

MERIDIAN BIOSCIENCE INC

Form 10-K

November 29, 2016

[Table of Contents](#)

**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, 2016.**

**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:**

<b>Title of each class</b>	<b>Name of each exchange of which registered</b>
<b>Common Shares, No Par Value</b>	<b>The NASDAQ Stock Market LLC (NASDAQ Global Select Market)</b>

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES NO

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act.

YES NO

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

YES NO

Indicate by check mark whether the registrant has submitted electronically 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, or a smaller reporting company. See definitions of large accelerated filer accelerated filer and smaller reporting 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

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

YES

NO

The aggregate market value of Common Shares held by non-affiliates as of March 31, 2016 was \$856,265,348 based on a closing sale price of \$20.61 per share on March 31, 2016. As of October 31, 2016, 42,108,217 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, 2016 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 2017 Annual Shareholders Meeting are incorporated by reference in Part III as specified.

**Table of Contents**

## MERIDIAN BIOSCIENCE, INC.

## INDEX TO ANNUAL REPORT

## ON FORM 10-K

	Page
<u>Part I</u>	
Item 1 <u>Business</u>	5
Item 1A <u>Risk Factors</u>	15
Item 1B <u>Unresolved Staff Comments</u>	24
Item 2 <u>Properties</u>	24
Item 3 <u>Legal Proceedings</u>	25
Item 4 <u>Mine Safety Disclosures</u>	25
<u>Part II</u>	
Item 5 <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	26
Item 6 <u>Selected Financial Data</u>	26
Item 7 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
Item 7A <u>Quantitative and Qualitative Disclosures about Market Risk</u>	44
Item 8 <u>Financial Statements and Supplementary Data</u>	45
Item 9 <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	78
Item 9A <u>Controls and Procedures</u>	78
Item 9B <u>Other Information</u>	78
<u>Part III</u>	
Item 10 <u>Directors, Executive Officers and Corporate Governance</u>	78
Item 11 <u>Executive Compensation</u>	78
Item 12 <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	78
Item 13 <u>Certain Relationships and Related Transactions, and Director Independence</u>	78
Item 14 <u>Principal Accounting Fees and Services</u>	78
Item 15 <u>Exhibits and Financial Statement Schedules</u>	79

## 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 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, and its ability to effectively sell such products. 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. 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 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

**Table of Contents**

United States Food and Drug Administration, can result in unanticipated expenses and delays and interruptions to the sale of new and existing products, as well as 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 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, and any similar initiatives in other countries on its results of operations. Efforts to reduce the U.S. federal deficit, breaches of Meridian's information technology systems and natural disasters and other events could have a materially adverse effect on Meridian's results of operations and revenues. In addition to the factors described in this paragraph, 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.

**Table of Contents**

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<sup>®</sup>, ImmunoCard<sup>®</sup>, ImmunoCard STAT!<sup>®</sup>, MyTaq, SensiFAST, PREMIER<sup>®</sup> and LeadCare<sup>®</sup>, 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 <sup>®</sup> 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 FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S.

## **Table of Contents**

Our website is [www.meridianbioscience.com](http://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](http://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, which also serves as the Diagnostics segment's base of manufacturing operations and research and development for infectious disease products. The Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits 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). As previously noted, the Diagnostics segment includes the Company's recent acquisition of Magellan, which is located in Billerica, Massachusetts (near Boston). Its facility includes research, development, manufacturing, marketing, sales, and distribution operations. 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 and business development offices in Singapore and Beijing, China to further pursue growing revenue opportunities in Asia. Financial information for Meridian's reportable segments is included in Note 8 to the consolidated financial statements.

## **Diagnostics Segment**

### ***Overview of Products and Markets***

Our primary source of revenues continues to be diagnostic products, with our Diagnostics segment providing 74% of consolidated net revenues for fiscal 2016. Third-party revenues for this segment were \$145,000, \$146,000 and \$142,000 for fiscal 2016, 2015 and 2014, respectively. As of September 30, 2016, our Diagnostics segment had approximately 440 employees in seven countries.

Our 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 (iv) have difficult sample handling requirements (stool, blood, urine and other body fluids). This approach has allowed us to establish significant market share in our target disease states.



## **Table of Contents**

Our 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 (*illumigene* brand)** high sensitivity, molecular platform that is suitable for virtually any size 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, *ImmunoCard* and *ImmunoCard STAT!* brands)** single-use immunoassays that can be used in point-of-care settings; 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 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*, *M. pneumoniae* (Mycoplasma) and *Bordetella pertussis*, among tests for other diseases

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

Our 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.



## **Table of Contents**

We continue to invest in new product development for our molecular testing platform, *illumigene*. This platform now has the following commercialized tests (assays):

1. *illumigene C. difficile* commercialized in August 2010
2. *illumigene* Group B *Streptococcus* (Group B Strep or GBS) commercialized in December 2011
3. *illumigene* Group A *Streptococcus* (Group A Strep) commercialized in September 2012
4. *illumigene* Mycoplasma (*M. pneumoniae*; walking pneumonia) commercialized in June 2013
5. *illumigene Bordetella pertussis* (whooping cough) commercialized in March 2014
6. *illumigene Chlamydia trachomatis* commercialized outside of U.S. in February 2015
7. *illumigene Neisseria gonorrhoea* commercialized outside of U.S. in February 2015
8. *illumigene* HSV 1&2 (Herpes Simplex Virus Type 1 & Type 2) commercialized in July 2015
9. *illumigene* Malaria commercialized outside of U.S. in February 2016

10. *illumigene* Mycoplasma Direct (*M. pneumoniae*; walking pneumonia) commercialized in June 2016  
We have several additional *illumigene* tests in development, a robust pipeline of *illumigene* opportunities and a plan to continue adding new assays to our *illumigene* platform menu.

We believe that our *illumigene* system has been well-accepted in our global markets. We now have over 1,500 customer account placements. Of these account placements, approximately 1,300 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 450 accounts that are regularly purchasing, evaluating and/or validating two or more assays.

## ***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.

- 8 -

## Table of Contents

We also continue to see aggregation of buying power in our U.S. market via multi-hospital group purchasing organizations and integrated delivery networks, consolidation among 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:

#### North America

In North America, our sales and distribution network consists of a direct sales force (U.S. only) complemented by independent distributors. The use of independent distributors in the U.S. 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 in the U.S. accounted for 10% or more of consolidated net revenues in fiscal 2016, 2015 and 2014: Cardinal Healthcare Corporation and Thermo Fisher Scientific. Our revenues from Cardinal were approximately \$20,000, \$29,000 and \$28,000 during fiscal 2016, 2015 and 2014, respectively. Our revenues from Thermo Fisher were approximately \$20,000, \$25,000 and \$23,000 during fiscal 2016, 2015 and 2014, 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 *illumigene* 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 ROW.

## **Table of Contents**

### ***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, Great Basin, Nanosphere and Quidel. These latter companies 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. These companies tend to compete strictly on price. 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 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 2016, 2015 and 2014 were approximately \$11,000, \$10,000 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 *illumigene* molecular platform, *H. pylori* product family and blood lead testing family were developed solely in-house, or substantially so.

### ***Manufacturing***

Our immunoassay and molecular products require the production of highly specific and sensitive antigens, antibodies, primers and enzymes. While we produce substantially all of our own requirements including monoclonal and polyclonal antibodies, and a variety of fungal, bacterial and viral antigens, currently a number of the raw materials used in our products, including our *illumigene* molecular products, are purchased from outside vendors. With the expansion of our molecular diagnostic manufacturing capacity at our Cincinnati, Ohio location in recent years, we brought in-house certain molecular component manufacturing that was previously outsourced. Our blood lead testing products require the production of electrical chemical sensors, for which we produce all of our own requirements. We

believe that we have sufficient manufacturing and sourcing capacity for anticipated growth over the next several years.

- 10 -

## **Table of Contents**

### ***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 *illumigene* products, which represented 20% and 21% of consolidated revenues for fiscal 2016 and fiscal 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, which represented 15% and 14% of consolidated revenues for fiscal 2016 and fiscal 2015, respectively, are owned by us and expired in May 2016 in the U.S., and will expire in fiscal 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase in fiscal 2017 as we currently market the only FDA-cleared tests to detect *H. pylori* antigen in stool samples. 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.

### ***Government Regulation***

Our diagnostic products are regulated by the Food & Drug Administration (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.



## **Table of Contents**

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. Meridian's TRU FLU rapid influenza assay was cleared in 2006 as a Class I device. In May 2014, the FDA proposed reclassifying rapid influenza assays as a Class II device, requiring the submission of a new 510(k) application and subjecting TRU FLU and similar competitive devices to increased requirements for sensitivity. If the proposed rule becomes effective, Meridian will have one year to bring its assay up to the new requirements or remove it from the market. Sales of the TRU FLU product totaled approximately \$1,000 in fiscal 2016.

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

Meridian's Cincinnati manufacturing facility is certified to ISO 13485:2012, and the Magellan facility in Billerica, Massachusetts is certified to ISO 9001:2008 and ISO 13485:2003.

### ***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 2016, 2015 and 2014, the Company recorded to cost of sales approximately \$500, \$1,900 and \$1,750, respectively, of medical device tax expense related to this legislation. During December 2015, the Consolidations Appropriations Act of 2016 imposed a two-year moratorium on this excise tax effective January 1, 2016. During calendar years 2016 and 2017, this moratorium would result in approximately \$2,000 of savings each year. 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 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.

## **Table of Contents**

### **Life Science Segment**

#### ***Overview of Products and Markets***

Our Life Science segment's business 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 \$51,000, \$49,000 and \$47,000 for fiscal 2016, 2015 and 2014, respectively. As of September 30, 2016, our Life Science segment had approximately 210 employees in seven countries.

