MERIDIAN BIOSCIENCE INC
Form 10-K
November 30, 2015
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS

PURSUANT TO SECTIONS 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2015.

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

Commission File No. 0-14902

MERIDIAN BIOSCIENCE, INC.

3471 River Hills Drive

Cincinnati, Ohio 45244

IRS Employer ID No. 31-0888197

Incorporated under the Laws of Ohio

Phone: (513) 271-3700

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

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

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

None

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

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 x 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 x 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. YES x NO ¨

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	x	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 x

The aggregate market value of Common Shares held by non-affiliates as of March 31, 2015 was $786,958,969 based on a closing sale price of $19.08 per share on March 31, 2015. As of October 31, 2015, 41,846,049 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, 2015 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 2016 Annual Shareholders Meeting are incorporated by reference in Part III as specified.

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MERIDIAN BIOSCIENCE, INC.

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ON FORM 10-K

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates , anticipates , projects , plans , seeks , may , will , intends , believes , should and similar expressions or the negative versions thereof and which also may be identified by their context. All statements that address operating performance or events or developments that Meridian expects or

anticipates will occur in the future, including, but not limited to, statements relating to per share diluted earnings and revenue, are forward-looking statements. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. Specifically, Meridian s forward-looking statements are, and will be, based on management s then-current views and assumptions regarding future events and operating performance. Meridian assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian s 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. Meridian relies on proprietary, patented and licensed technologies, and 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 United States Food and Drug Administration, can

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result in unanticipated expenses and delays and interruptions to the sale of new and existing products. 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 contains a list and description of uncertainties, risks and other matters that may affect the Company.

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PART I.

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

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

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

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; (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; and (iii) the contract development and manufacture of proteins and other biologicals under cGMP conditions for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines. The Company was incorporated in Ohio in 1976. Our principal corporate offices are located near Cincinnati, Ohio, USA.

Our website is www.meridianbioscience.com. We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments thereto, free of charge through this website, as soon as reasonably practicable after such material has been electronically filed with or furnished to the Securities and Exchange Commission (SEC). These reports may also be read and copied at the SEC s public reference room at 100 F Street, N.E., Washington, DC 20549, phone number 1-800-732-0330. The SEC maintains an internet site containing these filings and other information regarding Meridian at www.sec.gov. The information on our website is not and should not be considered part of this Annual Report on Form 10-K.

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Reportable Segments

Our reportable segments are Diagnostics and Life Science, both of which are headquartered in Cincinnati, Ohio. 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). 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. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines. Financial information for Meridian s reportable segments is included in Note 7 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 75% of consolidated net revenues for fiscal 2015. Third-party revenues for this segment were $146,000, $142,000 and $145,000 for fiscal 2015, 2014 and 2013, respectively, reflecting a three-year compound annual growth rate of 4%. As of September 30, 2015, our Diagnostics segment had approximately 360 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 acute 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.

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 (*illumi*gene® 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®, Immuno*Card*® and Immuno*Card* STAT!® brands) single-use immunoassays that can be used in point-of-care settings; these tests have fast turnaround times (generally under 20 minutes); and can reduce expensive send-outs for hospitals and outpatient clinics.

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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.

Our diagnostic products are used principally in the detection of infectious diseases caused by various bacteria, viruses, parasites and pathogens. Our focus product families in Diagnostics are:

1. *C. difficile* causative agent for antibiotic-associated diarrhea from a hospital-acquired infection
2. Foodborne Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter jejuni* (Campy)
3. *H. pylori* stomach ulcers
4. Respiratory Group A *Streptococcus*, *M. pneumonia* (Mycoplasma) and *Bordetella pertussis*, among tests for other diseases
5. Women s Health & Sexually Transmitted Diseases (STD) Group B *Streptococcus*, *Chlamydia trachomatis*, *Neisseria gonorrhea*, Herpes Simplex Virus Type 1 & Type 2

Revenues within these focus product families accounted for 79%, 77% and 77% of our Diagnostics segment s third-party revenues during fiscal 2015, 2014 and 2013, respectively. These same product families accounted for 59%, 58% and 59% of consolidated net revenues in fiscal 2015, 2014 and 2013, respectively.

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

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

1. ***illumi****gene*® *C. difficile* commercialized in August 2010
2. ***illumi****gene*® Group B *Streptococcus* (Group B Strep or GBS) commercialized in December 2011
3. ***illumi****gene*® Group A *Streptococcus* (Group A Strep) commercialized in September 2012
4. ***illumi****gene*® Mycoplasma (*M. pneumonia;* walking pneumonia) commercialized in June 2013
5. ***illumi****gene*® *Bordetella pertussis* (whooping cough) commercialized in March 2014

6. ***illumi****gene*® *Chlamydia trachomatis* commercialized outside of U.S. in February 2015

7. ***illumi****gene*® *Neisseria gonorrhea* commercialized outside of U.S. in February 2015

8. ***illumi****gene*® HSV 1&2 (Herpes Simplex Virus Type 1 & Type 2) commercialized outside of U.S. in May 2015; commercialized in U.S. in July 2015

We have several additional ***illumi****gene* tests in development, including bloodborne pathogens that are the causative agents for malaria. We have a robust pipeline of ***illumi****gene* opportunities and continue to add new assays to our ***illumi****gene* platform menu.

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We believe that our ***illumi****gene* system has been well-accepted in our global markets. We now have approximately 1,465 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 over 400 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. The creation of Accountable Care Organizations (ACOs) in our U.S. market, in particular, has 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 ACOs and health care systems that are transitioning from fee-for-service compensation models, to compensation models based on the total outcome costs of a given patient. 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.

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. We utilize multi-year supply agreements to secure our business where possible and 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 Focus Product Families

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

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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 2015, 2014 and 2013: Cardinal Healthcare Corporation and Thermo Fisher Scientific. Our revenues from Cardinal were approximately $29,000, $28,000 and $35,000 during fiscal 2015, 2014 and 2013, respectively. Our revenues from Thermo Fisher were approximately $25,000, $23,000 and $25,000 during fiscal 2015, 2014 and 2013, respectively.

EMEA

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

ROW

With the exception of Australia, in which we utilize a direct sales force, we utilize independent distributors throughout the ROW.

Our Diagnostics segment s focus product families are described below:

C. difficile

C. difficile, causative agent of serious hospital acquired bacterial infections, is our largest product family, generating approximately $31,000 in global revenues for fiscal 2015, a 12% decrease from fiscal 2014 reflecting a combination of sales of our molecular-based and traditional immunoassay products, with our molecular product now representing approximately 80% of this product category. This product family has experienced significant competition in recent years from new technologies, primarily other molecular testing platforms. See Competition discussion below.

Foodborne

Our foodborne product family achieved approximately $25,000 in global revenues for fiscal 2015, an increase of 8%, with over 95% of such sales occurring in the U.S. Our foodborne products include tests for Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter jejuni* (Campy). In the U.S. market, we believe that there are potentially 20 million stool cultures that are tested annually for foodborne illnesses. We believe that we have less than a 20% market share for EHEC and less than a 5% market share for Campy.

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We are continuing to re-emphasize the benefits of increased sensitivity and faster turnaround time versus culture methods in our marketing programs. The primary competition for our foodborne products is laboratory culture methods and an immunoassay EHEC shiga toxin test from one of our competitors. We believe that our test offers better workflow, less hands-on time and quicker results, in addition to being fully compliant with CDC-recommended testing methods.

Helicobacter pylori

H. pylori, a bacterium found in the stomach, is a major cause of peptic ulcers and is linked to duodenal ulcers and stomach cancer. *H. pylori* represents our second largest product family, generating approximately $30,000 in global revenues for 2015, or 6% growth. We offer both antibody and direct antigen tests in alternative formats (single-use and high volume batch). Our major competition in this product family is alternative test methods, serology and urea breath, and the prescription of symptom-relieving medications. Over 75% of our *H. pylori* product sales are in the U.S., where our strategy for this product line has been to partner with managed care companies to promote the health and economic benefits of a test and treat strategy, and to move physician behavior away from serology-based testing toward direct antigen testing. In the U.S. market, we believe that there are potentially 30 million people suffering from peptic ulcers and we believe that we currently have an approximate 5% market share.

The patents for our *H. pylori* products are owned by us and expire in May 2016 in the U.S. and in 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase upon the expiration of these patents in 2016 and 2017 as we currently market the only FDA-cleared test 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 upon patent expiration, among other things, we are researching and experimenting with new products (e.g., detection of *H. pylori* on molecular platforms) and attempting to secure significant customers under long-term contracts. We are unable to provide any 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.

Respiratory

In addition to our immunoassay tests to detect influenza, which have been part of our product portfolio for a number of years, during the last three years we have also introduced three molecular-based products on our ***illumi****gene* platform to detect various respiratory conditions. These molecular products, which are less seasonally-dependent than our influenza products, include ***illumi****gene* Group A Strep (2012), ***illumi****gene* Mycoplasma (2013) and ***illumi****gene* Pertussis (2014). Since their commercialization, these products have been widely accepted in the marketplace and during fiscal 2015 grew to represent over 40% of our total Respiratory product family revenues of $22,000.

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Women s Health & STD

In December 2011, we introduced our ***illumi****gene* Group B Strep product to detect Group B *Streptococcus* (GBS) in expectant mothers. Early detection of GBS, a major perinatal pathogen for both mothers and their infants that is associated with significant morbidity and mortality, is critical to the prevention and treatment of serious disease in infants. During fiscal 2015, we expanded our ***illumi****gene* molecular product platform to include three additional tests directly related to women s health; these include tests for *Chlamydia trachomatis* (Chlamydia), *Neisseria gonorrhea* (Gonorrhea) and Herpes Simplex Virus Type 1 & Type 2. With the GBS and HSV tests available worldwide, and the Chlamydia and Gonorrhea tests currently commercialized only outside the U.S., revenues from these women s health & STD products grew to over $7,000 during 2015, and are currently expected to exceed $10,000 in fiscal 2016.

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. We believe that with the breadth and depth of our product portfolio, we are well positioned to capitalize on the migration to molecular testing.

