500 and $2,000 on such earnings, after consideration of foreign tax credits, have not been recorded as of September 30, 2017 and September 30, 2016, respectively.

As described in Note 1, we utilize a comprehensive model for the recognition, measurement, presentation and disclosure of uncertain tax positions, assuming full knowledge of all relevant facts by the applicable tax authorities. The total amount of unrecognized tax benefits at September 30, 2017 and September 30, 2016 related to such positions was $517 and $502, respectively, of which $405 would favorably affect the effective tax rate if recognized. We generally recognize interest and penalties related to uncertain tax positions as a component of our income tax provision. During fiscal 2017, such penalties and interest totaled $35. During fiscal 2016, we increased our tax provision by approximately $8 for such penalties and interest, and recorded approximately $85 to the opening balance sheet of Magellan. We had approximately $165 accrued for the payment of interest and penalties at September 30, 2017 compared to $130 accrued at September 30, 2016. The amount of our liability for uncertain tax positions expected to be paid or settled in the next 12 months is uncertain.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows:

	2017	2016
Unrecognized income tax benefits beginning of year	**$ 502**	$ 238
Additions for tax positions of prior years	**144**	264
Tax examination and other settlements	**(129)**	
Unrecognized income tax benefits at end of year	**$ 517**	$ 502

We are subject to examination by the tax authorities in the U.S. (both federal and state) and the countries of Australia, Belgium, China, England, France, Germany, Holland, Italy and Singapore. In the U.S., open tax years are fiscal 2014, fiscal 2015 and fiscal 2016. In countries outside the U.S., open tax years generally range from fiscal 2012 and forward. However, in Australia, Belgium and Singapore, the utilization of local net operating loss carryforwards extends the statute of limitations for examination well into the foreseeable future. To the extent that adjustments result from the completion of these examinations or the lapsing of statutes of limitation, they will affect tax liabilities in the period known. We believe that the results of any tax authority examinations would not have a significant adverse impact on our financial condition or results of operations

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(6) Employee Benefits

(a) Savings and Investment Plan - We have a profit sharing and retirement savings plan covering substantially all full-time U.S. employees. Profit sharing contributions to the plan, which are discretionary, are approved by the board of directors. The plan permits participants to contribute to the plan through salary reduction. Under terms of the plan, we match 100% of an employee s contributions, up to a maximum match of 4% of eligible compensation (3% through December 31, 2016). Our discretionary and matching contributions to the plan amounted to approximately $1,912, $1,631 and $1,567, during fiscal 2017, 2016 and 2015, respectively.

(b) Stock-Based Compensation Plans - During fiscal 2017, we had two active stock-based compensation plans, the 2004 Equity Compensation Plan, which became effective December 7, 2004, as amended (the 2004 Plan) and the 2012 Stock Incentive Plan, which became effective January 25, 2012 (the 2012 Plan).

Each of the 2004 Plan and 2012 Plan authorized the granting of new shares for options, restricted shares or restricted share units for up to 3,000 shares, with the non-granted portion of the 2004 Plan permitted to be carried forward and added to the 2012 Plan authorized limit. As of September 30, 2017, we have granted 1,442 and 1,656 shares under the 2004 Plan and 2012 Plan, respectively, thereby resulting in a remaining authorized limit of 2,902 shares. Options may be granted at exercise prices not less than 100% of the closing market value of the underlying common shares on the date of grant and have maximum terms up to ten years. Vesting schedules for options, restricted shares and restricted share units are established at the time of grant and may be set based on future service periods, achievement of performance targets or a combination thereof. All options contain provisions restricting their transferability and limiting their exercise in the event of termination of employment or the disability or death of the optionee. We recognize compensation expense for all share-based payments made to employees, based upon the fair value of the share-based payment on the date of the grant.

During fiscal 2015, we granted approximately 270 restricted share units (with a weighted-average grant date fair value of $17.91 per share) to certain employees, generally with half of each employee s grant being time-vested restricted share units vesting in total on the fourth anniversary of the grant date, and the remaining half being subject to attainment of a specified earnings target for fiscal 2015. While dividend equivalents were paid on these units throughout fiscal 2015, the target for fiscal 2015 was not met and the performance-based portion of these restricted share units granted during fiscal 2015 were cancelled.

