MERIDIAN BIOSCIENCE INC Form 10-K November 29, 2012 Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
 FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2012.

" 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

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Phone: (513) 271-3700

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

Title of each class Common Shares, No Par Value Name of each exchange of which registered 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 $\ddot{}$

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 \times 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, 2012 was \$776,516,425 based on a closing sale price of \$19.38 per share on March 31, 2012. As of October 31, 2012, 41,287,417 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, 2012 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 2013 Annual Shareholders Meeting are incorporated by reference in Part III as specified.

MERIDIAN BIOSCIENCE, INC.

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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 , w expects, intends, believes, should and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company 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. 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 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 make results difficult to predict. One of Meridian s growth strategies is the acquisition of companies and product lines. There can be no assurance that

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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. The Company cannot predict the possible impact of recently-enacted United States healthcare legislation and any similar initiatives in other countries on its results of operations. 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.

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 develop 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 our 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 clinical 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 in Cincinnati, Ohio, USA.

Our website is <u>www.meridianbioscience.com</u>. 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 <u>www.sec.gov</u>. 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 U.S. Diagnostics, European Diagnostics and Life Science. The U.S. Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the U.S. and countries outside of Australia, Europe, Africa and the Middle East. The European Diagnostics segment consists of the sale and distribution of diagnostic test kits in Australia, Europe, Africa and the Middle East. 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. 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 segments is included in Note 8 to the consolidated financial statements.

Our primary source of revenues continues to be diagnostic products, with our Diagnostics segments providing 75% of consolidated net sales for fiscal 2012. 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. This approach has allowed us to establish significant market share in our target disease states. The acquisition of the Bioline group of companies (collectively the Bioline Group) in July 2010 dramatically increased the revenue base for our Life Science segment; revenues for our Life Science segment represented 25% of consolidated net sales for fiscal 2012.

Products and Markets

We have expertise in the development and manufacture of products based on multiple core diagnostic technologies. Our product technologies include DNA amplification, enzyme immunoassay, immunofluorescence, particle agglutination/aggregation, immunodiffusion, complement fixation and chemical stains. As a result, we are able to develop and manufacture diagnostic tests in a variety of formats that satisfy customer needs and preferences, whether in a hospital, commercial or reference laboratory, or alternate site location. Our product offering consists of approximately 140 clinical diagnostic products.

Sales within our focus product families *C. difficile*, foodborne and *H. pylori* accounted for 62%, 58% and 51% of our U.S. Diagnostics segment s third-party sales during fiscal 2012, 2011 and 2010, respectively. These same product families accounted for 47%, 44% and 43% of consolidated net sales in fiscal 2012, 2011 and 2010, respectively.

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U.S. Diagnostics Segment

Overview

Our U.S. Diagnostics segment s business focuses on the development, manufacture, sale and distribution of diagnostic test kits, primarily for certain gastrointestinal, viral, respiratory and parasitic infectious diseases. In addition to diagnostic test kits, products also include transport media that store and preserve specimen samples from patient collection to laboratory testing. Third-party sales for this segment were \$108,000, \$97,000 and \$92,000 for fiscal 2012, 2011 and 2010, respectively, reflecting a three-year compound annual growth rate of 3%. Excluding influenza-related sales, the three-year compound annual growth rate was 8%. The higher rate reflects the impact of influenza-related sales in 2009 in connection with the H1N1 influenza pandemic. As of September 30, 2012, our U.S. Diagnostics segment had approximately 290 employees.

Our diagnostic test kits utilize immunodiagnostic and molecular technologies, which test samples of stool, blood, urine and other body fluids or tissue for the presence of specific infectious diseases. Specific immunodiagnostic technologies used in our diagnostic test kits include enzyme immunoassay, immunofluorescence, particle agglutination/aggregation, immunodiffusion, complement fixation and chemical stains. During fiscal 2010 we commercialized our molecular amplification diagnostic testing platform, *illumigene®*, and introduced our first assay, *C. difficile*. The *illumigene® C. difficile* assay detects the presence of the toxin producing region from the *C. difficile* DNA, and provides highly accurate results in under an hour. Throughout fiscal 2011 and fiscal 2012, we continued with the development of additional tests for the *illumigene®* (Group B Strep or GBS) in December 2011 and *illumigene®* Group A *Streptococcus* (Group A Strep) in September 2012. A test for *Mycoplasma pneumoniae* (Walking Pneumonia) was recently submitted to the FDA for marketing clearance and is expected to be available for sale in the U.S. during the third or fourth quarter of fiscal 2013. Our development pipeline for *illumigene®* also includes two sexually-transmitted disease assays, expected to be available for sale in the U.S. during the third or fourth quarter of fiscal 2013. Our development pipeline for *illumigene®* also

Our diagnostic products are used principally in the detection of gastrointestinal diseases, such as antibiotic-associated diarrhea (*C. difficile*), pediatric diarrhea (Rotavirus and Adenovirus) and stomach ulcers (*H. pylori*); foodborne diseases such as Enterohemorrhagic *E. coli* infection (EHEC) and *Campylobacter jejuni* (Campy); *Streptococcus* bacterial infections (both Group A and Group B Strep); viral diseases, such as Mononucleosis, Herpes Simplex, Chicken Pox and Shingles (Varicella-Zoster) and Cytomegalovirus (organ transplant infections); parasitic diseases, such as Giardiasis, Cryptosporidiosis and Lyme; and respiratory diseases, such as Pneumonia, Valley Fever, Influenza and Respiratory Syncytial Virus (RSV). The primary markets and customers for these products are reference laboratories and hospitals.

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In particular, the three tests we currently offer on our *illumigene®* platform *C. difficile*, Group A Strep and Group B Strep are expected to drive the majority of growth in fiscal 2013.

C. difficile

Clostridium difficile (*C. difficile*) is a bacteria found in the gut that can cause serious damage to the colon and even death, primarily in hospital patients using antibiotics. It is the most common infection acquired by patients while they are in the hospital. Annually in the U.S., an estimated 8 million *C. difficile* tests are performed. This hospital acquired infection occurs when antibiotics disrupt other bacteria that normally prevent the colonization of *C. difficile*. Rapid, accurate diagnosis, followed by appropriate treatment is essential to improving patient outcomes and reducing the overall cost of care. Our strong line of *C. difficile* tests, including our *illumigene*[®] *C. difficile* molecular test, provide the most comprehensive and accurate testing options for this serious and life threatening infection.

Group A Strep

Group A *Streptococcus* is the bacterium commonly found in the throat which causes strep throat (acute pharyngitis). Pharyngitis is diagnosed in approximately 11 million patients in the U.S. each year. Our *illumigene®* Group A Strep test, the only FDA-cleared molecular Strep A test in the U.S. market, provides results in less than one hour, detects more positives than culture methods and is ideal for early diagnosis and proper patient management of the common, sometimes serious disease. In addition to front line testing in hospital and clinical settings, rapid strep throat tests performed in physician offices in the U.S. that are negative are routinely sent on to hospital and reference labs for confirmation testing, usually by culture methods that take up to 48 hours to run. With results in less than one hour and a 53% increase in the detection of positives, *illumigene®* Group A Strep provides improved patient care over culture methods.

Group B Strep

Each year in the U.S. there are over 4 million babies born. Appropriately testing women in the late stages of pregnancy for the presence of Group B *Streptococcus* is critical to the health of the baby. Without proper treatment during labor, GBS infection can lead to sepsis, pneumonia and even meningitis, and lead to hearing and vision loss. Testing with our *illumigene*[®] GBS improves accuracy by up to 29% over traditional culture methods, increasing the likelihood of improved outcomes and a healthy baby.

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.

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The increasing 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 expense. In addition, these pressures have led to a major consolidation among reference laboratories and the formation of multi-hospital group purchasing organizations and integrated delivery networks that have reduced the number of institutional customers for diagnostic products and resulted in changes in buying practices. Specifically, multi-year exclusive or primary source marketing or distribution contracts with institutional customers have become more common, replacing less formal distribution arrangements.

Sales and Marketing

Our U.S. Diagnostics segment s sales and distribution network in the U.S. consists of a direct sales force complemented by independent distributors. The use of independent distributors in the U.S. allows our products to reach any bed-size healthcare facility and also provides our customers the option to purchase our products direct or through distribution along with other supplies. For our export markets in Asia, Canada and South America, we use independent distributors. Two independent distributors in the U.S. accounted for 10% or more of consolidated net sales in fiscal 2012, 2011 and 2010: Cardinal Healthcare Corporation and Fisher Scientific. Our sales to Cardinal were approximately \$33,000, \$30,000 and \$34,000 during fiscal 2012, 2011 and 2010, respectively. Our sales to Fisher were approximately \$20,000, \$18,000 and \$18,000 during fiscal 2012, 2011 and 2010, respectively.

Consolidation of the U.S. healthcare industry is expected to continue and potentially affect our customers. Industry consolidation puts pressure on pricing and aggregates buying power. In response, we have looked to multi-year supply agreements with group purchasing organizations, integrated delivery networks and major reference laboratories to stabilize pricing.

Clostridium difficile

C. difficile, a serious hospital acquired bacterial infection, is our largest product family, generating approximately \$36,000 in global sales for fiscal 2012, or 21% growth from fiscal 2011. This product family has experienced significant competition over the last three years from new technologies, including molecular testing platforms. Our *illumigene*[®] molecular *C. difficile* product has now been available in markets around the world for over two years. Sales of this product were approximately \$22,000, \$9,000 and \$500 in fiscal 2012, 2011 and 2010, respectively. Approximately 950 clinical laboratories are current customers using our *illumigene*[®] platform, which now includes three tests (see below for a discussion of our second and third tests for Group B and Group A Strep). While the majority of these customers have adopted the *C. difficile* product has restored the *C. difficile* product family to positive sales growth, 21% and 10% during each of the last two fiscal years.

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Our major competitors in this product family are Cepheid and Becton Dickinson (molecular) and Alere (immunoassay). We believe that we have two principal advantages versus our competition. First, our molecular instrumentation package has a smaller footprint and significantly lower cost than either Cepheid or Becton Dickinson. We believe that this advantage allows our product to fit into virtually any size hospital or reference laboratory. We believe that our second principal advantage is the breadth of our *C. difficile* product offerings. With the launch of our molecular product and FDA clearance of our common antigen *C. difficile* products Premier *C. difficile* GDH received FDA clearance in May 2011, and Immuno*Card C. difficile* GDH received FDA clearance in December 2011 we believe we are in a unique position to offer a full line of testing solutions to our clinical laboratory customers around the world to counter the competitive pressures surrounding this market. Additionally, we hold the only FDA-approved claim for *C. difficile* testing in the pediatric population. These advantages, along with the performance features of the products in our *C. difficile* portfolio, give us a compelling product offering for any hospital testing method preference.

During fiscal 2012, we received FDA clearance for our second and third molecular tests for the *illumigene*[®] molecular platform *illumigene*[®] GBS (Group B *Streptococcus*) in December 2011 and *illumigene*[®] Group A Strep (Group A *Streptococcus*) in September 2012. As alluded to above, over 100 customers are now purchasing two assays for the *illumigene*[®] platform the majority being *C. difficile* and GBS with revenue generated by our GBS test approximating \$1,100 during fiscal 2012. In addition, with the recent introduction of the Group A Strep test, there are a growing number of customers adopting all three of our molecular-platform assays. A test for *Mycoplasma pneumoniae* was recently submitted to the FDA for marketing clearance and is expected to be available for sale in the U.S. during the second quarter of fiscal 2013. Our fifth test on the *illumigene*[®] platform is for *Bordetella pertussis*, which is expected to be available for sale in the U.S. during the third or fourth quarter of fiscal 2013. Our development pipeline for *illumigene*[®] also includes two sexually-transmitted disease assays, expected to be available for sale in the U.S. during the first half of fiscal 2014.

In addition to Cepheid, Becton Dickinson and Alere, other competitors have begun to enter the *C. difficile* market. During fiscal 2012, Quest Diagnostics and Great Basin received FDA clearance for a molecular *C. difficile* test and Quidel received CE marking approval for a molecular *C. difficile* test for sale within the European Union. Although we believe that the breadth of our *C. difficile* product offerings and our low cost molecular platform provide key advantages to the offerings of our competitors, selling prices may come under pressure as more competitors enter the market.

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Foodborne

Our foodborne product family achieved approximately \$21,000 in global sales for fiscal 2012, or growth of 13%, 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 annual stool cultures that are tested for foodborne illnesses. At present, we 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, one of our competitors, Alere, has recently cleared through the FDA a shiga toxin test that will compete with our EHEC test. We believe that our products have two principal advantages versus culture methods. The first principal advantage is test accuracy. Independent evaluations have shown our products to have higher sensitivity than culture methods. The second principal advantage is improved work flow of the testing process, resulting in significantly shortened time to test result. Our single-use rapid products provide a test result in approximately 20 minutes, whereas culture results can take up to 24-48 hours. Time to test result can be a critical factor in the physician s choice of therapies, as the mortality rate for EHEC is estimated to be 5% to 10%.

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 \$24,000 in global sales for 2012, 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 are test-method alternatives, serology and urea breath, and the prescription of symptom-relieving medications. In the U.S., our strategy 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.

In European markets, we face a greater number of competitive products for this product family. As a result, pricing pressures have led to 3% sales growth for fiscal 2012 for our European Diagnostics segment, excluding the effect of currency translation.

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Research and Development

Our U.S. Diagnostics segment s research and development organization has expertise in biochemistry, immunology, mycology, bacteriology, virology, parasitology and molecular biology. Research and development expenses for the U.S. Diagnostics segment for fiscal 2012, 2011 and 2010 were approximately \$8,000, \$7,000 and \$6,000, respectively. This research and development organization focuses its activities on new applications for our existing technologies, improvements to existing products and development of new technologies. 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 *C. difficile*, foodborne, and *H. pylori* product families were either developed solely in-house, or via collaboration with outside partners.