Most of the revenues for our Life Science segment currently come from the manufacture, sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents used by researchers and other diagnostic manufacturing companies focused on the development of immunoassay and molecular tests. Approximately 65% 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 component business, which historically focused on the academic/research market that comprises the remaining 35% 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. Opened in 2013, the Singapore sales and business development office is designed 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 2015 we opened a representative office in Beijing, China. We utilize a network of distributors in other major countries. During fiscal 2016, 18% of third-party revenues for this segment were from two diagnostic manufacturing customers.

Products such as antibodies, antigens and reagents are marketed primarily to diagnostic manufacturing customers as a source of raw materials for their immunoassay products, or as an outsourced step in their manufacturing processes. For example, we supply a number of major diagnostic manufacturers with proteins used to detect hepatitis A and rubella. 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.

## **Table of Contents**

### ***Market Trends***

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

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 2016, 2015 and 2014 were approximately \$3,000. The primary focus of this research and development organization is development of new molecular reagent products.

### ***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. Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S.

## **Table of Contents**

### **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 \$52,000 or 26% of consolidated fiscal 2016 revenues, \$49,000 or 25% of consolidated fiscal 2015 revenues, and \$55,000 or 29% of consolidated fiscal 2014 revenues. We expect to continue to look to international markets as a source of revenue growth in the future.

During fiscal 2016, currency exchange had an approximate \$1,700 unfavorable impact on revenues; \$700 within the Diagnostics segment and \$1,000 within the Life Science segment. This compares to currency exchange rates having an approximate \$4,700 unfavorable impact on revenues in fiscal 2015; \$3,200 within the Diagnostics segment and \$1,500 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 2016, 2015 or 2014.

### **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.

## **Table of Contents**

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 design stage 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.

*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, and financial risks of additional operating costs. 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.

*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 27% and 37%, respectively, of the Diagnostics segment's total revenues for fiscal 2016 and fiscal 2015, or 20% and 28%, respectively, of our consolidated revenues for fiscal 2016 and fiscal 2015. 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, but would not necessarily result in lower net income levels.

## **Table of Contents**

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.

### *Changing Diagnostic Market Conditions*

Changes in the U.S. health care delivery system have resulted in consolidation among 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. 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, 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 2016, 2015 and 2014, the Company recorded approximately \$500, \$1,900 and \$1,750, 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. During calendar years 2016 and 2017, this moratorium would result in approximately \$2,000 of savings each year. We are unable to predict any future legislative changes or developments related to this moratorium or excise tax.

**Table of Contents**

***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 18% and 16% of the Life Science segment's total revenues for fiscal 2016 and fiscal 2015, respectively; and 5% and 4% of our consolidated revenues for fiscal 2016 and fiscal 2015, respectively. Our Life Science segment has four other significant customers who purchase antigens, antibodies and reagents, which together comprised 8% and 10% of the segment's total revenues for fiscal 2016 and fiscal 2015, respectively. Any significant alteration of buying patterns from these customers could adversely affect our period over period revenues and results of operations.

***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.

**Table of Contents**

***We may face increased competition resulting from expiration of our H. pylori patents.***

The patents for our *H. pylori* products are owned by us and expired in May 2016 in the U.S., and will expire in fiscal 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase in fiscal 2017 as we currently market the only FDA-cleared tests to detect *H. pylori* antigen in stool samples. 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.

***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 26% and 25% of our net revenues for fiscal 2016 and 2015, respectively, were attributable to markets outside of the Americas. For fiscal 2016, approximately 35% of our international revenues were from sales made in Euros and 40% were from sales made in U.S. dollars, with the remaining 25% primarily being a combination of sales made in British pounds, Australian dollars and Singapore dollars. We are subject to the risks associated with fluctuations in the exchange rates for the Australian dollar, British pound, 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.

**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.



## **Table of Contents**

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.

***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, 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.

***We depend on sole-source suppliers for certain critical raw materials and 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 *illumipro-10* Incubator/Reader (instrument), a component of our *illumigene* 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.

## **Table of Contents**

Additionally, one third party manufactures one certain reagent for use with our *illumigene* 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.

### *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 12%, 15% and 14% of consolidated revenues in fiscal 2016, 2015 and 2014, respectively. Meridian owns all rights and title to the FDA 510(k) clearances for these products.

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.

*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 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.

**Table of Contents**

***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.

**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, 2016, we have approximately \$59,000 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.

---

**Table of Contents*****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.

On June 23, 2016, the United Kingdom voted to leave the European Union (commonly referred to as Brexit ) and while the impact of Brexit remains uncertain, the resulting immediate changes in foreign currency exchange rates has 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 highly likely 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 change 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. 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. 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. 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.



**Table of Contents**

***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**

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 such 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.

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 23,000 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.

**Table of Contents**

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 20,000 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 representative office space maintained for business development purposes.

ITEM 3.

**LEGAL PROCEEDINGS**

We are a party to various litigation matters 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. No material provision has been made in the accompanying consolidated financial statements for these matters.

ITEM 4.

**MINE SAFETY DISCLOSURES**

Not applicable.

**Table of Contents**

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 24 of this Annual Report.*

Common Stock Information on the inside back cover of the Annual Report to Shareholders for fiscal 2016 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.

During fiscal 2016, our indicated annual dividend rate of \$0.80 per share approximated 105% of full year diluted earnings per share (approximately 100% excluding the effect of costs related to acquisition activities and restructuring our sales and marketing leadership), exceeding our long-standing policy of establishing a cash dividend payout ratio of between 75% and 85% of each fiscal year's expected net earnings. Despite there being certain individual fiscal years in which our payout ratio has fallen outside of this policy range, since adopting this policy in November 2002, our cumulative cash dividend payout has only slightly exceeded this range, approximating 86% of cumulative net earnings during this timeframe. The declaration and amount of dividends will be determined by the board of directors in its discretion based upon its evaluation of earnings, cash flow requirements and future business developments and opportunities, including acquisitions. At its meeting on November 9, 2016, the board of directors announced a continuation of the \$0.80 indicated annual dividend rate per share for fiscal 2017. We paid dividends of \$0.80 per share in fiscal 2016, \$0.80 per share in fiscal 2015 and \$0.79 per share in fiscal 2014.

As of September 30, 2016, there were approximately 525 holders of record and approximately 17,700 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 2016.



---

**Table of Contents**

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 24 of this Annual Report.*

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

**Results of Operations:**

***Highlights***

As more fully detailed below, fiscal 2016 was highlighted by our March 24, 2016 acquisition of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, Inc. (collectively,

Magellan ). Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S.

In addition, during the year we (i) commercialized our *illumigene* Malaria product outside of the U.S.; and (ii) commercialized our *illumigene* Mycoplasma Direct product in the U.S. representing the ninth and tenth assays for our *illumigene* molecular platform menu.

***Fourth Quarter***

Net earnings for the fourth quarter of fiscal 2016 decreased 35% to \$5,491, or \$0.13 per diluted share, from net earnings for the fourth quarter of fiscal 2015 of \$8,467, or \$0.20 per diluted share. These 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 2016 totaled \$46,998, remaining relatively flat compared to the fourth quarter of fiscal 2015; increasing 1% on a constant-currency basis.

Revenues for the Diagnostics segment for the fourth quarter of fiscal 2016 remained flat compared to the fourth quarter of fiscal 2015 (increasing 1% on a constant-currency basis), comprised of a 15% decrease in molecular products and a 7% increase in non-molecular products, including \$5,282 of Magellan revenues. With a 2% increase in its molecular components business and a 4% decline in its immunoassay components business, revenues for our Life Science segment decreased 2% in the fourth quarter of fiscal 2016 compared to the fourth quarter of fiscal 2015. On a constant-currency basis, revenues for our Life Science Segment were flat.

**Table of Contents**

The fourth quarter revenues reflect a combination of ongoing competitive pressures within the *C. difficile* and foodborne product families, distributor order patterns and the timing of respiratory season stocking orders within the core diagnostics business offset by the positive effects of continued growth in our *H. pylori* product family and the addition of Magellan revenues.

***Fiscal Year***

Net earnings for fiscal 2016 decreased 9% to \$32,229, or \$0.76 per diluted share, from net earnings for fiscal 2015 of \$35,540, or \$0.85 per diluted share. Fiscal 2016 results included \$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 1% to \$196,082 for fiscal 2016 compared to fiscal 2015, and also increased 1% on a constant-currency basis.

In fiscal 2016, revenues for the Diagnostics segment decreased 1% compared to fiscal 2015 and were flat on a constant-currency basis, comprised of a 6% decrease in molecular products and a 1% increase in non-molecular products, including \$10,034 of Magellan revenues. With flat revenues in its molecular components business and an 8% increase in its immunoassay components business, revenues of our Life Science segment increased 5% during fiscal 2016 compared to fiscal 2015. Revenues increased 7% on a constant-currency basis.

**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 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 and business development offices in Singapore and Beijing, China to further pursue growing revenue opportunities in Asia.

**Table of Contents**

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 strength of certain diseases, 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.

	2016	2015	2014	2016 vs. 2015 Inc (Dec)	2015 vs. 2014 Inc (Dec)
<b>Diagnostics-</b>					
Americas	\$ 123,714	\$ 123,366	\$ 114,754	%	8%
EMEA	18,424	19,135	21,807	(4)%	(12)%
ROW	2,976	3,613	4,939	(18)%	(27)%
<b>Total Diagnostics</b>	<b>145,114</b>	<b>146,114</b>	<b>141,500</b>	<b>(1)%</b>	<b>3%</b>
<b>Life Science-</b>					
Americas	20,651	22,363	19,040	(8)%	17%
EMEA	19,406	17,845	20,005	9%	(11)%
ROW	10,911	8,508	8,287	28%	3%
<b>Total Life Science</b>	<b>50,968</b>	<b>48,716</b>	<b>47,332</b>	<b>5%</b>	<b>3%</b>
<b>Consolidated</b>	<b>\$ 196,082</b>	<b>\$ 194,830</b>	<b>\$ 188,832</b>	<b>1%</b>	<b>3%</b>
<b>% of total revenues-</b>					
Diagnostics	74%	75%	75%		
Life Science	26%	25%	25%		
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>		
Ex-Americas	26%	25%	29%		

**Table of Contents****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 tests that operate on our *illumigene* platform
- 2) Non-molecular 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.