Research and Development

Our Diagnostics segment s research and development organization, which is located at our corporate headquarters in Newtown, Ohio, a suburb of Cincinnati, has expertise in biochemistry, immunology, mycology, bacteriology, virology, parasitology and molecular biology. Research and development expenses for the Diagnostics segment for fiscal 2015, 2014 and 2013 were approximately $10,000, $10,000 and $8,000, respectively. This research and development organization focuses its activities on new product and new technology development, new applications for our existing technologies, and improvements to existing products. Research and development efforts may occur in-house or with collaborative partners. We believe that new product development is a key source for sustaining revenue growth. The products within our ***illumi***gene molecular platform and H. pylori product family were developed solely in-house.

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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 ***illumi****gene* molecular products, are purchased from outside vendors. With the recent expansion of our molecular diagnostic manufacturing capacity at our Cincinnati, Ohio location, we brought in-house certain molecular component manufacturing that was previously outsourced. We believe that we have sufficient manufacturing and sourcing capacity for anticipated growth over the next several years.

Intellectual Property, Patents and Licenses

We own or license U.S. and foreign patents, most of which are for 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. Revenues from these products in fiscal 2015 and fiscal 2014 were as follows:

Product/Technology Family	Number of products	% of fiscal year consolidated revenues	
		2015	2014
illumi*gene*	8	21%	20%
H. pylori	2	14%	14%
Respiratory immunoassay	4	2%	2%
Other	5	1%	1%
Total patented products	19	38%	37%

The patents for the ***illumi****gene* products are licensed from a third party 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 are owned by us and expire in May 2016 in the U.S. and in 2017 outside the U.S. (principally, Australia, Canada, European Community and Japan). We expect competition with respect to our *H. pylori* products to increase upon the expiration of these patents in 2016 and 2017 as we currently market the only FDA-cleared test 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 upon patent expiration, we are researching and experimenting with new products (e.g., detection of *H. pylori* in samples other than stool and detection of *H. pylori* on molecular platforms). We are unable to provide any 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.

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The patents for our immunoassay respiratory products are owned by us and expire in 2022 (two products) and 2027 (one product). These patents were issued in the U.S. and European Community, among other jurisdictions.

The remaining five patented products are spread over multiple product families. These patents are either owned by us, or we are free to practice the patents without any restriction or royalty obligation. These patents, where still in effect, collectively expire between 2016 and 2027.

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.

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 $2,000 in fiscal 2015.

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.

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Medical Device Tax

On January 1, 2013, the medical device tax established as part of the U.S. health care reform legislation became effective and as a result, the Company made its first required tax deposit near the end of January 2013. During fiscal 2015, 2014 and 2013, the Company recorded to cost of sales approximately $1,900, $1,750 and $1,300, respectively, of medical device tax expense related to this legislation.

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. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as foodborne illnesses, or pandemics such as the H1N1 influenza outbreak during fiscal 2009. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, we can make no assurance that revenues will not be impacted period over period by such factors.

Life Science Segment

Overview of Products and Markets

Our Life Science segment 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 and other diagnostic manufacturing companies, as well as contract development and manufacturing services under clinical cGMP conditions. Third-party revenues for this segment were approximately $49,000, $47,000 and $44,000 for fiscal 2015, 2014 and 2013, respectively. As of September 30, 2015, our Life Science segment had approximately 220 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 is 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 2015, 16% of third-party revenues for this segment were from two diagnostic manufacturing customers.

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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.

Our clinical cGMP protein production facility in Memphis, Tennessee serves as an enabling technology for process development and large-scale manufacturing for biologicals used in new drugs and vaccines. The size of the facility is intended to accommodate manufacturing requirements for Phase I and Phase II clinical trials for biopharmaceutical, biotechnology and government agency customers. Our revenues for contract services were approximately $3,000 in each of fiscal 2015, 2014 and 2013.

Market Trends

Globally, sales of molecular components are growing at a faster pace than immunoassay components, and this is consistent with our business in constant-currency. Geographic expansion is 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.

The market for contract manufacturing in a validated cGMP facility, such as our Memphis facility, is also competitive. Important competitive factors include reputation, customer service and price. Although the product application for this facility was built from our existing expertise in cell culture manufacturing techniques, we face competitors with greater experience in contract manufacturing in a clinical cGMP environment.

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Research and Development

Research and development expenses for our Life Science segment for each of fiscal 2015, 2014 and 2013 were approximately $3,000. This research and development organization is involved in activities for our cGMP facility and development of new molecular reagent products.

Manufacturing and Government Regulation

Our Life Science facilities are ISO 9001:2008 certified, and where appropriate, comply with Regulation EC 1069:2009.

The cGMP clinical grade proteins that are produced in our Memphis facility are intended to be used as injectibles, and, as such, they are produced under cGMP Regulations for Biologics and Human Drugs under the auspices of the FDA. Following clinical trials, approval and licensing of these products is the responsibility of the applicant, who owns the rights to each protein. Typically, the customer is the applicant, not Meridian Life Science.

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 any assurance that we will consummate any additional acquisitions in the future, nor can we provide any assurance that any acquisitions will accomplish these objectives, we expect that the potential for acquisitions will continue to provide opportunities for revenue and earnings growth in the future.

During November 2015, we made a minority investment in Oasis Diagnostics® Corporation in order to evaluate our interest in saliva diagnostics and collection devices. Oasis is located in Vancouver, Washington.

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 North America approximated $49,000 or 25% of consolidated fiscal 2015 revenues, $55,000 or 29% of consolidated fiscal 2014 revenues, and $54,000 or 29% of consolidated fiscal 2013 revenues. We expect to continue to look to international markets as a source of new revenues and growth in the future.

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During fiscal 2015, currency exchange had an approximate $4,700 unfavorable impact on revenues; $3,200 within the Diagnostics segment and $1,500 within the Life Science segment. This compares to currency exchange rates having an approximate $850 favorable impact on revenues in fiscal 2014; $600 favorable within the Diagnostics segment and $250 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 material during fiscal 2015, 2014 or 2013.

Environmental

We are a conditionally exempt, small quantity generator of hazardous waste and have a U.S. EPA identification number. We are in compliance with applicable portions of the federal and state hazardous waste regulations and have never been a party to any environmental proceeding.

ITEM 1A.

RISK FACTORS

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

Risks Affecting Growth and Profitability of our Business

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

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

In addition, we must regularly allocate considerable resources to research and development of new products, services and technologies. The research and development process generally takes a significant amount of time from 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.

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

One of our growth strategies is the acquisition of companies and/or products. Although additional acquisitions of companies and products may enhance the opportunity to increase net earnings over time, such acquisitions could result in greater administrative burdens, increased exposure to the uncertainties inherent in marketing new products 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 any 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 37% and 36%, respectively, of the Diagnostics segment s total revenues for fiscal 2015 and fiscal 2014, or 28% and 27%, respectively, of our consolidated revenues for fiscal 2015 and fiscal 2014. 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.

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. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as foodborne illnesses, or pandemics such as H1N1 influenza. While we believe that the breadth of our diagnostic product lines reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, we can make no assurance that revenues will not be negatively impacted period over period by such factors.

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Changing Diagnostic Market Conditions

Changes in the U.S. health care delivery system have resulted in consolidation among reference laboratories 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. At present, we are unable to predict what effect the legislation might ultimately have on 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 2015, 2014 and 2013, the Company recorded approximately $1,900, $1,750 and $1,300, respectively, of Medical Device Tax expense, which is reflected as a component of cost of sales in the accompanying Consolidated Statements of Operations.

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.

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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 16% of the Life Science segment s total revenues for each of fiscal 2015 and fiscal 2014, or 4% of our consolidated revenues for each of fiscal 2015 and fiscal 2014. Our Life Science segment has four other significant customers who purchase antigens, antibodies and reagents, which together comprised 10% and 8%, respectively, of the segment s total revenues for fiscal 2015 and fiscal 2014. Any significant alteration of buying patterns from these customers could adversely affect our period over period revenues and results of operations.

Revenues relating to research, development and manufacturing services for our Life Science segment are generated on a contract by contract basis. The nature of this business is such that each contract provides a unique product and/or service and corresponding revenue stream. While this business has historically generated annual revenues of approximately $2,000 to $4,000, there can be no assurance that future contracts will be secured, and if secured, will be profitable.

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 any assurance that our products and services will be able to compete successfully with the products and services of our competitors.

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We may face increased competition upon expiration of our H. pylori patents in 2016 and 2017.

Our patents related to our *H. pylori* products expire in May 2016 in the U.S. and in 2017 in countries outside the U.S. Revenues from our *H. pylori* products were approximately $30,000 in fiscal 2015. We expect competition with respect to our *H. pylori* products to increase upon the expiration of these patents in 2016 and 2017 as we currently market the only FDA-cleared test to detect *H. pylori* antigen in stool samples. Such competition may have an adverse impact on our selling prices for these products and 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 upon patent expiration, among other things, we are researching and experimenting with new products (e.g., detection of H. pylori on molecular platforms) and attempting to secure significant customers under long-term contracts. We are unable to provide any 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 25% and 29% of our net revenues for fiscal 2015 and 2014, respectively, were attributable to markets outside of North America. For fiscal 2015, 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 any assurance that we will be able to obtain necessary governmental clearances or approvals or timely clearances or approvals to market future products in the United States and other countries. Costs and difficulties in complying with laws and regulations administered by the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Department of Commerce, the U.S. Drug Enforcement Agency, the Centers for Disease Control or other regulators can result in unanticipated expenses and delays and interruptions to the sale of new and existing products.

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

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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 due to FDA regulations, 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.

One third party manufactures our proprietary ***illumi****pro-10* Incubator Reader (instrument), a component of our ***illumi****gene* molecular system. This instrument is manufactured exclusively for Meridian according to our specifications. While other manufacturers for this type of instrument are available, we source solely from one manufacturer due to the FDA regulations and costs involved in clearing the system for marketing in the United States. If this third-party manufacturer fails 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. As revenues for our ***illumi****gene* molecular system accounted for $41,000 or 21% of consolidated revenues for fiscal 2015, $37,000 or 20% for fiscal 2014 and $34,000 or 18% for fiscal 2013, an interruption in the manufacturing of this system could have a material adverse effect on our operating results.

Additionally, one third party manufactures one certain reagent for use with our ***illumi****gene* assays. While alternative suppliers exist, we elect to utilize this third party exclusively in order to maintain consistency in our materials, which is critical in complying with FDA regulatory requirements.