The introduction of our molecular amplification diagnostic testing platform, *illumigene*[®], introduced in markets around the world over two years ago, followed nearly four years of exploration and development of a molecular-based diagnostic testing technology to complement our existing antigen/antibody-based testing technologies. Our *illumigene*[®] *C. difficile* assay, the initial assay introduced for the *illumigene*[®] platform, detects the presence of a key toxin producing region from the *C. difficile* DNA, and provides highly accurate results in under an hour. We believe this molecular assay uniquely positions us in the market to provide a full line of testing solutions that will meet the needs of both our domestic and international customers and, as a result, throughout fiscal 2011 and fiscal 2012, we continued with the development of additional tests for the *illumigene*[®] molecular platform, receiving FDA clearance for our second and third molecular tests for the platform *illumigene*[®] GBS (Group B *Streptococcus*) in December 2011 and *illumigene*[®] Group A Strep (Group A *Streptococcus*) in September 2012. A test for *Mycoplasma pneumoniae* (Walking Pneumonia) was recently submitted to the FDA for marketing clearance and is expected to be available for sale in the U.S. during the second quarter of fiscal 2013. Our fifth test on the *illumigene*[®] platform is for *Bordetella pertussis* (Whooping Cough), which is expected to be available for sale in the U.S. during the third or fourth quarter of fiscal 2013. Our development pipeline for *illumigene*[®] also includes two sexually-transmitted disease assays, expected to be available for sale in the U.S. during the first half of fiscal 2014. We currently hold registrations to sell *illumigene*[®] in 37 countries, including the U.S., with registrations pending in 5 additional countries.

During fiscal 2008, we launched our first products under our patented TRU rapid test technology. The design of this technology enhances laboratory safety by containing the specimen in a closed system during testing as recommended by CDC guidelines. TRU tests also use less space than other immunoassay technologies, which is an advantage in space-constrained clinical laboratories. Products using this technology include TRU FLU[®], TRU RSV[®], TRU EBV-M[®] and TRU EBV-G[®]. TRU LEGIONELLATM and TRU HSV 1 and 2 IgGTM the latest additions to the TRU line of products. Legionella was launched in foreign markets during the fourth quarter of fiscal 2011, and became available in the U.S. market during the second quarter of fiscal 2012, while TRU HSV 1 and 2 IgGTM were registered for sale in Europe during September 2012.

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Manufacturing

Our immunodiagnostic 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 antibodies and polyclonal antibodies, plus a variety of fungal, bacterial and viral antigens, currently a number of the raw materials used in our products, including our *illumigene*[®] molecular products, are purchased from outside vendors. We believe that we have sufficient manufacturing and sourcing capacity for anticipated growth in the near term.

Intellectual Property, Patents and Licenses

We own or license U.S. and foreign patents, most of which are for products manufactured by our U.S. Diagnostics segment. Sales of these products are as follows:

	Number of	% of consolidated sales		
Product/Technology Family	products	2012	2011	
illumigene [®]	3	13%	6%	
H. pylori	2	13%	13%	
Respiratory	3	2%	2%	
Other	6	1%	1%	
Total patented products	14	29%	22%	

The patents for the *illumigene®* products expire between 2020 and 2022; the patents for the two *H. pylori* products expire between 2016 and 2017; and the patents for the three respiratory products expire in 2022 (two products) and 2027. The remaining six patented products for which we own or license patents are spread over three product families.

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.

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

Sales of our diagnostic products in foreign countries are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ.

Meridian s Cincinnati manufacturing facility is certified to ISO 13485:2003.

Medical Device Tax

Included within the U.S. government s comprehensive healthcare reform legislation, enacted during 2010, was the establishment of a 2.3% excise tax on the sales of medical devices beginning in calendar 2013. We currently anticipate that this legislation will result in an excise tax for our company of approximately \$2,000 in fiscal 2013. At the present time it is believed that little, if any, of this cost can be passed on to customers.

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.

European Diagnostics Segment

Our European Diagnostics segment s business focuses on the sale and distribution of diagnostic test kits, manufactured both by our U.S. Diagnostics segment and by third-party vendors. Approximately 85% of third-party sales for fiscal 2012 for this segment were products purchased from our U.S. Diagnostics segment. Third-party sales for this segment were approximately \$23,000, \$24,000 and \$24,000 for fiscal 2012, 2011 and 2010, respectively. As of September 30, 2012, the European Diagnostics segment had approximately 40 employees. Our European Diagnostics segment s sales and distribution network consists of direct sales forces in Australia, Belgium, France, Holland and Italy, and independent distributors in other European countries, Africa and the Middle East. The European Diagnostics segment maintains a distribution center near Milan, Italy. The primary markets and customers for this segment are hospitals and reference laboratories.

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The European Diagnostics segment s functional currency is the Euro. The translation of Euros into U.S. dollars is subject to exchange rate fluctuations.

Life Science Segment

Overview

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 companies, as well as contract development and manufacturing services under clinical cGMP conditions. Third-party sales for this segment were approximately \$43,000, \$38,000 and \$27,000 for fiscal 2012, 2011 and 2010, respectively. As of September 30, 2012, our Life Science segment had approximately 180 employees.

Most of the revenue for our Life Science segment currently comes 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 companies. During fiscal 2012, 19% of third-party sales for this segment were to two diagnostic manufacturing customers. For one of these two customers, we have exclusive supply agreements that have annual, automatic renewal provisions. We have a long-standing relationship with this customer; and although there can be no assurances, we intend to renew these supply agreements in the normal course of business.

In July 2010, we acquired the Bioline Group and in so doing added important technologies and capabilities to our Life Science business and complemented our expanding life science product lines sold into the research, pharmaceutical and commercial diagnostic markets. In addition to technological capabilities, Bioline also added proprietary know-how in the production of high-volume nucleotides and PCR enzymes, as well as a growing portfolio of intellectual property in the form of patents and licenses. The Bioline Group contributed approximately \$17,000 and \$15,000 in sales for fiscal 2012 and 2011, respectively.

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. The customer base for this aspect of our Life Science business includes biopharmaceutical and biotechnology companies, as well as government agencies. Revenues for our 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 our immunodiagnostic and molecular biology products, as well as buying patterns of major customers. See Note 1 (i) to the Consolidated Financial Statements herein for revenue recognition policies. Our revenues for contract services were approximately \$2,000, \$3,000 and \$2,000 in fiscal 2012, 2011 and 2010, respectively.

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As a result of the order volume trends in bulk antigens, antibodies and reagents, during the fourth quarter of fiscal 2011, we announced the closure of our Saco, Maine facility, and completed the consolidation of manufacturing operations into our Memphis, Tennessee facility during the third fiscal quarter of 2012. Total costs to complete the consolidation of facilities approximated \$2,100, consisting of fixed asset impairments, inventory impairments, stay bonuses and moving costs, among other similar items. During the fourth quarter of 2011, we recognized approximately \$1,100 of these costs, and recognized the remaining \$1,000 during the first three quarters of fiscal 2012.

Products, Markets and Growth Strategies

Our Life Science segment s businesses have been assembled via acquisitions (BIODESIGN International in fiscal 1999, Viral Antigens in fiscal 2000, OEM Concepts in fiscal 2005, and the Bioline Group in July 2010). Historically, these businesses were run autonomously. In recent years, growth strategies have been developed around sales and marketing integration, new product development integration, and the acquisition of complementary product lines.

Immunodiagnostic products such as antibodies, antigens and reagents are marketed primarily to diagnostic manufacturing customers as a source of raw materials for their products, or as an outsourced step in their manufacturing processes. 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 agreements 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 primarily to research customers. These products are typically sold in small quantities.

Research and Development

Research and development expenses for our Life Science segment for fiscal 2012, 2011 and 2010 were approximately \$2,000, \$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 components.

Manufacturing and Government Regulation

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. Approval and licensing, following clinical trials, 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.

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The Meridian Life Science facilities are ISO 9001:2000 certified and EC 1069:2009 approved, where appropriate and as required.

Competition

Diagnostics

The market for diagnostic tests is a multi-billion dollar international industry, which is highly competitive. Many of our competitors are larger than we are with greater financial, research, manufacturing and marketing resources. Important competitive factors for Meridian s products include product quality, price, ease of use, customer service and reputation. In a broader sense, industry competition is based upon scientific and technological capability, proprietary know-how, access to adequate capital, the ability to develop and market products and processes, the ability to attract and retain qualified personnel, and the availability of patent protection. To the extent that our product lines do not reflect technological advances, our ability to compete in those product lines could be adversely affected.

The diagnostic test industry is highly fragmented and segmented. Of importance in the industry are mid-sized medical diagnostic specialty companies, like Meridian, that offer multiple, broad product lines and have the ability to deliver new, high value products quickly to the marketplace. Among the companies with which we compete in the marketing of one or more of our products are the diagnostic product divisions of Abbott Laboratories Inc., Becton, Dickinson and Company, Thermo Fisher and Siemens. We also compete with smaller companies such as Cepheid, Quidel Corporation and Alere, Inc.

Life Science

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 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.

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.

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International Markets

International markets are an important source of revenue and future growth opportunities for all of our segments. For all segments combined, international sales were approximately \$54,000 or 31% of consolidated fiscal 2012 sales, \$53,000 or 33% of consolidated fiscal 2011 sales and \$43,000 or 30% of consolidated fiscal 2010 sales. We expect to continue to look to international markets as a source of new revenues and growth in the future. See Notes 6 and 8 to the Consolidated Financial Statements for information concerning sales, long-lived assets and deferred tax assets by country.

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 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.

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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.

Revenues for our diagnostic segments may be impacted by our reliance upon two key distributors, seasonal factors and sporadic outbreaks, and changing diagnostic market conditions.

Key Distributors

Our U.S. Diagnostic segment s sales through two national distributors were 49% of the U.S. Diagnostics segment s total sales for both fiscal 2012 and 2011, or 30% of our consolidated sales for both fiscal 2012 and 2011. These parties distribute our products and other laboratory products to end-user customers. The loss of either of these distributors could negatively impact our sales and results of operations unless suitable alternatives were timely found or lost sales to one distributor were absorbed by another distributor. Finding a suitable alternative on satisfactory terms may pose challenges in our industry s competitive environment. As an alternative, we could expand our efforts to distribute and market our products directly. This alternative, however, would require substantial investment in additional sales, marketing and logistics resources, including hiring additional sales and customer service personnel, which would significantly increase our future selling, general and administrative expenses.

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

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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 healthcare delivery system have resulted in major consolidation among reference laboratories and in the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. Consolidation in the U.S. healthcare 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 healthcare reform legislation.

Third-party payers for medical products and services, including state and federal 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 healthcare reform. At present, given the infancy 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 sales and/or results of operations.

In addition, this legislation established a 2.3% excise tax on the sales of medical devices beginning in calendar 2013. We currently anticipate that this legislation will result in an excise tax for our company of approximately \$2,000 in fiscal 2013. At the present time it is believed that little, if any, of this cost can be passed on to customers.

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

Our Life Science segment s sales of purified antigens and reagents to two diagnostics manufacturing customers were 19% and 15%, respectively, of the Life Science segment s total sales for fiscal 2012 and fiscal 2011, or 5% and 4%, respectively, of our consolidated sales for fiscal 2012 and fiscal 2011. For one of these two customers, we have exclusive supply agreements that have annual, automatic renewal provisions. Although we have a long-standing relationship with this customer, we cannot provide any assurance that we will be able to renew these supply agreements, which could adversely affect our sales and results of operations.

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Our Life Science segment has four other significant customers who purchase antigens, antibodies and reagents, which together comprised 9% and 10%, respectively, of the segment s total sales for fiscal 2012 and fiscal 2011. Any significant alteration of buying patterns from these customers could adversely affect our period over period sales 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 revenue 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 in the United States supply immunodiagnostic tests and purified reagents. These companies range from multinational healthcare entities, for which immunodiagnostics 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.

In recent years, molecular tests have been introduced for the first time into the *C. difficile* market, which is a significant source of revenues for us. Our ability to continue to successfully compete in the *C. difficile* market is partly dependent upon the success and market acceptance of our own molecular-based product, *illumigene*[®] *C. difficile*.

We depend on international sales, 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 31% of our net sales for fiscal 2012 and approximately 33% of our net sales for fiscal 2011 were attributable to international markets. For fiscal 2012, approximately 40% of our international sales were made in Euros and 40% were made in U.S. dollars, with the remaining 20% being a combination of the British pound and the Australian dollar. We are subject to the risks associated with fluctuations in the exchange rates for the Australian dollar, British pound and Euro 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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In addition, in recent months there have been a number of media reports that have called into question the longevity of the Euro currency, and whether certain countries might exit the Euro currency. We have no opinion on the longevity of the Euro currency, or if any countries ultimately will exit the Euro currency. In the event that the Euro currency would completely dissolve, or in the event certain countries exited the Euro currency, the carrying value of our assets and liabilities in European countries where we have a direct presence could be materially affected as legacy currencies are re-implemented. We continue to monitor this situation and have begun to prepare contingency plans.

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. Contract manufacturing of proteins and other biologicals is regulated by the U.S. Food and Drug Administration.

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 our Cincinnati, Ohio; Boca Raton, Florida; Memphis, Tennessee; London, England; Luckenwalde, Germany; and Sydney, Australia facilities comprised 77% of our Diagnostics revenues and 83% of our Life Science 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 third-party manufacturing capabilities could materially and adversely affect our operating results.

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

Our products are made from a wide variety of raw materials that are generally available from multiple sources of supply. However, certain critical raw materials and supplies required for the production of some of our principal products are available only from a single supplier. In addition, certain finished products, for which we act as a distributor, are available only from a single supplier. If these suppliers become unable or unwilling to supply the required raw materials or products, we would need to find another source, and perform additional development work and obtain regulatory approvals for the use of the alternative raw materials for our products. Completing that development and obtaining such approvals could require significant time and resources, and may not occur at all. Any disruption in the supply of these raw materials or finished products could have a material adverse affect on us.

We currently sole-source from a U.S. manufacturer the *illumipro*-10[®] instrument on which our *illumigene*[®] molecular testing platform operates. Additionally, two of our foodborne products sourced from another vendor accounted for 15%, 14% and 11% of third-party sales for our U.S. Diagnostics segment in fiscal 2012, 2011 and 2010, respectively.

