

MERIDIAN BIOSCIENCE INC  
Form 10-Q  
February 09, 2015  
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**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-Q**

x **QUARTERLY REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Quarterly Period Ended December 31, 2014**

**OR**

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 0-14902**

**MERIDIAN BIOSCIENCE, INC.**

**Incorporated under the laws of Ohio**

**31-0888197**

**(I.R.S. Employer Identification No.)**

**3471 River Hills Drive**

**Cincinnati, Ohio 45244**

**(513) 271-3700**

Indicate by a 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 (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

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

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding January 31, 2015
Common Stock, no par value	41,705,940

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*This Quarterly Report on Form 10-Q contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates, anticipates, projects, plans, seeks, may, will, expects, intends, believes, should and similar expressions or the negative versions thereof and which also may be identified by their context. All statements that address operating performance or events or developments that Meridian expects or anticipates will occur in the future, including, but not limited to, statements relating to per share diluted earnings and revenue, are forward-looking statements. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. Specifically, Meridian's forward-looking statements are, and will be, based on management's then-current views and assumptions regarding future events and operating performance. Meridian assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties*

*and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian's continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition, and its ability to effectively sell such products. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Meridian relies on proprietary, patented and licensed technologies, and the Company's ability to protect its intellectual property rights, as well as the potential for intellectual property litigation, would impact its results. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. Costs and difficulties in complying with laws and regulations, including those administered by the United States Food and Drug Administration, can result in*

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*unanticipated expenses and delays and interruptions to the sale of new and existing products. The international scope of Meridian's operations, including changes in the relative strength or weakness of the U.S. dollar and general economic conditions in foreign countries, can impact results and make them difficult to predict. One of Meridian's growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses will be successfully integrated into Meridian's operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention and there may be additional risks with respect to Meridian's ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. Meridian cannot predict the possible impact of U.S. health care legislation enacted in 2010 – the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act – and any modification or repeal of any of the provisions thereof, and any similar initiatives in other countries on its results of operations. Efforts to reduce the U.S. federal deficit, breaches of Meridian's information technology systems and natural disasters and other events could have a materially adverse effect on Meridian's results of operations and revenues. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.*

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Operations (Unaudited)****(in thousands, except per share data)**

	<b>Three Months Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
NET REVENUES	\$ 48,013	\$ 44,794
COST OF SALES	18,776	16,787
<b>GROSS PROFIT</b>	<b>29,237</b>	<b>28,007</b>
<b>OPERATING EXPENSES</b>		
Research and development	3,103	2,853
Selling and marketing	6,080	5,978
General and administrative	7,385	7,550
Total operating expenses	16,568	16,381
<b>OPERATING INCOME</b>	<b>12,669</b>	<b>11,626</b>
<b>OTHER INCOME (EXPENSE)</b>		
Interest income	6	4
Other, net	(582)	(220)
Total other income (expense)	(576)	(216)
<b>EARNINGS BEFORE INCOME TAXES</b>	<b>12,093</b>	<b>11,410</b>
<b>INCOME TAX PROVISION</b>	<b>4,192</b>	<b>3,984</b>
<b>NET EARNINGS</b>	<b>\$ 7,901</b>	<b>\$ 7,426</b>
<b>BASIC EARNINGS PER COMMON SHARE</b>	<b>\$ 0.19</b>	<b>\$ 0.18</b>
<b>DILUTED EARNINGS PER COMMON SHARE</b>	<b>\$ 0.19</b>	<b>\$ 0.18</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC</b>	<b>41,607</b>	<b>41,408</b>
<b>EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARES AND UNITS</b>	<b>334</b>	<b>691</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING DILUTED</b>	<b>41,941</b>	<b>42,099</b>

ANTI-DILUTIVE SECURITIES:

Common share options and restricted shares and units	566	110
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.20	\$ 0.19