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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 three separate and independent companies accounted for 18%, 17% and 17% of consolidated revenues in fiscal 2015, 2014 and 2013, 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 any 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 any 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. We currently carry intellectual property insurance that covers damages and defense costs from our potential infringement on certain other third-party patents at levels that we believe are commercially reasonable, although there is no assurance that it will be adequate to cover claims that may arise. Any substantial underinsured loss resulting from such a claim could have a material adverse effect on our profitability and the damage to our reputation in the industry could have a material adverse effect on our business.

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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 agreement imposes restrictions with respect to our operations.

Our bank credit agreement contains 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 agreement, we would be in default under the credit agreement. If an event of default is not cured or waived, it could result in acceleration of any indebtedness under our credit agreement, which could have a material adverse effect on our business. At the present time, no borrowings are outstanding under our bank credit agreement.

We face risks related to global economic conditions.

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

monitor and plan for the potential impact of these global economic factors.

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Approximately $1,600 and $2,700 of our accounts receivable at September 30, 2015 and September 30, 2014, respectively, was due from Italian hospital customers whose funding ultimately comes from the Italian government. In addition, the amount of our annual revenues in the country of Greece and the corresponding amount of customer receivables outstanding at any point in time is not significant, and therefore, we do not expect any meaningful impact from the financial crisis in the country of Greece.

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.

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

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

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Risks Related to Our Common Stock

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. We also operate a Diagnostics sales and distribution center near Milan, Italy in an approximately 18,000 square foot two-story building. This facility is owned by our wholly-owned Italian subsidiary, Meridian Bioscience Europe s.r.l. We also rent office space in Paris, France and Braine-l Alleud, Belgium for sales and administrative functions.

Our Life Science operations are conducted in several facilities in Memphis, Tennessee; Boca Raton, Florida; Taunton, Massachusetts; London, England; Luckenwalde, Germany; Sydney, Australia; Singapore; and Beijing, China. Our facility in Memphis, Tennessee consists of two buildings totaling approximately 44,000 square feet and is owned by us. Our leased facility in Boca Raton, Florida contains approximately 7,500 square feet of manufacturing space. Following are details of our other Life Science facilities, all of which are leased: Taunton approximately 10,000 square feet of sales and warehouse space; London approximately 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 8,000 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.

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ITEM 3.

LEGAL PROCEEDINGS

We are a party to various litigation matters that we believe are in the normal course of business. 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.

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 17 through 26 of this Annual Report.

Common Stock Information on the inside back cover of the Annual Report to Shareholders for 2015 and Quarterly Financial Data (Unaudited) relating to our dividends in Note 9 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 2015, our indicated annual dividend rate of $0.80 per share approximated 94% of full year diluted earnings per share, 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 approximated 85% 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 4, 2015, the board of directors announced a continuation of the $0.80 indicated annual dividend rate per share for fiscal 2016. We paid dividends of $0.80 per share in fiscal 2015, $0.79 per share in fiscal 2014 and $0.76 per share in fiscal 2013.

As of September 30, 2015, there were approximately 800 holders of record and approximately 16,500 beneficial owners of our common shares.

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ITEM 6.

SELECTED FINANCIAL DATA

Incorporated by reference from inside front cover of the Annual Report to Shareholders for 2015.

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 17 through 26 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:

Fourth Quarter

Net earnings for the fourth quarter of fiscal 2015 increased 3% to $8,467, or $0.20 per diluted share, from net earnings for the fourth quarter of fiscal 2014 of $8,182, or $0.20 per diluted share. Consolidated revenues for the fourth quarter of fiscal 2015 increased $376, or 1%, to $47,068 compared to the fourth quarter of fiscal 2014; increasing 4% on a constant-currency basis.

Included within the fourth quarter 2015 results were revenues from our ***illumi****gene*® molecular platform of products totaling $10,215, representing a 12% increase from the fiscal 2014 fourth quarter. Also contributing to the consolidated revenues increase were increased revenues in three of our diagnostic focus product families (foodborne, respiratory and women s health & STD) and our Life Science segment s molecular components business. Serving to partially offset these increases were decreased revenues in our *C. difficile* and *H. pylori* focus product families and our Life Science segment s immunoassay components business.

Revenues for the Diagnostics segment for the fourth quarter of fiscal 2015 increased 1% compared to the fourth quarter of fiscal 2014 (3% on a constant-currency basis), reflecting the following for each of our focus product families: 6% growth in our foodborne products, 39% in our women s health & STD products, 42% growth in our respiratory products, 5% decline in our *H. pylori* products and 17% decline in our *C. difficile* products. As it relates to our respiratory products, the growth was driven by several products in both our molecular and immunoassay categories. Our molecular products (***illumi****gene* Group A Strep, ***illumi****gene* Mycoplasma and ***illumi****gene* Pertussis) experienced volume growth from new assay placements. Our immunoassay products (influenza and Mycoplasma) experienced growth in distribution channels. With growth in its molecular components business and a decline in its immunoassay components business, revenues of our Life Science segment were flat in the fourth quarter of fiscal 2015 compared to the fourth quarter of fiscal 2014; increasing 4% on a constant-currency basis.

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Fiscal Year

Net earnings for fiscal 2015 increased 2% to $35,540, or $0.85 per diluted share, from net earnings for fiscal 2014 of $34,743, or $0.83 per diluted share.

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

- By Disease Family (Diagnostics only)

Revenue Overview- By Reportable Segment & Geographic Region

Our reportable segments are Diagnostics and Life Science. 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). 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. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

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 the timing and nature of arrangements for contract services work, which may have longer production cycles than bioresearch reagents and bulk antigens and antibodies, as well as 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.

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

	2015	2014	2013	2015 vs. 2014 Inc (Dec)	2014 vs. 2013 Inc (Dec)
Diagnostics-					
Americas	$ 123,366	$ 114,754	$ 116,509	8%	(2)%
EMEA	19,135	21,807	21,378	(12)%	2%
ROW	3,613	4,939	6,742	(27)%	(27)%
Total Diagnostics	146,114	141,500	144,629	3 %	(2)%
Life Science-					
Americas	22,363	19,040	17,688	17%	8 %
EMEA	17,845	20,005	18,721	(11)%	7 %
ROW	8,508	8,287	7,648	3%	8 %
Total Life Science	48,716	47,332	44,057	3%	7 %
Consolidated	$ 194,830	$ 188,832	$ 188,686	3%	%
% of total revenues-					
Diagnostics	75%	75%	77%		
Life Science	25%	25%	23%		
Total	100%	100%	100%		
Ex-Americas	25%	29%	29%		

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 ***illum****igene* platform

2) Immunoassay tests on multiple technology platforms

Life Science

1) Molecular components

2) Immunoassay components

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

	2015	2014	2013	2015 vs. 2014 Inc (Dec)	2014 vs. 2013 Inc (Dec)
Diagnostics-					
Molecular tests	$ 40,880	$ 36,981	$ 33,597	11%	10%
Immunoassay tests	105,234	104,519	111,032	1%	(6)%
Total Diagnostics	$ 146,114	$ 141,500	$ 144,629	3%	(2)%
Life Science-					
Molecular components	$ 20,601	$ 20,824	$ 18,777	(1)%	11%
Immunoassay components	28,115	26,508	25,280	6%	5%
Total Life Science	$ 48,716	$ 47,332	$ 44,057	3%	7%
% of Diagnostics revenues-					
Molecular tests	28%	26%	23%		
Immunoassay tests	72%	74%	77%		
Total Diagnostics	100%	100%	100%		
% of Life Science revenues-					
Molecular components	42%	44%	43%		
Immunoassay components	58%	56%	57%		
Total Life Science	100%	100%	100%		

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

Diagnostics Products

illumi*gene Molecular Platform Products*

During fiscal 2015, revenues from our ***illumi****gene* molecular platform of products totaled $40,880, representing an 11% increase from the fiscal 2014. We have approximately 1,465 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 over 400 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, ***illumi****gene*. This platform now has the following commercialized tests:

1. ***illumi****gene*® *C. difficile* commercialized in August 2010

2. ***illumi***gene® Group B Streptococcus (Group B Strep or GBS) commercialized in December 2011

3. ***illumi***gene® Group A Streptococcus (Group A Strep) commercialized in September 2012

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4. ***illumi***gene® Mycoplasma (M. pneumonia; walking pneumonia) commercialized in June 2013

5. ***illumi***gene® Bordetella pertussis (whooping cough) commercialized in March 2014

6. ***illumi***gene® Chlamydia trachomatis commercialized outside of U.S. in February 2015

7. ***illumi***gene® Neisseria gonorrhea commercialized outside of U.S. in February 2015

8. ***illumi****gene*® HSV 1&2 (Herpes Simplex Virus Type 1 & Type 2) commercialized outside of U.S. in May 2015; commercialized in U.S. in July 2015

We have several additional ***illumi****gene* tests in development, including bloodborne pathogens that are the causative agents for malaria. We have a robust pipeline of ***illumi****gene* opportunities and continue to add new assays to our ***illumi****gene* platform menu.

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, ***illumi****gene* platform, with its expanding menu, requires no expensive equipment purchase and little to no maintenance cost. We believe these features, along with its small footprint and the performance of the ***illumi****gene* assays, make ***illumi****gene* an attractive molecular platform to any size hospital or physician office laboratory that runs moderately-complex tests.

Immunoassay Products

Revenues from our Diagnostics segment s immunoassay products increased 1% in fiscal 2015, following a 6% decrease in fiscal 2014. As described in the product discussions below, the current year increase results primarily from the revenue growth of our foodborne and *H. pylori* products, partially offset by the decline in revenues from our *C. difficile* and respiratory immunoassay products.

Life Science Products

During fiscal 2015, revenues from our Life Science segment increased 3%, with revenues from molecular components sales decreasing 1% from fiscal 2014 and revenues from immunoassay components sales increasing 6%. Life Science segment revenues increased 7% in fiscal 2014, with revenues from molecular component sales increasing 11% over fiscal 2013 and revenues from immunoassay component sales increasing 5%. Our molecular components business growth was negatively impacted by the movement in currency exchange rates since fiscal 2014, with revenues increasing 6% on a constant-currency basis over fiscal 2014. Our Life Science segment continued to benefit from increased sales into China, with such sales totaling approximately $2,100 during fiscal 2015 (approximately $600 in the molecular components business and $1,500 in the immunoassay components business).