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 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 affect on our profitability and the damage to our reputation in the industry could have a material adverse affect 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 affect 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 affect on our profitability and the damage to our reputation in the industry could have a material adverse affect 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.

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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 healthcare systems are the primary payers for healthcare, 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 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. See a discussion of Euro currency risk in the above risk factor related to international market activities.

Approximately \$4,600 of our accounts receivable at September 30, 2012 is due from Italian hospital customers whose funding ultimately comes from the Italian government. During the fourth quarter of fiscal 2011 and first quarter of fiscal 2012, we experienced a deterioration in the aging of our Italian accounts receivable. While such aging appeared to stabilize during fiscal 2012, we continue to monitor such accounts closely.

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.

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ITEM 2.

PROPERTIES

Our corporate offices, U.S. Diagnostics manufacturing facility and U.S. Diagnostics research and development facility are located in four buildings totaling approximately 114,000 square feet on 10 acres of land in the Village of Newtown, a suburb of Cincinnati, Ohio. These properties are owned by us. We have approximately 39,000 square feet of manufacturing space and 14,000 square feet of warehouse space in these facilities. Included within these properties is an approximately 21,000 square foot building located on 3.5 acres of land within one mile of our primary headquarters facility. Since purchasing this property in September 2009, we have transformed the property into a state-of-the-art facility, which since July 2011 has housed our research and development operations and our sales and marketing departments. The facility is called the Meridian Innovation Center and was designed to stimulate our product development and marketing efforts.

Our European Diagnostics distribution center in Italy conducts its operations in a two-story building near Milan, consisting of approximately 18,000 square feet. 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 Nivelles, Belgium for sales and administrative functions.

Our Life Science operations are conducted in several facilities in Memphis, Tennessee; and Boca Raton, Florida, as well as the Bioline Group facilities located in Taunton, Massachusetts; London, England; Luckenwalde, Germany; and Sydney, Australia. Our facility in Memphis, Tennessee consists of two buildings totaling approximately 44,000 square feet, including approximately 27,000 square feet of manufacturing space, 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 approximate 23,000 square foot facility in Saco, Maine, which we have been marketing for sale or lease since consolidation of the Maine operations with the Tennessee location in early fiscal 2012. Following are details of the Bioline Group facilities, all of which are leased: Taunton approximately 10,000 square feet of sales and warehouse space; London approximately 17,000 square feet of sales, warehouse, distribution, research and development, manufacturing and administrative office space; Luckenwalde approximately 10,000 square feet of sales, warehouse, research and development and manufacturing space.

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ITEM 3.

LEGAL PROCEEDINGS

We are a party to various litigation matters that we believe are in the normal course of business. 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 the Form 10-K and Item 1A Risk Factors on Pages 16 through 23 of this Annual Report.

Common Stock Information on the inside back cover of the Annual Report to Shareholders for 2012 and Quarterly Financial Data (Unaudited) relating to our dividends in Note 10 to the Consolidated Financial Statements are incorporated herein by reference. Except as may otherwise be prohibited by applicable law, there are no restrictions on cash dividend payments.

During fiscal 2012, our indicated annual dividend rate of \$0.76 per share approximated 95% of full year diluted earnings per share, nearly in line with our long-standing policy of setting a cash dividend payout ratio of between 75% and 85% of each fiscal year s expected net earnings. This 2012 payout ratio reflects an improvement over the course of the fiscal year from 118% in the first quarter to 90% in the third and fourth quarters and follows two fiscal years in which our cash dividend payout ratio approximated 115% of diluted earnings per share. We believe that this positive dividend payout relationship will continue, although no assurances can be made in this regard. 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.

We paid dividends of \$0.76 per share in each of fiscal 2012 and fiscal 2011, and \$0.74 per share in fiscal 2010.

As of September 30, 2012, there were approximately 950 holders of record and approximately 17,600 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 2012.

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 16 through 23 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 2012 increased 28% to \$8,573, or \$0.21 per diluted share, from net earnings for the fourth quarter of fiscal 2011 of \$6,710, or \$0.16 per diluted share. This increase reflects the combined effects of both increased sales and increased operating expenses. Additionally, the fiscal 2011 fourth quarter included \$1,057 of costs associated with the consolidation of the Saco, Maine operations into the Memphis, Tennessee facility (impact on net earnings of \$691, or \$0.02 per diluted share see Non-GAAP Information below). Sales for the fourth quarter of fiscal 2012 were \$43,694, an increase of \$2,345, or 6%, compared to the fourth quarter of fiscal 2011, reflecting increased sales across all of our diagnostic focus product families: *C. difficile*, Foodborne and *H. pylori*.

Sales for the U.S. Diagnostics segment for the fourth quarter of fiscal 2012 increased 11% compared to the fourth quarter of fiscal 2011, reflecting growth across all of our focus product families ranging from 9% growth in *H. pylori* products to 20% growth in our *C. difficile* product family. Fourth quarter 2012 sales for our European Diagnostics segment decreased 11% compared to the fourth quarter of fiscal 2011 due primarily to a negative currency effect. On an organic basis, which excludes the effects of currency translation, sales for our European Diagnostics segment were flat during the fourth quarter, reflecting growth in *H. pylori* product sales being offset by a decline in sales of our *C. difficile* and foodborne product families. Reflecting growth in its molecular reagent business being partially offset by a decline in its core bulk reagent business, sales of our Life Science segment increased by 1% during the fourth quarter of fiscal 2012 compared to the fourth quarter of fiscal 2011.

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Fiscal Year

Net earnings for fiscal 2012 increased 24% to \$33,371, or \$0.80 per diluted share from net earnings for fiscal 2011 of \$26,831, or \$0.65 per diluted share. Fiscal 2012 results includes \$1,013 of costs associated with the consolidation of the Saco, Maine operations into the Memphis, Tennessee facility (impact on earnings of \$659 or \$0.02 per diluted share see Non-GAAP Information below), while fiscal 2011 included \$1,057 of costs related to the Maine facility consolidation and \$1,240 of costs incurred in connection with the reorganization of our sales and marketing leadership during the second quarter of fiscal 2011 (combined impact on fiscal 2011 net earnings of \$1,563 or \$0.04 per diluted share). Results of operations for fiscal 2012 compared to fiscal 2011 are discussed below.

Non-GAAP Information

The tables below provide information on net earnings, basic earnings per share and diluted earnings per share, excluding the effect of costs associated with the consolidation of our Saco, Maine operations into our Memphis, Tennessee facility (fiscal 2012 and fiscal 2011), costs of reorganizing our sales and marketing leadership (fiscal 2011) and transaction costs associated with the acquisition of the Bioline Group (fiscal 2010), each of which is a non-GAAP financial measure, as well as reconciliations to amounts reported under U.S. Generally Accepted Accounting Principles. We believe that this information is useful to those who read our financial statements and evaluate our operating results because:

- 1. These measures help to appropriately evaluate and compare the results of operations from period to period by removing the impact of non-routine costs related to consolidating the Maine operations (fiscal 2012 and fiscal 2011) and reorganizing our sales and marketing leadership (fiscal 2011), and the one-time transaction costs related to the acquisition of the Bioline Group (fiscal 2010); and
- 2. These measures are used by our management for various purposes, including evaluating performance against incentive bonus achievement targets, comparing performance from period to period in presentations to our Board of Directors, and as a basis for strategic planning and forecasting.

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		2012	2	2011	2	2010
Net Earnings						
U.S. GAAP basis	\$3	33,371	\$ 2	6,831	\$ 2	6,647
Facility consolidation costs (1)		659		691		
Sales & Marketing Leadership Reorganization (2)				872		
Transaction costs for Bioline Group acquisition (3)						1,240
Adjusted earnings	\$ 3	34,030	\$ 2	28,394	\$ 2	7,887
	+ -	.,	+ -			.,
Net Earnings per Basic Common Share						
U.S. GAAP basis	\$	0.81	\$	0.66	\$	0.66
Facility consolidation costs (1)		0.02		0.02		
Sales & Marketing Leadership Reorganization (2)				0.02		
Transaction costs for Bioline Group acquisition (3)						0.03
Adjusted Basic EPS	\$	0.83	\$	0.70	\$	0.69
	Ψ	0.05	Ψ	0.70	Ψ	0.07
Net Earnings per Diluted Common Share						
U.S. GAAP basis	\$	0.80	\$	0.65	\$	0.65
Facility consolidation costs (1)	Ŧ	0.02	Ŧ	0.02	-	
Sales & Marketing Leadership Reorganization (2)				0.02		
Transaction costs for Bioline Group acquisition (3)						0.03
Adjusted Diluted EPS	\$	0.82	\$	0.69	\$	0.68
Aujusica Difuica El 5	ψ	0.02	ψ	0.09	Ψ	0.00

- (1) These facility consolidation costs are net of income tax effects of \$354 and \$366 for fiscal 2012 and fiscal 2011, respectively, which were calculated using the effective tax rates of the jurisdictions in which the costs were incurred.
- (2) These leadership reorganization costs are net of the \$368 income tax effect for fiscal 2011, which were calculated using the effective tax rates of the jurisdictions in which the costs were incurred.
- (3) Since the Bioline Group transaction costs were not deductible, there are no income tax effects.

<u>Revenue Overview:</u>

Our Diagnostics segments provide the largest share of our consolidated revenues, 75%, 76% and 81% for fiscal 2012, 2011 and 2010, respectively. The percentage decline from fiscal 2010 to fiscal 2011 results primarily from the addition of the Bioline Group to our Life Science segment in July 2010. Sales from our focus families (*C. difficile*, Foodborne and *H. pylori*) comprised 62% of our Diagnostics segments revenues during fiscal 2012.

The overall revenue change for our Diagnostics segments during fiscal 2012 was an increase of 8%, reflecting growth in all of our focus product families 7% growth in our *H. pylori* products, 13% growth in our foodborne products and 21% growth in our *C. difficile* products. Excluding the effects of currency translation, sales of our European Diagnostics segment increased by 2% in fiscal 2012, reflecting the combined effects of increases in our *C. difficile* and *H. pylori* product families, partially offset by a decline in the sales of our foodborne and respiratory products.

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C. difficile Products

Our *illumigene*[®] molecular *C. difficile* product has now been available in markets around the world for over two years. Sales of this product were approximately \$22,000 and \$9,000 in fiscal 2012 and fiscal 2011, respectively. Approximately 950 clinical laboratories are current customers using our *illumigene*[®] platform, which now includes three tests (see below for a discussion of our second and third tests for Group B and Group A Strep). While the majority of these customers have adopted the *C. difficile* assay, a growing number of customers are purchasing multiple assays for the platform. Our *illumigene*[®] molecular *C. difficile* product has restored the *C. difficile* product family to positive sales growth, 21% and 10% in fiscal 2012, negretively.

Our major competitors in this product family are Cepheid and Becton Dickinson (molecular) and Alere (immunoassay). We believe that we have two principal advantages versus our competition. First, our molecular instrumentation package has a smaller footprint and significantly lower cost than either Cepheid or Becton Dickinson. We believe that this advantage allows our product to fit into virtually any size hospital or reference laboratory. We believe that our second principal advantage is the breadth of our *C. difficile* product offerings. With the launch of our molecular product and FDA clearance of our common antigen *C. difficile* products Premier *C. difficile* GDH received FDA clearance in May 2011, and Immuno*Card C. difficile* GDH received FDA clearance in December 2011 we believe we are in a unique position to offer a full line of testing solutions to our clinical laboratory customers around the world to counter the competitive pressures surrounding this market. Additionally, we hold the only FDA-approved claim for *C. difficile* testing in the pediatric population. These advantages, along with the performance features of the products in our *C. difficile* portfolio, give us a compelling product offering for any hospital testing method preference.

During fiscal 2012, we received FDA clearance for our second and third molecular tests for the *illumigene*[®] molecular platform *illumigene*[®] GBS (Group B *Streptococcus*) in December 2011 and *illumigene*[®] Group A Strep (Group A *Streptococcus*) in September 2012. As alluded to above, over 100 customers are now purchasing two assays for the *illumigene*[®] platform the majority being *C. difficile* and GBS with revenue generated by our GBS test approximating \$1,100 during fiscal 2012. In addition, with the recent introduction of our Group A Strep test, there are a growing number of customers adopting all three of our molecular-platform assays. A test for *Mycoplasma pneumoniae* (Walking Pneumonia) was recently submitted to the FDA for marketing clearance and is expected to be available for sale in the U.S. during the second quarter of fiscal 2013. Our fifth test on the *illumigene*[®] platform is for *Bordetella pertussis* (Whooping Cough), which is expected to be available for sale in the U.S. during the third or fourth quarter of fiscal 2013. Our development pipeline for *illumigene*[®] also includes two sexually-transmitted disease assays, expected to be available for sale in the U.S. during the first half of fiscal 2014.

In addition to Cepheid, Becton Dickinson and Alere, other competitors are beginning to enter the *C. difficile* market. Quest Diagnostics and Great Basin recently received FDA clearance for a molecular *C. difficile* test and Quidel received CE marking approval for a molecular *C. difficile* test for sale within the European Union. Although we believe that the breadth of our *C. difficile* product offerings and our low cost molecular platform provide key advantages to the offerings of our competitors, selling prices may come under pressure as more competitors enter the market.

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Foodborne Products

Although our foodborne products are marketed and sold on a global basis, most of our sales volume is within the U.S. Diagnostics segment. We continue to see demand increases in the United States, as laboratories realize the benefits of increased sensitivity and faster turnaround time with our tests for Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*, compared to traditional culture methods. Sales increases for these products within the U.S. Diagnostics segment were 15% and 35% during fiscal 2012 and fiscal 2011, respectively. The market acceptance and volume growth of these products has resulted in annual global revenues for this disease family surpassing the \$20,000 mark.

We believe that the primary competition for our foodborne products is laboratory culture methods. We believe that our products have two principal advantages versus culture methods. The first principal advantage is test accuracy. Independent evaluations have shown our products to have higher sensitivity than culture methods. The second principal advantage is improved work flow of the testing process, resulting in a significantly shortened time to test result. Our single-use rapid products provide a test result in approximately 20 minutes, whereas culture results can take up to 24-48 hours. Time to test result can be a critical factor in the physician s choice of therapies.