Additionally, during fiscal 2015 in connection with the extension of an Amended and Restated Employment Agreement, we granted to our Chairman and Chief Executive Officer at that time (i) 25 restricted share units (with a grant date fair value of $16.50 per share) to be earned only if specified revenue and earnings per share targets were achieved for fiscal 2015; and (ii) 100 time-vested options (with a weighted-average grant date fair value of $3.73 per share), with half vesting September 30, 2015 and half vesting September 30, 2016. As a result of the fiscal 2015 performance targets being achieved, the restricted share units have been earned and the related compensation expense recorded in fiscal 2015.

During fiscal 2016, we granted approximately 370 restricted share units (with a weighted-average grant date fair value of $19.38 per share) to certain employees, generally with half of each employee s grant being time-vested restricted share units vesting in total on the fourth anniversary of the grant date, and the remaining half being subject to attainment of a specified earnings target for fiscal 2016. While dividend equivalents were paid on these units throughout fiscal 2016, the target for fiscal 2016 was not met and the performance-based portion of these restricted share units granted during fiscal 2016 have been cancelled.

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Additionally, during fiscal 2016 in connection with the Amended and Restated Employment Agreement described above, we granted to our Chairman and Chief Executive Officer at that time, 25 restricted share units (with a grant date fair value of $17.03 per share) to be earned only if specified revenue and earnings per share targets were achieved for fiscal 2016. As a result of the fiscal 2016 performance targets not being achieved, the restricted share units have been cancelled.

Similar to previous years, during fiscal 2017, we granted approximately 410 restricted share units (with a weighted-average grant date fair value of $16.93 per share) to certain employees, generally with half of each employee s grant being time-vested restricted share units vesting in total on the fourth anniversary of the grant date, and the remaining half being subject to attainment of a specified earnings target for fiscal 2017. While dividend equivalents were paid on these units throughout fiscal 2017, the target for fiscal 2017 was not met and the performance-based portion of these restricted share units granted during fiscal 2017 have been cancelled.

Additionally, during fiscal 2017 in connection with the Amended and Restated Employment Agreement, we granted to our Chairman and Chief Executive Officer at the time, 25 restricted share units (with a grant date fair value of $19.09 per share) to be earned only if specified revenue and earnings per share targets were achieved for fiscal 2017. As a result of the fiscal 2017 performance targets not being achieved, the restricted share units have been cancelled.

Giving effect to these grants, cancellations and certain other activities for restricted shares and restricted share units throughout the years, including conversions to common shares, forfeitures, and new hire and employee promotion grants, approximately 550 restricted share units remain outstanding as of September 30, 2017, with a weighted-average grant date fair value of $19.15 per share, a weighted-average remaining vesting period of 1.92 years and an aggregate intrinsic value of $7,859. The weighted-average grant date fair value of the approximate 91 restricted share units that vested during fiscal 2017 was $19.42 per share.

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The amount of stock-based compensation expense reported was $3,381, $2,911 and $3,324 in fiscal 2017, 2016 and 2015, respectively. The fiscal 2017 expense is comprised of $662 related to stock options and $2,719 related to restricted share units; the fiscal 2016 expense is comprised of $560 related to stock options and $2,351 related to restricted share units; and the fiscal 2015 expense is comprised of $591 related to stock options and $2,733 related to restricted share units. The total income tax benefit recognized in the income statement for these stock-based compensation arrangements was $861, $1,100 and $1,250, for fiscal 2017, 2016 and 2015, respectively. As of September 30, 2017, we expect future stock compensation expense for unvested options and unvested restricted share units to total $323 and $2,524, respectively, which will be recognized during fiscal years 2018 through 2021.

We recognize compensation expense only for the portion of shares that we expect to vest. As such, we apply estimated forfeiture rates to our compensation expense calculations. These rates have been derived using historical forfeiture data, stratified by several employee groups. During fiscal 2017, 2016 and 2015, we recorded $106, $76 and $86, respectively, in stock compensation expense to adjust estimated forfeiture rates to actual.