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Diagnostics Revenue Overview- By Disease Family

Revenues from our focus families (*C. difficile*, foodborne, *H. pylori*, respiratory and women s health & STD) comprised 79%, 77% and 77% of our Diagnostics segment s revenues during fiscal 2015, 2014 and 2013, respectively. Following is a discussion of the revenues generated by each product family:

C. difficile Products

During fiscal 2015, revenues for our *C. difficile* product family decreased 12% to $31,000. This followed a decrease of 12% in fiscal 2014. Our molecular products now represent approximately 80% of this product category. The *C. difficile* test market continues to be highly competitive, with over 10 suppliers in the United States, certain of which choose to compete solely on price. During fiscal 2015, the amount and rate of decline in constant-currency revenues has decreased. We believe this is due largely to the expansion of our ***illumi****gene* molecular platform menu having a positive effect on defending our *C. difficile* business.

Foodborne Products

Revenues for our foodborne products (Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*), all of which are immunoassay products, totaled $25,000 during fiscal 2015, an 8% increase from fiscal 2014 (9% in constant-currency). During fiscal 2014, this product line experienced a 3% decrease in revenues from the previous year. Revenues for our foodborne products on a quarterly basis (up 5% in the first quarter, up 27% in the second quarter, down 2% in the third quarter and up 6% in the fourth quarter) have been affected by distributor ordering patterns and our inside and field sales programs, which are designed to protect and expand our current customer base. We are continuing to re-emphasize the benefits of increased sensitivity and faster turnaround time versus culture methods in our marketing programs. The primary competition for our foodborne products is laboratory culture methods and an immunoassay EHEC shiga toxin test from one of our competitors. We believe that our test offers better workflow, less hands-on time and quicker results, in addition to being fully compliant with CDC-recommended testing methods.

H. pylori Products

During fiscal 2015, revenues from our *H. pylori* products, all of which are immunoassay products, increased 6% (10% in constant-currency) to $30,000, which followed a 7% increase during fiscal 2014. 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 to reference labs, whose buying patterns may not be consistent period to period.

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The patents for our *H. pylori* products are owned by us and expire in May 2016 in the U.S. and in 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase upon the expiration of these patents in 2016 and 2017 as we currently market the only FDA-cleared test 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 upon patent expiration, among other things, we are researching and experimenting with new products (e.g., detection of *H. pylori* on molecular platforms) and attempting to secure significant customers under long-term contracts. We are unable to provide any 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.

Respiratory Products

Total respiratory revenues from our Diagnostics segment increased 27% to $22,000 during fiscal 2015, following a 5% decrease in the revenues from such products in fiscal 2014. Growth was driven by several products in both our molecular and immunoassay categories. Our molecular products (***illumi****gene* Group A Strep, ***illumi****gene* Mycoplasma and ***illumi****gene* Pertussis) experienced volume growth from new assay placements. Our immunoassay products (influenza and Mycoplasma) experienced growth as a result of increases in Japanese orders of our Mycoplasma product and a large purchase by a distributor of influenza product in advance of the influenza season.

Women s Health & STD Products

During fiscal 2015, revenues from our women s health & STD products, all of which are molecular products, increased 20% to $7,000. This growth reflects our commercialization during fiscal 2015 of three ***illumi****gene* tests for sexually transmitted diseases (Chlamydia, Gonorrhea and HSV), along with revenue growth for our ***illumi****gene* Group B Strep product, which was introduced to the market in December 2011.

Foreign Currency

During fiscal 2015, currency exchange had an approximate $4,700 unfavorable impact on revenues; $3,200 within the Diagnostics segment and $1,500 within the Life Science segment. This compares to currency exchange rates having an approximate $850 favorable impact on revenues in fiscal 2014; $600 favorable within the Diagnostics segment and $250 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 material during fiscal 2015, 2014 or 2013.

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Significant Customers

Two U.S. distributors accounted for 37%, 36% and 42% of our Diagnostics segment s total revenues for fiscal 2015, 2014 and 2013, respectively. These revenues represented 28%, 27% and 32% of consolidated revenues for fiscal 2015, 2014 and 2013, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 16%, 16% and 17% of the segment s total revenues for fiscal 2015, 2014 and 2013, respectively. These revenues represented 4% of our consolidated revenues for each of fiscal 2015, 2014 and 2013.

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 2015, 2014 and 2013, the Company recorded approximately $1,900, $1,750 and $1,300, respectively, of medical device tax expense, which is reflected as a component of cost of sales in the accompanying Consolidated Statements of Operations.

Gross Profit:

	2015	2014	2013	2015 vs. 2014 Inc (Dec)	2014 vs. 2013 Inc (Dec)
Gross Profit	$ 121,882	$ 117,243	$ 121,044	4%	(3)%
Gross Profit Margin	63%	62%	64%	1 point	-2 points

The overall gross profit margin increase during fiscal 2015 primarily results from 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. The overall decrease in the gross profit margin from fiscal 2013 to fiscal 2014 reflects the combined effects of (i) mix of revenues from the Company s segments; (ii) mix of products sold; (iii) declines in pricing on selected products; (iv) unfavorable manufacturing facility overhead absorption; and (v) the medical device tax, which did not exist during the first quarter of fiscal 2013.

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, proficiency panels, and contract research and development, and contract manufacturing services. Product revenue mix shifts, in the normal course of business, can cause the consolidated gross profit margin to fluctuate by several points.

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Operating Expenses:

	Research & Development	Selling & Marketing	General & Administrative	Total Operating Expenses
2013 Expenses	**$ 10,787**	**$ 22,424**	**$ 30,519**	**$ 63,730**
% of Revenues	6%	12%	16%	34%
Fiscal 2014 Increases (Decreases):				
Diagnostics	1,701	1,289	(2,036)	954
Life Science	64	1,197	(1,094)	167
2014 Expenses	**$ 12,552**	**$ 24,910**	**$ 27,389**	**$ 64,851**
% of Revenues	7%	13%	15%	34%
% Increase (Decrease)	16%	11%	(10%)	2%
Fiscal 2015 Increases (Decreases):				
Diagnostics	(306)	730	745	1,169
Life Science	359	(39)	(518)	(198)
2015 Expenses	**$ 12,605**	**$ 25,601**	**$ 27,616**	**$ 65,822**
% of Revenues	6%	13%	14%	34%
% Increase		3%	1%	1%

Total operating expenses increased during both fiscal 2015 and fiscal 2014, while remaining consistent as a percentage of consolidated revenues. Fiscal 2015 expenses primarily reflect the combined net effects of our (i) ongoing efforts to control spending in each of our segments; and (ii) favorable effects of currency rates.

During fiscal 2014, the increase in operating expenses resulted in large part from the combined net effects of our (i) ongoing efforts to control spending in each of our segments, while investing the necessary resources in our strategic areas of growth, including increased investment in Research & Development for our molecular platform products and increased investment in Sales and Marketing personnel and programs; and (ii) decreased incentive compensation compared to fiscal 2013 in light of the decline in corporate-wide operating profits.

Operating expenses for the Diagnostics segment increased $1,169 for fiscal 2015 compared to fiscal 2014, and increased $954 for fiscal 2014 compared to fiscal 2013. These overall increases result largely from the combined effects of (i) currency exchange rates (decrease of $1,100 for fiscal 2015 and increase of $200 for fiscal 2014); and (ii) the following:

Fiscal 2015

Selling & Marketing

Increase in personnel costs resulting from increased Sales and Marketing headcount, and increased sales commission payments made in connection with increased sales levels.

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General & Administrative

Increase in legal spending over the prior year, largely related to a foreign distributor matter, partially offset by a decrease in various personnel related costs resulting in part from the death of our Executive Chairman during the fourth quarter of fiscal 2014.

Fiscal 2014

Research & Development

Overall increase in spending on new product development activities, related primarily to the previously noted products for our ***illumi****gene* molecular platform, as well as immunoassay products in development.

Selling & Marketing

Addition of field sales force and other personnel, including the filling of open territorial positions, along with increased product sample expense.

General & Administrative

A decrease in bonus expense as a result of the previously noted decline in corporate-wide operating profits, partially offset by an approximate $1,100 increase in stock-based compensation including $429 of stock-based compensation expense related to the accelerated vesting of certain stock-based awards held by our Executive Chairman at the time of his death in the fourth quarter of fiscal 2014, and other less significant general operating expense increases.

The amount of stock-based compensation expense reported for fiscal 2015, 2014 and 2013 was $3,324, $3,557 and $2,502, respectively. During fiscal 2012, we granted restricted share units and options to certain executive management employees to reward them for meeting Company revenue targets in advance of planned expectations. These awards could only be earned if specified cumulative revenue thresholds were achieved, with the three measurement dates for ratably earning one-third of the grant being (i) the 21-month period ended June 30, 2013; (ii) the 33-month period ended June 30, 2014; and (iii) the 45-month period ended June 30, 2015. With the exception of the final tranche of these awards being held by our Executive Chairman at the time of his death in the fourth quarter of fiscal 2014, no expense was recognized for these restricted share units and options, and as a result of none of the cumulative thresholds being met, all of these restricted share units and options granted have been cancelled.

During fiscal 2013 through fiscal 2015, 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.

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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) restricted share units to be earned only if specified revenue and earnings per share targets were achieved for fiscal 2015; 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 have been earned and the related compensation expense was recorded in fiscal 2015.

Operating Income

Operating income increased 7% and decreased 9% in fiscal 2015 and 2014, respectively, as a result of the factors discussed above.

Other Income and Expense

In fiscal 2015, other income and expense included $1,100 of foreign currency losses, which related primarily to a foreign subsidiary intercompany loan being marked-to-market. This compares to $300 of foreign currency losses in fiscal 2014.

Income Taxes

The effective rate for income taxes was 35%, 33% and 34% for fiscal 2015, 2014 and 2013, respectively. Our effective tax rate has ranged from 33% to 35% over the last three fiscal years as a result of (i) increased apportionments in certain state taxing jurisdictions (2015); (ii) reversal of valuation allowances on net operating loss benefits in certain non-U.S. jurisdictions (2014); (iii) net benefits on dividends from a non-U.S. subsidiary (2014); and (iv) the timing of renewal/expiration of the research and experimentation credit in the U.S. during this three year period.