H. pylori Products

During fiscal 2012, sales of our *H. pylori* products grew 11% for our U.S. Diagnostics segment and increased 3% for our European Diagnostics segment on an organic basis, compared to the year-over-year sales activity these segments experienced in 2011 of 14% growth and 3% decline, respectively. The increase for our U.S. Diagnostics segment continues to reflect the benefits of our partnerships with managed care companies in promoting the health and economic benefits of a test and treat strategy, and the ongoing effects of such strategy moving physician behavior away from serology-based testing toward direct antigen testing. We continue to expect that our efforts with managed care companies in the U.S. will provide low to mid-teens growth opportunities for the next several years. The sales results for our European Diagnostics segment reflect the ongoing impact of pricing pressures from competitive products in European markets.

Respiratory Products

During fiscal 2012, respiratory sales for our Diagnostics segments decreased 3% compared to fiscal 2011, following a 26% year-over-year decrease from fiscal 2010 to fiscal 2011. The dramatic sales fluctuation for this family in recent years is a direct result of the end of the novel A (H1N1) outbreak late in the fiscal 2010 first quarter. Total non-influenza respiratory product sales remained relatively flat compared to fiscal 2011, with sales of such products increasing 4% for our U.S. Diagnostics segment and decreasing 18% for our European Diagnostics segment on an organic basis. At present, we do not expect significant revenue increases from influenza products in fiscal 2013 and expect annual influenza product revenues to be approximately \$2,500 to \$3,000, consistent with the last two fiscal years.

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Group Purchasing Organizations and Integrated Delivery Networks

In our U.S. Diagnostics segment, consolidation of the U.S. healthcare industry over the last several years has 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. We have multi-year supply agreements with several GPOs and IDNs.

Life Science Segment

Sales for our Life Science segment increased 11% in fiscal 2012, reflecting increases in both our core bulk reagent business (8%) and our molecular reagent business (15%). The year-over-year increase in the core bulk reagent business largely results from increased orders for Rubella and Hepatitis A proteins. Our molecular reagent business, operated through our Bioline Group, continues to benefit from its new product launches and advancements during recent months most notably its new SensiFAST and MyTaq PCR components. Revenues for our Life Science segment are inherently dependent upon customer order patterns and timing of contract manufacturing work. For fiscal 2013, we expect overall revenue growth of our Life Science segment to be in the range of 5% to 6%, led by the Bioline Group, which we expect to generate double-digit increases in sales of its molecular reagent products. We expect sales of our bulk antigen, antibody and reagent products to decline slightly in fiscal 2013 due to a slowing immunoassay demand profile. While we are seeing opportunities in China for our bulk antigen, antibody and reagent products, it will likely take the next year to generate actual revenue.

As a result of the order volume trends in bulk antigens, antibodies and reagents, during the fourth quarter of fiscal 2011, we announced the closure of our Saco, Maine facility, and completed the consolidation of manufacturing operations into our Memphis, Tennessee facility during the second fiscal quarter of 2012. Total costs to complete the consolidation of facilities approximated \$2,100, consisting of fixed asset impairments, inventory impairments, stay bonuses and moving costs, among other similar items. During the fourth quarter of 2011, we recognized approximately \$1,100 of these costs, and recognized the remaining \$1,000 during the first three quarters of fiscal 2012.

Foreign Currency

During fiscal 2012, currency exchange rates had an approximate \$1,700 unfavorable impact on revenue; \$1,450 within the European Diagnostics segment and \$250 in the Life Science segment. This compares to currency exchange having an approximate \$600 favorable impact on revenue in fiscal 2011.

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The volatility in the Euro-USD exchange rate increased significantly during the last half of the fiscal year, and this may continue into the foreseeable future until such time as the sovereign debt crisis situation in Europe is resolved. Each one-point decline in the Euro-USD exchange rate (e.g., 1.30 to 1.29) negatively affects the revenues of our European Diagnostics segment by approximately \$160. However, we would not expect such exchange rate fluctuations to have a significant impact on operating income. This results from the fact that we are also exposed to foreign currency risk related to the supply of certain European-manufactured diagnostic test kits, which serves to provide a natural hedge against the impact on European Diagnostics revenue.

Significant Customers

Our U.S. Diagnostic segment s sales through two national distributors were 49% of the U.S. Diagnostics segment s total sales for both fiscal 2012 and fiscal 2011, or 30% of consolidated sales, for both fiscal 2012 and fiscal 2011.

Our Life Science segment s sales of purified antigens and reagents to two diagnostic manufacturing customers were 19% of the Life Science segment s total sales for fiscal 2012 or 5% of our consolidated sales for fiscal 2012, compared to 15% and 4% of fiscal 2011 Life Science segment and consolidated sales, respectively.

Segment Revenues:

Our reportable segments are U.S. Diagnostics, European Diagnostics and Life Science. The U.S. Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the U.S. and countries outside of Australia, Europe, Africa and the Middle East. The European Diagnostics segment consists of the sale and distribution of diagnostic test kits in Australia, Europe, Africa and the Middle East. 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. The Life Science segment also includes 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.

Revenues for the Diagnostics segments, in the normal course of business, may be affected 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 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. We believe that the overall breadth of our product lines serves to reduce the variability in consolidated revenues.

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Revenues for each of our segments are shown below.

	2012	2011	2010	2012 vs. 2011 Inc (Dec)	2011 vs. 2010 Inc (Dec)
U.S. Diagnostics	\$ 108,010	\$ 97,133	\$ 92,020	11%	6%
European Diagnostics	23,000	24,187	24,041	(5)%	1%
Life Science	42,532	38,403	26,939	11%	43%
Consolidated	\$ 173,542	\$ 159,723	\$ 143,000	9%	12%
International					
U.S. Diagnostics	\$ 6,553	\$ 6,692	\$ 6,268	(2)%	7%
European Diagnostics	23,000	24,187	24,041	(5)%	1%
Life Science	24,866	22,283	13,082	12%	70%
Total	\$ 54,419	\$ 53,162	\$ 43,391	2%	23%
% of total sales Gross Profit:	31%	33%	30%		

				2012 vs.	2011 vs.
				2011	2010
	2012	2011	2010	Inc (Dec)	Inc (Dec)
Gross Profit	\$ 109,878	\$ 99,298	\$ 88,696	11%	12%
Gross Profit Margin	63%	62%	62%	+1 point	NONE

The improvement in our overall gross profit margins from 2010 to 2012 reflects the combined effects of 1) the margin contribution of Bioline Group products; 2) continued operating efficiencies in our Cincinnati, Ohio diagnostic test manufacturing facility; 3) consolidation of our Maine facility into our Tennessee facility; and 4) the year-over-year declines in respiratory product sales. Our respiratory product family generally has a lower gross profit margin than our focus product families (*C. difficile, H. pylori* and foodborne). Sales of respiratory products during fiscal 2012, 2011 and 2010 were approximately 9%, 10% and 15%, respectively, of our consolidated sales. Specifically, sales of the Company s influenza products during fiscal 2012, 2011 and 2010 represented approximately 1%, 2% and 6%, respectively, of consolidated sales.

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, proficiency panels, and contract research and development and contract manufacturing services. Product sales 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:

	esearch & velopment	Selling & Marketing	 eneral & inistrative	Other	Total Operating Expenses
2010 Expenses	\$ 8,396	\$ 18,250	\$ 19,672	\$ 1,240	\$ 47,558
% of Sales	6%	13%	14%	1%	33%
Fiscal 2011 Increases (Decreases):					
U.S. Diagnostics	844	1,236	183	365	2,628
European Diagnostics		143	156	875	1,174
Life Science					
Bioline Group	636	3,293	5,235		9,164
Core	(54)	(150)	(363)	548	(19)
Transaction Costs				(1,240)	(1,240)
2011 Expenses	\$ 9,822	\$ 22,772	\$ 24,883	\$ 1,788	\$ 59,265
% of Sales	6%	14%	16%	1%	37%
% Increase (Decrease)	17%	25%	26%	44%	25%
Fiscal 2012 Increases (Decreases):					
U.S. Diagnostics	644	(1,068)	2,439	(365)	1,650
European Diagnostics		(69)	674	(875)	(270)
Life Science					
Bioline Group	25	1,337	(874)		488
Core	(216)	(50)	(750)	465	(551)
2012 Expenses	\$ 10,275	\$ 22,922	\$ 26,372	\$ 1,013	\$ 60,582
% of Sales	6%	13%	15%	1%	35%
% Increase (Decrease)	5%	1%	6%	(43%)	2%

Overall, the relative stability in total operating expense during fiscal 2012 and the increase in fiscal 2011 result in large part from the combined effects of our (i) fiscal 2012 efforts to control spending in each of our segments while investing the necessary resources in our strategic areas of growth; (ii) beginning to realize cost savings during 2012 from the consolidation of our Core Life Science operations into one facility; (iii) incurring costs in connection with the consolidation of our Saco, Maine operations into our Memphis, Tennessee location of approximately \$1,013 during fiscal 2012, and approximately \$1,057 during fiscal 2011 (\$548 of an Operating Expense nature); (iv) incurring during the second quarter of fiscal 2011 approximately \$1,240 of costs in connection with the reorganization of our European and Global Sales and Marketing Leadership; and (v) realizing the impact on all three operating expense categories (i.e., Research & Development, Selling & Marketing, and General & Administrative) during fiscal 2011 of adding the Bioline Group s full-year operating expenses.

Operating expenses for the U.S. Diagnostics segment increased \$1,650 for fiscal 2012 compared to fiscal 2011, and increased \$2,628 for fiscal 2011 compared to fiscal 2010. These overall increases result largely from the combined effects of the following:

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Fiscal 2012

Research & Development

Overall increase in spending on new product development activities, related primarily to our *illumigene®* platform-based test for Group A *Streptococcus*, including an approximate \$350 increase in personnel-related costs.

Selling & Marketing

Field sales force realignment activities during the year resulting in decreased sales commission expenses of approximately \$1,050.

General & Administrative

Improved corporate-wide operating results resulting in increased bonus, profit sharing and deferred compensation expenses of approximately \$2,800, partially offset by an approximate \$650 decrease in stock-based compensation during fiscal 2012.

Fiscal 2011

Research & Development

Overall increase in spending on new product development activities related to products submitted to the FDA during the year and planned for submission during fiscal 2012, as well as spending on increased *illumigene®* component qualification activities. Costs include increased personnel-related and quality control costs of approximately \$450 and \$150, respectively.

Selling & Marketing

The launch of *illumigene®* resulting in increased sales commissions expenses and increased travel and trade show expenses of approximately \$750 and \$300, respectively.

General & Administrative

The positive effects of overall cost containment and reduction efforts being offset by an approximate \$750 increase in stock-based compensation during fiscal 2011.

Operating expenses for the European Diagnostics segment decreased \$270 for fiscal 2012 compared to fiscal 2011, and increased \$1,174 for fiscal 2011 compared to fiscal 2010. The 2012 decrease primarily reflects the effect of the aforementioned reorganization of our sales and marketing leadership during the fiscal 2011 second quarter being partially offset by increased costs of additional management personnel. The fiscal 2011 increase was primarily attributable to costs associated with the sales and marketing leadership reorganization during the fiscal 2011 second quarter.

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Operating expenses for the Life Science segment decreased \$63 for fiscal 2012 compared to fiscal 2011, and increased \$9,145 for fiscal 2011 compared to fiscal 2010, excluding the effect of one-time transaction costs of \$1,240 in fiscal 2010. The decrease in 2012 primarily results from (1) realizing cost savings from the Maine-Tennessee facility consolidation, and (2) an increased investment in Bioline Group sales resources. The increase in 2011 resulted from the addition of the Bioline Group s full-year operating expenses and the costs related to consolidating the Maine and Tennessee facilities.

The amount of stock-based compensation expense reported for fiscal 2012, 2011 and 2010 was \$1,987, \$2,614 and \$1,866, respectively. In November 2009, we granted restricted shares and restricted share units to certain employees, with half of each employee s grant being time-vested restricted shares or restricted share units vesting in total in four years, and the remaining half being subject to attainment of a specified earnings target for fiscal 2010. Dividend equivalents were paid on these shares and units throughout fiscal 2010. While the fiscal 2010 earnings target was not met, on September 30, 2010, the Compensation Committee of the Board of Directors chose to convert the performance-based restricted shares to time-vested restricted shares vesting in total after four years in recognition of the achievement in fiscal 2010 of several strategic initiatives. Expense totaling \$472 was recorded in fiscal 2010 as a result of this conversion, and is included in the total amount of stock-based compensation set forth above.

During November 2010, we granted restricted shares and restricted share units to certain employees, with half of each employee s grant being time-vested restricted shares or restricted share units vesting in full in four years, and the remaining half being subject to attainment of a specified earnings target for fiscal 2011. Although dividend equivalents were paid on these shares and units throughout fiscal 2011, because Meridian s fiscal net earnings did not reach the minimum level in 2011, the performance-based awards were not earned and no stock-based compensation has been recorded for these performance-based awards.

Similar to previous years, during fiscal 2012, we granted restricted share units to certain employees, 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 2012. While dividend equivalents were paid on these units throughout fiscal 2012, the target for fiscal 2012 was not met and the performance-based portion of the restricted share units granted during fiscal 2012 has been cancelled. Additionally, 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 can only be earned if specified cumulative revenue thresholds are met one fiscal quarter in advance of planned revenue expectations through fiscal 2015, with the three measurement dates for ratably earning one-third of the grant being (i) the 21-month period ending June 30, 2013, (ii) the 33-month period ending June 30, 2014 and (iii) the 45-month period ending June 30, 2015. To date, no expense has been recognized for these restricted share units and options.

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Operating Income

Operating income increased 23% and decreased 3% in fiscal 2012 and fiscal 2011, respectively, as a result of the factors discussed above.