	2016	2015	2014	2016 vs. 2015 Inc (Dec)	2015 vs. 2014 Inc (Dec)
<b>Diagnostics-</b>					
Molecular	\$ 38,302	\$ 40,880	\$ 36,981	(6)%	11%
Non-molecular	106,812	105,234	104,519	1%	1%
Total Diagnostics	\$ 145,114	\$ 146,114	\$ 141,500	(1)%	3%
<b>Life Science-</b>					
Molecular components	\$ 20,599	\$ 20,601	\$ 20,824	%	(1)%
Immunoassay components	30,369	28,115	26,508	8%	6%
Total Life Science	\$ 50,968	\$ 48,716	\$ 47,332	5%	3%
<b>% of Diagnostics revenues-</b>					
Molecular	26%	28%	26%		
Non-molecular	74%	72%	74%		
Total Diagnostics	100%	100%	100%		
<b>% of Life Science revenues-</b>					
Molecular components	40%	42%	44%		

Immunoassay components	60%	58%	56%
Total Life Science	100%	100%	100%

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

**Diagnostics Products**

Molecular Products

During fiscal 2016, revenues from our *illumigene* molecular platform of products totaled \$38,302, representing a 6% decrease from fiscal 2015 (also 6% in constant-currency). This decrease reflects the ongoing intense competition within the molecular-based testing market.

## Table of Contents

We have over 1,500 customer account placements. Of these account placements, approximately 1,300 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 450 accounts that are regularly purchasing, evaluating and/or validating two or more assays.

We continue to invest in new product development for our molecular testing platform, and this platform now has the following commercialized tests:

1. *illumigene C. difficile* commercialized in August 2010
2. *illumigene* Group B *Streptococcus* (Group B Strep or GBS) commercialized in December 2011
3. *illumigene* Group A *Streptococcus* (Group A Strep) commercialized in September 2012
4. *illumigene* Mycoplasma (*M. pneumoniae*; walking pneumonia) commercialized in June 2013
5. *illumigene Bordetella pertussis* (whooping cough) commercialized in March 2014
6. *illumigene Chlamydia trachomatis* commercialized outside of U.S. in February 2015
7. *illumigene Neisseria gonorrhoea* commercialized outside of U.S. in February 2015
8. *illumigene* HSV 1&2 (Herpes Simplex Virus Type 1 & Type 2) commercialized in July 2015
9. *illumigene* Malaria commercialized outside of U.S. in February 2016

10. *illumigene* Mycoplasma Direct (*M. pneumoniae*; walking pneumonia) commercialized in June 2016

We believe that the diagnostic testing market 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. While this market is competitive, with molecular companies such as Cepheid and Becton Dickinson, and others such as Quidel, Great Basin, Nanosphere and Alere, we believe we are well-positioned to capitalize on the migration to molecular testing. Our simple, easy-to-use, *illumigene* 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 *illumigene* assays, make *illumigene* an attractive molecular platform to any size hospital or physician office laboratory that runs moderately-complex tests.

## Non-molecular Products

Revenues from our Diagnostics segment's non-molecular products increased 1% in fiscal 2016, also following a 1% increase in fiscal 2015. These current year results reflect the addition of Magellan's revenue, increased revenues in our *H. pylori* immunoassay products, and an overall decrease in revenues of our other immunoassay product lines, most notably our foodborne and certain other legacy product families.

Since the March 24, 2016 acquisition, revenues from Magellan's sale of products to test for elevated levels of lead in blood have totaled \$10,034. This level of revenues reflects an 11% increase over the six-month period ended September 30, 2015, which was prior to Meridian ownership.

---

**Table of Contents**

During fiscal 2016, revenues from our *H. pylori* products increased 8% (9% in constant-currency) to \$32,300, which followed a 6% increase during fiscal 2015. This increase continues to reflect the benefits of 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 from reference labs, whose buying patterns may not be consistent period to period. In addition to our managed care strategy, we have also employed bulk-buy sales promotions into selected distribution and laboratory channels as a defensive strategy against potential new competitive product introductions expected in fiscal 2017.

The patents for our *H. pylori* products are owned by us and expired in May 2016 in the U.S., and will expire in fiscal 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase in fiscal 2017 as we currently market the only FDA-cleared tests to detect *H. pylori* antigen in stool samples. 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.

During fiscal 2016, revenues from our other immunoassay products (including *C. difficile*, foodborne and respiratory) decreased 16% (15% in constant-currency) to \$63,000, following a 2% decrease in fiscal 2015. This decrease results primarily from the effects of continued increased competition, distributor order patterns and the timing of our promotional stock-and-block programs in previous periods.

**Life Science Products**

During fiscal 2016, revenues from our Life Science segment increased 5%, with revenues from molecular components sales remaining flat compared to fiscal 2015 and revenues from immunoassay components sales increasing 8%. Life Science segment revenues increased 3% in fiscal 2015, with revenues from molecular component sales decreasing 1% from fiscal 2014 and revenues from immunoassay component sales increasing 6%. Our molecular components business growth was negatively impacted by the movement in currency exchange rates since fiscal 2015, with revenues increasing 4% on a constant-currency basis over fiscal 2015. Our Life Science segment continued to benefit from increased sales into China, with such sales totaling approximately \$4,100 during fiscal 2016 (approximately \$1,000 in the molecular components business and \$3,100 in the immunoassay components business).



**Table of Contents*****Foreign Currency***

During fiscal 2016, currency exchange had an approximate \$1,700 unfavorable impact on revenues; \$700 within the Diagnostics segment and \$1,000 within the Life Science segment. This compares to currency exchange rates having an approximate \$4,700 unfavorable impact on revenues in fiscal 2015; \$3,200 within the Diagnostics segment and \$1,500 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 2016, 2015 or 2014.

***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.

***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 2016, 2015 and 2014, the Company recorded approximately \$500, \$1,900 and \$1,750, 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. During calendar years 2016 and 2017, this moratorium would result in approximately \$2,000 of savings each year. We are unable to predict any future legislative changes or developments related to this moratorium or excise tax.

**Gross Profit:**

	2016	2015	2014	2016 vs. 2015 Inc (Dec)	2015 vs. 2014 Inc (Dec)
Gross Profit	\$ 127,787	\$ 121,882	\$ 117,243	5%	4%
Gross Profit Margin	65%	63%	62%	2 points	1 point

The overall gross profit margin increase during fiscal 2016 primarily results from 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 *illumigene* 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. The overall increase in the gross profit margin from fiscal 2014 to fiscal 2015 reflects the combined effects of (i) mix of products sold; (ii) realization of manufacturing facility efficiencies; and (iii) 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.

**Table of Contents**

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

**Operating Expenses:**

	<b>Research &amp; Development</b>	<b>Selling &amp; Marketing</b>	<b>General &amp; Administrative</b>	<b>Other</b>	<b>Total Operating Expenses</b>
<b>2014 Expenses</b>	<b>\$ 12,552</b>	<b>\$ 24,910</b>	<b>\$ 27,389</b>	<b>\$</b>	<b>\$ 64,851</b>
% of Revenues	7%	13%	15%	%	34%
<b>Fiscal 2015 Increases (Decreases):</b>					
Diagnostics	(306)	730	803		1,227
Life Science	359	(39)	(576)		(256)
<b>2015 Expenses</b>	<b>\$ 12,605</b>	<b>\$ 25,601</b>	<b>\$ 27,616</b>	<b>\$</b>	<b>\$ 65,822</b>
% of Revenues	6%	13%	14%		34%
% Increase (Decrease)	%	3%	1%	%	1%
<b>Fiscal 2016 Increases (Decreases):</b>					
Diagnostics	1,505	3,257	3,051	2,158	9,971
Life Science	(295)	1,013	(102)		616
<b>2016 Expenses</b>	<b>\$ 13,815</b>	<b>\$ 29,871</b>	<b>\$ 30,565</b>	<b>\$ 2,158</b>	<b>\$ 76,409</b>
% of Revenues	7%	15%	16%	1%	39%
% Increase	10%	17%	11%	NMF	16%

Total operating expenses increased during both fiscal 2016 and fiscal 2015, resulting primarily from the combined effects of the following:

**Diagnostics****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 connections 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.

- 34 -

**Table of Contents**

**Fiscal 2015 increase**

Increased personnel costs resulting from increased Sales & Marketing headcount, and increased sales commission payments made in connection with increased sales levels;

Increased legal spending over the prior year, largely related to a foreign distributor matter; and

Decreased various personnel related costs resulting in part from the death of our Executive Chairman during the fourth quarter of fiscal 2014.

**Life Science**

**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 2016, 2015 and 2014 was \$2,911, \$3,324 and \$3,557, respectively. During fiscal 2014 through fiscal 2016, we granted restricted share units 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 each respective fiscal year. Although dividend equivalents were paid on these units throughout each of the respective fiscal years, because Meridian's net earnings did not reach the minimum levels in any of these three fiscal years, the performance-based awards were not earned and no stock-based compensation was recorded for the performance-based awards, except for those performance-based restricted share units being held by our Executive Chairman at the time of his death in the fourth quarter of fiscal 2014.

Additionally, during both fiscal 2015 and fiscal 2016, in connection with the extension of an Amended and Restated Employment Agreement, we granted to our Chairman and Chief Executive Officer (i) restricted share units to be earned only if specified revenue and earnings per share targets were achieved for each of fiscal 2015 and fiscal 2016; and (ii) time-vested options, 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 were earned and the related compensation expense recorded in fiscal 2015. However, as a result of the fiscal 2016 performance targets not being achieved, the restricted share units have been cancelled and no related compensation expense was recorded in fiscal 2016.

