MERIDIAN BIOSCIENCE INC
Form 10-K
December 01, 2014
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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, 2014.

¨ **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 ¨ NO x

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, 2014 was $887,064,755 based on a closing sale price of $21.79 per share on March 31, 2014. As of October 31, 2014, 41,644,524 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, 2014 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 2015 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.

Reportable Segments

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 U.S. and Canada (North America); Europe, Middle East and Africa (EMEA); and other countries outside of North America

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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 a sales and business development location in Singapore. Additionally, in order to further pursue revenue opportunities in Asia, and China in particular, our Life Science segment is in the process of opening a representative office in Beijing, China. 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 2014. Third-party revenues for this segment were $142,000, $145,000 and $130,000 for fiscal 2014, 2013 and 2012, respectively, reflecting a three-year compound annual growth rate of 6%. As of September 30, 2014, our Diagnostics segment had approximately 350 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 *C. difficile* (causative agent for antibiotic-associated diarrhea from a hospital-acquired infection), foodborne (Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter jejuni* (Campy)), and *H. pylori* (stomach ulcers). Revenues within our focus product families *C. difficile,* foodborne and *H. pylori* accounted for 61%, 62% and 62% of our Diagnostics segment s third-party revenues during fiscal 2014, 2013 and 2012, respectively. These same product families accounted for 46%, 47% and 47% of consolidated net revenues in fiscal 2014, 2013 and 2012, respectively.

Our product portfolio, over 140 diagnostic tests and transport media, extends beyond our focus families, reaching into prenatal care (Group B *Streptococcus*), respiratory (Group A *Streptococcus, Bordetella pertussis*, influenza and respiratory syncytial virus, among others), and immunocompromised patients (Cytomegalovirus), among other infectious disease areas. During the next three to five years, we expect revenue growth from products operating on our ***illumi****gene*® molecular testing platform (see below) that fall outside of our focus families noted above. The primary markets and customers for our products are acute care hospitals, reference laboratories and outpatient clinics in over 60 countries around the world.

We continue to invest in new product development for our molecular testing platform, ***illumi****gene*. This platform now has five commercialized tests (assays), with three additional tests expected to be available for sale in fiscal 2015:

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* expected fiscal 2015 (launch outside of U.S.)
7. ***illumi****gene*® *Neisseria gonorrhea* expected fiscal 2015 (launch outside of U.S.)
8. ***illumi****gene*® Herpes Simplex Virus I & II expected fiscal 2015

Additional ***illumi****gene* tests in early-stage research and development include foodborne pathogens such as *Campylobacter jejuni*, and bloodborne pathogens such as the causative agents for malaria.

We believe that our ***illumi****gene* system has been well-accepted in our global markets. We currently have approximately 1,300 customer account placements. Of these account placements, over 1,150 accounts have completed evaluations and validations and are regularly purchasing product, with the remaining account placements being in some stage of product evaluation and/or validation. Of our account placements, we have over 300 accounts that are multi-assay users.

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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 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:

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

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products direct or through distribution along with other supplies. Two independent distributors in the U.S. accounted for 10% or more of consolidated net revenues in fiscal 2014, 2013 and 2012: Cardinal Healthcare Corporation and Thermo Fisher Scientific. Our revenues from Cardinal were approximately $28,000, $35,000 and $33,000 during fiscal 2014, 2013 and 2012, respectively. Our revenues from Fisher were approximately $23,000, $25,000 and $20,000 during fiscal 2014, 2013 and 2012, 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 are implementing a direct sales presence in Germany and the U.K. for our ***illumi****gene* products. We maintain a distribution center near Milan, Italy.

ROW

With the exception of Australia and Singapore, 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 $35,000 in global revenues for fiscal 2014, or a 12% decrease from fiscal 2013 reflecting a combination of sales of our molecular-based and traditional immunoassay products. This product family has experienced significant competition in recent years from new technologies, including other molecular testing platforms. See Competition discussion below.

Foodborne

Our foodborne product family achieved approximately $23,000 in global revenues for fiscal 2014, or a decrease of 3%, 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 continue to believe that we have less than a 20% market share for EHEC and less than a 5% market share for Campy.

While historically the primary competition for our foodborne products has been laboratory culture methods, during 2012 one of our competitors received FDA clearance for a shiga toxin test that competes with our EHEC test. We are continuing to re-emphasize the benefits of increased sensitivity and faster turnaround time versus culture methods in our marketing programs, and 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.

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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 $28,000 in global revenues for 2014, or 7% 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 70% 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 a 5% market share.

Our patents related to our *H. pylori* stool antigen tests expire in 2016 in the U.S. and 2017 in countries outside the U.S. Upon patent expiration, we may be subject to competitive product introductions, which could lead to downward pressure on selling prices.

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 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 the breadth and depth of our product portfolio provides us with a competitive advantage. For *C. difficile*, we believe that we are the only company able to offer a full line of FDA-approved immunoassay (GDH and Toxin) and molecular products, allowing the customer to choose the solution that best suits them.

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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 2014, 2013 and 2012 were approximately $10,000, $8,000 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.

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 completion of an expansion of our molecular diagnostic manufacturing capacity at our Cincinnati, Ohio location, 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. Revenues from these products are as follows:

Product/Technology Family	Number of products	% of consolidated revenues	
		2014	2013
illumi*gene*	5	20%	18%
H. pylori	2	14%	13%
Respiratory	3	2%	3%
Other	5	1%	1%
Total patented products	15	37%	35%

The patents for the ***illumi****gene* products expire between 2020 and 2022; the patents for the two *H. pylori* products expire in 2016 in the U.S. and in 2017 for countries outside the U.S.; and the patents for the three respiratory products expire in 2022 (two products) and 2027. The remaining five patented products for which we own or license patents are spread over three product families.