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

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**Table of Contents****MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Comprehensive Income (Unaudited)****(in thousands)**

	<b>Three Months Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>NET EARNINGS</b>	<b>\$ 7,901</b>	<b>\$ 7,426</b>
Foreign currency translation adjustment	(1,365)	723
<b>COMPREHENSIVE INCOME</b>	<b>\$ 6,536</b>	<b>\$ 8,149</b>

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

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**Table of Contents****MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Cash Flows (Unaudited)****(in thousands)**

<b>Three Months Ended December 31,</b>	<b>2014</b>	<b>2013</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 7,901	\$ 7,426
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	927	888
Amortization of intangible assets	469	526
Amortization of deferred <i>illumigene</i> instrument costs	395	438
Stock-based compensation	1,428	1,651
Deferred income taxes	100	293
Change in current assets	4,878	1,600
Change in current liabilities	246	(3,434)
Other, net	(259)	(43)
Net cash provided by operating activities	16,085	9,345
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property, plant and equipment	(1,331)	(899)
Purchases of intangible assets		(1,638)
Net cash used for investing activities	(1,331)	(2,537)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(8,330)	(7,875)
Proceeds and tax benefits from exercises of stock options	499	407
Net cash used for financing activities	(7,831)	(7,468)
Effect of Exchange Rate Changes on Cash and Equivalents	(454)	107
Net Increase (Decrease) in Cash and Equivalents	6,469	(553)
Cash and Equivalents at Beginning of Period	43,047	44,282
Cash and Equivalents at End of Period	\$ 49,516	\$ 43,729

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

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## MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

## Condensed Consolidated Balance Sheets

(in thousands)

ASSETS

	December 31, 2014 (Unaudited)	September 30, 2014
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 49,516	\$ 43,047
Accounts receivable, less allowances of \$247 and \$272	23,613	23,232
Inventories	34,428	35,495
Prepaid expenses and other current assets	3,212	7,058
Deferred income taxes	3,890	3,916
<b>Total current assets</b>	<b>114,659</b>	<b>112,748</b>
<b>PROPERTY, PLANT AND EQUIPMENT, at Cost</b>		
Land	1,167	1,173
Buildings and improvements	29,251	29,146
Machinery, equipment and furniture	40,454	40,192
Construction in progress	1,185	652
<b>Subtotal</b>	<b>72,057</b>	<b>71,163</b>
Less: accumulated depreciation and amortization	44,137	43,553
<b>Net property, plant and equipment</b>	<b>27,920</b>	<b>27,610</b>
<b>OTHER ASSETS</b>		
Goodwill	22,638	23,193
Other intangible assets, net	7,159	7,813
Restricted cash	1,000	1,000
Deferred <i>illumigene</i> instrument costs, net	2,477	2,740
Deferred income taxes	1,185	1,483
Other assets	400	342
<b>Total other assets</b>	<b>34,859</b>	<b>36,571</b>
<b>TOTAL ASSETS</b>	<b>\$ 177,438</b>	<b>\$ 176,929</b>

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



Table of Contents**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets****(dollars in thousands)**LIABILITIES AND SHAREHOLDERS' EQUITY

	<b>December 31, 2014 (Unaudited)</b>	<b>September 30, 2014</b>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 5,941	\$ 4,966
Accrued employee compensation costs	4,517	4,761
Other accrued expenses	3,018	3,149
Income taxes payable	1,073	859
Total current liabilities	14,549	13,735
<b>NON-CURRENT LIABILITIES</b>	2,043	2,165
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>SHAREHOLDERS' EQUITY</b>		
Preferred stock, no par value, 1,000,000 shares authorized, none issued		
Common shares, no par value, 71,000,000 shares authorized, 41,700,686 and 41,622,216 shares issued, respectively		
Additional paid-in capital	113,462	111,851
Retained earnings	48,440	48,869
Accumulated other comprehensive income (loss)	(1,056)	309
Total shareholders' equity	160,846	161,029
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 177,438</b>	<b>\$ 176,929</b>