*Operating Income*

Operating income decreased 8% and increased 7% in fiscal 2016 and 2015, respectively, as a result of the factors discussed above.

## **Table of Contents**

### *Other Income and Expense*

Fiscal 2016 other income and expense includes interest costs on a 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 \$600 of foreign currency gains and \$300 of foreign currency losses in fiscal 2016 and fiscal 2014, respectively.

### *Income Taxes*

The effective rate for income taxes was 36%, 35% and 33% for fiscal 2016, 2015 and 2014, respectively. The increases over the last two fiscal years result from (i) the non-deductibility of certain expenses incurred in connection with the Company's acquisition activities (2016); (ii) increased apportionments in certain state taxing jurisdictions (2016 and 2015); and (iii) the timing of renewal/expiration of the research and experimentation credit in the U.S. during these periods.

### *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 2016, 2015 or 2014.

## **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.

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.

**Table of Contents**

On June 23, 2016, the United Kingdom voted to leave the European Union (commonly referred to as Brexit ) and while the impact of Brexit remains uncertain, the resulting immediate changes in foreign currency exchange rates has 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.

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 30<sup>th</sup> each year, and is performed at the reporting unit level. There have been no impairments from these annual reviews. As of September 30, 2016, our stock price was \$19.29 per share, compared to our book value per share of \$3.95. This relationship, stock price trading at a 4.9x 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 impairment of our goodwill and other long-lived assets.

Net cash provided by operating activities totaled \$37,223 during fiscal 2016, a 13% decrease from the \$42,809 provided during fiscal 2015. While reflecting the effects of the timing of payments from customers, and to suppliers and taxing authorities, this decrease also results in large part from the increase in inventory levels. The levels of inventory in our Life Science segment have been increased in anticipation of demand related to various initiatives, most notably further expansion into the Asian market. 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.

During fiscal 2016, the per share amount of our cash dividends paid represented 105% of our diluted earnings per share (approximately 100% excluding the effect of costs related to acquisition activities and restructuring our Sales and Marketing leadership), exceeding our long-standing policy of establishing a cash dividend payout ratio of between 75% and 85% of diluted earnings per share. Despite there being certain individual fiscal years in which our payout ratio has fallen outside of this policy range, since adopting this policy in November 2002, our cumulative cash dividend payout has only slightly exceeded this range, approximating 86% of cumulative net earnings during this timeframe.

**Table of Contents*****Capital Resources***

In connection with the acquisition of Magellan, 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 at the end of five years (see **Known Contractual Obligations** below). In addition, we have a \$30,000 revolving credit facility with a commercial bank that expires March 31, 2021. As of November 22, 2016, 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 2016, 2015 or 2014.

Our capital expenditures are estimated to range between approximately \$3,000 to \$4,000 for fiscal 2017, with the actual amount dependent upon actual operating results and the phasing of certain projects. Such expenditures may be funded with cash and equivalents on hand, operating cash flows and/or availability under the \$30,000 revolving credit facility discussed above.

**Known Contractual Obligations:**

Known contractual obligations and their related due dates were as follows as of September 30, 2016:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases <sup>(1)</sup>	\$ 4,454	\$ 1,969	\$ 2,297	\$ 188	\$
Purchase obligations <sup>(2)</sup>	13,653	11,970	1,683		
Term loan principal payments <sup>(3)</sup>	58,500	3,750	15,750	39,000	
Scheduled interest payments <sup>(3)</sup>	6,186	1,605	4,046	535	
Uncertain income tax positions liability and interest <sup>(4)</sup>	632	632			
Total	\$ 83,425	\$ 19,926	\$ 23,776	\$ 39,723	\$

- (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 machines 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 and service items. These contractual commitments are not in excess of expected production requirements over the next twelve months.

---

**Table of Contents**

- (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. The term loan requires quarterly principal and interest payments, with interest at a variable rate tied to LIBOR, and a balloon principal payment at the end of five years. The interest payments 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%.
- (4) As of September 30, 2016, our liabilities for uncertain tax positions and related interest and penalties were \$502 and \$130, 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 85% 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 \$3,500 in fiscal 2017.

***Off-Balance Sheet Arrangements***

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

**Market Risk Exposure:**

***Foreign Currency Risk***

We have market risk exposure related to foreign currency transactions from our operations outside the United States, as well as certain suppliers to our domestic businesses located outside the United States. The foreign currencies where we have market risk exposure are the Australian dollar, the British pound, the Euro and the 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 27% of the segment's total revenues or 20% of consolidated revenues for fiscal 2016. Additionally, five of our product families accounted for 73% of our Diagnostics segment's third-party revenues during fiscal 2016, and 54% of our fiscal 2016 consolidated revenues.

Our Life Science segment's revenues from sales of purified antigens and reagents to two diagnostics manufacturing customers were 18% of the segment's total revenues for fiscal 2016, and 5% of our fiscal 2016 consolidated revenues.



## **Table of Contents**

### ***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. Management believes that the following accounting policies are critical to understanding the accompanying consolidated financial statements because the application of such policies requires the use of significant estimates and assumptions, and the carrying values of related assets and liabilities are material.

### ***Revenue Recognition***

Our revenue is generally recognized from sales when product is shipped and title has passed to the customer. 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.

Revenue for our Diagnostics segment includes revenue for our *illumigene* 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.

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 *illumigene* 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 and instrument accessories and test kits is recognized upon shipment and transfer of title to the customers. In these markets, our *illumigene* molecular test system is sold to independent distributors who inventory the instruments, instrument accessories and test kits for resale to end-users.

## **Table of Contents**

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.

### ***Inventories***

Our inventories are carried at the lower of cost or market. Cost is determined on a first-in, first-out (FIFO) basis. 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. 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.

### ***Intangible Assets***

Our intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include customer lists and relationships, supply agreements, manufacturing technologies, patents, licenses, trade names, and non-compete agreements. All of Meridian's identifiable intangibles have finite lives.

Goodwill is subject to an annual impairment review (or more frequently if impairment indicators arise). There have been no impairments from these analyses.

Identifiable intangibles with finite lives are reviewed for impairment when events or circumstances indicate that such assets may not be recoverable at their current carrying value. Whether an event or circumstance triggers impairment is determined by comparing an estimate of the asset's undiscounted future cash flows to its carrying value. If impairment has occurred, it is measured by a fair-value based test. There were no events or circumstances in fiscal 2016, 2015 or 2014 indicating that the carrying value of such assets may not be recoverable.

Our ability to recover intangible assets, both identifiable intangibles and goodwill, is dependent upon the future cash flows of the related acquired businesses and assets. We are required to 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, we also make judgments and assumptions regarding useful lives.

## **Table of Contents**

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 decrease, 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.

## ***Income Taxes***

Our 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 purposes 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.

Our deferred tax assets include net operating loss carryforwards. The realization of tax benefits related to net operating loss carryforwards is dependent upon the generation of future taxable income in the applicable jurisdictions. We assess the level of deferred tax asset valuation allowance needed, if any, by taking into consideration historical and future projected operating results, future reversals of taxable temporary differences, and tax planning strategies. The amount of net deferred tax assets considered realizable could be reduced in future years if estimates of future taxable income during the carryforward period are reduced.

Undistributed earnings in our non-U.S. subsidiaries are considered by us to be permanently re-invested in such subsidiaries. Consequently, U.S. deferred tax liabilities on such earnings have not been recorded.

From time to time, our tax returns in federal, state and foreign jurisdictions are examined by the applicable tax authorities. 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.

## **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 not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

**Table of Contents**

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which simplifies the financial statement presentation of deferred income taxes by requiring that deferred income tax assets and liabilities be classified as noncurrent within a classified statement of financial position. Adoption and implementation of the guidance is not required by the Company until issuance of fiscal 2018 first quarter financial statements. However, due to early adoption being permitted and believing the required presentation results in more useful and comparable information related to our net deferred income taxes, the Company has chosen to adopt the guidance during fiscal 2016 and retrospectively apply the guidance to the prior period presented. This retrospective application results in \$3,431 of deferred income tax assets being reclassified from current assets to non-current assets in the September 30, 2015 balance sheet included herein. Adoption of this guidance did not have an impact on the Company's consolidated results of operations or cash flows.

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 has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

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 not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

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.

**Table of Contents**

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.

ITEM 7A.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

See Market Risk Exposure and Capital Resources under Item 7 above beginning on page 27.

- 44 -

**Table of Contents**

ITEM 8.

**FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Index to Consolidated Financial Statements

<u>Management's Report on Internal Control over Financial Reporting</u>	46
<u>Reports of Independent Registered Public Accounting Firm</u>	47
<u>Consolidated Statements of Operations for the years ended September 30, 2016, 2015 and 2014</u>	50
<u>Consolidated Statements of Comprehensive Income for the years ended September 30, 2016, 2015 and 2014</u>	51
<u>Consolidated Balance Sheets as of September 30, 2016 and 2015</u>	52
<u>Consolidated Statements of Shareholders' Equity for the years ended September 30, 2016, 2015 and 2014</u>	54
<u>Consolidated Statements of Cash Flows for the years ended September 30, 2016, 2015 and 2014</u>	55
<u>Notes to Consolidated Financial Statements</u>	56
<u>Schedule No. II Valuation and Qualifying Accounts for the years ended September 30, 2016, 2015 and 2014</u>	83

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.

---

**Table of Contents**

**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, 2016, based on the framework and criteria in the 2013 *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management's evaluation and those criteria, the Company concluded that its system of internal control over financial reporting was effective as of September 30, 2016. The Company's assessment of and conclusion on the effectiveness of its internal control over financial reporting did not include the internal controls of Magellan Biosciences, Inc., which was acquired during fiscal 2016 and the results of which since the date of acquisition were included in the 2016 consolidated financial statements. Magellan constituted \$78,977 or 31.4% of the Company's total assets as of September 30, 2016, and \$10,034 or 5.1% of total net revenues, for the year end September 30, 2016.