In September 2013, the Internal Revenue Service issued Treasury Decision 9636, which enacted final tax regulations regarding the capitalization and expensing of amounts paid to acquire, produce or improve tangible property. The regulations also include guidance regarding the retirement of depreciable property. Our adoption of these regulations on October 1, 2014 did not have a significant impact on the Company s consolidated results of operations, cash flows or financial position.

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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 2015, 2014 or 2013.

Liquidity and Capital Resources:

Liquidity

Our cash flow and financing requirements are determined by analyses of operating and capital spending budgets, 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. Our investment portfolio presently consists of overnight repurchase agreements.

We have an investment policy that guides the holdings of our investment portfolio. 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.

We do not expect current conditions in the financial markets, or overall economic 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 credit facility. Approximately $1,600 and $2,700 of our accounts receivable at September 30, 2015 and September 30, 2014, respectively, was due from Italian hospital customers whose funding ultimately comes from the Italian government. In addition, the amount of our annual revenues in the country of Greece and the corresponding amount of customer receivables outstanding at any point in time is not significant, and therefore, we do not expect any meaningful impact from the financial crisis in the country of Greece. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets remains tight 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.

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Fluctuations in overall stock market valuations may raise questions as to the potential impairment of goodwill and other long-lived assets. Our annual goodwill impairment review takes place as of June 30th each year, and is performed at the reporting unit level. There have been no impairments from these annual reviews. As of September 30, 2015, our stock price was $17.10 per share, compared to our book value per share of $3.96 as of September 30, 2015. This relationship, stock price trading at a 4.3x 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.

During fiscal 2015, our overall cash position increased by approximately $7,000 to $50,000 at September 30, 2015. Net cash provided by operating activities totaled $42,809 for fiscal 2015, a 12% increase over the $38,262 provided during fiscal 2014. This $4,547 increase results in large part from approximately $5,500 of incentive bonus payments related to fiscal 2013 being made in the first quarter of fiscal 2014, with no such payments having been made during fiscal 2015.

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 twelve months. During fiscal 2015, the per share amount of our cash dividend paid represented 94% of our diluted earnings per share, exceeding our long-standing policy of establishing a cash dividend payout ratio 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 approximated 85% of cumulative net earnings during this timeframe.

Capital Resources

We have a $30,000 credit facility with a commercial bank which expires April 21, 2018. As of November 23, 2015, 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 facility during fiscal 2015, 2014 or 2013.

Our capital expenditures are estimated to range between approximately $3,000 to $4,000 for fiscal 2016, with the actual amount depending 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 credit facility discussed above.

During June 2015, we sold the land and building related to our former Life Science facility in Saco, Maine. Net proceeds from the sale were approximately $1,138.

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Known Contractual Obligations:

Known contractual obligations and their related due dates were as follows as of September 30, 2015:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases (1)	$ 4,143	$ 1,632	$ 2,422	$ 89	$
Purchase obligations (2)	8,463	8,226	237		
Uncertain income tax positions liability and interest (3)	275	275			
Total	$ 12,881	$ 10,133	$ 2,659	$ 89	$

(1) Meridian and its subsidiaries are lessees of (i) office and warehouse buildings in Ohio, Massachusetts, Florida, Australia, Belgium, France, Holland, 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) Meridian s purchase obligations are primarily outstanding purchase orders for inventory and service items. These contractual commitments are not in excess of expected production requirements over the next twelve months.

(3) As of September 30, 2015, our liabilities for uncertain tax positions and related interest and penalties were $238 and $37, 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 (1% to 14%). Meridian expects that payments under these agreements will amount to approximately $4,000 in fiscal 2016. These royalty payments primarily relate to the Diagnostics segment.

Off-Balance Sheet Arrangements

Except for the operating lease arrangements noted above, we have no 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 believe appropriate.

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Concentration of Customers/Products Risk

Our Diagnostics segment s revenues from sales through two U.S. distributors were 37% of the segment s total revenues or 28% of consolidated revenues for fiscal 2015. Our *C. difficile,* foodborne, *H. pylori*, respiratory and women s health & STD product families accounted for 79% of our Diagnostics segment s third-party revenues during fiscal 2015, and 59% of our fiscal 2015 consolidated revenues.

Our Life Science segment s revenues from sales of purified antigens and reagents to two diagnostics manufacturing customers were 16% of the segment s total revenues for fiscal 2015 or 4% of our fiscal 2015 consolidated revenues. Our Life Science segment has four other significant customers who purchase antigens, antibodies and reagents, which together comprised 10% of the segment s total revenues for fiscal 2015.

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 polices 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 certain distributors under local contracts. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, estimates of inventories of certain of our products held 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 ***illumi****gene* molecular test system. This system includes an instrument, instrument accessories and test kits. In markets where the test system is sold via multiple deliverable arrangements, the cost of the instrument and instrument accessories is deferred upon placement at a customer and amortized on a straight-line basis into cost of sales over the expected utilization period, generally three years.

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

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

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

Life Science revenue for contract services may come from research and development services or manufacturing services, including process development work, or a combination of both. Revenue is recognized based on each of the deliverables in a given arrangement having distinct and separate customer pricing. Depending on the nature of the arrangement, revenue is recognized as services are performed and billed, upon completion and acceptance by the customer, or upon delivery of product and acceptance by the customer.

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.

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Intangible Assets

Our intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include customer lists, supply agreements, manufacturing technologies, patents, licenses and trade names. 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 2015, 2014 or 2013 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.

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.

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Our deferred tax assets include net operating loss carryforwards in foreign jurisdictions. 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.

In September 2013, the Internal Revenue Service issued Treasury Decision 9636, which enacted final tax regulations regarding the capitalization and expensing of amounts paid to acquire, produce or improve tangible property. The regulations also include guidance regarding the retirement of depreciable property. Our adoption of these regulations on October 1, 2014 did not have a significant impact on the Company s consolidated results of operations, cash flows or financial position.

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 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 September 2015, the FASB issued ASU No. 2015-16, *Business Combinations Simplifying the Accounting for Measurement-Period Adjustments*, which amends currently-existing U.S. GAAP business combinations guidance. This guidance, which removes the requirement to retroactively apply adjustments identified during the measurement period, will be effective for the Company beginning October 1, 2016 (fiscal 2017). We do not expect adoption of this guidance to have a significant impact on the Company s consolidated results of operations, cash flows or financial position.

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ITEM 7A.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

See Market Risk Exposure and Capital Resources under Item 7 above.

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ITEM 8.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

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

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Management s Report on Internal Control over Financial Reporting

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

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

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

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting 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, 2015.

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 30, 2015

/s/ Melissa A. Lueke
Melissa A. Lueke
Executive Vice President and
Chief Financial Officer
November 30, 2015

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Meridian Bioscience, Inc.

We have audited the accompanying consolidated balance sheets of Meridian Bioscience, Inc. (an Ohio corporation) and subsidiaries (the Company) as of September 30, 2015 and 2014, 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, 2015. Our audits of the basic consolidated financial statements included the financial statement schedule listed in the index and appearing under Schedule No. II. We also have audited the Company s internal control over financial reporting as of September 30, 2015, 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 these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and financial statement schedule and an opinion on the Company s internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

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, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2015 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. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2015, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by COSO.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio

November 30, 2015

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

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2015**	2014	2013
Net Revenues	**$ 194,830**	$ 188,832	$ 188,686
Cost of Sales	**72,948**	71,589	67,642
Gross Profit	**121,882**	117,243	121,044
Operating Expenses:			
Research and development	**12,605**	12,552	10,787
Selling and marketing	**25,601**	24,910	22,424
General and administrative	**27,616**	27,389	30,519
Total operating expenses	**65,822**	64,851	63,730
Operating Income	**56,060**	52,392	57,314
Other Income (Expense):			
Interest income	**23**	25	44
Other, net	**(1,020)**	(309)	4
Total other income (expense)	**(997)**	(284)	48
Earnings Before Income Taxes	**55,063**	52,108	57,362
Income Tax Provision	**19,523**	17,365	19,330
Net Earnings	**$ 35,540**	$ 34,743	$ 38,032
Earnings Per Share Data:			
Basic earnings per common share	**$ 0.85**	$ 0.84	$ 0.92
Diluted earnings per common share	**$ 0.85**	$ 0.83	$ 0.91
Common shares used for basic earnings per common share	**41,659**	41,455	41,226
Effect of dilutive stock options and restricted shares and units	**353**	458	669
Common shares used for diluted earnings per common share	**42,012**	41,913	41,895
Dividends declared per common share	**$ 0.80**	$ 0.79	$ 0.76
Anti-dilutive Securities:			
Common share options and restricted shares and units	**551**	272	254

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

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2015**	2014	2013
Net Earnings	**$ 35,540**	$ 34,743	$ 38,032
Foreign currency translation adjustment	**(2,639)**	(436)	650
Comprehensive Income	**$ 32,901**	$ 34,307	$ 38,682

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

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CONSOLIDATED STATEMENTS OF CASH FLOWS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	**2015**	2014	2013
Cash Flows From Operating Activities			
Net earnings	**$ 35,540**	$ 34,743	$ 38,032
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	**3,470**	3,523	3,354
Amortization of intangible assets	**1,748**	2,039	2,269
Amortization of deferred ***illumi****gene* instrument costs	**1,391**	1,702	1,529
Stock-based compensation	**3,324**	3,557	2,502
Deferred income taxes	**(122)**	(140)	(1,823)
Loss on disposition and write-down of fixed assets and other assets	**94**	6	30
Change in current assets	**(6,079)**	(1,528)	(3,486)
Change in current liabilities	**3,238**	(5,996)	2,669
Other, net	**205**	356	(640)
Net cash provided by operating activities	**42,809**	38,262	44,436
Cash Flows From Investing Activities			
Purchases of property, plant and equipment	**(4,613)**	(5,306)	(3,234)
Proceeds from sale of building	**1,138**		
Purchases of intangibles and other assets	**(151)**	(1,696)	(43)
Net cash used for investing activities	**(3,626)**	(7,002)	(3,277)
Cash Flows From Financing Activities			
Dividends paid	**(33,357)**	(32,762)	(31,354)
Proceeds and tax benefits from exercises of stock options	**2,614**	1,009	2,752
Net cash used for financing activities	**(30,743)**	(31,753)	(28,602)
Effect of Exchange Rate Changes on Cash and Equivalents	**(1,514)**	(742)	132
Net Increase (Decrease) in Cash and Equivalents	**6,926**	(1,235)	12,689
Cash and Equivalents at Beginning of Period	**43,047**	44,282	31,593
Cash and Equivalents at End of Period	**$ 49,973**	$ 43,047	$ 44,282
Supplemental Cash Flow Information			
Cash paid for income taxes	**$ 20,168**	$ 19,952	$ 20,093

