MERIDIAN BIOSCIENCE INC
Form 10-K
November 29, 2012
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

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

Phone: (513) 271-3700

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES x NO ¨

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act. YES ¨ NO x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this Chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. YES ¨ NO x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). YES ¨ NO x

The aggregate market value of Common Shares held by non-affiliates as of March 31, 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.

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MERIDIAN BIOSCIENCE, INC.

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ON FORM 10-K

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates , anticipates , projects , plans , seeks , may , wi 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

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.

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PART I.

This Annual Report on Form 10-K includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties. See Forward Looking Statements above. Factors that could cause or contribute to such differences include those discussed in Item 1A. Risk Factors. In addition to the risk factors discussed herein, we are also subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of these risks and uncertainties 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 www.meridianbioscience.com. We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments thereto, free of charge through this website, as soon as reasonably practicable after such material has been electronically filed with or furnished to the Securities and Exchange Commission (SEC). These reports may also be read and copied at the SEC s public reference room at 100 F Street, N.E., Washington, DC 20549, phone number 1-800-732-0330. The SEC maintains an internet site containing these filings and other information regarding Meridian at www.sec.gov. The information on our website is not and should not be considered part of this Annual Report on Form 10-K.

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Reportable Segments

Our reportable segments are 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, ***illumi****gene*®, and introduced our first assay, *C. difficile*. The ***illumi****gene*® *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 ***illumi****gene*® molecular platform, receiving FDA clearance for our second and third molecular tests for the platform ***illumi****gene*® Group B *Streptococcus* (Group B Strep or GBS) in December 2011 and ***illumi****gene*® 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 second quarter of fiscal 2013. Our fifth test on the ***illumi****gene*® 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 ***illumi****gene*® also includes two sexually-transmitted disease assays, expected to be available for sale in the U.S. during the first half of fiscal 2014.

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 ***illumi****gene*® 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 ***illumi****gene*® *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 ***illumi****gene*® 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, ***illumi****gene*® 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 ***illumi****gene*® 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 ***illumi****gene*® 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 ***illumi****gene*® 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 ***illumi****gene*® molecular *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 ***illumi****gene*® molecular platform ***illumi****gene*® GBS (Group B *Streptococcus*) in December 2011 and ***illumi****gene*® Group A Strep (Group A *Streptococcus*) in September 2012. As alluded to above, over 100 customers are now purchasing two assays for the ***illumi****gene*® 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 ***illumi****gene*® 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 ***illumi****gene*® 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, ***illumi****gene*®, 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 ***illumi****gene*® *C. difficile* assay, the initial assay introduced for the ***illumi****gene*® 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 ***illumi****gene*® molecular platform, receiving FDA clearance for our second and third molecular tests for the platform ***illumi****gene*® GBS (Group B *Streptococcus*) in December 2011 and ***illumi****gene*® 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 ***illumi****gene*® 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 ***illumi****gene*® 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 ***illumi****gene*® 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 LEGIONELLA™ and TRU HSV 1 and 2 IgG™ 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 IgG™ 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 ***illumi****gene*® 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:

Product/Technology Family	Number of products	% of consolidated sales 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 ***illumi****gene*® 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, ***illumi****gene*® *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 ***illumi****pro*-10® instrument on which our ***illumi****gene*® molecular testing platform operates. Additionally, two of our foodborne products sourced from another vendor accounted for 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 liabiliti