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

/s/ John A. Kraeutler  
John A. Kraeutler  
Chief Executive Officer  
November 29, 2016

/s/ Melissa A. Lueke  
Melissa A. Lueke  
Executive Vice President and  
Chief Financial Officer  
November 29, 2016

**Table of Contents**

**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, 2016 and 2015, 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, 2016. 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, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2016 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.

As discussed in Note 1 to the consolidated financial statements, the Company adopted new accounting guidance during the year ended September 30, 2016 related to the presentation of deferred income taxes.

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, 2016, 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, 2016 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio

November 29, 2016



**Table of Contents**

**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, 2016, 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. Our audit of, and opinion on, the Company's internal control over financial reporting does not include the internal control over financial reporting of Magellan Biosciences, Inc. (Magellan), a wholly-owned subsidiary, whose financial statements reflect total assets and revenues constituting 31.4 and 5.1 percent, respectively, of the related consolidated financial statement amounts as of and for the year ended September 30, 2016. As indicated in Management's Report, Magellan was acquired during fiscal year 2016. Management's assertion on the effectiveness of the Company's internal control over financial reporting excluded internal control over financial reporting of Magellan.

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.

**Table of Contents**

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2016, 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, 2016, and our report dated November 29, 2016 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio

November 29, 2016

**Table of Contents****CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data)****Meridian Bioscience, Inc. and Subsidiaries**

For the Year Ended September 30,	2016	2015	2014
Net Revenues	\$ 196,082	\$ 194,830	\$ 188,832
Cost of Sales	68,295	72,948	71,589
Gross Profit	127,787	121,882	117,243
Operating Expenses:			
Research and development	13,815	12,605	12,552
Selling and marketing	29,871	25,601	24,910
General and administrative	30,565	27,616	27,389
Acquisition-related costs	1,481		
Sales and marketing leadership reorganization costs	677		
Total operating expenses	76,409	65,822	64,851
Operating Income	51,378	56,060	52,392
Other Income (Expense):			
Interest income	67	23	25
Interest expense	(897)		
Other, net	96	(1,020)	(309)
Total other income (expense)	(734)	(997)	(284)
Earnings Before Income Taxes	50,644	55,063	52,108
Income Tax Provision	18,415	19,523	17,365
Net Earnings	\$ 32,229	\$ 35,540	\$ 34,743
Earnings Per Share Data:			
Basic earnings per common share	\$ 0.77	\$ 0.85	\$ 0.84
Diluted earnings per common share	\$ 0.76	\$ 0.85	\$ 0.83
Common shares used for basic earnings per common share	42,010	41,659	41,455
Effect of dilutive stock options and restricted shares and units	383	353	458
Common shares used for diluted earnings per common share	42,393	42,012	41,913
Dividends declared per common share	\$ 0.80	\$ 0.80	\$ 0.79
Anti-dilutive Securities:			
Common share options and restricted shares and units	462	551	272

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



**Table of Contents****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (dollars in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

For the Year Ended September 30,	2016	2015	2014
Net Earnings	\$ 32,229	\$ 35,540	\$ 34,743
Other comprehensive income (loss):			
Foreign currency translation adjustment	(2,732)	(2,639)	(436)
Unrealized loss on cash flow hedge	(729)		
Income taxes related to items of other comprehensive income	275		
Other comprehensive income (loss), net of tax	(3,186)	(2,639)	(436)
Comprehensive Income	\$ 29,043	\$ 32,901	\$ 34,307

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

**Table of Contents****CONSOLIDATED BALANCE SHEETS (dollars in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

As of September 30,	2016	2015
<b>Assets</b>		
<b><i>Current Assets:</i></b>		
Cash and equivalents	\$ 47,226	\$ 49,973
Accounts receivable, less allowances of \$334 and \$248, respectively	27,102	26,254
Inventories	45,057	35,817
Prepaid expenses and other current assets	7,406	7,378
<b>Total current assets</b>	<b>126,791</b>	<b>119,422</b>
<b><i>Property, Plant and Equipment, at Cost:</i></b>		
Land	1,155	1,068
Buildings and improvements	31,487	29,974
Machinery, equipment and furniture	45,085	41,541
Construction in progress	1,947	1,139
<b>Subtotal</b>	<b>79,674</b>	<b>73,722</b>
Less: accumulated depreciation and amortization	49,224	46,230
<b>Net property, plant and equipment</b>	<b>30,450</b>	<b>27,492</b>
<b><i>Other Assets:</i></b>		
Goodwill	61,982	22,349
Other intangible assets, net	29,855	5,931
Restricted cash	1,000	1,000
Deferred instrument costs, net	1,392	1,750
Deferred income taxes		4,954
Other assets	353	384
<b>Total other assets</b>	<b>94,582</b>	<b>36,368</b>
<b>Total assets</b>	<b>\$ 251,823</b>	<b>\$ 183,282</b>

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

**Table of Contents****CONSOLIDATED BALANCE SHEETS (dollars in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

As of September 30,	2016	2015
<b>Liabilities and Shareholders' Equity</b>		
<b><i>Current Liabilities:</i></b>		
Accounts payable	\$ 7,627	\$ 6,646
Accrued employee compensation costs	7,106	5,132
Other accrued expenses	2,606	2,587
Current portion of long-term debt	3,750	
Income taxes payable	1,482	886
<b>Total current liabilities</b>	<b>22,571</b>	<b>15,251</b>
<b><i>Non-Current Liabilities</i></b>		
Acquisition consideration	2,383	
Non-current compensation liabilities	2,305	2,158
Interest rate swap liability	729	
Long-term debt	54,610	
Deferred income taxes	2,753	
<b>Total non-current liabilities</b>	<b>62,780</b>	<b>2,158</b>
<b><i>Commitments and Contingencies</i></b>		
<b><i>Shareholders' Equity:</i></b>		
Preferred stock, no par value; 1,000,000 shares authorized; none issued		
Common shares, no par value; 71,000,000 shares authorized, 42,106,587 and 41,838,399 issued, respectively		
Additional paid-in capital	122,356	117,151
Retained earnings	49,632	51,052
Accumulated other comprehensive loss	(5,516)	(2,330)
<b>Total shareholders' equity</b>	<b>166,472</b>	<b>165,873</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 251,823</b>	<b>\$ 183,282</b>

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

Table of Contents**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
<b>Balance at September 30, 2013</b>	41,518	\$ 107,412	\$ 46,888	\$ 745	\$ 155,045
Cash dividends paid - \$0.79 per share			(32,762)		(32,762)
Exercise of stock options	78	882			882
Issuance of restricted shares, net of forfeitures	(1)				
Conversion of restricted stock units	27				
Stock compensation expense		3,557			3,557
Net earnings			34,743		34,743
Foreign currency translation adjustment				(436)	(436)
<b>Balance at September 30, 2014</b>	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 stock units	29				
Stock compensation expense		3,324			3,324
Net earnings			35,540		35,540
Foreign currency translation adjustment				(2,639)	(2,639)
<b>Balance at September 30, 2015</b>	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 stock 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)
<b>Balance at September 30, 2016</b>	42,107	\$ 122,356	\$ 49,632	\$ (5,516)	\$ 166,472

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



**Table of Contents****CONSOLIDATED STATEMENTS OF CASH FLOWS (dollars in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

For the Year Ended September 30,	2016	2015	2014
<b>Cash Flows From Operating Activities</b>			
Net earnings	\$ 32,229	\$ 35,540	\$ 34,743
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	3,937	3,470	3,523
Amortization of intangible assets	2,690	1,748	2,039
Amortization of deferred instrument costs	1,091	1,391	1,702
Stock-based compensation	2,911	3,324	3,557
Deferred income taxes	(233)	(122)	(140)
Losses on long-lived assets	659	94	6
Change in current assets, net of acquisition	(8,115)	(6,079)	(1,528)
Change in current liabilities, net of acquisition	2,237	3,238	(5,996)
Other, net	(183)	205	356
Net cash provided by operating activities	37,223	42,809	38,262
<b>Cash Flows From Investing Activities</b>			
Purchases of property, plant and equipment	(4,004)	(4,613)	(5,306)
Purchase of equity method investment	(600)		
Proceeds from sale of assets		1,138	
Purchases of intangibles and other assets		(151)	(1,696)
Acquisition of Magellan, net of cash acquired	(62,091)		
Net cash used for investing activities	(66,695)	(3,626)	(7,002)
<b>Cash Flows From Financing Activities</b>			
Dividends paid	(33,649)	(33,357)	(32,762)
Proceeds from term loan, net of issuance costs	59,860		
Payments on term loan	(1,500)		
Proceeds and tax benefits from exercises of stock options	2,494	2,614	1,009
Net cash provided by (used for) financing activities	27,205	(30,743)	(31,753)
<b>Effect of Exchange Rate Changes on Cash and Equivalents</b>	(480)	(1,514)	(742)
<b>Net (Decrease) Increase in Cash and Equivalents</b>	(2,747)	6,926	(1,235)
<b>Cash and Equivalents at Beginning of Period</b>	49,973	43,047	44,282
<b>Cash and Equivalents at End of Period</b>	\$ 47,226	\$ 49,973	\$ 43,047
<b>Supplemental Cash Flow Information</b>			
Cash paid for interest	\$ 879	\$	\$
Cash paid for income taxes	\$ 17,915	\$ 20,168	\$ 19,952

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

**Table of Contents**

**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 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 refer to 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, Euro and Singapore dollar currencies. These gains and losses are included in other income and expense in the accompanying consolidated statements of operations. Included within other income and expense in the consolidated statements of operations for the year ending September 30, 2015 is \$1,174 in currency losses related to a foreign subsidiary intercompany loan being marked-to-market.