Other Income and Expense

Interest income was \$42, \$115 and \$124, for fiscal 2012, 2011 and 2010, respectively. The decreases during the periods reflect (i) lower interest yields in the current interest rate environment, (ii) the use of cash early in the fiscal 2010 fourth quarter to acquire the Bioline Group, and (iii) the use of cash in fiscal 2011 to fund facility expansions in Cincinnati and Memphis, and to build *illumigene®* inventory. The increased level of other income during fiscal 2012 reflects an approximate \$160 increase in net currency gains, partially offset by an approximate \$100 decrease in the Bioline Group s grant income from a foreign government. During fiscal 2011, the higher level of other income, net, can primarily be attributed to the addition of the Bioline Group, as it contributed grant income from a foreign government agency of approximately \$200. As noted, the level of grant income significantly decreased in fiscal 2012 and is not expected to continue at a significant level, if at all, in fiscal 2013 due to the local country s rules regarding ownership by a U.S. parent.

Income Taxes

The effective rate for income taxes was 33%, 34% and 36% for fiscal 2012, 2011 and 2010, respectively. The decrease in the effective tax rate for fiscal 2012 primarily resulted from the net tax benefit on dividends from a foreign-based subsidiary, while the decrease in the effective tax rate for fiscal 2011 was primarily attributable to the release of certain reserves for uncertain tax positions due to the passage of the relevant statutes of limitations and the nondeductible nature of Bioline acquisition costs.

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, revenue or operating income in fiscal 2012, 2011 and 2010.

Liquidity and Capital Resources:

Comparative Cash Flow Analysis

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.

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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.

At the present time, 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, \$4,600 of our accounts receivable at September 30, 2012 is due from Italian hospital customers whose funding ultimately comes from the Italian government. During the fourth quarter of fiscal 2011 and first quarter of fiscal 2012, we experienced a deterioration in the aging of our Italian accounts receivable. While such aging appeared to stabilize during fiscal 2012, we continue to monitor such accounts closely. 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.

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. There have been no impairments from these annual reviews. As of October 31, 2012, our stock price was \$19.75 per share, compared to our book value per share of \$3.46 as of September 30, 2012. This relationship, stock price trading at a 5.7x multiple of book value, is an indicator that the fluctuation in overall stock market valuations and its impact on our stock price has not been a triggering event for impairment of our goodwill and other long-lived assets.

Net cash provided by operating activities increased 89% to \$42,446 in fiscal 2012 reflecting the 24% increase in net earnings and the effects of net working capital changes related to our investments in *illumigene*[®] inventory, including readers, and the timing of payments from customers and payments to suppliers.

Net cash used for investing activities was \$4,435 for fiscal 2012 compared to \$9,151 for fiscal 2011. This decrease in cash used primarily results from an approximate \$5,600 decrease in expenditures for property, plant and equipment compared to fiscal 2011, which included significant facility expansions in both Cincinnati and Memphis.

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Net cash used for financing activities was \$30,674 for fiscal 2012 compared to \$27,520 for fiscal 2011. This increase was attributable to the combined effects of a 1% increase in dividend payments and an approximate \$2,900 decrease in proceeds and tax benefits from the exercise of stock options.

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 the last two quarters of fiscal 2012, as well as for the full fiscal year, the per share amount of our cash dividend was lower than our diluted earnings per share, nearly in line with our long-standing policy of establishing a dividend payout ratio between 75% and 85% of diluted earnings per share. During fiscal 2013, we believe that this positive dividend payout relationship will continue, although no assurances can be made in this regard. During fiscal 2012, cash generated from the Company s operating activities exceeded the quarterly dividend by 36%.

Capital Resources

We have a \$30,000 credit facility with a commercial bank which expires September 15, 2015. As of November 23, 2012, 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 2012 or fiscal 2011.

Our capital expenditures are estimated to range between approximately \$3,500 to \$5,000 for fiscal 2013, 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.

Medical Device Tax

Included within the U.S. government s comprehensive healthcare reform legislation, enacted during 2010, was the establishment of a 2.3% excise tax on the sales of medical devices beginning in calendar 2013. We currently anticipate that this legislation will result in an excise tax for our company of approximately \$2,000 in fiscal 2013. At the present time it is believed that little, if any, of this cost can be passed on to customers.

Known Contractual Obligations:

Known contractual obligations and their related due dates were as follows as of September 30, 2012:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases (1)	\$ 3,970	\$ 1,890	\$ 1,918	\$ 124	\$ 38
Purchase obligations (2)	9,214	8,452	762		
Uncertain income tax positions liability and interest (3)	471	471			
Total	\$ 13,655	\$ 10,813	\$ 2,680	\$ 124	\$ 38

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- (1) Meridian and its subsidiaries are lessees of (i) office and warehouse buildings in Ohio, Massachusetts, Florida, Australia, Belgium, France, Holland, Germany 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, 2012, our liabilities for uncertain tax positions and related interest and penalties were \$369 and \$102, 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 \$3,500 in fiscal 2013. These royalty payments primarily relate to the U.S. Diagnostics segment.

Meridian entered into a license agreement in October 2006 with a third party that provides rights to a molecular technology for infectious disease testing in the United States, Europe and other geographic markets. The agreement, as amended, calls for remaining payments of up to approximately \$2,050, based on the achievement of certain product development milestones and on-going royalties once products are available for commercial sale.

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. We are exposed to foreign currency risk related to our European distribution operations where the billing currency is the Euro for most of our customers in these markets. We also are exposed to foreign currency risk related to the supply of certain diagnostic test kits by manufacturers located in Germany and Spain. These foreign currency risks are opposite one another, providing a natural hedge with respect to consolidated gross profit and operating income. Additionally, as a result of the July 2010 Bioline Group acquisition, we are exposed to foreign currency risks related to the Bioline Group s operations in Australia (Australian dollar), Germany (Euro), and the U.K. (British pound). 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 U.S. Diagnostic segment s sales through two national distributors were 49% of the U.S. Diagnostics segment s total sales or 30% of consolidated sales for fiscal 2012. Our *C. difficile*, foodborne and *H. pylori* product families accounted for 62% of our U.S. Diagnostics segment s third-party sales during fiscal 2012. These same products accounted for 59% of our European Diagnostics segment s third-party sales and 47% of our consolidated sales for fiscal 2012.

Our Life Science segment s sales of purified antigens and reagents to two diagnostics manufacturing customers were 19% of the Life Science segment s total sales for fiscal 2012 or 5% of our consolidated sales for fiscal 2012. Our Life Science segment has four other significant customers who purchase antigens, antibodies and reagents, which together comprise 9% of the segment s total sales for fiscal 2012.

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 revenues are derived primarily from product sales. Revenue is generally recognized from sales when product is shipped and title has passed to the buyer. Revenue for the U.S. Diagnostics segment is reduced at the date of sale for product price adjustments due certain distributors under local contracts designed to reimburse such distributors for their cost in handling our products. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, estimates of inventories 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 segments includes bundled product revenue for our *illumigene®* molecular test system. The bundled product includes an instrument, instrument accessories and test kits. If not sold outright, amounts invoiced for the *illumigene®* test kits cover the instrument, accessories and test kits. Revenue is recognized based on test kit sales. If not sold outright, costs for the instruments are recognized in cost of sales over the expected instrument utilization period, generally three years.

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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. Pricing is often subject to a competitive bidding process. Contract research and development services may be performed on a time and materials basis or fixed fee basis. For time and materials arrangements, revenue is recognized upon completion and acceptance by the customer. For contract manufacturing services, revenue is generally recognized upon delivery of product and acceptance by the customer. In some cases, customers may request that we store on their behalf, clinical grade biologicals that we produce under contract manufacturing agreements. These cases arise when customers do not have clinical grade storage facilities or do not want to risk contamination during transport. For such cases, revenue may be recognized on a bill-and-hold basis. No such bill-and-hold arrangements existed at September 30, 2012 or September 30, 2011.

Inventories

Our inventories are carried at the lower of cost or market. Cost is determined on a first-in, first-out (FIFO) basis for substantially all of our inventories. 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. Management estimates these reserves based on assumptions about future demand and market conditions. If actual demand and market conditions were to be less favorable than such estimates, additional inventory write-downs would be required and recorded in the period known. Such adjustments would negatively affect gross profit margin and overall results of operations.

Intangible Assets

Our intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include customer lists, 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) by applying a fair-value based test. There have been no impairments from these analyses.

Identifiable intangibles with finite lives are subject to impairment testing. 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 2012, 2011 or 2010 indicating that the carrying value of such assets may not be recoverable.

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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. Management is 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, management also makes judgments and assumptions regarding useful lives.

Management considers 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.

Income Taxes

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

Our deferred tax assets include net operating loss carryforwards 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. Management assesses the level of deferred tax asset valuation allowance by taking into consideration historical and future projected operating results, future reversals of taxable temporary differences, as well as 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 management to be permanently re-invested in such subsidiaries. Consequently, U.S. deferred tax liabilities on such earnings have not been recorded. We believe that such U.S. taxes would be largely offset by foreign tax credits for taxes paid locally.

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 financial condition or results of operations.

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Recent Accounting Pronouncements:

In May 2011, FASB issued Accounting Standards Update (ASU) No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs.* FASB ASU No. 2011-04 amends and clarifies the measurement and disclosure requirements of FASB ASC 820, resulting in common requirements for measuring fair value and for disclosing information about fair value measurement, clarification of how to apply existing fair value measurement and disclosure requirements, and changes to certain principles and requirements for measuring fair value measurements. The new requirements were effective for fiscal years beginning after December 15, 2011. The Company s adoption of this amended guidance on October 1, 2012 had no material impact on the Company s consolidated results of operations, cash flows or financial position.

In June 2011, FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*, which amends the disclosure and presentation requirements of Comprehensive Income. Specifically, FASB ASU No. 2011-05 requires that all nonowner changes in shareholders equity be presented either in 1) a single continuous statement of comprehensive income or 2) two separate but consecutive statements, in which the first statement presents total net income and its components, and the second statement presents total other comprehensive income and its components. These new presentation requirements, as currently set forth, are effective for the Company as of October 1, 2012 and will impact financial statement presentation, but will not impact the Company s consolidated results of operations, cash flows or financial position.

In September 2011, FASB issued ASU No. 2011-08, *Testing Goodwill for Impairment*, which amended goodwill impairment guidance to provide an option for entities to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. After assessing the totality of events and circumstances, if an entity determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount. After assessing the totality of amount, performance of the two-step impairment test is no longer required. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted. Adoption of this guidance in fiscal 2013 is not expected to have any impact on the Company s consolidated results of operations, cash flow or financial position.

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

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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 *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, 2012.

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

/s/ John A. Kraeutler John A. Kraeutler Chief Executive Officer November 29, 2012 /s/ Melissa A. Lueke Melissa A. Lueke Executive Vice President and Chief Financial Officer November 29, 2012

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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 as of September 30, 2012 and 2011, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended September 30, 2012. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Schedule No. II. We also have audited Meridian Bioscience, Inc. s internal control over financial reporting as of September 30, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Meridian Bioscience, Inc. 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 Meridian Bioscience, Inc. 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 statement, 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, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2012 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.

In our opinion, Meridian Bioscience, Inc. and subsidiaries, maintained, in all material respects, effective internal control over financial reporting as of September 30, 2012, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio

November 29, 2012

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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,	2012	2011	2010
Net Sales	\$ 173,542	\$ 159,723	\$ 143,000
Cost of Sales	63,664	59,916	54,304
Cost of Sales Plant consolidation	00,001	509	5 1,50 1
		507	
Gross Profit	109,878	99,298	88,696
Operating Expenses:			
Research and development	10,275	9,822	8,396
Selling and marketing	22,922	22,772	18,250
General and administrative	26,372	24,883	19,672
Plant consolidation costs	1,013	548	
Sales and marketing leadership reorganization		1,240	
Bioline Group transaction costs			1,240
Total operating expenses	60,582	59,265	47,558
	,	,	,
Operating Income	49,296	40.033	41,138
operating income	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	10,055	11,150
Other Income:			
Interest income	42	115	124
Other, net	378	352	138
Total other income	420	467	262
Earnings Before Income Taxes	49,716	40,500	41,400
Income Tax Provision	16,345	13,669	14,753
	10,545	15,009	14,755
	¢ 22.2 7 1	• • • • • • • • • •	• • • • • • •
Net Earnings	\$ 33,371	\$ 26,831	\$ 26,647
Earnings Per Share Data:			
Basic earnings per common share	\$ 0.81	\$ 0.66	\$ 0.66
Diluted earnings per common share	\$ 0.80	\$ 0.65	\$ 0.65
Common shares used for basic earnings per common share	41,080	40,715	40,515
Effect of dilutive stock options and restricted shares and units	528	643	634
······································			
Common shares used for diluted earnings per common share	41,608	41,358	41,149
common shares used for unded earnings per common share	41,000	41,556	41,149
Dividende deelered per common share	\$ 0.76	\$ 0.76	\$ 0.74
Dividends declared per common share	φ U./O	\$ 0.76	φ 0.74
Anti-dilutive Securities:			
Common share options and restricted shares and units	320	191	217
The accompanying notes are an integral part of these consolidated financial statements.			