We have elected to use the Black-Scholes option pricing model to determine grant-date fair value for stock options, with the following assumptions: (i) expected share price volatility based on the average of Meridian s historical volatility over the options expected lives and implied volatility based on the value of tradable call options; (ii) expected life of options based on contractual lives, employees historical exercise behavior and employees historical post-vesting employment termination behavior; (iii) risk-free interest rates based on treasury rates that correspond to the expected lives of the options; and (iv) dividend yield based on the expected yield on underlying Meridian common stock.

Year ended September 30,	**2017**	2016	2015
Risk-free interest rates	**1.34%**	1.63%	2.07%
Dividend yield	**4.1%**	4.4%	3.7%
Life of option	**6.44 yrs.**	6.39 yrs.	6.33 yrs.
Share price volatility	**27%**	31%	33%
Forfeitures (by employee group)	**0%-19%**	0%-16%	0%-15%

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A summary of the status of our stock option plans as of September 30, 2017, and changes during the year ended September 30, 2017, is presented in the table and narrative below:

	Options	Wtd Avg Exercise Price	Wtd Avg Remaining Life (Yrs)	Aggregate Intrinsic Value
Outstanding beginning of period	780	$ 20.97		
Grants	266	16.38		
Exercises	(18)	16.54		
Forfeitures	(61)	18.34		
Cancellations	(25)	19.41		
Outstanding end of period	942	$ 19.98	6.51	$ 120
Exercisable end of period	661	$ 21.04	5.49	$ 48

A summary of the status of our nonvested options as of September 30, 2017, and changes during the year ended September 30, 2017, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested beginning of period	197	$ 3.64
Granted	266	2.65
Vested	(157)	3.15
Cancelled	(25)	3.66
Nonvested end of period	281	$ 3.00

The weighted average grant-date fair value of options granted was $2.65, $3.46 and $3.95 for fiscal 2017, 2016 and 2015, respectively. The total intrinsic value of options exercised was $9, $616 and $850 for fiscal 2017, 2016 and 2015, respectively. The total grant-date fair value of options that vested during fiscal 2017, 2016 and 2015 was $494, $474 and $571, respectively.

Cash received from options exercised was $302, $2,364 and $2,478 for fiscal 2017, 2016 and 2015, respectively. Tax expense recorded to additional paid-in capital from option exercises totaled $431, $70 and $502 for fiscal 2017, 2016 and 2015, respectively.

In connection with the October 9, 2017 employment of the Company s new Chief Executive Officer, in October 2017 we granted to our new Chief Executive Officer (i) options to purchase 100 shares of common stock of the Company vesting on a pro rata basis over four years; and (ii) 13 restricted share units vesting 100% on the second anniversary of

the grant. On November 8, 2017, we granted (i) 25 restricted share units vesting 100% on the fourth anniversary of the grant; and (ii) 25 restricted share units subject to attainment of a specified earnings target for fiscal 2018.

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(7) Non-Current Liabilities

The Company has provided certain post-employment benefits to its Executive Chairman (formerly Chairman and Chief Executive Officer) and its Chief Commercial Officer. These obligations total $1,680 and $1,628 at September 30, 2017 and 2016, respectively. In addition, we are required by the governments of certain of the foreign countries in which we operate to maintain a level of reserves for potential future severance indemnity. These reserves total $652 and $565 at September 30, 2017 and 2016, respectively.

(8) Reportable Segments and Major Concentration Data

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations for infectious disease products in Cincinnati, Ohio and, as a result of the acquisition of Magellan, manufacturing operations for products detecting elevated lead levels in blood in Billerica, Massachusetts (near Boston), and the sale and distribution of diagnostics products domestically and abroad. The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents domestically and abroad, including sales, business development and distribution facilities in Singapore and Beijing, China to further pursue growing revenue opportunities in Asia.