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

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CONSOLIDATED BALANCE SHEETS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	**2015**	2014
Assets		
Current Assets:		
Cash and equivalents	**$ 49,973**	$ 43,047
Accounts receivable, less allowances of $248 in 2015 and $272 in 2014	**26,254**	23,232
Inventories	**35,817**	35,495
Prepaid expenses and other current assets	**7,378**	7,058
Deferred income taxes	**3,431**	3,916
Total current assets	**122,853**	112,748
Property, Plant and Equipment, at Cost:		
Land	**986**	1,173
Buildings and improvements	**30,056**	29,146
Machinery, equipment and furniture	**41,541**	40,192
Construction in progress	**1,139**	652
Subtotal	**73,722**	71,163
Less: accumulated depreciation and amortization	**46,230**	43,553
Net property, plant and equipment	**27,492**	27,610
Other Assets:		
Goodwill	**22,349**	23,193
Other intangible assets, net	**5,931**	7,813
Restricted cash	**1,000**	1,000
Deferred ***illumi****gene* instrument costs, net	**1,750**	2,740
Deferred income taxes	**1,523**	1,483
Other assets	**384**	342
Total other assets	**32,937**	36,571
Total assets	**$ 183,282**	$ 176,929

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

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CONSOLIDATED BALANCE SHEETS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	**2015**	2014
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	**$ 6,646**	$ 4,966
Accrued employee compensation costs	**5,132**	4,761
Other accrued expenses	**2,587**	3,149
Income taxes payable	**886**	859
Total current liabilities	**15,251**	13,735
Non-Current Liabilities	**2,158**	2,165
Commitments and Contingencies		
Shareholders Equity:		
Preferred stock, no par value; 1,000,000 shares authorized; none issued		
Common shares, no par value; 71,000,000 shares authorized; 41,838,399 and 41,622,216 issued, respectively		
Additional paid-in capital	**117,151**	111,851
Retained earnings	**51,052**	48,869
Accumulated other comprehensive income (loss)	**(2,330)**	309
Total shareholders equity	**165,873**	161,029
Total liabilities and shareholders equity	**$ 183,282**	$ 176,929

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

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CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (dollars and shares in thousands, except per share data)

Meridian Bioscience, Inc. and Subsidiaries

	Common Shares Issued	Additional Paid-in Capital	Retained Earnings	Accum Other Comp Income (Loss)	Total
Balance at September 30, 2012	41,284	$ 102,443	$ 40,210	$ 95	$ 142,748
Cash dividends paid - $0.76 per share			(31,354)		(31,354)
Exercise of stock options	226	2,564			2,564
Conversion of restricted stock units	8				
Stock compensation expense		2,405			2,405
Net earnings			38,032		38,032
Foreign currency translation adjustment				650	650
Balance at September 30, 2013	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)
Balance at September 30, 2014	41,622	111,851	48,869	309	161,029
Cash dividends paid - $0.80 per share			(33,357)		(33,357)
Exercise of stock options	187	1,976			1,976
Conversion of restricted stock units	29				
Stock compensation expense		3,324			3,324
Net earnings			35,540		35,540
Foreign currency translation adjustment				(2,639)	(2,639)
Balance at September 30, 2015	41,838	$ 117,151	$ 51,052	$ (2,330)	$ 165,873

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Meridian Bioscience, Inc. and Subsidiaries

(dollars and shares in thousands, except per share data)

(1) Summary of Significant Accounting Policies

(a) Nature of Business - Meridian is a fully-integrated life science company whose principal businesses are (i) the development, manufacture and distribution of diagnostic test kits primarily for certain gastrointestinal, viral, respiratory and parasitic infectious diseases; (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; and (iii) the contract development and manufacture of proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

(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. 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.

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(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 or better, and long-term ratings of at least A, Baa1 and A or better, 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:

	September 30, 2015		September 30, 2014	
	Cash and Equivalents	**Other**	Cash and Equivalents	Other
Overnight repurchase agreements	**$ 25,436**	**$**	$ 26,407	$
Cash on hand				
Restricted		**1,000**		1,000
Unrestricted	**24,537**		16,640	
Total	**$ 49,973**	**$ 1,000**	$ 43,047	$ 1,000

(f) Inventories - Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out (FIFO) basis. ***illumi****gene*® instruments are carried in inventory until customer placement, at which time they are transferred to deferred ***illumi****gene* instrument costs, unless sold outright.

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 $2,456 and $2,942 at September 30, 2015 and 2014, 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 of property, plant and equipment, 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

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(h) Intangible Assets - Goodwill is subject to an annual impairment review (or more frequently if impairment indicators arise) by first performing a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. In the event that a 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. Goodwill is considered impaired if the carrying value of the reporting unit exceeds its fair value. We perform our annual impairment review as of June 30, the end of our third fiscal quarter. We have no intangible assets with indefinite lives other than goodwill. There have been no impairments from these analyses for fiscal 2015, 2014 or 2013.

The change in goodwill was a decrease of $844 in fiscal 2015 and an increase of $78 in fiscal 2014. Both years reflect the effect of the Life Science segment s Bioline Group and the currency translation adjustments thereon.

A summary of Meridian s acquired intangible assets subject to amortization, as of September 30, 2015 and 2014 is as follows.

	2015		2014	
As of September 30,	**Gross Carrying Value**	**Accum. Amort.**	Gross Carrying Value	Accum. Amort.
Manufacturing technologies, core products and cell lines	**$ 11,582**	**$ 10,906**	$ 11,685	$ 10,568
Trademarks, licenses and patents	**6,410**	**3,296**	6,463	2,766
Customer lists and supply agreements	**12,105**	**9,964**	12,378	9,379
	$ 30,097	**$ 24,166**	$ 30,526	$ 22,713

During fiscal 2014, we acquired the remaining licensing rights related to patents that are part of our ***illumi****gene* molecular technology for $1,638. These rights are being amortized over a weighted average period of approximately 8.5 years.

The actual aggregate amortization expense for these intangible assets for fiscal 2015, 2014 and 2013 was $1,748, $2,039 and $2,269, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2016 - $1,411, fiscal 2017 - $1,116, fiscal 2018 - $1,095, fiscal 2019 - $1,054 and fiscal 2020 - $880.

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 test.

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

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

If actual cash flows are less favorable than projections, this could trigger impairment of intangible assets and other long-lived assets. If impairment were to occur, this would negatively affect overall results of operations. No triggering events have been identified by the Company for fiscal 2015, 2014 or 2013.

(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 certain distributors under local contracts. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, estimates of inventories of certain of our products held 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 $5,581 at September 30, 2015 and $4,220 at September 30, 2014, and have been netted against accounts receivable. Revenue for our Diagnostics segment includes revenue for our ***illumi****gene* molecular test system. This system includes an instrument, instrument accessories and test kits. In markets where the test system is sold via multiple deliverable arrangements, the cost of the instrument and instrument accessories is deferred upon placement at a customer and amortized on a straight-line basis into cost of sales over the expected utilization period, generally three years.

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

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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 ***illumi****gene* molecular test system is sold to independent distributors who inventory the instruments, instrument accessories and test kits for resale to end-users.

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

Life Science revenue for contract services may come from research and development services or manufacturing services, including process development work, or a combination of both. Revenue is recognized based on each of the deliverables in a given arrangement having distinct and separate customer pricing. Depending on the nature of the arrangement, revenue is recognized as services are performed and billed, upon completion and acceptance by the customer, or upon delivery of product and acceptance by the customer.

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

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

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

We account for uncertain tax positions using a benefit recognition model with a two-step approach: (i) a more-likely-than-not recognition criterion; and (ii) a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being ultimately realized upon ultimate settlement. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. We recognize accrued interest related to unrecognized tax benefits as a portion of our income tax provision in the consolidated statements of operations. See Note 4.

(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 5(b).

(m) Comprehensive Income (Loss) - Comprehensive income (loss) represents the net change in shareholders equity during a period from sources other than transactions with shareholders. As reflected in the accompanying consolidated statements of comprehensive income, our comprehensive income or loss is comprised of net earnings and foreign currency translation.

(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 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.

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

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(2) Inventories

Inventories are comprised of the following:

As of September 30,	**2015**	2014
Raw materials	**$ 7,095**	$ 5,674
Work-in-process	**10,096**	10,591
Finished goods - ***illumi****gene* instruments	**1,890**	1,710
Finished goods - kits and reagents	**16,736**	17,520
Total	**$ 35,817**	$ 35,495

(3) Bank Credit Arrangements

We have a $30,000 credit facility with a commercial bank, which expires in April 2018. This credit facility is collateralized by our business assets, except for those of non-U.S. subsidiaries, which totaled approximately $156,000 at September 30, 2015. There were no borrowings outstanding on this credit facility at September 30, 2015 or September 30, 2014. Available borrowings under this credit facility were $30,000 at September 30, 2015 and September 30, 2014. In connection with this bank credit facility, we are required to comply with financial covenants that limit the amount of debt obligations and require a minimum amount of tangible net worth. We are in compliance with all covenants. We are also required to maintain a cash compensating balance with the bank in the amount of $1,000, pursuant to this bank credit facility and are in compliance with this requirement.