CONSOLIDATED STATEMENTS OF CASH FLOWS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

For the Year Ended September 30,	2012	2011	2010
Cash Flows From Operating Activities			
Net earnings	\$ 33,371	\$ 26,831	\$ 26,647
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	3,490	3,380	3,104
Amortization of intangible assets	2,165	2,321	1,581
Amortization of deferred illumigene instrument costs	942	172	
Stock-based compensation	1,987	2,504	1,866
Deferred income taxes	(1,448)	(1,218)	12
Loss on disposition and write-down of fixed assets and other assets	359	446	26
Change in current assets, net of acquisition	1,234	(10,762)	2,429
Change in current liabilities, net of acquisition	3,216	(570)	(5,775)
Other, net	(2,870)	(648)	(157)
Net cash provided by operating activities	42,446	22,456	29,733
Cash Flows From Investing Activities			
Purchases of property, plant and equipment	(3,530)	(9,139)	(3,083)
Proceeds from sale of assets	400		
Proceeds from sales and calls of short-term investments			7,275
Acquisition of Bioline Group, net of cash received			(20,404)
Purchases of intangibles and other assets	(1,305)	(12)	(120)
Net cash used for investing activities	(4,435)	(9,151)	(16,332)
Cash Flows From Financing Activities			
Dividends paid	(31,226)	(30,943)	(29,985)
Proceeds and tax benefits from exercises of stock options	552	3,423	795
•			
Net cash used for financing activities	(30,674)	(27,520)	(29,190)
Effect of Exchange Rate Changes on Cash and Equivalents	630	(38)	(362)
Net Increase (Decrease) in Cash and Equivalents	7,967	(14,253)	(16,151)
Cash and Equivalents at Beginning of Period	23,626	37,879	54,030
Cash and Equivalents at End of Period	\$ 31,593	\$ 23,626	\$ 37,879
Supplemental Cash Flow Information			
Cash paid for income taxes The accompanying notes are an integral part of these consolidated financial statements.	\$ 16,010	\$ 17,991	\$ 16,036

CONSOLIDATED BALANCE SHEETS (dollars in thousands)

Meridian Bioscience, Inc. and Subsidiaries

As of September 30,	2012	2011
Assets		
Current Assets:	¢ 21.502	¢ 02 (2(
Cash and equivalents	\$ 31,593	\$ 23,626
Accounts receivable, less allowances of \$574 in 2012 and \$310 in 2011 Inventories	24,183	24,844
	31,682	32,689
Prepaid expenses and other current assets	6,203	6,343
Deferred income taxes	2,929	2,852
Total current assets	96,590	90,354
Property, Plant and Equipment, at Cost:		
Land	1,175	1,184
Buildings and improvements	25,983	23,033
Machinery, equipment and furniture	34,917	32,408
Construction in progress	1,149	3,887
Subtotal	63,224	60,512
Less: accumulated depreciation and amortization	37,069	33,973
Net property, plant and equipment	26,155	26,539
Net property, plant and equipment	20,135	20,339
Other Assets:		
Goodwill	23,146	23,124
Other intangible assets, net	10,264	10,947
Restricted cash	1,000	1,000
Deferred illumigene instrument costs, net	3,958	3,304
Other assets	268	225
	200	223
Total other assets	38,636	38,600
	50,050	50,000
Total acceta	¢ 171 901	¢ 155 402
Total assets	\$ 161,381	\$ 155,493

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, Liabilities and Shareholders Equity	2012	2011
Current Liabilities:		
Accounts payable	\$ 5,794	\$ 5,548
Accrued employee compensation costs	5,827	4,235
Other accrued expenses	5,247	4,692
Income taxes payable	1,594	789
Total current liabilities	18,462	15,264
Deferred Income Taxes	171	1,705
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, 41,284,485 and 41,237,120 issued		
Additional paid-in capital	102,443	100,010
Retained earnings	40,210	38,065
Accumulated other comprehensive income	95	449
Total shareholders equity	142,748	138,524
Total liabilities and shareholders equity	\$ 161,381	\$ 155,493

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)	Comp Income (Loss)	Total
Balance at September 30, 2009	40,493	\$ 91,668	\$ 45,515	\$ 722		\$ 137,905
Cash dividends paid \$0.74 per share			(29,985)			(29,985)
Exercise of stock options	67	995				995
Issuance of restricted shares, net of forfeitures	94					
Stock compensation expense		1,866				1,866
Comprehensive income:						
Net earnings			26,647		\$ 26,647	26,647
Other comprehensive income taxes				36	36	36
Foreign currency translation adjustment				(103)	(103)	(103)
Comprehensive income					\$ 26,580	
Balance at September 30, 2010	40,654	94,529	42,177	655		137,361
•						
Cash dividends paid \$0.76 per share			(30,943)			(30,943)
Exercise of stock options	485	2,977	(2,977
Issuance of restricted shares, net of forfeitures	165					
Cancellation of restricted shares	(85)					
Conversion of restricted stock units	18					
Stock compensation expense		2,504				2,504
Comprehensive income:						
Net earnings			26,831		\$ 26,831	26,831
Other comprehensive income taxes				114	114	114
Foreign currency translation adjustment				(320)	(320)	(320)
Comprehensive income					\$ 26,625	
Balance at September 30, 2011	41,237	100,010	38,065	449		138,524
Cash dividends paid \$0.76 per share			(31,226)			(31,226)
Exercise of stock options	47	446				446
Issuance of restricted shares, net of forfeitures	(5)					
Conversion of restricted stock units	5					
Stock compensation expense		1,987				1,987
Comprehensive income:						
Net earnings			33,371		\$ 33,371	33,371
Other comprehensive income taxes				148	148	148
Foreign currency translation adjustment				(502)	(502)	(502)
Comprehensive income					\$ 33,017	
Balance at September 30, 2012	41,284	\$ 102,443	\$ 40,210	\$ 95		\$ 142,748

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Meridian Bioscience, Inc. and Subsidiaries

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

(1) Summary of Significant Accounting Policies

- (a) Nature of Business Meridian is a fully-integrated life science company whose principal businesses are (i) the development, manufacture and distribution of clinical diagnostic test kits primarily for certain gastrointestinal, viral, respiratory and parasitic infectious diseases, (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 and Euro currencies. These gains and losses are included in other income and expense in the accompanying consolidated statements of operations.
- (e) Cash, Cash Equivalents and Investments The primary objectives of our investment activities are to preserve capital and provide sufficient liquidity to meet operating requirements and fund strategic initiatives such as acquisitions. We maintain a written investment policy that governs the management of our investments in fixed income securities. This policy, among other things, provides that we may purchase only high credit-quality securities, that have short-term ratings of at least A-2, P-2 and F-1 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 (FDIC) insurance limit.

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Our investment portfolio includes the following components:

	September 30, 2012 Cash		September	30, 2011	
	and	0.1	Cash and		
	Equivalents	Other	Equivalents	Other	
Overnight repurchase agreements	\$ 13,492	\$	\$11,784	\$	
Cash on hand					
Restricted		1,000		1,000	
Unrestricted	18,101		11,842		
Total	\$ 31,593	\$ 1,000	\$ 23,626	\$ 1,000	

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

We establish reserves against cost for excess and obsolete materials, finished goods whose shelf life may expire before sale to customers, and other identified exposures. Such reserves were \$2,271 and \$3,175 at September 30, 2012 and 2011, 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.

During the fourth quarter of fiscal 2011, we announced the closure of our Saco, Maine facility, and began the consolidation of manufacturing operations from this facility with our Memphis, Tennessee facility. In connection with this consolidation, inventory write-downs totaling \$509 have been recorded as Cost of Sales Plant consolidation during the fiscal year ended September 30, 2011 in the accompanying Consolidation Statements 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 as follows:

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Buildings and improvements 18 to 40 years

Machinery, equipment and furniture 3 to 10 years

Computer equipment and software 3 to 5 years

In connection with the consolidation of our Maine facility noted in Note 1 (f) above, the carrying value of certain property, plant and equipment, including the building, was determined to be impaired and a write-down of approximately \$210 and \$425 has been recorded as a component of Plant consolidation costs during the fiscal year ended September 30, 2012 and 2011, respectively, in the accompanying Consolidation Statements of Operations. The building and the property on which it sits have been written down to current value, less selling costs, as determined by an independent outside appraisal.

(h) Intangible Assets Goodwill and other intangible assets with indefinite lives are subject to an annual impairment review (or more frequently if impairment indicators arise) by applying a fair-value based test. Fair value is determined via a market approach from three perspectives. These three perspectives are (i) an allocation of our actual enterprise value (defined as market capitalization plus debt less cash and cash equivalents) to each of the reporting units based on revenue and EBITDA contributions to consolidated results; (ii) an allocation of implied enterprise values to each of our reporting units based on average and median EBITDA multiples from a comparable group of companies; and (iii) a review of enterprise value to EBITDA multiples from recent industry merger and acquisition transactions. 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 2012, 2011 or 2010.

The change in goodwill was an increase of \$22 in fiscal 2012 and a decrease of \$178 in fiscal 2011. Both years reflect the effect of the Life Science segment s Bioline Group and the currency translation adjustments thereon. See Note 2.

A summary of Meridian s acquired intangible assets subject to amortization, as of September 30, 2012 and 2011 is as follows.

	2012		20)11	
	Gross		Gross		
	Carrying	Accum.	Carrying	Accum.	
As of September 30,	Value	Amort.	Value	Amort.	
Manufacturing technologies, core products and cell lines	\$ 11,678	\$ 9,327	\$11,626	\$ 8,545	
Trademarks, licenses and patents	4,704	1,616	3,538	1,337	
Customer lists and supply agreements	12,360	7,535	12,222	6,557	
	\$ 28,742	\$ 18,478	\$ 27,386	\$ 16,439	

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The actual aggregate amortization expense for these intangible assets for fiscal 2012, 2011 and 2010 was \$2,165, \$2,321 and \$1,581, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2013 \$2,196, fiscal 2014 \$1,771, fiscal 2015 \$1,523, fiscal 2016 \$1,179 and fiscal 2017 \$930.

Long-lived assets, excluding goodwill and identifiable intangibles with indefinite lives, 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.

Our ability to recover 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 impairment write-downs related to the consolidation of our Maine operations.

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.

(i) Revenue Recognition Revenue is generally recognized from sales when product is shipped and title has passed to the buyer. Revenue for the U.S. 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 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 \$3,877 at September 30, 2012 and \$4,176 at September 30, 2011, and have been netted against accounts receivable.

Revenue for our Diagnostics segments includes bundled product revenue for our *illumigene®* molecular test system. The bundled product includes an instrument, instrument accessories and test kits. If not sold outright, amounts invoiced for the *illumigene®* test kits cover the instrument, accessories and test kits. Revenue is recognized based on test kit sales. If not sold outright, costs for the instruments are recognized in cost of sales over the expected instrument utilization period, generally three years.

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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. Pricing is often subject to a competitive bidding process. Contract research and development services may be performed on a time and materials basis or fixed fee basis. For time and materials arrangements, revenue is recognized upon completion and acceptance by the customer. For contract manufacturing services, revenue is generally recognized upon delivery of product and acceptance by the customer. In some cases, customers may request that we store on their behalf, clinical grade biologicals that we produce under contract manufacturing agreements. These cases arise when customers do not have clinical grade storage facilities or do not want to risk contamination during transport. For such cases, revenue may be recognized on a bill-and-hold basis. No such bill-and-hold arrangements existed at September 30, 2012 or September 30, 2011.

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. The allowance for doubtful accounts and related metrics, such as days sales outstanding, are reviewed monthly. Accounts with past due balances over 90 days are reviewed individually for collectibility. Customer invoices are charged off against the allowance when we believe it is probable that the invoices will not be paid.

- (j) Research and Development Costs Research and development costs are charged to expense as incurred. Research and development costs include, among other things, salaries and wages for research scientists, materials and supplies used in the development of new products, costs for development of instrumentation equipment, costs for clinical trials, and costs for facilities and equipment.
- (k) Income Taxes The provision for income taxes includes federal, foreign, state and local income taxes currently payable and those deferred because of temporary differences between income for financial reporting and income for tax purposes. We prepare estimates of permanent and temporary differences between income for financial reporting purposes and income for tax purposes. These differences are adjusted to actual upon filing of our tax returns, typically occurring in the third and fourth quarters of the current fiscal year for the preceding fiscal year s estimates.

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

- (1) **Stock-based Compensation** We recognize compensation expense for all share-based awards made to employees, based upon the fair value of the share-based award on the date of the grant. See Note 7(b).
- (m) Comprehensive Income (Loss) Comprehensive income (loss) represents the net change in shareholders equity during a period from sources other than transactions with shareholders. Our comprehensive income or loss is comprised of net earnings, foreign currency translation, and the related income tax effects. Components of beginning and ending accumulated other comprehensive income or loss, and related activity, are shown in the following table:

	Foreign Currency Translation Adjustment	Income Taxes	Total
Balance at September 30, 2011	\$ 687	\$ (238)	\$ 449
Currency translation	(502)		(502)
Income taxes		148	148
Balance at September 30, 2012	\$ 185	\$ (90)	\$ 95

- (n) Shipping and Handling costs Shipping and handling costs invoiced to customers are included in net sales. 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 sales) in the accompanying consolidated statements of operations.

(2) Acquisition of Bioline Group

On July 20, 2010, we acquired all of the outstanding common stock of the Bioline group of companies (collectively the Bioline Group). We paid \$23,849 from cash and equivalents on hand to acquire the Bioline Group. Headquartered in London, the Bioline Group is a leading manufacturer and distributor of molecular biology reagents with additional operations in Germany, Australia and the United States. The highly specialized molecular biology reagents it supplies to the life science research, biotech, pharmaceutical and commercial diagnostics markets are the critical components used in PCR testing for DNA, RNA and other genomic testing.

As a result of the consideration paid exceeding the fair value of the net assets being acquired, goodwill in the amount of \$12,992 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. This goodwill resulted largely from the addition of key global operations and direct sales capabilities, management talent and a research-oriented customer base, to complement our existing Life Science operations. In addition to the Bioline Group s results of operations since the acquisition date, which are included in our fiscal 2012, 2011 and 2010 Consolidated Statements of Operations and reported as part of the Life Science segment, the consolidated results for fiscal 2012, 2011 and 2010 also include:

- \$587 and \$230 of Cost of Sales for fiscal 2011 and fiscal 2010, respectively, related to the roll-out of fair value inventory adjustments for sales of products that were in the Bioline Group s inventory on the date of acquisition and, therefore, were valued at fair value, rather than manufactured cost, in the opening balance sheet; and
- \$879, \$1,003 and \$166 of General and Administrative Expenses for fiscal 2012, 2011 and 2010, respectively, related to the amortization of specific identifiable intangible assets recorded on the opening balance sheet, including customer relationships, license agreements, non-compete agreements, manufacturing processes and trade names.