Revenues from individual customers constituting 10% or more of consolidated net revenues are as follows:

Year Ended September 30,	**2017**		2016		2015	
Customer A	**$ 23,029**	**(11)%**	$ 20,246	(10)%	$ 29,155	(15)%
Customer B	**$ 18,395**	**(9)%**	$ 19,585	(10)%	$ 25,276	(13)%

Accounts receivable from these two Diagnostics distributor customers accounted for 11% and 16% of consolidated accounts receivable at September 30, 2017 and September 30, 2016, respectively. The Company s international revenues totaled $61,936, $55,291 and $52,313 in fiscal years 2017, 2016 and 2015, respectively. Six of our product families *C. difficile,* foodborne, *H. pylori*, respiratory, women s health & STD, and blood lead testing accounted for 58%, 60% and 59% of consolidated net revenues in fiscal 2017, 2016 and 2015, respectively. We currently purchase on a sole-source basis from a U.S. and an Italian manufacturer, respectively, the ***illumi****pro*-10 instruments on which our ***illumi****gene* molecular testing platform operates and the LeadCare instruments used to test for blood lead levels. Additionally, two of our foodborne products sourced from another vendor accounted for 10%, 11% and 14% of third-party revenues for our Diagnostics segment in fiscal 2017, 2016 and 2015, respectively.

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Significant revenue information by country for the Diagnostics and Life Science segments is as follows. Revenues are attributed to the geographic area based on the location to which the product is delivered.

Year Ended September 30,	**2017**	2016	2015
United States	**$ 118,342**	$ 120,826	$ 120,599
Italy	**6,540**	6,599	7,090
Japan	**1,913**	1,644	2,603
France	**1,862**	1,605	1,603
United Kingdom	**1,766**	1,991	1,964
Belgium	**1,561**	1,501	1,289
Holland	**1,240**	1,188	1,326
Other countries	**10,297**	9,760	9,640
Total Diagnostics	**$ 143,521**	$ 145,114	$ 146,114

Year Ended September 30,	**2017**	2016	2015
United States	**$ 20,493**	$ 19,965	$ 21,918
Germany	**7,266**	6,982	5,699
United Kingdom	**6,880**	6,410	5,782
China	**5,862**	4,080	2,526
Australia	**3,998**	3,153	3,590
France	**2,739**	2,167	2,026
South Korea	**2,425**	1,185	406
Japan	**1,369**	1,320	1,158
Other countries	**6,218**	5,706	5,611
Total Life Science	**$ 57,250**	$ 50,968	$ 48,716

Identifiable assets for our Italian distribution organization were $7,712 and $8,782 at September 30, 2017 and 2016, respectively. At September 30, 2017, identifiable assets for the Bioline Group s operations in the U.K., Germany and Australia totaled approximately $15,755, $6,915 and $4,376, respectively; and totaled approximately $14,973, $7,024 and $3,780, respectively, at September 30, 2016.

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Segment information for the years ended September 30, 2017, 2016 and 2015 is as follows:

	Diagnostics	Life Science	Elim (1)	Total
Fiscal Year 2017 -				
Net revenues				
Third-party	**$ 143,521**	**$ 57,250**	$	**$ 200,771**
Inter-segment	**389**	**537**	**(926)**	
Operating income	**23,086**	**14,086**	**210**	**37,382**
Depreciation and amortization	**7,037**	**2,053**		**9,090**
Capital expenditures	**2,554**	**1,913**		**4,467**
Goodwill	**35,213**	**19,713**		**54,926**
Other intangible assets	**24,973**	**1,731**		**26,704**
Total assets	**180,226**	**69,938**	**(387)**	**249,777**
Fiscal Year 2016 -				
Net revenues				
Third-party	$ 145,114	$ 50,968	$	$ 196,082
Inter-segment	289	893	(1,182)	
Operating income	38,202	12,997	179	51,378
Depreciation and amortization	5,471	2,247		7,718
Capital expenditures	2,690	1,314		4,004
Goodwill	42,608	19,374		61,982
Other intangible assets	27,534	2,321		29,855
Total assets	185,446	66,624	(42)	252,028
Fiscal Year 2015 -				
Net revenues				
Third-party	$ 146,114	$ 48,716	$	$ 194,830
Inter-segment	334	1,300	(1,634)	
Operating income	44,136	12,057	(133)	56,060
Depreciation and amortization	4,099	2,510		6,609
Capital expenditures	3,112	1,501		4,613
Goodwill	1,250	21,099		22,349
Other intangible assets	2,364	3,567		5,931
Total assets	119,939	63,670	(327)	183,282

(1) Eliminations consist of intersegment transactions.