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(4) Income Taxes

(a) Earnings before income taxes, and the related provision for income taxes for the years ended September 30, 2015, 2014 and 2013 were as follows:

Year Ended September 30,	**2015**	2014	2013
Domestic	**$ 50,653**	$ 48,350	$ 53,963
Foreign	**4,410**	3,758	3,399
Total earnings before income taxes	**$ 55,063**	$ 52,108	$ 57,362
Provision (credit) for income taxes -			
Federal -			
Current	**$ 16,152**	$ 15,021	$ 18,311
Temporary differences			
Fixed asset basis differences and depreciation	**50**	108	121
Intangible asset basis differences and amortization	**(421)**	(210)	(339)
Currently non-deductible expenses and reserves	**217**	50	(425)
Stock-based compensation	**126**	59	(282)
Tax credit carryforwards	**250**	225	(717)
Other, net	**19**	66	43
Subtotal	**16,393**	15,319	16,712
State and local	**2,236**	1,762	2,013
Foreign	**894**	284	605
Total income tax provision	**$ 19,523**	$ 17,365	$ 19,330

(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,	**2015**		2014		2013	
Computed income taxes at statutory rate	**$ 19,264**	**35.0 %**	$ 18,238	35.0 %	$ 20,078	35.0 %
Increase (decrease) in taxes resulting from -						
State and local income taxes	**1,365**	**2.5**	1,061	2.0	1,270	2.2
Net benefit on foreign dividend			(274)	(0.5)	(84)	(0.2)
Foreign tax rate differences	**(217)**	**(0.4)**	(430)	(0.8)	(18)	
Qualified domestic production incentives	**(1,197)**	**(2.2)**	(1,175)	(2.3)	(1,621)	(2.8)
Other, net	**308**	**0.6**	(55)	(0.1)	(295)	(0.5)
	$ 19,523	**35.5 %**	$ 17,365	33.3 %	$ 19,330	33.7 %

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

As of September 30,	**2015**	2014
Deferred tax assets -		
Valuation reserves and non-deductible expenses	**$ 1,931**	$ 1,984
Stock compensation expense not deductible	**3,221**	3,328
Net operating loss carryforwards	**348**	544
Tax credit carryforwards	**242**	492
Inventory basis differences	**1,186**	1,340
Other	8	8
Subtotal	**6,936**	7,696
Less valuation allowance	**(15)**	(8)
Deferred tax assets	**6,921**	7,688
Deferred tax liabilities -		
Fixed asset basis differences and depreciation	**(995)**	(951)
Intangible asset basis differences and amortization	**(972)**	(1,338)
Deferred tax liabilities	**(1,967)**	(2,289)
Net deferred tax assets	**$ 4,954**	$ 5,399

For income tax purposes, we have tax benefits related to operating loss carryforwards in the countries of Australia, Belgium and Singapore, which have no expiration date, on which we have recorded deferred tax assets. We also have tax benefits related to tax credit carryforwards in the U.S., which expire in fiscal 2022, on which we have recorded deferred tax assets.

The realization of deferred tax assets in foreign jurisdictions is dependent upon the generation of future taxable income in these countries. We have considered the levels of currently anticipated pre-tax income in foreign jurisdictions in assessing the required level of the deferred tax asset valuation allowance. 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 for foreign jurisdictions will be realized except for Singapore, for which a full valuation allowance has been recorded. The amount of the net deferred tax asset considered realizable in foreign jurisdictions, however, could be reduced in future years if estimates of future taxable income during the carryforward period are reduced.

Undistributed earnings reinvested indefinitely in our non-U.S. operations were approximately $10,000 and $8,000 at September 30, 2015 and September 30, 2014, respectively. U.S. deferred tax liabilities of approximately $1,800 and $1,300 on such earnings, after consideration of foreign tax credits, have not been recorded as of September 30, 2015 and September 30, 2014, respectively.

As described in Note 1, we utilize a comprehensive model for the recognition, measurement, presentation and disclosure of uncertain tax positions, assuming full knowledge of all relevant facts by the applicable tax authorities. The total amount of unrecognized tax benefits at September 30, 2015 and September 30, 2014 related to such positions was $275 and $372, 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 2015 we decreased our tax provision by approximately $19 for such interest and penalties, while during fiscal 2014 they resulted in an approximate $26 increase in our tax provision. We had approximately $37 accrued for the payment of interest and penalties at September 30, 2015 compared to $56 accrued at September 30, 2014. The amount of our liability for uncertain tax positions expected to be paid or settled in the next 12 months is uncertain.

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

	2015	2014
Unrecognized income tax benefits beginning of year	**$ 372**	$ 208
Additions for tax positions related to the current year		11
Additions for tax positions of prior years	**9**	153
Reductions for tax positions of prior years	**(28)**	
Tax examination and other settlements	**(78)**	
Unrecognized income tax benefits at end of year	**$ 275**	$ 372

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 for fiscal 2012, fiscal 2013 and fiscal 2014. In countries outside the U.S., open tax years generally range from fiscal 2010 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.

(5) 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 50% 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 $1,567, $1,542 and $1,539, during fiscal 2015, 2014 and 2013, respectively.

(b) Stock-Based Compensation Plans - During fiscal 2015, 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). In addition, we have an Employee Stock Purchase Plan (the ESP Plan), which became effective October 1, 1997. Under the ESP Plan, we sell shares of stock to our full-time and part-time employees up to the number of shares equivalent to a 1% to 15% payroll deduction from an employee s base salary plus an additional 5% dollar match of this deduction by Meridian.

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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, 2015, we have granted 1,503 and 903 shares under the 2004 Plan and 2012 Plan, respectively, thereby resulting in a remaining authorized limit of 3,594 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 2012, we granted approximately 110 restricted share units (with a grant date fair value of $17.57 per share) and 1,035 options (with a weighted-average grant date fair value of $4.66 per option) to certain executive management employees to incentivize the achievement of Company revenue targets in advance of planned expectations. These awards could only be earned if specified cumulative revenue thresholds were achieved, with the three measurement dates for ratably earning one-third of the grant being (i) the 21-month period ended June 30, 2013; (ii) the 33-month period ended June 30, 2014; and (iii) the 45-month period ended June 30, 2015. With the exception of the final tranche of these awards being held by our Executive Chairman at the time of his death in the fourth quarter of fiscal 2014, no expense was recognized for these restricted share units and options, and as a result of none of the cumulative thresholds being met, these restricted share units and options have been cancelled.

During fiscal 2013, we granted approximately 204 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 2013. While dividend equivalents were paid on these units throughout fiscal 2013, the target for fiscal 2013 was not met and the performance-based portion of the restricted share units granted during fiscal 2013 have been cancelled.

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 have been cancelled.

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Similar to previous years, 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 have been 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.

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 440 restricted share units remain outstanding as of September 30, 2015, with a weighted-average grant date fair value of $19.76 per share, a weighted-average remaining vesting period of 1.68 years and an aggregate intrinsic value of $7,466. The weighted-average grant date fair value of the approximate 75 restricted shares and units that vested during fiscal 2015 was $22.90 per share.

The amount of stock-based compensation expense reported was $3,324, $3,557 and $2,502 in fiscal 2015, 2014 and 2013, respectively. The fiscal 2015 expense is comprised of $591 related to stock options and $2,733 related to restricted shares and units; the fiscal 2014 expense is comprised of $486 related to stock options and $3,071 related to restricted shares and units; and the fiscal 2013 expense is comprised of $336 related to stock options, $2,069 related to restricted shares and units, and $97 related to the granting of unrestricted common shares to two executive officers. The total income tax benefit recognized in the income statement for these stock-based compensation arrangements was $1,250, $1,185 and $850, for fiscal 2015, 2014 and 2013, respectively. As of September 30, 2015, we expect future stock compensation expense for unvested options and unvested restricted stock units to total $277 and $2,029, respectively, which will be recognized during fiscal years 2016 through 2019.

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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 2015, 2014 and 2013, we recorded $86, $108 and $93, respectively, in stock compensation expense to adjust estimated forfeiture rates to actual.

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

Year ended September 30,	**2015**	2014	2013
Risk-free interest rates	**2.07%**	1.80%	0.88%
Dividend yield	**3.7%**	3.5%	4.1%
Life of option	**6.33 yrs.**	6.29 yrs.	6.23 yrs.
Share price volatility	**33%**	33%	36%
Forfeitures (by employee group)	**0%-15%**	0%-14%	0%-10%

A summary of the status of our stock option plans at September 30, 2015 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	1,142	$ 19.11		
Grants	247	17.48		
Exercises	(187)	13.28		
Forfeitures	(12)	20.11		
Cancellations	(374)	17.78		
Outstanding end of period	816	$ 20.54	4.86	$ 341
Exercisable end of period	677	$ 20.98	4.02	$ 308

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A summary of the status of our nonvested options as of September 30, 2015, and changes during the year ended September 30, 2015, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested beginning of period	360	$ 4.78
Granted	247	3.95
Vested	(131)	4.36
Forfeitures	(1)	5.03
Cancelled	(336)	4.58
Nonvested end of period	139	$ 4.18

The weighted average grant-date fair value of options granted was $3.95, $5.48 and $4.19 for fiscal 2015, 2014 and 2013, respectively. The total intrinsic value of options exercised was $850, $1,110 and $2,483, for fiscal 2015, 2014 and 2013, respectively. The total grant-date fair value of options that vested during fiscal 2015, 2014 and 2013 was $571, $701 and $712, respectively.

Cash received from options exercised was $2,478, $567 and $2,258 for fiscal 2015, 2014 and 2013, respectively. Tax (expense) benefits recorded to additional paid-in capital from option exercises totaled ($502), $315 and $306 for fiscal 2015, 2014 and 2013, respectively.

(6) Non-Current Liabilities

The Company and its Chairman and Chief Executive Officer are parties to an employment agreement and a supplemental benefit agreement, under which we are obligated to provide certain post-retirement benefits. These obligations total $1,399 and $1,247 at September 30, 2015 and September 30, 2014, 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 $668 and $831 at September 30, 2015 and September 30, 2014, respectively.