The results of the Bioline Group included in the consolidated results of the Company for fiscal 2012, 2011 and 2010 are as follows, reflecting the items noted above:

	2012	2011	2010
Net Sales	\$ 17,078	\$ 14,869	\$ 2,084
Operating Income (Loss)	\$ 1,881	\$ 26	\$ (126)
Net Earnings (Loss)	\$ 1,649	\$ 240	\$ (1,262)

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The recognized amounts of identifiable assets acquired and liabilities assumed in the acquisition of the Bioline Group, reflecting finalization of the of the purchase price allocation during fiscal 2011, were as follows:

	July 20, 2010
Fair value of assets acquired -	
Cash and equivalents	\$ 3,445
Accounts receivable	1,897
Inventories	2,807
Other current assets	350
Property, plant and equipment, net	816
Goodwill	12,992
Other intangible assets (estimated useful life)	
Customer relationships (10 years)	3,898
Manufacturing processes (6 years)	1,467
License agreements (approximate 8 year wtd. avg.)	718
Non-compete agreements (1 year)	122
Trade names (10 years)	995
	29,507
Fair value of liabilities assumed -	
Accounts payable and accrued expenses	3,181
Deferred income tax liabilities	2,477
Total consideration paid	\$ 23,849

The consolidated pro forma results of the combined entities of Meridian and the Bioline Group, had the acquisition date been October 1, 2009, are as follows for the periods indicated:

		(UNAUDITED)			
	Fiscal Ye	Fiscal Year Ended September 30,			
	2012	2011	2010		
Net Sales	\$ 173,542	\$ 159,723	\$ 153,635		
Net Earnings	\$ 33,371	\$ 27,282	\$ 25,980		
Diluted Earnings Per Common Share	\$ 0.80	\$ 0.66	\$ 0.63		

These pro forma amounts have been calculated after adjusting the results of the Bioline Group to reflect the transaction costs incurred by the Company and the additional amortization that would have been charged assuming the previously-discussed fair value adjustments to inventory and identifiable intangible assets had been applied on October 1, 2009, together with the consequential tax effects. Although this results in no pro forma adjustments to fiscal 2012 results, fiscal 2011 pro forma earnings exclude \$694 related to amortization of the fair value adjustments to inventory and certain of the identifiable intangible assets, and the related tax effects, as these amounts have been included in the fiscal 2010 pro forma earnings. Fiscal 2010 pro forma earnings include an additional \$1,443 of amortization (\$587 related to fair value adjustments to inventory and \$856 related to identifiable intangible assets), and the related tax effects, that would have resulted from applying the previously-discussed fair value adjustments as of October 1, 2009.

(3) Inventories

Inventories are comprised of the following:

As of September 30,	2012	2011
Raw materials	\$ 6,916	\$ 7,272
Work-in-process	9,540	7,016
Finished goods illumigene instruments	2,326	4,179
Finished goods kits and reagents	12,900	14,222
Total	\$ 31,682	\$ 32,689

(4) Bank Credit Arrangements

We have a \$30,000 credit facility with a commercial bank, which expires in September 2015. This credit facility is collateralized by our business assets, except for those of non-U.S. subsidiaries, which totaled approximately \$134,000 at September 30, 2012. There were no borrowings outstanding on this credit facility at September 30, 2012 or September 30, 2011. Available borrowings under this credit facility were \$30,000 at September 30, 2012 and September 30, 2011. 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.

(5) Fair Value Measurements

We use a fair value measurement to value our financial assets and liabilities. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value hierarchy prioritizes inputs to valuation techniques used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are accessible at the measurement date for assets and liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly. These include quoted prices for identical or similar assets or liabilities in markets that are not active, that is, markets in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers, or in which little information is released publicly and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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Level 3: Unobservable inputs, developed using our estimates and assumptions, which reflect those that the market participants would use. Such inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

Determining where an asset or liability falls within the hierarchy depends on the lowest level input that is significant to the fair value measurement as a whole. In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in the assessment of fair value.

We had no financial assets or liabilities carried at fair value at September 30, 2012 or 2011 to be classified as Level 1, 2 or 3.

(6) Income Taxes

(a) Earnings before income taxes, and the related provision for income taxes for the years ended September 30, 2012, 2011 and 2010 were as follows:

Vers Ended Contembor 20	2012	2011	2010
Year Ended September 30,			
Domestic	\$ 44,774	\$ 37,955	\$ 38,329
Foreign	4,942	2,545	3,071
Total earnings before income taxes	\$ 49,716	\$ 40,500	\$ 41,400
Provision (credit) for income taxes			
Federal			
Current	\$ 15,077	\$ 13,336	\$ 13,626
Temporary differences			
Fixed asset basis differences and depreciation	2	(155)	58
Intangible asset basis differences and amortization	(354)	(312)	(335)
Currently non-deductible expenses and reserves	(397)	(627)	(29)
Stock-based compensation	(599)	(706)	(618)
Other, net	74	35	(75)
Subtotal	13,803	11,571	12,627
State and local	1,521	1,213	1,186
Foreign	1,021	885	940
Total income tax provision	\$ 16,345	\$ 13,669	\$ 14,753
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(b) The following is a reconciliation between the statutory U.S. income tax rate and the effective rate derived by dividing the provision for income taxes by earnings before income taxes:

Year Ended September 30,	2012		2011		2010	
Computed income taxes at statutory rate	\$ 17,398	35.0 %	\$ 14,175	35.0 %	\$ 14,490	35.0 %
Increase (decrease) in taxes resulting from						
State and local income taxes	994	2.0	834	2.1	777	1.9
Net benefit on foreign dividend	(373)	(0.8)				
Foreign tax rate differences	(114)	(0.2)	58	0.1	(87)	(0.2)
Qualified domestic production incentives	(1,226)	(2.5)	(1,025)	(2.5)	(786)	(1.9)
Bioline Group transaction costs					434	1.0
U.S. book-to-return and uncertain tax position activity	(421)	(0.8)	(422)	(1.0)	8	
Other, net	87	0.2	49	0.1	(83)	(0.2)
	\$ 16,345	32.9 %	\$ 13,669	33.8 %	\$ 14,753	35.6 %

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

As of September 30,	2012	2011
Deferred tax assets		
Valuation reserves and non-deductible expenses	\$ 1,575	\$ 1,529
Stock compensation expense not deductible	3,067	2,562
Net operating loss carryforwards	598	767
Inventory basis differences	1,376	1,322
Subtotal	6,616	6,180
Less valuation allowance	(283)	(439)
Deferred tax assets	6,333	5,741
Deferred tax liabilities		
Fixed asset basis differences and depreciation	(761)	(731)
Intangible asset basis differences and amortization	(2,508)	(3,421)
Other	(306)	(442)
Deferred tax liabilities	(3,575)	(4,594)
Net deferred tax assets	\$ 2,758	\$ 1,147

For income tax purposes, we have tax benefits related to operating loss carryforwards in the countries of Australia, Belgium and the Netherlands. These net operating loss carryforwards have no expiration date. We have recorded deferred tax assets for these carryforwards totaling \$598 and \$767 at September 30, 2012 and September 30, 2011, respectively, excluding valuation allowances for the country of Belgium.

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, after consideration of the valuation allowance, which has been established, will be realized. 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.

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Undistributed earnings reinvested indefinitely in our non-U.S. operations were approximately \$14,000 at September 30, 2012. U.S. deferred tax liabilities of approximately \$5,000 on such earnings have not been recorded. We believe that such U.S. taxes would be largely offset by foreign tax credits for taxes paid in non-U.S. jurisdictions.

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, 2012 and September 30, 2011 related to such positions was \$471 and \$542, 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 2012 and fiscal 2011, we decreased our tax provision by approximately \$18 and \$109, respectively, for such interest and penalties. We had approximately \$102 accrued for the payment of interest and penalties at September 30, 2012 compared to \$120 accrued at September 30, 2011. The amount of our liability for uncertain tax positions expected to be paid or settled in the next 12 months is uncertain.

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

	2012	2011
Unrecognized income tax benefits beginning of year	\$ 542	\$ 725
Additions for tax positions of prior years	159	333
Reductions for tax positions of prior years		(269)
Tax examination settlements		(4)
Expirations of statute of limitations	(230)	(243)
Unrecognized income tax benefits at end of year	\$ 471	\$ 542

We are subject to examination by the tax authorities in the U.S. (both federal and state) and the countries of Australia, Belgium, England, France, Germany, Holland and Italy. In the U.S., open tax years are for fiscal 2010 and forward, with an examination of fiscal 2011 currently underway. The IRS has completed its examination of our federal returns for fiscal 2008 and fiscal 2009. In countries outside the U.S., open tax years generally range from fiscal 2006 and forward. However, in Belgium, the utilization of local net operating loss carryforwards extends the statute of limitations for examination well into the foreseeable future.

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(7) 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 maximum match of 3% of eligible compensation. Our discretionary and matching contributions to the plan amounted to approximately \$2,033, \$637 and \$1,282, during fiscal 2012, 2011 and 2010, respectively.
- (b) Stock-Based Compensation Plans During fiscal 2012, 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.

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, 2012, we have granted 2,638 and 30 shares under the 2004 Plan and 2012 Plan, respectively, thereby resulting in a remaining authorized limit of 3,332 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 have granted options for 4,479 shares under similar plans that have expired. 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.

On November 12, 2009, we granted approximately 105 restricted shares and restricted share units (with a weighted-average grant date fair value of \$22.18 per share) to certain employees, with half of each employee s grant being time-vested restricted shares or restricted share units vesting in total on November 12, 2013, and the remaining half being subject to attainment of a specified earnings target for fiscal 2010. Dividend equivalents were paid on these shares and units throughout fiscal 2010. While the fiscal 2010 earnings target was not met, on September 30, 2010, the Compensation Committee of the Board of Directors chose to convert the performance-based restricted shares to time-vested restricted shares vesting in total on November 12, 2013. This conversion impacted approximately fifty employees and resulted in expense totaling \$472, which was recorded in fiscal 2010 and is included in the total amount of stock-based compensation set forth below.

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During fiscal 2011, we granted approximately 214 restricted shares and restricted share units (with a weighted-average grant date fair value of \$22.93 per share) to certain employees, with half of each employee s grant being time-vested restricted shares or 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 2011. While dividend equivalents were paid on these shares and units throughout fiscal 2011, the target for fiscal 2011 was not met and the performance-based portion of the restricted shares and restricted share units granted during fiscal 2011 were cancelled.

Similar to previous years, during fiscal 2012, we granted approximately 210 restricted share units (with a weighted-average grant date fair value of \$17.99 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 2012. While dividend equivalents were paid on these units throughout fiscal 2012, the target for fiscal 2012 was not met and the performance-based portion of the restricted share units granted during fiscal 2012 have been cancelled. Additionally, 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, as included in the options table below) to certain executive management employees to reward them for meeting Company revenue targets in advance of planned expectations. These awards can only be earned if specified cumulative revenue thresholds are met one fiscal quarter in advance of planned revenue expectations through fiscal 2015, with the three measurement dates for ratably earning one-third of the grant being (i) the 21-month period ending June 30, 2013, (ii) the 33-month period ending June 30, 2014 and (iii) the 45-month period ending June 30, 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 400 restricted shares and restricted share units remain outstanding as of September 30, 2012, with a weighted-average grant date fair value of \$19.89 per share, a weighted-average remaining vesting period of 2.31 years and an aggregate intrinsic value of \$7,696. The weighted-average grant date fair value of the approximate 5 restricted share units that vested during fiscal 2012 was \$24.28 per share.

The amount of stock-based compensation expense reported was \$1,987, \$2,614 and \$1,866 in fiscal 2012, 2011 and 2010, respectively. The fiscal 2012 expense is comprised of \$426 related to stock options and \$1,561 related to restricted shares and units; the fiscal 2011 expense is comprised of \$495 related to stock options, \$2,009 related to restricted shares and units, and \$110 related to the granting of unrestricted common shares to a retiring director; and the fiscal 2010 expense is comprised of \$908 related to stock options and \$958 related to restricted shares and units. The total income tax benefit recognized in the income statement for these stock-based compensation arrangements was \$588, \$865 and \$665, for fiscal 2012, 2011 and 2010, respectively. As of September 30, 2012, we expect future stock compensation expense for unvested options and unvested restricted stock and units to total \$242 and \$2,018, respectively, which will be recognized during fiscal years 2013 through 2016.

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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 2012, 2011 and 2010, we recorded \$73, \$39 and \$17, 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 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,	2012	2011	2010
Risk-free interest rates	1.24 %	1.91 %	2.93 %
Dividend yield	3.42 %	3.74 %	3.12 %
Life of option	6.22 yrs.	5.93 yrs.	5.90 yrs.
Share price volatility	39 %	34 %	42 %
Forfeitures (by employee group)	0%-10%	0%-10%	0%-10%

A summary of the status of our stock option plans at September 30, 2012 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	988	\$ 15.86		
Grants	1,101	17.61		
Exercises	(47)	9.22		
Forfeitures	(10)	20.48		
Cancellations	(6)	20.90		
Outstanding end of period	2,026	\$ 16.93	6.8301	\$ 6,420
Exercisable end of period	864	\$ 15.31	3.9314	\$ 4,694

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A summary of the status of our nonvested options as of September 30, 2012, and changes during the year ended September 30, 2012, is presented below:

	Options	Av Gra	ighted- verage nt Date r Value
Nonvested beginning of period	129	\$	7.91
Granted	1,101		4.68
Vested	(58)		6.18
Forfeited	(10)		5.52
Nonvested end of period	1,162	\$	4.95

The weighted average grant-date fair value of options granted was \$4.68, \$4.97 and \$6.70 for fiscal 2012, 2011 and 2010, respectively. The total intrinsic value of options exercised was \$452, \$8,038 and \$813, for fiscal 2012, 2011 and 2010, respectively. The total grant-date fair value of options that vested during fiscal 2012, 2011 and 2010 was \$361, \$1,594 and \$1,558, respectively.

Cash received from options exercised was \$431, \$1,721 and \$592 for fiscal 2012, 2011 and 2010, respectively. Tax benefits realized and recorded to additional paid-in capital from option exercises totaled \$15, \$1,256 and \$403 for fiscal 2012, 2011 and 2010, respectively.

(8) Major Customers and Segment Data

Our reportable segments are U.S. Diagnostics, European Diagnostics and Life Science. Initial segmentation between Diagnostics and Life Science has been determined based upon products and customers, with further segmentation of Diagnostics between U.S. and European being based upon geographic regions served and management responsibility. The U.S. Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the U.S. and countries outside of Australia, Europe, Africa and the Middle East. The European Diagnostics segment consists of the sale and distribution of diagnostic test kits in Australia, Europe, Africa and the Middle East. 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. 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.