A reconciliation of segment operating expenses to consolidated earnings before income taxes for the years ended September 30, 2017, 2016 and 2015 is as follows:

Year Ended September 30,	**2017**	2016	2015

Segment operating income	**$ 37,382**	$ 51,378	$ 56,060
Interest income	**171**	67	23
Interest expense	**(1,642)**	(897)	
Other, net	**518**	96	(1,020)
Consolidated earnings before income taxes	**$ 36,429**	$ 50,644	$ 55,063

Transactions between segments are accounted for at established intercompany prices for internal and management purposes with all intercompany amounts eliminated in consolidation.

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(9) Commitments and Contingencies

(a) Royalty Commitments - We have entered into various license agreements that require payment of royalties based on a specified percentage of the sales of licensed products. Approximately 90% of our royalty expenses relate to our Diagnostics operating segment, where the royalty rates range from 4% to 8%. These royalty expenses are recognized on an as-earned basis and recorded in the year earned as a component of cost of sales. Annual royalty expenses associated with these agreements were approximately $2,600, $3,134 and $3,106 for the fiscal years ended September 30, 2017, 2016 and 2015, respectively.

(b) Purchase Commitments - Excluding the operating lease commitments reflected in Note 9(c) below, we have purchase commitments primarily for inventory and service items as part of the normal course of business. Commitments made under these obligations are $18,885, $1,935 and $944 for fiscal 2018, 2019 and 2020, respectively. No purchase commitments have been made beyond fiscal 2020.

(c) Operating Lease Commitments - Meridian and its subsidiaries are lessees of (i) certain office and warehouse buildings in the U.S., Europe, Australia, Singapore and China; (ii) automobiles for use by the 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. Amounts charged to expense under operating leases were $2,140, $1,966 and $1,797 for fiscal 2017, 2016 and 2015, respectively. Operating lease commitments for each of the five succeeding fiscal years are as follows: fiscal 2018 - $1,978; fiscal 2019 - $1,325; fiscal 2020 - $609; fiscal 2021 - $490; and fiscal 2022 - $426.

(d) Litigation - We are a party to various litigation matters from time to time that we believe are in the normal course of business. 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. See Item 3. Legal Proceedings for a discussion of the status of certain litigation related to our intellectual property.

(e) Indemnifications - In conjunction with certain contracts and agreements, we provide routine indemnifications related to our performance obligations. The terms of these indemnifications range in duration and in some circumstances are not explicitly defined. The maximum obligation under some such indemnifications is not explicitly stated and, as a result of our having no history of paying such indemnifications, cannot be reasonably estimated. We have not made any payments for these indemnifications and no liability is recorded at September 30, 2017 or September 30, 2016. We believe that if we were to incur a loss on any of these matters, the loss would not have a material effect on our financial condition.

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(10) Quarterly Financial Data (Unaudited)

The sum of the earnings per common share may not equal the corresponding annual amounts due to interim quarter rounding.

For the Quarter Ended in Fiscal 2017	**December 31**	**March 31**	**June 30**	**September 30**
Net revenues	**$ 46,809**	**$ 54,125**	**$ 50,140**	**$ 49,697**
Gross profit	**29,450**	**33,531**	**31,197**	**30,655**
Net earnings	**6,279**	**9,312**	**240**	**5,726**
Basic earnings per common share	**0.15**	**0.22**	**0.01**	**0.14**
Diluted earnings per common share	**0.15**	**0.22**	**0.01**	**0.13**
Cash dividends per common share	**0.20**	**0.125**	**0.125**	**0.125**