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

Table of Contents**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****Condensed Consolidated Statement of Changes in Shareholders' Equity (Unaudited)****(dollars and shares in thousands)**

	Common Shares Issued	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
<b>Balance at September 30, 2014</b>	41,622	\$ 111,851	\$ 48,869	\$ 309	\$ 161,029
Cash dividends paid			(8,330)		(8,330)
Exercise of stock options	53	183			183
Conversion of restricted stock units	26				
Stock compensation expense		1,428			1,428
Net earnings			7,901		7,901
Foreign currency translation adjustment				(1,365)	(1,365)
<b>Balance at December 31, 2014</b>	41,701	\$ 113,462	\$ 48,440	\$ (1,056)	\$ 160,846

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

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**

**Notes to Condensed Consolidated Financial Statements**

**Dollars in Thousands, Except Per Share Amounts**

**(Unaudited)**

**1. Basis of Presentation**

The interim condensed consolidated financial statements are unaudited and are prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information, and the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of Management, the interim financial statements include all normal adjustments and disclosures necessary to present fairly the Company's financial position as of December 31, 2014, the results of its operations for the three month periods ended December 31, 2014 and 2013, and its cash flows for the three month periods ended December 31, 2014 and 2013. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company's fiscal 2014 Annual Report on Form 10-K. Financial information as of September 30, 2014 has been derived from the Company's audited consolidated financial statements.

The results of operations for interim periods are not necessarily indicative of the results to be expected for the year.

**2. Significant Accounting Policies**

**(a) *Revenue Recognition and Accounts Receivable***

Revenue is generally recognized from sales when product is shipped and title has passed to the customer. Revenue for the Diagnostics segment is reduced at the date of sale for product price adjustments due certain distributors under local contracts. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, estimates of inventories of certain of our products held by distributors, historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Such accruals were \$4,950 at December 31, 2014 and \$4,220 at September 30, 2014, and have been netted against accounts receivable.

Revenue for our Diagnostics segment includes revenue for our *illumigene*<sup>®</sup> molecular test system. This system includes an instrument, instrument accessories and test kits. In markets where the test system is sold via multiple deliverable arrangements, the cost of the instrument and instrument accessories is deferred upon placement at a customer and amortized on a straight-line basis into cost of sales over the expected utilization period, generally three years.

We evaluate whether each deliverable in the arrangement is a separate unit of accounting. The significant deliverables are an instrument, instrument accessories (e.g., printer) and test kits. An instrument and instrument accessories are delivered to the customer prior to the start of the customer utilization period, in order to accommodate customer set-up

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

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

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

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

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

### **(b) *Comprehensive Income (Loss)***

As reflected in the accompanying Condensed Consolidated Statements of Comprehensive Income, our comprehensive income or loss is comprised of net earnings and foreign currency translation.

Assets and liabilities of foreign operations are translated using period-end exchange rates with gains or losses resulting from translation included as a separate component of comprehensive income or loss. Revenues and expenses are translated using exchange rates prevailing during the period. We also recognize foreign currency transaction gains and losses on certain assets and liabilities that are denominated in the non-functional currencies of the Company or its subsidiaries. These gains and losses are included in other income and expense in the accompanying Condensed Consolidated Statements of Operations.

### **(c) *Income Taxes***

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

We account for uncertain tax positions using a benefit recognition model with a two-step approach: (i) a more-likely-than-not recognition criterion; and (ii) a measurement attribute that measures the position as the largest



amount of tax benefit that is greater than 50% likely of being ultimately realized upon 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 and penalties related to unrecognized tax benefits as a portion of our income tax provision in the Condensed Consolidated Statements of Operations.