(7) Reportable Segments and Major Concentration Data

Our reportable segments are Diagnostics and Life Science, with segmentation between the two determined based upon the nature of products and the types of customers. The Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits 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. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and

other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

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

Year Ended September 30,	**2015**		2014		2013	
Customer A	**$ 29,155**	**(15)%**	$ 28,278	(15)%	$ 35,082	(19)%
Customer B	**$ 25,276**	**(13)%**	$ 22,780	(12)%	$ 25,457	(13)%

Accounts receivable from these two Diagnostics distributor customers accounted for 21% and 15% of consolidated accounts receivable at September 30, 2015 and September 30, 2014, respectively. The Company s international revenues totaled $52,313, $57,051, and $56,224 in fiscal years 2015, 2014 and 2013, respectively. Our diagnostic focus product families *C. difficile,* foodborne, *H. pylori*, respiratory and women s health & STD accounted for 59%, 58% and 59% of consolidated net revenues in fiscal 2015, 2014 and 2013, respectively. We currently sole-source from a U.S. manufacturer the ***illumi****pro*-10 instrument on which our ***illumi****gene* molecular testing platform operates. Additionally, two of our foodborne products sourced from another vendor accounted for 14% of third-party revenues for our Diagnostics segment in each of fiscal 2015, 2014 and 2013.

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,	**2015**	2014	2013
United States	**$ 120,599**	$ 112,917	$ 114,935
Italy	**7,090**	8,469	7,427
Japan	**2,603**	2,097	3,937
United Kingdom	**1,964**	1,942	2,141
France	**1,603**	1,841	1,936
Holland	**1,326**	1,613	1,764
Canada	**1,315**	1,359	1,248
Belgium	**1,289**	1,241	1,285
Other countries	**8,325**	10,021	9,956
Total Diagnostics	**$ 146,114**	$ 141,500	$ 144,629

Year Ended September 30,	**2015**	2014	2013
United States	**$ 21,918**	$ 18,864	$ 17,527
United Kingdom	**5,782**	5,647	5,590
Germany	**5,699**	7,232	6,465
Australia	**3,590**	4,063	3,454
China	**2,107**	776	557
France	**2,026**	1,633	1,440
Other countries	**7,594**	9,117	9,024
Total Life Science	**$ 48,716**	$ 47,332	$ 44,057

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Identifiable assets for our Italian distribution organization were $8,497 and $10,861 at September 30, 2015 and 2014, respectively. At September 30, 2015, identifiable assets for the Bioline Group s operations in the U.K., Germany and Australia totaled approximately $15,647, $6,909 and $3,891, respectively; and totaled $14,985, $7,713 and $4,171, respectively, at September 30, 2014.

Segment information for the years ended September 30, 2015, 2014 and 2013 is as follows:

	Diagnostics	Life Science	Elim (1)	Total
Fiscal Year 2015 -				
Net revenues -				
Third-party	**$ 146,114**	**$ 48,716**	**$**	**$ 194,830**
Inter-segment	**334**	**1,300**	**(1,634)**	
Operating income	**43,305**	**12,888**	**(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**
Fiscal Year 2014 -				
Net revenues				
Third-party	$ 141,500	$ 47,332	$	$ 188,832
Inter-segment	432	1,009	(1,441)	
Operating income	41,629	10,861	(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
Fiscal Year 2013 -				
Net revenues				
Third-party	$ 144,629	$ 44,057	$	$ 188,686
Inter-segment	533	1,223	(1,756)	
Operating income	46,735	10,627	(48)	57,314
Depreciation and amortization	4,328	2,824		7,152
Capital expenditures	2,031	1,203		3,234
Goodwill	1,250	21,865		23,115
Other intangible assets	1,561	6,496		8,057
Total assets	111,719	65,393	(364)	176,748

(1) Eliminations consist of intersegment transactions.

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A reconciliation of segment operating expenses to consolidated earnings before income taxes for the years ended September 30, 2015, 2014 and 2013 is as follows:

Year Ended September 30,	**2015**	2014	2013
Segment operating income	**$ 56,060**	$ 52,392	$ 57,314
Interest income	**23**	25	44
Other, net	**(1,020)**	(309)	4
Consolidated earnings before income taxes	**$ 55,063**	$ 52,108	$ 57,362

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

(8) 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 (1% to 14%). 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 $3,106, $3,482 and $3,611, respectively, for the fiscal years ended September 30, 2015, 2014 and 2013.

(b) Purchase Commitments - Excluding the operating lease commitments reflected in Note 8(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 $8,226 and $237 for fiscal 2016 and 2017, respectively. No purchase commitments have been made beyond fiscal 2017.

(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 $1,797, $1,951 and $1,744 for fiscal 2015, 2014 and 2013, respectively. Operating lease commitments for each of the five succeeding fiscal years are as follows: fiscal 2016 - $1,632, fiscal 2017 - $1,395, fiscal 2018 - $787, fiscal 2019 - $240, and fiscal 2020 - $89.

(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.

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(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, 2015 or September 30, 2014. 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.

(9) Quarterly Financial Data (Unaudited)

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

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

For the Quarter Ended in Fiscal 2014	December 31	March 31	June 30	September 30
Net revenues	$ 44,794	$ 50,134	$ 47,212	$ 46,692
Gross profit	28,007	31,593	29,242	28,401
Net earnings	7,426	10,300	8,835	8,182
Basic earnings per common share	0.18	0.25	0.21	0.20
Diluted earnings per common share	0.18	0.24	0.21	0.20
Cash dividends per common share	0.19	0.20	0.20	0.20

(10) Subsequent Events

We evaluated subsequent events after the balance sheet date of September 30, 2015 and there were no material subsequent events that required recognition or additional disclosure in these financial statements.

During November 2015, we made a minority investment in Oasis Diagnostics® Corporation in order to evaluate our interest in saliva diagnostics and collection devices. Oasis is located in Vancouver, Washington.

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ITEM 9.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS

ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A.

CONTROLS AND PROCEDURES

As of September 30, 2015, 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, 2015. 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, 2015.

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.

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PART III.

The information required by Items 10, 11, 12 (other than that portion set forth below), 13 and 14, of Part III are incorporated by reference from the Registrant s Proxy Statement for its 2016 Annual Shareholders Meeting to be filed with the Commission pursuant to Regulation 14A.

ITEM 12.

EQUITY COMPENSATION PLAN INFORMATION

The following table presents summary information as of September 30, 2015 with respect to all of our equity compensation plans (number of securities information in thousands).

Plan Category	(a) Number of Securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (1)	816	$ 20.543	3,594
Total (2)	816	$ 20.543	3,594

(1) 2004 Equity Compensation Plan, as amended
2012 Stock Incentive Plan
(2) Weighted-average remaining term of 4.86 years

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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*	Supplemental Benefit Agreement between Meridian and John A. Kraeutler, as amended April 24, 2001, December 29, 2008, August 3, 2011 and June 12, 2012 (referred to as the Salary Continuation Agreement prior to June 12, 2012) (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on June 14, 2012)
10.4	Dividend Reinvestment Plan (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 1999)
10.5*	Second Amended and Restated Employment Agreement Dated January 15, 2015 between Meridian and John A. Kraeutler (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on January 20, 2015)
10.6*	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)
10.7*	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)

10.8*	Fiscal 2016 Officer s Performance Compensation Plan (Filed herewith)

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Exhibit Number	Description of Exhibit
10.9	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)
10.10.1	Amended and Restated Revolving Note with 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)
10.10.2	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)
10.10.3	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)
10.10.4	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)
10.10.5	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)
10.11*	Form of Time-Based Restricted Share Unit Award Agreement dated November 4, 2015 (Filed herewith)
10.12*	Form of Performance Award Restricted Share Unit Award Agreement dated November 4, 2015 (Filed herewith)
10.13*	Meridian Bioscience, Inc. Change in Control Severance Compensation Policy dated March 18, 2011 (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on March 24, 2011)
13	2015 Annual Report to Shareholders (1)
14	Code of Ethics (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2003)
21	Subsidiaries of the Registrant (Filed herewith)
23	Consent of Independent Registered Public Accounting Firm (Filed herewith)
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) (Filed herewith)
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) (Filed herewith)
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, 2015 filed with the SEC on November 30, 2015, formatted in XBRL includes: (i) Consolidated Statements of Operations for the years ended September 30, 2015, 2014 and 2013; (ii) Consolidated Statements of Comprehensive Income for the years ended September 30, 2015, 2014 and 2013; (iii) Consolidated Statements of Cash Flows for the years ended September 30, 2015, 2014 and 2013; (iv) Consolidated Balance Sheets as of September 30, 2015 and 2014; (v) Consolidated Statements of Shareholders Equity for the years ended September 30, 2015, 2014 and 2013; and (vi) the Notes to Consolidated Financial Statements

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* Management Compensatory Contracts

(1) Only specific portions of the 2015 Annual Report to Shareholders are incorporated by reference in this Form 10-K as filed herewith. A supplemental paper copy of the 2015 Annual Report to Shareholders has been furnished to the Securities and Exchange Commission for informational purposes only.

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.

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SIGNATURES

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

MERIDIAN BIOSCIENCE, INC.

By: /s/ John A. Kraeutler
Date: November 30, 2015
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 John A. Kraeutler	Chairman of the Board and Chief Executive Officer	November 30, 2015
/s/ Melissa A. Lueke Melissa A. Lueke	Executive Vice President, Chief Financial Officer, and Secretary (Principal Financial and Accounting Officer)	November 30, 2015
/s/ James M. Anderson James M. Anderson	Director	November 30, 2015
/s/ Dwight E. Ellingwood Dwight E. Ellingwood	Director	November 30, 2015
/s/ John C. McIlwraith John C. McIlwraith	Director	November 30, 2015
/s/ David C. Phillips	Director	November 30, 2015

David C. Phillips		
/s/ Catherine A. Sazdanoff	Director	November 30, 2015
Catherine A. Sazdanoff		

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SCHEDULE II

Meridian Bioscience, Inc.

and Subsidiaries

Valuation and Qualifying Accounts

(Dollars in thousands)

Years Ended September 30, 2015, 2014 and 2013

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Other (a)	Balance at End of Period
Year Ended September 30, 2015:					
Allowance for doubtful accounts	$ 272	$ 73	$ (41)	$ (56)	$ 248
Inventory realizability reserves	2,942	208	(590)	(104)	2,456
Valuation allowances deferred taxes	8	7			15
Year Ended September 30, 2014:					
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
Year Ended September 30, 2013:					
Allowance for doubtful accounts	$ 574	$ (116)	$ (239)	$ 14	$ 233
Inventory realizability reserves	2,271	1,132	(938)	34	2,499
Valuation allowances deferred taxes	450	150	(289)	(15)	296

(a) Balances reflect the effects of currency translation.