For the Quarter Ended in Fiscal 2016	December 31	March 31	June 30	September 30
Net revenues	$ 47,160	$ 51,259	$ 50,665	$ 46,998
Gross profit	31,583	33,572	32,909	29,723
Net earnings	8,893	9,091	8,754	5,491
Basic earnings per common share	0.21	0.22	0.21	0.13
Diluted earnings per common share	0.21	0.21	0.21	0.13
Cash dividends per common share	0.20	0.20	0.20	0.20

(11) Subsequent Events

On November 15, 2017, a class action complaint was filed naming Meridian, its Chief Executive Officer and its Chief Financial Officer (in their capacities as such) as defendants. The complaint alleges that Meridian made false and misleading representations concerning certain lead test systems used by Magellan at or around the time of Meridian s acquisition of Magellan and subsequent thereto. The lawsuit underlying plaintiff s class action complaint seeks compensatory damages, injunctive relief and attorneys fees to all members of the proposed class. Because the litigation and related discovery are in preliminary stages, we do not have sufficient information 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 these Consolidated Financial Statements for fiscal 2017.

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ITEM 9.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS

ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A.

CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

The term disclosure controls and procedures as defined by Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act) refers to the controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

In accordance with Exchange Act Rule 13a-15(b), Meridian s management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the Company s disclosure controls and procedures as of September 30, 2017. In conducting this evaluation, Meridian concluded there is a material weakness in the design and operating effectiveness of its internal control over financial reporting, as described below. As a result of such evaluation and this conclusion, Meridian also has concluded that its disclosure controls and procedures were not effective in providing reasonable assurance that information required to be disclosed in our reports filed under the Exchange Act was recorded, processed, summarized and reported within the time periods prescribed by SEC rules and regulations, and that such information was accumulated and communicated to our management to allow timely decisions regarding required disclosure.

Meridian s management does not expect that its disclosure controls and procedures will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur due to simple errors or mistakes. The design of any system of controls is based in part upon certain assumptions regarding the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

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(b) 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, 2017, 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 this evaluation, we concluded that the Company s internal control over financial reporting was not effective as of September 30, 2017 for the reasons described below.

During the course of completing this evaluation we identified deficiencies related to Information Technology General Controls (ITGC) intended to restrict access to certain data and applications, resulting in inappropriate access at both the Information Technology and end user levels within an application impacting financial reporting functions and controls.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Although no material misstatements were identified in our consolidated financial statements, these control deficiencies create a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. We have concluded that these identified deficiencies, when aggregated, constitute a material weakness in internal control over financial reporting.

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Item 8 includes the adverse audit report of the Company s independent registered public accounting firm on Meridian s internal control over financial reporting as of September 30, 2017.

(c) Changes in Internal Control over Financial Reporting

There were no changes in the Company s internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, Meridian s internal control over financial reporting, except as otherwise described in this Item 9A.

(d) Remediation of the Material Weakness

We have begun remediation efforts to address the control deficiencies identified, which gave rise to the material weakness noted above. We are performing a comprehensive review of the financial reporting application in which the control deficiencies were identified in order to further restrict access and improve authorization protocols. Our objective is to complete remediation efforts in fiscal 2018.

ITEM 9B.

OTHER INFORMATION

Not applicable.

PART III.

The information required by Items 10, 11, 12 (other than that portion set forth below), 13 and 14, of Part III are incorporated by reference from the Registrant s Proxy Statement for its 2018 Annual Shareholders Meeting to be filed with the Commission pursuant to Regulation 14A.

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ITEM 12.

EQUITY COMPENSATION PLAN INFORMATION

The following table presents summary information as of September 30, 2017 with respect to all of our equity compensation plans (number of securities information in thousands).

Plan Category	(a) Number of Securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (1)	942	$ 19.975	2,902
Total (2)	942	$ 19.975	2,902

(1) 2004 Equity Compensation Plan, as amended
2012 Stock Incentive Plan

(2) Weighted-average remaining term of 6.51 years

ITEM 15.

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) and (2) FINANCIAL STATEMENTS AND SCHEDULES.
All financial statements and schedules required to be filed by Item 8 of this Form and included in this report have been so identified under Item 8. No additional financial statements or schedules are being filed since the requirements of paragraph (c) under Item 15 are not applicable to Meridian.