In September 2013, the Internal Revenue Service issued Treasury Decision 9636, which enacted final tax regulations regarding the capitalization and expensing of amounts paid to acquire, produce, or improve tangible property. The regulations also include guidance regarding the retirement of depreciable property. The regulations are required to be effective in taxable years beginning on or after January 1, 2014, although

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taxpayers may choose to apply them in taxable years beginning on or after January 1, 2012. Our adoption of these regulations on October 1, 2014 did not have a significant impact on the Company's consolidated results of operations, cash flows or financial position.

**(d) 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. Awards are expensed over their requisite service periods.

**(e) Cash and Cash Equivalents**

Cash and cash equivalents include the following components:

	December 31, 2014		September 30, 2014	
	Cash and Equivalents	Other Assets	Cash and Equivalents	Other Assets
Overnight repurchase agreements	\$ 31,881	\$	\$ 26,407	\$
Cash on hand				
Restricted		1,000		1,000
Unrestricted	17,635		16,640	
<b>Total</b>	<b>\$ 49,516</b>	<b>\$ 1,000</b>	<b>\$ 43,047</b>	<b>\$ 1,000</b>

**(f) Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2014-09, *Revenue from Contracts with Customers*, which supersedes and replaces nearly all currently-existing U.S. GAAP revenue recognition guidance including related disclosure requirements. This guidance will be effective for the Company beginning October 1, 2017. The Company has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

In November 2014, the FASB issued ASU No. 2014-17, *Pushdown Accounting*, which provides companies with the option to apply pushdown accounting in its separate financial statements upon occurrence of an event in which an acquirer obtains control of the acquired entity. The election to apply pushdown accounting can be made either in the period in which the change of control occurred or in a subsequent period. This guidance, which was effective as of November 18, 2014, has had no impact on the Company's consolidated results of operations, cash flows or financial position.

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

**(g) *Reclassifications***

Certain reclassifications have been made to the prior period financial statements to conform to the current fiscal period presentation. Such reclassifications had no impact on net earnings or shareholders' equity.

**Table of Contents****3. Inventories**

Inventories are comprised of the following:

	<b>December 31, 2014</b>	<b>September 30, 2014</b>
Raw materials	\$ 7,060	\$ 5,674
Work-in-process	9,770	10,591
Finished goods <i>illumigene</i> instruments	1,459	1,710
Finished goods kits and reagents	16,139	17,520
<b>Total</b>	<b>\$ 34,428</b>	<b>\$ 35,495</b>

**4. Reportable Segment and Major Customers Information**

Meridian was formed in 1976 and functions as a fully-integrated research, development, manufacturing, marketing and sales organization with primary emphasis in the fields of in vitro diagnostics and life science. Our principal businesses are (i) the development, manufacture and distribution of diagnostic test kits primarily for gastrointestinal, viral, respiratory and parasitic infectious diseases; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents used by researchers and other diagnostic manufacturers, and 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.

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment is headquartered in Cincinnati, Ohio, which also serves as the base of manufacturing operations and research and development. The Diagnostics segment has sales and distribution facilities in the United States, Europe and Australia. The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad, including sales and business development offices in Singapore and Beijing, China to further pursue growing revenue opportunities in Asia. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Amounts due from two Diagnostics distributor customers accounted for 17% and 15% of consolidated accounts receivable at December 31, 2014 and September 30, 2014, respectively. Revenues from these two distributor customers accounted for 41% and 38% of the Diagnostics segment third-party revenues during the three months ended December 31, 2014 and 2013, respectively. In addition, approximately \$2,100 and \$2,700 of our consolidated accounts receivable at December 31, 2014 and September 30, 2014, respectively, was due from Italian hospital customers whose funding ultimately comes from the Italian government, representing 9% and 12% of consolidated accounts receivable in each of the respective periods.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 18% and 10% of the segment's third-party revenues during the three months ended December 31, 2014 and 2013, respectively.