During the fourth quarter of fiscal 2011, we announced our plans to consolidate the Saco, Maine operations into the Memphis, Tennessee facility. This consolidation of facilities is now complete. During fiscal 2012, the Company incurred \$1,013 of costs associated with the facility consolidation, primarily related to employee retention and an additional \$210 write-down of the Maine building facility based on a third-party appraisal. During fiscal 2011, such costs totaled \$1,057 (\$509 in Cost of Sales related to inventory writedowns, and \$548 in Operating Expenses related primarily to employee retention and asset write-downs).

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Sales to individual customers constituting 10% or more of consolidated net sales are as follows:

Year Ended September 30,	2012		2011		2010	
Customer A	\$ 32,771	(19)%	\$ 29,632	(19)%	\$ 33,821	(24)%
Customer B	\$ 19,903	(11)%	\$ 18,308	(11)%	\$ 18,204	(13)%

Combined international sales for the U.S. Diagnostics and Life Science segments were \$31,419, \$28,975, and \$19,350 in fiscal years 2012, 2011 and 2010, respectively. Our focus product families *C. difficile,* foodborne and *H. pylori* accounted for 47%, 44% and 43% of consolidated net sales in fiscal 2012, 2011 and 2010, respectively. Approximately 22% of the consolidated accounts receivable balance at September 30, 2012 is largely dependent upon funds from the Italian government. We currently sole-source from a U.S. manufacturer the *illumipro*-10[®] instrument on which our *illumigene*[®] molecular testing platform operates. Additionally, two of our foodborne products sourced from another vendor accounted for 15%, 14% and 11% of third-party sales for our U.S. Diagnostics segment in fiscal 2012, 2011 and 2010, respectively.

Significant sales information by country for the European Diagnostics and Life Science segments is as follows. Sales are attributed to the geographic area based on the location to which the product is shipped.

Year Ended September 30,	2012	2011	2010
Italy	\$ 7,473	\$ 8,544	\$ 8,183
United Kingdom	2,441	2,373	2,646
France	2,149	2,537	2,590
Holland	1,818	2,142	2,045
Belgium	1,271	1,289	1,291
Other countries	7,848	7,302	7,286
Total European Diagnostics	\$ 23,000	\$ 24,187	\$ 24,041

Year Ended September 30,	2012	2011	2010
United States	\$ 17,805	\$ 15,711	\$ 13,907
United Kingdom	5,251	4,890	2,575
Germany	4,872	4,922	3,376
Australia	3,423	3,105	1,289
France	1,282	1,111	1,318
Other countries	9,899	8,664	4,474
Total Life Science	\$ 42,532	\$ 38,403	\$ 26,939

Identifiable assets for our Italian distribution organization were \$12,537 and \$17,192 at September 30, 2012 and 2011, respectively. At September 30, 2012, identifiable assets for the Bioline Group s operations in the U.K., Germany and Australia totaled approximately \$13,464, \$6,684 and \$4,568, respectively; and totaled \$12,825, \$5,550 and \$2,675, respectively, at September 30, 2011.

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Segment information for the years ended September 30, 2012, 2011 and 2010 is as follows:

	U.S. Diagnostics	European Diagnostics	Life Science	Elim (1)	Total
Fiscal Year 2012	Diagnostics	Diagnostics	Life Science	EIIII (1)	Total
Net sales					
Third-party	\$ 108,010	\$ 23,000	\$ 42,532	\$	\$ 173,542
Inter-segment	9,421	9	1,097	(10,527)	
Operating income (2)	38,234	2,428	8,473	161	49,296
Depreciation and amortization	3,477	255	2,865		6,597
Capital expenditures	2,214	127	1,189		3,530
Goodwill	1,250		21,896		23,146
Other intangible assets	2,239		8,025		10,264
Total assets	82,654	15,443	101,706	(38,422)	161,381
Fiscal Year 2011					
Net sales					
Third-party	\$ 97,133	\$ 24,187	\$ 38,403	\$	\$ 159,723
Inter-segment	10,322	27	756	(11,105)	
Operating income (3)	35,191	2,199	2,595	48	40,033
Depreciation and amortization	2,854	116	2,903		5,873
Capital expenditures	4,964	77	4,098		9,139
Goodwill	1,381		21,743		23,124
Other intangible assets	1,604		9,343		10,947
Total assets	73,850	19,390	92,467	(30,214)	155,493
Fiscal Year 2010					
Net sales					
Third-party	\$ 92,020	\$ 24,041	\$ 26,939	\$	\$ 143,000
Inter-segment	10,285	20	561	(10,866)	
Operating income (4)	33,432	3,367	3,615	724	41,138
Depreciation and amortization	2,722	86	1,877		4,685
Capital expenditures	1,869	213	1,001		3,083
Goodwill	1,381		21,921		23,302
Other intangible assets	2,283	9	11,035		13,327
Total assets	72,030	18,044	90,388	(25,821)	154,641

(1) Eliminations consist of intersegment transactions.

(2) Life Science includes \$1,013 related to consolidation of the Maine operations into the Tennessee facility.

(3) U.S. Diagnostics and European Diagnostics include \$365 and \$875, respectively, related to sales and marketing leadership reorganization costs; and Life Science includes \$1,057 related to consolidation of the Maine operations into the Tennessee facility.

(4) Life Science includes \$1,240 of Bioline transaction costs.

Year Ended September 30,	2012	2011	2010
Segment operating income	\$ 49,296	\$ 40,033	\$41,138
Interest income	42	115	124
Other, net	378	352	138
Consolidated earnings before income taxes	\$ 49,716	\$ 40,500	\$41,400

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The accounting policies of the segments are the same as those described in the summary of significant accounting policies in Note 1. Transactions between segments are accounted for at established intercompany prices for internal and management purposes with all intercompany amounts eliminated in consolidation.

(9) Commitments and Contingencies

(a) **Royalty Commitments** We have entered into various license agreements that require payment of royalties based on a specified percentage of the sales of licensed products (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 \$3,040, \$1,853 and \$734, respectively, for the fiscal years ended September 30, 2012, 2011 and 2010.

Meridian entered into a license agreement in October 2006 with a third party that provides rights to a molecular technology for infectious disease testing in the United States, Europe and other geographic markets. The agreement, as amended, calls for remaining payments of up to approximately \$2,050, based on the achievement of certain product development milestones and on-going royalties once products are available for commercial sale.

- (b) **Purchase Commitments** Excluding the operating lease commitments reflected in Note 9 (c) below, we have purchase commitments primarily for inventory and service items as part of the normal course of business. Commitments made under these obligations are \$8,452, \$698 and \$64 for fiscal 2013, 2014 and 2015, respectively. No purchase commitments have been made beyond fiscal 2015.
- (c) Operating Lease Commitments Meridian and its subsidiaries are lessees of (i) certain office and warehouse buildings in the U.S., Europe and Australia; (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 \$1,524, \$1,391 and \$759 for fiscal 2012, 2011 and 2010, respectively. Operating lease commitments for each of the five succeeding fiscal years are as follows: fiscal 2013 \$1,890, fiscal 2014 \$1,178, fiscal 2015 \$457, fiscal 2016 \$283, and fiscal 2017 \$124.
- (d) Litigation We are a party to various litigation matters from time to time that we believe are in the normal course of business. The ultimate resolution of these matters is not expected to have a material adverse effect on our financial position, results of operations or cash flows.
- (e) Indemnifications In conjunction with certain contracts and agreements, we provide routine indemnifications whose terms range in duration and in some circumstances are not explicitly defined. The maximum obligation under some such indemnifications is not explicitly stated and, as a result of our having no history of paying such indemnifications, cannot be reasonably estimated. We have not made any payments for these indemnifications and no liability is recorded at September 30, 2012 or September 30, 2011. We believe that if we were to incur a loss on any of these matters, the loss would not have a material effect on our financial condition.

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(10) Quarterly Financial Data

(10) Quarterly Financial Data (Unaudited)

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

For the Quarter Ended in Fiscal 2012	December 31	March 31	June 30	September 30
Net sales	\$ 40,266	\$ 47,441	\$ 42,141	\$ 43,694
Gross profit	24,733	29,750	27,643	27,752
Net earnings	6,578	9,626	8,594	8,573
Basic earnings per common share	0.16	0.23	0.21	0.21
Diluted earnings per common share	0.16	0.23	0.21	0.21
Cash dividends per common share	0.19	0.19	0.19	0.19

For the Quarter Ended in Fiscal 2011	December 31	March 31	June 30	September 30
Net sales	\$ 37,263	\$ 41,059	\$40,052	\$ 41,349
Gross profit	23,502	25,957	25,351	24,488
Net earnings	6,025	7,260	6,836	6,710
Basic earnings per common share	0.15	0.18	0.17	0.16
Diluted earnings per common share	0.15	0.18	0.17	0.16
Cash dividends per common share	0.19	0.19	0.19	0.19

(11) Subsequent Events

We evaluated subsequent events after the balance sheet date of September 30, 2012 and there were no material subsequent events that required recognition or additional disclosure in these financial statements.

ITEM 9.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS

ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

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ITEM 9A.

CONTROLS AND PROCEDURES

As of September 30, 2012, 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, 2012. 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, 2012.

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 2013 Annual Shareholders Meeting to be filed with the Commission pursuant to Regulation 14A.

ITEM 12.

EQUITY COMPENSATION INFORMATION

The following table presents summary information as of September 30, 2012 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	avera I out war	Weighted- age exercise orice of tstanding options, rrants 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)	2,020	\$	16.921	3,332
Equity compensation plans not approved by security holders	6		19.285	
Total (2)	2,026	\$	16.928	3,332

(1) 1996 Stock Option Plan, as amended in 2001

1999 Director s Stock Option Plan

2004 Equity Compensation Plan, as amended

- 2012 Stock Incentive Plan
- (2) Weighted-average remaining term of 6.8301 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*	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)
10.3	Dividend Reinvestment Plan (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 1999)
10.4*	Amended and Restated Employment Agreement Dated June 12, 2012 between Meridian and John A. Kraeutler (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on June 14, 2012)
10.5*	Agreement Concerning Disability and Death dated September 10, 2003, between Meridian and William J. Motto (Incorporated by reference to Meridian s Annual Report on Form 10-K for the Fiscal Year Ended September 30, 2003)
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 2012 Officers Performance Compensation Plan (Filed herewith)
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)

- 10.9.1 Amended and Restated Revolving Note with Fifth Third Bank dated September 15, 2012 (Filed herewith)
- 10.9.2 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)
- 10.9.3 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)
- 10.9.4 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 (Filed herewith)
- 10.10* Sample Time-Based Restricted Stock Unit Award Agreement dated November 9, 2011 (Filed herewith)
- 10.11* Sample Performance Award Restricted Stock Unit Award Agreement dated November 9, 2011 (Filed herewith)
- 10.12* 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)
- 10.13* Antonio Interno Retirement-Related Agreements related to retirement as of March 31, 2011 (Incorporated by reference to Meridian s Quarterly Report on Form 10-Q for the Quarterly Period Ended March 31, 2011)
- 13 2012 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 year ended September 30, 2012 filed with the SEC on November 29, 2012, formatted in XBRL includes: (i) Consolidated Statements of Operations for the years ended September 30, 2012, 2011 and 2010; (ii) Consolidated Statements of Cash Flows for the years ended September 30, 2012, 2011 and 2010; (iii) Consolidated Balance Sheets as of September 30, 2012 and 2011; (iv) Consolidated Statements of Shareholders Equity for the years ended September 30, 2012, 2011 and 2010; (v) the Notes to Consolidated Financial Statements; and (vi) Schedule No. II - Valuation and Qualifying Accounts for the years ended September 30, 2012, 2011 and 2010.
- * Management Compensatory Contracts
- (1) Only specific portions of the 2012 Annual Report to Shareholders are incorporated by reference in this Form 10-K as filed herewith. A supplemental paper copy of the 2012 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.

SIGNATURES

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

MERIDIAN BIOSCIENCE, INC.

By: /s/ John A. Kraeutler Date: November 29, 2012 John A. Kraeutler Chief Executive Officer

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/ William J. Motto	Executive Chairman of the Board of Directors	November 29, 2012
William J. Motto		
/s/ John A. Kraeutler	Chief Executive Officer, Director	November 29, 2012
John A. Kraeutler		
/s/ Melissa A. Lueke	Executive Vice President, Chief Financial Officer, and Secretary	November 29, 2012
Melissa A. Lueke		
/s/ James M. Anderson	Director	November 29, 2012
James M. Anderson		
/s/ David C. Phillips	Director	November 29, 2012
David C. Phillips		
/s/ Robert J. Ready	Director	November 29, 2012
Robert J. Ready		

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SCHEDULE

SCHEDULE II

Meridian Bioscience, Inc.

and Subsidiaries

Valuation and Qualifying Accounts

(Dollars in thousands)

Years Ended September 30, 2012, 2011 and 2010

Description Year Ended September 30, 2012:	Begi	nce at nning eriod	Cos	rged to sts and penses	De	ductions	Otl	her (a)	E	lance at End of Period
Allowance for doubtful accounts	\$	310	\$	370	\$	(89)	\$	(17)	\$	574
Inventory realizability reserves	3	3,175		198		(1,024)		(78)		2,271
Valuation allowances deferred taxes		439				(131)		(25)		283
Year Ended September 30, 2011:										
Allowance for doubtful accounts	\$	241	\$	68	\$		\$	1	\$	310
Inventory realizability reserves	2	2,670		1,056		(550)		(1)		3,175
Valuation allowances deferred taxes		439								439
Year Ended September 30, 2010:										
Allowance for doubtful accounts	\$	247	\$	82	\$	(56)	\$	(32)	\$	241
Inventory realizability reserves	1	,025		606		(610)		1,649		2,670
Valuation allowances deferred taxes		470				. ,		(31)		439

(a) Balances reflect the effects of currency translation and, in fiscal 2010, the effect of acquiring the Bioline Group.

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