(b) (3) EXHIBITS.

Exhibit Number	Description of Exhibit
3.1	Articles of Incorporation, including amendments not related to Company name change (Incorporated by reference to Registration Statement No. 333-02613 on Form S-3 filed with the Securities and Exchange Commission on April 18, 1996 and Meridian s Form 8-K filed with the Securities and Exchange Commission on May 16, 2007)
3.2	Amended Code of Regulations (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on November 13, 2012)
10.1*	Amendment No. 1 to Supplemental Benefit Agreement Dated September 23, 2014 between Meridian and John A. Kraeutler (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on September 25, 2014)

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10.2*	Third Amended and Restated Employment Agreement Dated October 3, 2016 between Meridian and John A. Kraeutler (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on October 5, 2016)
10.3*	Letter Agreement Dated July 26, 2016 between Meridian and Richard L. Eberly (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended June 30, 2016)
10.4*	Executive Employment Agreement dated March 21, 2016 between Meridian and Amy Winslow (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended March 31, 2016)
10.5*	Employment Agreement dated October 9, 2017 between Meridian and John P. Kenny (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on October 11, 2017)
10.6*	Dividend Reinvestment Plan (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 1999)
10.7*	2004 Equity Compensation Plan, amended and restated effective January 25, 2012 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended December 31, 2011)
10.8*	2012 Stock Incentive Plan, effective January 25, 2012 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended December 31, 2011)
10.9*	Fiscal 2018 Cash-Based Incentive Compensation Plan-Officers and Selected Executives (Filed herewith)
10.10*	Form of Time-Based Restricted Share Unit Award Agreement dated November 8, 2017 (Filed herewith)
10.11*	Form of Performance Award Restricted Share Unit Award Agreement dated November 8, 2017 (Filed herewith)
10.12*	Form of Time-Based Nonqualified Stock Option Award Agreement dated November 8, 2017 (Filed herewith)
10.13*	Form of Performance Award Nonqualified Stock Option Award Agreement dated November 8, 2017 (Filed herewith)
10.14*	Form of Meridian Bioscience, Inc. Change in Control Agreement dated August 4, 2016 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended June 30, 2016)
10.15	Agreement and Plan of Merger among Meridian Bioscience, Inc., Mariner Merger Sub, Inc., Magellan Biosciences, Inc. and Ampersand 2006 Limited Partnership as the Stockholder Representative dated as of March 24, 2016 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended March 31, 2016)
10.16	Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc. Meridian Life Science, Inc. and Fifth Third Bank dated August 1, 2007 (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2007)

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10.16.1	Term Note among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc. Meridian Life Science, Inc., Bioline USA, Inc. and Fifth Third Bank dated March 22, 2016 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Fiscal Quarter Ended March 31, 2016)
10.16.2	Amended and Restated Revolving Note with Fifth Third Bank dated March 22, 2016 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Fiscal Quarter Ended March 31, 2016)
10.16.3	First Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc. and Fifth Third Bank dated September 2, 2010 (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2010)
10.16.4	Second Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc. and Fifth Third Bank dated December 1, 2010 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Fiscal Quarter Ended December 31, 2010)
10.16.5	Third Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc. and Fifth Third Bank dated September 15, 2012 (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2012)
10.16.6	Fifth Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc., Bioline USA, Inc. and Fifth Third Bank dated April 21, 2015 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Fiscal Quarter Ended June 30, 2015)
10.16.7	Sixth Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc., Bioline USA, Inc. and Fifth Third Bank dated March 22, 2016 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Fiscal Quarter Ended March 31, 2016)
10.16.8	Seventh Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc., Bioline USA, Inc. and Fifth Third Bank dated February 6, 2017 (Filed herewith)
10.16.9	Eighth Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc., Bioline USA, Inc. and Fifth Third Bank dated July 20, 2017 (Filed herewith)
13	2017 Annual Report to Shareholders (1)
14	Code of Ethics (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2003)
21	Subsidiaries of the Registrant (Filed herewith)
23	Consent of Independent Registered Public Accounting Firm (Filed herewith)
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) (Filed herewith)
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) (Filed herewith)