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Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Eliminations(1)	Total
<b>Three Months Ended December 31, 2014</b>				
Net revenues				
Third-party	\$ 36,586	\$ 11,427	\$	\$ 48,013
Inter-segment	104	297	(401)	
Operating income	9,927	2,846	(104)	12,669
Goodwill (December 31, 2014)	1,250	21,388		22,638
Other intangible assets, net (December 31, 2014)	2,649	4,510		7,159
Total assets (December 31, 2014)	110,922	66,892	(376)	177,438
<b>Three Months Ended December 31, 2013</b>				
Net revenues				
Third-party	\$ 34,837	\$ 9,957	\$	\$ 44,794
Inter-segment	109	259	(368)	
Operating income	9,384	2,261	(19)	11,626
Goodwill (September 30, 2014)	1,250	21,943		23,193
Other intangible assets, net (September 30, 2014)	2,756	5,057		7,813
Total assets (September 30, 2014)	109,350	67,834	(255)	176,929

(1) Eliminations consist of inter-segment transactions.

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

**5. Intangible Assets**

A summary of our acquired intangible assets subject to amortization, as of December 31, 2014 and September 30, 2014 is as follows:

	December 31, 2014		September 30, 2014	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	\$ 11,617	\$ 10,626	\$ 11,685	\$ 10,568
Trademarks, licenses and patents	6,357	2,870	6,463	2,766
Customer lists and supply agreements	12,198	9,517	12,378	9,379
	\$ 30,172	\$ 23,013	\$ 30,526	\$ 22,713

The actual aggregate amortization expense for these intangible assets was \$469 and \$526 for the three months ended December 31, 2014 and 2013, respectively. The estimated aggregate amortization expense for these intangible assets for each of the fiscal years through fiscal 2020 is as follows: remainder of fiscal 2015 \$1,233, fiscal 2016 \$1,360, fiscal 2017 \$1,135, fiscal 2018 \$1,114, fiscal 2019 \$1,074 and fiscal 2020 \$898.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Refer to *Forward Looking Statements* following the Table of Contents in front of this Form 10-Q. In the discussion that follows, all dollar amounts are in thousands (both tables and text), except per share data.

Following is a discussion and analysis of the financial statements and other statistical data that management believes will enhance the understanding of Meridian's financial condition, changes in financial condition and results of operations. This discussion should be read in conjunction with the financial statements and notes thereto beginning on page 1.

**Results of Operations**

Net earnings for the first quarter of fiscal 2015 increased 6% to \$7,901, or \$0.19 per diluted share, from net earnings for the first quarter of fiscal 2014 of \$7,426, or \$0.18 per diluted share. This increase reflects the combined effects of increased revenues, decreased gross profit margin percentages and modestly increased operating expenses. Consolidated revenues increased 7% to \$48,013 for the first quarter of fiscal 2015 compared to the same period of the prior year, increasing 8% on a constant-currency basis.

Included within the first quarter of fiscal 2015 were revenues from our *illumigene*<sup>®</sup> molecular platform of products totaling \$9,908, representing a 16% increase over the fiscal 2014 first quarter. Also contributing to the consolidated revenues increase were increased revenues in three of our diagnostic focus product families (*H. pylori*, foodborne and respiratory) and both of our Life Science segment's business lines (i.e., molecular component and immunoassay component). Serving to partially offset these increases were decreased revenues in our *C. difficile* focus product family.

Revenues for the Diagnostics segment for the first quarter of fiscal 2015 increased 5% compared to the first quarter of fiscal 2014, increasing 6% on a constant-currency basis and reflecting the following for each of our focus product families: 5% growth in our foodborne products, 12% growth in our *H. pylori* products, 31% growth in our respiratory products, and 11% decline in our *C. difficile* products. As it relates to our respiratory products, the growth is substantially driven by our molecular respiratory products (*illumigene* Group A Strep, *illumigene* Mycoplasma and *illumigene* Pertussis products), which were launched into the market over the past two-plus years and represent an ever-increasing percentage of our respiratory product family revenues. With growth in both its molecular component and immunoassay component business, revenues of our Life Science segment increased by 15% during the first quarter of fiscal 2015 compared to the first quarter of fiscal 2014, increasing 16% on a constant-currency basis.