**Table of Contents**

- (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.

Our investment portfolio includes the following components:

	<b>September 30, 2016</b>		September 30, 2015	
	<b>Cash and Equivalents</b>	<b>Other</b>	Cash and Equivalents	Other
Overnight repurchase agreements	\$ 9,988	\$	\$ 25,436	\$
Institutional money market funds	<b>10,020</b>			
Cash on hand				
Restricted		<b>1,000</b>		1,000
Unrestricted	<b>27,218</b>		24,537	
Total	<b>\$ 47,226</b>	<b>\$ 1,000</b>	\$ 49,973	\$ 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. *illumigene* instruments are carried in inventory until customer placement, at which time they are transferred to deferred *illumigene* instrument costs, unless sold outright.

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 \$2,680 and \$2,456 at September 30, 2016 and 2015, 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

Machinery, equipment and furniture - 3 to 10 years

Computer equipment and software - 3 to 5 years

- 57 -

**Table of Contents**

**(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, 2016, we had six reporting units, four of which contained goodwill (Americas Diagnostics, Bioline, Life Science-U.S. 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.

During fiscal 2016, the annual impairment review for our Americas Diagnostics reporting unit consisted of a qualitative assessment. A qualitative assessment is first performed to determine whether it was more likely than not that the fair value of the reporting unit is less than its carrying value using qualitative indicators. In the event that the reporting unit does not pass the qualitative assessment, the reporting unit's carrying value is compared to its fair value, with fair value of the reporting unit estimated using market and discounted cash flow approaches. Our Americas Diagnostics reporting unit satisfied the qualitative assessment for fiscal 2016.

For each of our Bioline and Life Science-U.S. reporting units, we performed a quantitative assessment in order to determine if impairment existed. 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, as well as an average of the two, the fair values of each reporting unit exceeded their carrying values; therefore, both the Bioline and Life Science-U.S. reporting units satisfied the quantitative assessment for fiscal 2016.

The goodwill held by our Magellan reporting unit was recorded at estimated fair value as part of the March 24, 2016 acquisition (see Note 2) and no events have occurred since that date that would indicate the existence of an impairment.

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. There have been no impairments from the analyses performed for fiscal 2016, 2015 or 2014.

During fiscal 2016, goodwill increased \$39,633, reflecting \$41,358 from the acquisition of Magellan (Diagnostics operating segment; see Note 2) and a \$1,725 decrease from the currency translation adjustment on the goodwill of the Life Science segment's Bioline Group. The decrease of \$844 in fiscal 2015 solely reflects the effect of the Bioline Group and the currency translation adjustments thereon.

**Table of Contents**

A summary of Meridian's acquired intangible assets subject to amortization, as of September 30, 2016 and 2015 is as follows:

As of September 30,	2016		2015	
	Gross Carrying Value	Accum. Amort.	Gross Carrying Value	Accum. Amort.
Manufacturing technologies, core products and cell lines	\$ 21,921	\$ 11,540	\$ 11,582	\$ 10,906
Trade names, licenses and patents	9,037	3,947	6,410	3,296
Customer lists, customer relationships and supply agreements	24,385	10,511	12,105	9,964
Non-compete agreements	680	170		
	<b>\$ 56,023</b>	<b>\$ 26,168</b>	<b>\$ 30,097</b>	<b>\$ 24,166</b>

The actual aggregate amortization expense for these intangible assets for fiscal 2016, 2015 and 2014 was \$2,690, \$1,748 and \$2,039, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2017 - \$3,671, fiscal 2018 - \$3,480, fiscal 2019 - \$3,269, fiscal 2020 - \$3,107 and fiscal 2021 - \$2,510.

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.

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. No triggering events have been identified by the Company for fiscal 2016, 2015 or 2014.

**Table of Contents**

- (i) **Revenue Recognition and Accounts Receivable** - Revenue is generally recognized from sales when product is shipped and title has passed to the customer. 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 \$4,178 at September 30, 2016 and \$5,581 at September 30, 2015, and have been netted against accounts receivable.

Revenue for our Diagnostics segment includes revenue for our *illumigene* 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.

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 *illumigene* 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 and instrument accessories and test kits is recognized upon shipment and transfer of title to the customers. In these markets, our *illumigene* molecular test system is sold to independent distributors who inventory the instruments, instrument accessories and test kits for resale to end-users.



**Table of Contents**

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.

**(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).

---

**Table of Contents**

- (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 not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements. In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which simplifies the financial statement presentation of deferred income taxes by requiring that deferred income tax assets and liabilities be classified as noncurrent within a classified statement of financial position. Adoption and implementation of the guidance is not required by the Company until issuance of fiscal 2018 first quarter financial statements. However, due to early adoption being permitted and believing the required presentation results in more useful and comparable information related to our net deferred income taxes, the Company has chosen to adopt the guidance during fiscal 2016 and retrospectively apply the guidance to the prior period presented. This retrospective application results in \$3,431 of deferred income tax assets being reclassified from current assets to non-current assets in the September 30, 2015 balance sheet included herein. Adoption of this guidance did not have an impact on the Company's consolidated results of operations or cash flows.
- 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 has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

## **Table of Contents**

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 not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

Issued but not yet effective accounting pronouncements are not expected to have a material impact on the Consolidated Financial Statements.

**(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 \$2,383 remains payable to the sellers, pending the realization of tax benefits for certain net operating loss carryforwards in future tax returns. Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of \$41,358 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. 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.

**Table of Contents**

In addition to Magellan's results of operations, which are included in our fiscal 2016 Consolidated Statement of Operations and reported as part of the Diagnostics operating segment, the consolidated results for fiscal 2016 also include:

- (i) \$181 of cost of sales 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) \$1,337 of general and administrative expenses related to the depreciation of the fair value adjustment to acquired property, plant and equipment, and the amortization of specific identifiable intangible assets recorded on the opening balance sheet including customer relationships, technology, non-compete agreements, and trade names.

The Company's fiscal 2016 consolidated results include net revenues and net earnings of Magellan totaling \$10,034 and \$848, respectively, reflecting the items noted above but excluding interest expense on the debt secured by Meridian in connection with the transaction.

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

	<b>March 24, 2016 (as initially reported)</b>	<b>PRELIMINARY Measurement Period Adjustments</b>	<b>March 24, 2016 (as adjusted)</b>
<b>Fair value of assets acquired -</b>			
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	(1,400)	41,400
<b>Other intangible assets (estimated useful life):</b>			
Customer relationships (15 years)	12,600	200	12,800
Technology (10 years)	10,600		10,600
Non-compete agreements (2 years)	700		700
Trade names (approximate 9 year weighted average)	3,700	(800)	2,900
	<b>80,000</b>	<b>(2,200)</b>	<b>77,800</b>
<b>Fair value of liabilities assumed -</b>			
Accounts payable and accrued expenses	1,600	100	1,700
Deferred income tax liabilities	10,600	(2,400)	8,200

Total consideration paid (including \$2,400 accrued to be paid)	\$ 67,800	\$	100	\$	67,900
---	-----------	----	-----	----	--------

- 64 -

**Table of Contents**

As indicated, the allocation of the purchase price and estimated useful lives of property, plant and equipment, and intangible assets shown remain preliminary, pending final completion of valuations. We are currently assessing the amount of tax net operating loss carryforwards available to us. Upon completion of this analysis, an amount will be reclassified from goodwill to deferred taxes.

The consolidated pro forma results of the combined entities of Meridian and Magellan, had the acquisition date been October 1, 2014, are as follows for the periods indicated:

	<b>(UNAUDITED)</b>	
	<b>Fiscal Year Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
Net Revenues	<b>\$ 203,720</b>	<b>\$ 211,250</b>
Net Earnings	<b>\$ 32,675</b>	<b>\$ 34,182</b>

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, 2014, together with the consequential tax effects thereon:

- (i) remove the effect of transaction costs incurred by the Company (\$1,105);
- (ii) reflect the additional depreciation and amortization that would have been charged in connection with the preliminary fair value adjustments to inventory, property, plant and equipment, and identifiable intangible assets (\$800 and \$2,885 in fiscal 2016 and fiscal 2015, respectively);
- (iii) reflect 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 (\$250 in fiscal 2015); and
- (iv) reflect the interest expense that would have been incurred on the Company's \$60,000 term note (\$690 and \$1,685 in fiscal 2016 and fiscal 2015, respectively).

**(3) Inventories**

Inventories are comprised of the following:

As of September 30,	<b>2016</b>	<b>2015</b>
Raw materials	<b>\$ 7,639</b>	<b>\$ 7,095</b>
Work-in-process	<b>13,146</b>	10,096

Edgar Filing: MERIDIAN BIOSCIENCE INC - Form 10-K

Finished goods - instruments	<b>2,378</b>	1,890
Finished goods - kits and reagents	<b>21,894</b>	16,736
<b>Total</b>	<b>\$ 45,057</b>	\$ 35,817

- 65 -

---

**Table of Contents*****(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 at the end of five years. The required principal payments on the term loan for each of the five succeeding fiscal years are as follows: fiscal 2017 - \$3,750, fiscal 2018 - \$4,500, fiscal 2019 - \$5,250, fiscal 2020 - \$6,000, and fiscal 2021 - \$39,000. Due to the recent execution date of the term loan and interest being determined on a variable rate basis, the fair value of the term loan at September 30, 2016 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 has been 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 and accumulated other comprehensive loss in the accompanying Consolidated Balance Sheets. At September 30, 2016, the fair value of the interest rate swap was a liability of \$729, and is reflected as a non-current liability in the accompanying Consolidated Balance Sheet. 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.

In addition, the Company continues to maintain a \$30,000 revolving credit facility with a commercial bank, which expires March 31, 2021. As there were no borrowings outstanding on this revolving credit facility at September 30, 2016 or September 30, 2015, available borrowings as of both dates totaled \$30,000.