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32	Section 1350 Certification of Chief Executive Officer and Chief Financial Officer (Filed herewith)
101	The following financial information from Meridian Bioscience Inc. s Annual Report on Form 10-K for the fiscal year ended September 30, 2017 filed with the SEC on November 29, 2017, formatted in XBRL includes: (i) Consolidated Statements of Operations for the years ended September 30, 2017, 2016 and 2015; (ii) Consolidated Statements of Comprehensive Income for the years ended September 30, 2017, 2016 and 2015; (iii) Consolidated Statements of Cash Flows for the years ended September 30, 2017, 2016 and 2015; (iv) Consolidated Balance Sheets as of September 30, 2017 and 2016; (v) Consolidated Statements of Shareholders Equity for the years ended September 30, 2017, 2016 and 2015; and (vi) the Notes to Consolidated Financial Statements

* Management Compensatory Contracts

(1) Only specific portions of the 2017 Annual Report to Shareholders are incorporated by reference in this Form 10-K as filed herewith. A supplemental paper copy of the 2017 Annual Report to Shareholders has been furnished to the Securities and Exchange Commission for informational purposes only or will be posted on our website, www.meridianbioscience.com.

Meridian will provide shareholders with any exhibit upon the payment of a specified reasonable fee, which fee shall be limited to Meridian s reasonable expenses in furnishing such exhibit.

ITEM 16.

FORM 10-K SUMMARY

None.

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SIGNATURES

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

MERIDIAN BIOSCIENCE, INC.

By: /s/ Jack Kenny
Date: November 29, 2017
Jack Kenny
Chief Executive Officer

We, the undersigned directors and officers of the Registrant, hereby severally constitute Jack Kenny and Melissa A. Lueke, and each of them singly, our true and lawful attorneys with full power to them and each of them to sign for us, in our names in the capacities indicated below, any and all amendments to the Annual Report on Form 10-K filed with the Securities and Exchange Commission.

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

Signature	Capacity	Date
/s/ Jack Kenny Jack Kenny	Chief Executive Officer and Director	November 29, 2017
/s/ Melissa A. Lueke Melissa A. Lueke	Executive Vice President, Chief Financial Officer, and Secretary (Principal Financial and Accounting Officer)	November 29, 2017
/s/ John A. Kraeutler John A. Kraeutler	Executive Chairman of the Board	November 29, 2017
/s/ James M. Anderson James M. Anderson	Director	November 29, 2017
/s/ Dwight E. Ellingwood Dwight E. Ellingwood	Director	November 29, 2017
/s/ John C. McIlwraith John C. McIlwraith	Director	November 29, 2017

/s/ David C. Phillips	Director	November 29, 2017
David C. Phillips		
/s/ John M. Rice, Jr.	Director	November 29, 2017
John M. Rice, Jr.		
/s/ Catherine A. Sazdanoff	Director	November 29, 2017
Catherine A. Sazdanoff		

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SCHEDULE II

Meridian Bioscience, Inc.

and Subsidiaries

Valuation and Qualifying Accounts

(Dollars in thousands)

Years Ended September 30, 2017, 2016 and 2015

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Other (a)	Balance at End of Period
Year Ended September 30, 2017:					
Allowance for doubtful accounts	$ 334	$ 90	$ (134)	$ 17	$ 307
Inventory realizability reserves	2,680	35	(661)	5	2,059
Valuation allowances deferred taxes	342				342
Year Ended September 30, 2016:					
Allowance for doubtful accounts	$ 248	$ 139	$ (69)	$ 16	$ 334
Inventory realizability reserves	2,456	1,285	(1,072)	11	2,680
Valuation allowances deferred taxes	15	327			342
Year Ended September 30, 2015:					
Allowance for doubtful accounts	$ 272	$ 73	$ (41)	$ (56)	$ 248
Inventory realizability reserves	2,942	208	(590)	(104)	2,456
Valuation allowances deferred taxes	8	7			15

(a) Balances reflect the effects of currency translation and in 2016, the acquisition of Magellan.