**REVENUE OVERVIEW**

Below are analyses of the Company's revenue, provided for each of the following:

- By Reportable Segment & Geographic Region
- By Product Platform/Type
- By Disease Family (Diagnostics only)

**Revenue Overview- By Reportable Segment & Geographic Region**



Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the countries comprising North, Central and South America (the Americas); Europe, Middle East and Africa (EMEA); and other countries outside of the Americas and EMEA (rest of the world, or ROW). The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad, including a sales and business development location in Singapore. Additionally, in order to further pursue growing revenue opportunities in Asia, and China in particular, our Life Science segment has opened a business development office in Beijing, China. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

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Revenues for the Diagnostics segment, in the normal course of business, may be affected from quarter to quarter by buying patterns of major distributors, seasonality and strength of certain diseases, and foreign currency exchange rates. Revenues for the Life Science segment, in the normal course of business, may be affected from quarter to quarter by the timing and nature of arrangements for contract services work, which may have longer production cycles than bioresearch reagents and bulk antigens and antibodies, as well as buying patterns of major customers, and foreign currency exchange rates. We believe that the overall breadth of our product lines serves to reduce the variability in consolidated revenues due to these factors.

	<b>Three Months Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>Inc (Dec)</b>
<b>Diagnostics</b>			
Americas	\$ 30,913	\$ 28,261	9%
EMEA	5,003	5,373	(7)%
ROW	670	1,203	(44)%
<b>Total Diagnostics</b>	<b>36,586</b>	<b>34,837</b>	<b>5%</b>
<b>Life Science</b>			
Americas	5,299	4,313	23%
EMEA	3,758	3,810	(1)%
ROW	2,370	1,834	29%
<b>Total Life Science</b>	<b>11,427</b>	<b>9,957</b>	<b>15%</b>
<b>Consolidated</b>	<b>\$ 48,013</b>	<b>\$ 44,794</b>	<b>7%</b>
<b>% of total revenues</b>			
Diagnostics	76%	78%	
Life Science	24%	22%	
<b>Total</b>	<b>100%</b>	<b>100%</b>	
Ex-Americas	25%	27%	

**Revenue Overview- By Product Platform/Type**

The revenues generated by each of our reportable segments result primarily from the sale of the following segment-specific categories of products:

**Diagnostics**

- 1) Molecular tests that operate on our *illumigene* platform

2) Immunoassay tests  
Life Science

1) Molecular components

2) Immunoassay components

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

	<b>Three Months Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>Inc (Dec)</b>
<b>Diagnostics</b>			
Molecular	\$ 9,908	\$ 8,550	16%
Immunoassay	26,678	26,287	1%
Total Diagnostics	\$ 36,586	\$ 34,837	5%
<b>Life Science</b>			
Molecular components	\$ 5,012	\$ 4,870	3%
Immunoassay components	6,415	5,087	26%
Total Life Science	\$ 11,427	\$ 9,957	15%
<b>% of Diagnostics revenues</b>			
Molecular	27%	25%	
Immunoassay	73%	75%	
Total Diagnostics	100%	100%	
<b>% of Life Science revenues</b>			
Molecular components	44%	49%	
Immunoassay components	56%	51%	
Total Life Science	100%	100%	

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

**Diagnostics Products****illumigene Molecular Platform Products**

We have nearly 1,370 customer account placements. Of these account placements, approximately 1,200 accounts have completed evaluations and validations and are regularly purchasing product, with the balance of our account placements being in some stage of product evaluation and/or validation. Of our account placements, we have over 400 accounts that are regularly purchasing, evaluating and/or validating two or more assays.