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, 2016, 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, pursuant to this bank revolving credit facility and is in compliance with this requirement.



**Table of Contents****(5) Income Taxes**

- (a) Earnings before income taxes, and the related provision for income taxes for the years ended September 30, 2016, 2015 and 2014 were as follows:

Year Ended September 30,	2016	2015	2014
Domestic	\$ 44,795	\$ 50,653	\$ 48,350
Foreign	5,849	4,410	3,758
<b>Total earnings before income taxes</b>	<b>\$ 50,644</b>	<b>\$ 55,063</b>	<b>\$ 52,108</b>
Provision (credit) for income taxes -			
Federal -			
Current	\$ 16,178	\$ 16,152	\$ 15,021
Temporary differences			
Fixed asset basis differences and depreciation	(45)	50	108
Intangible asset basis differences and amortization	(744)	(421)	(210)
Currently non-deductible expenses and reserves	(694)	217	50
Stock-based compensation	129	126	59
Tax credit carryforwards	41	250	225
Other, net	181	19	66
Subtotal	15,046	16,393	15,319
State and local	2,421	2,236	1,762
Foreign	948	894	284
<b>Total income tax provision</b>	<b>\$ 18,415</b>	<b>\$ 19,523</b>	<b>\$ 17,365</b>

- (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,	2016		2015		2014	
Computed income taxes at statutory rate	\$ 17,719	35.0%	\$ 19,264	35.0%	\$ 18,238	35.0%
Increase (decrease) in taxes resulting from -						
State and local income taxes	1,329	2.6	1,365	2.5	1,061	2.0
Net benefit on foreign dividend					(274)	(0.5)
Foreign tax rate differences	(337)	(0.7)	(217)	(0.4)	(430)	(0.8)
Qualified domestic production incentives	(1,290)	(2.5)	(1,197)	(2.2)	(1,175)	(2.3)
Acquisition-related costs	215	0.4				
Uncertain tax position activity	122	0.2	(25)		164	0.3
Valuation allowance	327	0.7	7		(288)	(0.5)
Other, net	330	0.7	326	0.6	69	0.1

<b>\$ 18,415</b>	<b>36.4%</b>	\$ 19,523	35.5%	\$ 17,365	33.3%
------------------	--------------	-----------	-------	-----------	-------

- 67 -

**Table of Contents**

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

As of September 30,	2016	2015
Deferred tax assets -		
Valuation reserves and non-deductible expenses	\$ 2,366	\$ 1,931
Stock compensation expense not deductible	3,110	3,221
Net operating loss and tax credit carryforwards	2,190	590
Basis difference in equity-method investee	302	
Inventory basis differences	1,620	1,186
Other	297	8
Subtotal	9,885	6,936
Less valuation allowance	(342)	(15)
Deferred tax assets	9,543	6,921
Deferred tax liabilities -		
Fixed asset basis differences and depreciation	(1,526)	(995)
Intangible asset basis differences and amortization	(10,770)	(972)
Deferred tax liabilities	(12,296)	(1,967)
Net deferred tax (liabilities) assets	\$ (2,753)	\$ 4,954

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 \$1,945 and \$245, respectively, as of September 30, 2016. At September 30, 2015, such deferred tax assets totaled \$590. 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 \$4,956, \$3,981 and \$836, respectively, at September 30, 2016. The use of the federal and state losses is limited by the change of ownership provisions of the Internal Revenue Code.

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 \$9,543 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 \$10,000 at both September 30, 2016 and September 30, 2015. U.S. deferred tax liabilities of approximately \$2,000 and \$1,800 on such earnings, after consideration of foreign tax credits, have not been recorded as of September 30, 2016 and September 30, 2015, respectively.



**Table of Contents**

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, 2016 and September 30, 2015 related to such positions was \$502 and \$238, respectively, of which the full amounts would favorably affect the effective tax rate if recognized. We recognize interest and penalties related to uncertain tax positions as a component of our income tax provision. 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. During fiscal 2015, we decreased our tax provision by approximately \$19 for such penalties and interest. We had approximately \$130 accrued for the payment of interest and penalties at September 30, 2016 compared to \$37 accrued at September 30, 2015. 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:

	2016	2015
Unrecognized income tax benefits beginning of year	\$ 238	\$ 316
Additions for tax positions of prior years	264	9
Reductions for tax positions of prior years		(28)
Tax examination and other settlements		(59)
<b>Unrecognized income tax benefits at end of year</b>	<b>\$ 502</b>	<b>\$ 238</b>

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 2013, fiscal 2014 and fiscal 2015. In countries outside the U.S., open tax years generally range from fiscal 2011 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.

**(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 3% of eligible compensation. Our discretionary and matching contributions to the plan amounted to approximately \$1,631, \$1,567 and \$1,542, during fiscal 2016, 2015 and 2014, respectively.

**(b) Stock-Based Compensation Plans** - During fiscal 2016, 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).

**Table of Contents**

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, 2016, we have granted 1,492 and 1,241 shares under the 2004 Plan and 2012 Plan, respectively, thereby resulting in a remaining authorized limit of 3,267 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 2014, we granted approximately 270 restricted share units (with a weighted-average grant date fair value of \$24.82 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 2014. While dividend equivalents were paid on these units throughout fiscal 2014, the target for fiscal 2014 was not met and, with the exception of these awards being held by our Executive Chairman at the time of his death in the fourth quarter of fiscal 2014, the performance-based portion of the restricted share units granted during fiscal 2014 were cancelled.

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 (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, as included in the options table below), 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.

## **Table of Contents**

Similar to previous years, 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.

Additionally, during fiscal 2016 in connection with the Amended and Restated Employment Agreement described above, we granted to our Chairman and Chief Executive Officer, 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.

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 460 restricted share units remain outstanding as of September 30, 2016, with a weighted-average grant date fair value of \$20.17 per share, a weighted-average remaining vesting period of 1.89 years and an aggregate intrinsic value of \$8,867. The weighted-average grant date fair value of the approximate 116 restricted share units that vested during fiscal 2016 was \$17.38 per share.

The amount of stock-based compensation expense reported was \$2,911, \$3,324 and \$3,557 in fiscal 2016, 2015 and 2014, respectively. The fiscal 2016 expense is comprised of \$560 related to stock options and \$2,351 related to restricted shares and units; the fiscal 2015 expense is comprised of \$591 related to stock options and \$2,733 related to restricted shares and units; and the fiscal 2014 expense is comprised of \$486 related to stock options and \$3,071 related to restricted shares and units. The total income tax benefit recognized in the income statement for these stock-based compensation arrangements was \$1,100, \$1,250 and \$1,185, for fiscal 2016, 2015 and 2014, respectively. As of September 30, 2016, we expect future stock compensation expense for unvested options and unvested restricted stock units to total \$376 and \$2,232, respectively, which will be recognized during fiscal years 2017 through 2020.

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 2016, 2015 and 2014, we recorded \$76, \$86 and \$108, respectively, in stock compensation expense to adjust estimated forfeiture rates to actual.

**Table of Contents**

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,	<b>2016</b>	2015	2014
Risk-free interest rates	<b>1.63%</b>	2.07%	1.80%
Dividend yield	<b>4.4%</b>	3.7%	3.5%
Life of option	<b>6.39 yrs.</b>	6.33 yrs.	6.29 yrs.
Share price volatility	<b>31%</b>	33%	33%
Forfeitures (by employee group)	<b>0%-16%</b>	0%-15%	0%-14%

A summary of the status of our stock option plans at September 30, 2016 and changes during the year 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	816	\$ 20.54		
Grants	239	19.02		
Exercises	(152)	15.64		
Forfeitures	(63)	23.64		
Cancellations	(60)	17.88		
Outstanding end of period	780	\$ 20.97	6.05	\$ 604
Exercisable end of period	583	\$ 21.42	4.99	\$ 560

A summary of the status of our nonvested options as of September 30, 2016, and changes during the year ended September 30, 2016, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested beginning of period	139	\$ 4.18
Granted	239	3.46
Vested	(121)	3.91



Cancelled	(60)		3.48
Nonvested end of period	197	\$	3.64

- 72 -

**Table of Contents**

The weighted average grant-date fair value of options granted was \$3.46, \$3.95 and \$5.48 for fiscal 2016, 2015 and 2014, respectively. The total intrinsic value of options exercised was \$616, \$850 and \$1,110 for fiscal 2016, 2015 and 2014, respectively. The total grant-date fair value of options that vested during fiscal 2016, 2015 and 2014 was \$474, \$571 and \$701, respectively.

Cash received from options exercised was \$2,364, \$2,478 and \$567 for fiscal 2016, 2015 and 2014, respectively. Tax (expense) benefits recorded to additional paid-in capital from option exercises totaled (\$70), (\$502) and \$315 for fiscal 2016, 2015 and 2014, respectively.

***(7) Non-Current Liabilities***

The Company has provided certain post-employment benefits to its Chairman and Chief Executive Officer and its Chief Commercial Officer. These obligations total \$1,628 and \$1,399 at September 30, 2016 and 2015, 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 \$565 and \$668 at September 30, 2016 and 2015, 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 and business development offices 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,	2016		2015		2014	
Customer A	\$ 20,246	(10)%	\$ 29,155	(15)%	\$ 28,278	(15)%
Customer B	\$ 19,585	(10)%	\$ 25,276	(13)%	\$ 22,780	(12)%

**Table of Contents**

Accounts receivable from these two Diagnostics distributor customers accounted for 16% and 21% of consolidated accounts receivable at September 30, 2016 and September 30, 2015, respectively. The Company's international revenues totaled \$55,291, \$52,313 and \$57,051 in fiscal years 2016, 2015 and 2014, respectively. Five of our product families—*C. difficile*, foodborne, *H. pylori*, respiratory and women's health & STD—accounted for 54%, 59% and 58% of consolidated net revenues in fiscal 2016, 2015 and 2014, respectively. We currently purchase on a sole-source basis from a U.S. and an Italian manufacturer, respectively, the *illumipro*-10 instruments on which our *illumigene* 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 11%, 14% and 14% of third-party revenues for our Diagnostics segment in fiscal 2016, 2015 and 2014, respectively.