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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 execute confidentiality and non-disclosure agreements designed to protect our proprietary products.

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. Once 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 $2,500 in fiscal 2014.

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.

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 2014 and 2013, the Company recorded to cost of sales approximately $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

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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 $47,000, $44,000 and $43,000 for fiscal 2014, 2013 and 2012, respectively. As of September 30, 2014, our Life Science segment had approximately 200 employees in five countries.

Most of the revenues for our Life Science segment currently come from the manufacture, sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents used by 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 for our Bioline molecular component business, which historically focused on the academic/research market that comprises the remaining 35% of 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, we are in the process of opening a representative office in Beijing, China. We utilize a network of distributors in other major countries. During fiscal 2014, 16% of third-party revenues for this segment were from two diagnostic manufacturing customers.

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

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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, $3,000 and $2,000 in fiscal 2014, 2013 and 2012, respectively.

Market Trends

Globally, sales of molecular components are growing at a faster pace than immunoassay components, and this is consistent with our business. 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. From time to time, customers 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.

Research and Development

Research and development expenses for our Life Science segment for fiscal 2014, 2013 and 2012 were approximately $3,000, $3,000 and $2,000, respectively. This research and development organization is heavily involved in vaccine development and production activities for our cGMP facility and development of new molecular products.

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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 revenues and earnings growth in the future.

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 $55,000 or 29% of consolidated fiscal 2014 revenues, $54,000 or 29% of consolidated fiscal 2013 revenues and $53,000 or 31% of consolidated fiscal 2012 revenues. We expect to continue to look to international markets as a source of new revenues and growth in the future.

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.

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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 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.

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.

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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 36% and 42%, respectively, of the Diagnostics segment s total revenues for fiscal 2014 and fiscal 2013, or 27% and 32%, respectively, of our consolidated revenues for fiscal 2014 and fiscal 2013. 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.

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.

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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, given the early stages of the enacted reform, 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 2014 and 2013, the Company recorded approximately $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) over the next decade have gone into effect, beginning in 2013, and will remain in effect in the absence of further legislative action. Half of the automatic reductions will come from lowering the caps imposed on non-defense discretionary spending and cutting domestic entitlement programs, including reductions in payments to Medicare providers. Government research funding has also been reduced as a result of sequestration. 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% and 17%, respectively, of the Life Science segment s total revenues for fiscal 2014 and fiscal 2013, or 4% and 4%, respectively, of our consolidated revenues for fiscal 2014 and fiscal 2013. Our Life Science segment has four other significant customers who purchase antigens, antibodies and reagents, which together comprised 8% of the segment s total revenues for each of fiscal 2014 and fiscal 2013. Any significant alteration of buying patterns from these customers could adversely affect our period over period revenues and results of operations.

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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 purified 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.

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

Our patents related to our *H. pylori* stool antigen tests expire in 2016 in the U.S. and 2017 in countries outside the U.S. Upon patent expiration, we may be subject to competitive product introductions, which could lead to downward pressure on selling prices. Our global revenues for *H. pylori* products were $28,000 in fiscal 2014.

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 60 countries. Approximately 29% of our net revenues for both fiscal 2014 and 2013 were attributable to markets outside of North America. For fiscal 2014, approximately 40% of our international revenues were from sales made in Euros and 40% were from sales made in U.S. dollars, with the remaining 20% primarily being a combination of sales made in British pounds and Australian 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.

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Risks Affecting our Manufacturing Operations

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

Medical device diagnostics and the manufacture, sale and distribution of bulk antigens, antibodies and reagents are highly regulated industries. 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 delay in obtaining authorization to sell products, seizure or recall of products, suspension or revocation of authority to manufacture or sell products, and other civil or criminal sanctions.

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

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

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

Raw Materials and Components

Our diagnostic products are made from a wide variety of raw materials that are biological or chemical in nature, and that generally are available from multiple sources of supply. We sole-source certain raw materials and components 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.

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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, with the cost of each instrument being relatively inexpensive. 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 $37,000 or 20% of consolidated revenues for fiscal 2014, $34,000 or 18% for fiscal 2013 and $23,000 or 13% for fiscal 2012, 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.

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.

Three products manufactured exclusively for us by two separate and independent companies accounted for 14%, 14% and 13% of consolidated revenues in fiscal 2014, 2013, and 2012, 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.

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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.

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.

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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.

Approximately $2,700 of our accounts receivable at September 30, 2014 is due from Italian hospital customers whose funding ultimately comes from the Italian government, which is down from approximately $3,500 at September 30, 2013.

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

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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.

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.

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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. In addition, we continue to own an approximately 23,000 square foot facility in Saco, Maine, which we have been marketing for sale or lease. 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 4,000 square feet of sales, warehouse, research and development and manufacturing space; Singapore approximately 1,000 square feet of sales and business development space; Beijing less than 1,000 square feet of representative office space maintained for business development purposes.

ITEM 3.

LEGAL PROCEEDINGS

We are a party to various litigation matters that we believe are in the normal course of business. The ultimate resolution of these matters is not expected to have a material adverse effect on our financial position, results of operations or cash flows. No material provision has been made in the accompanying consolidated financial statements for these matters.

ITEM 4.