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

1. *illumigene*<sup>®</sup> *C. difficile* commercialized in August 2010
2. *illumigene*<sup>®</sup> Group B *Streptococcus* (Group B Strep or GBS) commercialized in December 2011

3. *illumigene*<sup>®</sup> Group A *Streptococcus* (Group A Strep) commercialized in September 2012
4. *illumigene*<sup>®</sup> Mycoplasma (*M. pneumoniae*; walking pneumonia) commercialized in June 2013
5. *illumigene*<sup>®</sup> *Bordetella pertussis* (whooping cough) commercialized in March 2014
6. *illumigene*<sup>®</sup> *Chlamydia trachomatis* expected fiscal 2015 (launch outside of U.S.)
7. *illumigene*<sup>®</sup> *Neisseria gonorrhoea* expected fiscal 2015 (launch outside of U.S.)
8. *illumigene*<sup>®</sup> Herpes Simplex Virus I & II expected fiscal 2015

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

We believe that the diagnostic testing market is continuing to move away from culture and immunoassay testing to molecular testing for diseases where there is a favorable cost/benefit position for the total cost of health care. While this market is competitive, with molecular companies such as Cepheid and Becton Dickinson and more recent

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entrants such as Quidel, Great Basin, Nanosphere, and others, we believe we are well positioned to capitalize on the migration to molecular testing. Our simple, easy-to-use, *illumigene* platform, with its expanding menu, requires no expensive equipment purchase and little to no maintenance cost. We believe these features, along with its small footprint and the performance of the *illumigene* assays, make *illumigene* an attractive molecular platform to any size hospital or physician office laboratory.

### **Immunoassay Products**

Revenues from our Diagnostics segment's immunoassay products increased 1% in the first quarter of fiscal 2015. As described in the product discussion below, this minimal revenue growth results primarily from the growth in our foodborne and *H. pylori* products, substantially offset by the decline in revenues from the immunoassay products within our *C. difficile* and respiratory product families.

### **Life Science Products**

During the first quarter of fiscal 2015, revenues from our Life Science segment increased 15%, with revenues from molecular component sales and immunoassay component sales increasing 3% and 26%, respectively, over the comparable fiscal 2014 quarter. Our molecular component business' growth was negatively impacted by the movement in currency exchange rates since the 2014 first quarter and the ordering patterns of industrial customers, as such customers become an increasing percentage of the molecular component business; while our immunoassay component business experienced in excess of a 150% increase in sales into China.

### **Diagnostics Revenue Overview- By Disease Family**

Revenues from our focus families (*C. difficile*, foodborne, *H. pylori* and respiratory) comprised 74% and 73% of our Diagnostics segment's revenues during the first quarter of fiscal 2015 and 2014, respectively. Following is a discussion of the revenues generated by each product family:

#### ***C. difficile* Products**

During the fiscal 2015 first quarter, revenues for our *C. difficile* product family decreased 11% to \$7,600 from the first quarter of fiscal 2014, as this market continues to be competitive, with over 10 suppliers in the United States. Certain of these suppliers choose to compete solely on price. We believe that two factors will help us respond to these challenging market conditions. First, our marketing programs emphasize that we are the only company that can offer a full range of high performing, FDA cleared, *C. difficile* testing formats, including toxin, GDH and molecular tests. Second, our *illumigene* molecular platform, with its expanding menu, requires no expensive equipment purchase or maintenance contract, which we believe makes it an attractive and affordable option for any size hospital.

#### ***Foodborne* Products**

Revenues from our foodborne products (Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*), all of which are immunoassay products, totaled \$6,000 during the first quarter of fiscal 2015, a 5% increase from the fiscal 2014 first quarter. We are continuing to re-emphasize the benefits of increased sensitivity and faster turnaround time versus culture methods in our marketing programs. The primary competition for our foodborne products is laboratory culture methods and an immunoassay shiga toxin test from one of our competitors. We believe that our test offers better workflow, less hands-on time and quicker results, in addition to being fully compliant with CDC-recommended testing methods.