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,	2016	2015	2014
United States	\$ 120,826	\$ 120,599	\$ 112,917
Italy	6,599	7,090	8,469
United Kingdom	1,991	1,964	1,942
Japan	1,644	2,603	2,097
France	1,605	1,603	1,841
Belgium	1,501	1,289	1,241
Holland	1,188	1,326	1,613
Canada	1,024	1,315	1,359
Other countries	8,736	8,325	10,021
Total Diagnostics	\$ 145,114	\$ 146,114	\$ 141,500

Year Ended September 30,	2016	2015	2014
United States	\$ 19,965	\$ 21,918	\$ 18,864
Germany	6,982	5,699	7,232
United Kingdom	6,410	5,782	5,647
China	4,080	2,526	1,003
Australia	3,153	3,590	4,063
France	2,167	2,026	1,633
Japan	1,320	1,158	1,306
Other countries	6,891	6,017	7,584
Total Life Science	\$ 50,968	\$ 48,716	\$ 47,332

Identifiable assets for our Italian distribution organization were \$8,782 and \$8,497 at September 30, 2016 and 2015, respectively. At September 30, 2016, identifiable assets for the Bioline Group's operations in the U.K., Germany and Australia totaled approximately \$14,973, \$7,024 and \$3,780, respectively; and totaled approximately \$15,647, \$6,909 and \$3,891, respectively, at September 30, 2015.



**Table of Contents**

Segment information for the years ended September 30, 2016, 2015 and 2014 is as follows:

	Diagnostics	Life Science	Elim <sup>(1)</sup>	Total
<b>Fiscal Year 2016 -</b>				
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	185,241	66,624	(42)	251,823
<b>Fiscal Year 2015 -</b>				
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
<b>Fiscal Year 2014 -</b>				
Net revenues				
Third-party	\$ 141,500	\$ 47,332	\$	\$ 188,832
Inter-segment	432	1,009	(1,441)	
Operating income	40,740	11,750	(98)	52,392
Depreciation and amortization	4,283	2,981		7,264
Capital expenditures	4,176	1,130		5,306
Goodwill	1,250	21,943		23,193
Other intangible assets	2,756	5,057		7,813
Total assets	109,350	67,834	(255)	176,929

(1) Eliminations consist of intersegment transactions.

A reconciliation of segment operating expenses to consolidated earnings before income taxes for the years ended September 30, 2016, 2015 and 2014 is as follows:

Year Ended September 30,	2016	2015	2014
Segment operating income	\$ 51,378	\$ 56,060	\$ 52,392
Interest income	67	23	25
Interest expense	(897)		

Other, net	<b>96</b>	(1,020)	(309)
Consolidated earnings before income taxes	<b>\$ 50,644</b>	\$ 55,063	\$ 52,108

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

- 75 -

---

**Table of Contents**

**(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 85% 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 \$3,134, \$3,106 and \$3,482, respectively, for the fiscal years ended September 30, 2016, 2015 and 2014.
- (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 \$11,970, \$1,620 and \$63 for fiscal 2017, 2018 and 2019, respectively. No purchase commitments have been made beyond fiscal 2019.
- (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 \$1,966, \$1,797 and \$1,951 for fiscal 2016, 2015 and 2014, respectively. Operating lease commitments for each of the five succeeding fiscal years are as follows: fiscal 2017 - \$1,969, fiscal 2018 - \$1,451, fiscal 2019 - \$648, fiscal 2020 - \$198; and fiscal 2021 - \$188.
- (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.
- (e) Indemnifications** - In conjunction with certain contracts and agreements, we provide routine indemnifications whose terms 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, 2016 or September 30, 2015. 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.

**Table of Contents****(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.

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

<b>For the Quarter Ended in Fiscal 2015</b>	<b>December 31</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>
<b>Net revenues</b>	<b>\$ 48,013</b>	<b>\$ 51,545</b>	<b>\$ 48,204</b>	<b>\$ 47,068</b>
<b>Gross profit</b>	<b>29,237</b>	<b>32,521</b>	<b>30,331</b>	<b>29,793</b>
<b>Net earnings</b>	<b>7,901</b>	<b>10,070</b>	<b>9,102</b>	<b>8,467</b>
<b>Basic earnings per common share</b>	<b>0.19</b>	<b>0.24</b>	<b>0.22</b>	<b>0.20</b>
<b>Diluted earnings per common share</b>	<b>0.19</b>	<b>0.24</b>	<b>0.22</b>	<b>0.20</b>
<b>Cash dividends per common share</b>	<b>0.20</b>	<b>0.20</b>	<b>0.20</b>	<b>0.20</b>

**(11) Subsequent Events**

We evaluated subsequent events after the balance sheet date of September 30, 2016 and there were no material subsequent events that required recognition or additional disclosure in these financial statements.



**Table of Contents**

ITEM 9.

**CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS**

**ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

ITEM 9A.

**CONTROLS AND PROCEDURES**

As of September 30, 2016, an evaluation was completed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) promulgated under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective as of September 30, 2016. Noting that the Company's assessment of and conclusion on the effectiveness of its internal control over financial reporting did not include the internal controls of Magellan Biosciences, Inc., which was acquired during fiscal 2016 and the results of which since the date of acquisition were included in the 2016 consolidated financial statements, there have been no changes in our internal control over financial reporting identified in connection with the evaluation of internal control that occurred during the fourth fiscal quarter that has materially affected, or is reasonably likely to affect, our internal control over financial reporting, or in other factors that could significantly affect internal control subsequent to September 30, 2016.

Our internal control report is included in this Annual Report on Form 10-K after Item 8, under the caption Management's Report on Internal Control over Financial Reporting.

ITEM 9B.

**OTHER INFORMATION**

Not applicable.

PART III.

The information required by Items 10, 11, 12, 13 and 14, of Part III are incorporated by reference from the Registrant's Proxy Statement for its 2017 Annual Shareholders Meeting to be filed with the Commission pursuant to Regulation 14A.

**Table of Contents**

## 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*	Savings and Investment Plan Prototype Adoption Agreement (Incorporated by reference to Meridian's Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2003)
10.2*	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)
10.3*	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)
10.4*	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)
10.5*	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)
10.6*	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 2017 Officer s Performance Compensation Plan (Filed herewith)
10.10*	Form of Time-Based Restricted Share Unit Award Agreement dated November 9, 2016 (Filed herewith)

---

**Table of Contents**

- 10.11\* Form of Performance Award Restricted Share Unit Award Agreement dated November 9, 2016 (Filed herewith)
- 10.12\* 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)
- 10.13 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)
- 10.14 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)
- 10.14.1 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 June 30, 2016)
- 10.14.2 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 June 30, 2016)
- 10.14.3 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)
- 10.14.4 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 Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2010)
- 10.14.5 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)
- 10.14.6 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)
- 10.14.7 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 June 30, 2016)
- 13 2016 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)



**Table of Contents**

- 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)
- 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, 2016 filed with the SEC on November 29, 2016, formatted in XBRL includes: (i) Consolidated Statements of Operations for the years ended September 30, 2016, 2015 and 2014; (ii) Consolidated Statements of Comprehensive Income for the years ended September 30, 2016, 2015 and 2014; (iii) Consolidated Statements of Cash Flows for the years ended September 30, 2016, 2015 and 2014; (iv) Consolidated Balance Sheets as of September 30, 2016 and 2015; (v) Consolidated Statements of Shareholders' Equity for the years ended September 30, 2016, 2015 and 2014; and (vi) the Notes to Consolidated Financial Statements

\* Management Compensatory Contracts

- (1) Only specific portions of the 2016 Annual Report to Shareholders are incorporated by reference in this Form 10-K as filed herewith. A supplemental paper copy of the 2016 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](http://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.

Table of Contents

## 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/ John A. Kraeutler  
 Date: November 29, 2016  
 John A. Kraeutler  
 Chairman of the Board and  
 Chief Executive Officer

We, the undersigned directors and officers of the Registrant, hereby severally constitute John A. Kraeutler 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/ John A. Kraeutler	Chairman of the Board and Chief	November 29, 2016
John A. Kraeutler	Executive Officer	
/s/ Melissa A. Lueke	Executive Vice President, Chief	November 29, 2016
Melissa A. Lueke	Financial Officer, and Secretary (Principal Financial and Accounting Officer)	
/s/ James M. Anderson	Director	November 29, 2016
James M. Anderson		
/s/ Dwight E. Ellingwood	Director	November 29, 2016
Dwight E. Ellingwood		
/s/ John C. McIlwraith	Director	November 29, 2016
John C. McIlwraith		

/s/ David C. Phillips

Director

November 29, 2016

David C. Phillips

/s/ Catherine A. Sazdanoff

Director

November 29, 2016

Catherine A. Sazdanoff

- 82 -



Table of Contents

## SCHEDULE II

Meridian Bioscience, Inc.

and Subsidiaries

Valuation and Qualifying Accounts

(Dollars in thousands)

Years Ended September 30, 2016, 2015 and 2014

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Other (a)	Balance at End of Period
<b>Year Ended September 30, 2016:</b>					
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
<b>Year Ended September 30, 2015:</b>					
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
<b>Year Ended September 30, 2014:</b>					
Allowance for doubtful accounts	\$ 233	\$ 116	\$ (68)	\$ (9)	\$ 272
Inventory realizability reserves	2,499	1,325	(834)	(48)	2,942
Valuation allowances deferred taxes	296	8	(296)		8

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