***H. pylori Products***

During the fiscal 2015 first quarter, revenues from our *H. pylori* products, all of which are immunoassay products, increased 12% to \$7,300. This increase 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. A significant amount of the *H. pylori* product revenues are from sales to reference labs, whose buying patterns may not be consistent period to period.

**Table of Contents*****Respiratory Products***

Total respiratory revenues for our Diagnostics segment increased 31% to \$6,200 during the first quarter of fiscal 2015. Our molecular respiratory products (*illumigene* Group A Strep, *illumigene* Mycoplasma and *illumigene* Pertussis products), which were launched into the market over the past two-plus years, experienced in excess of 200% growth during the first quarter of fiscal 2015. Serving to partially offset this increase was a 6% decline in our immunoassay respiratory products, reflecting the decline in revenues from sales of such products in Japan due to continuing issues related to our Japanese distributor having been acquired last year.

***Foreign Currency***

During the first quarter of fiscal 2015, currency exchange rates had a \$600 unfavorable impact on revenues; \$400 within the Diagnostics segment and \$200 within the Life Science segment.

***Significant Customers***

Two U.S. distributors accounted for 41% and 38% of our Diagnostics segment's total revenues for the first quarter of fiscal 2015 and 2014, respectively. These revenues represented 31% and 29% of consolidated revenues for the fiscal 2015 and 2014 first quarters, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 18% and 10% of the segment's total revenues for the first quarter of fiscal 2015 and 2014, respectively.

***Medical Device Tax***

On January 1, 2013, the medical device tax established as part of the U.S. health care reform legislation became effective, and as a result, the Company made its first required tax deposit near the end of January 2013. During the first quarter of fiscal 2015 and fiscal 2014, the Company recorded approximately \$500 and \$400, respectively, of medical device tax expense, which is reflected as a component of cost of sales in the accompanying Condensed Consolidated Statements of Operations.

**Gross Profit**

	<b>Three Months Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>Change</b>
Gross Profit	\$ 29,237	\$ 28,007	4%
Gross Profit Margin	61%	63%	-2 points

The overall gross profit margin decrease for the three months ended December 31, 2014 primarily results from the combined effects of (i) mix of revenues from the Company's segments; (ii) mix of products sold; and (iii) unfavorable manufacturing facility overhead absorption. Due to our growing *illumigene* platform, we have invested approximately \$4,000 in new molecular manufacturing facilities, which will provide additional manufacturing capacity, as well as improved manufacturing efficiency and quality. We believe that we will begin to realize these efficiencies late in fiscal 2015.

Our overall operations consist of the sale of diagnostic test kits for various disease states and in alternative test formats, as well as bioresearch reagents, bulk antigens and antibodies, PCR/qPCR reagents, nucleotides, competent



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

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	<b>Changes for the Three Months Ended December 31, 2014</b>			
	<b>Research &amp; Development</b>	<b>Selling &amp; Marketing</b>	<b>General &amp; Administrative</b>	<b>Total Operating Expenses</b>
<b>2014 Expenses</b>	\$ 2,853	\$ 5,978	\$ 7,550	\$ 16,381
% of Revenues	6%	13%	17%	37%
<b>Fiscal 2015 Increases (Decreases):</b>				
Diagnostics	181	120	15	316
Life Science	69	(18)	(180)	(129)
<b>2015 Expenses</b>	\$ 3,103	\$ 6,080	\$ 7,385	\$ 16,568
% of Revenues	6%	13%	15%	35%
% Increase (Decrease)	9%	2%	(2)%	1%

Overall, total operating expenses increased slightly during the first quarter of fiscal 2015 relative to the comparable prior fiscal year quarter, while decreasing slightly as a percentage of consolidated revenues. The increase results in large part from the combined effects of our (i) ongoing efforts to control spending in each of our segments while investing the necessary resources in our strategic areas of growth, including increased investment in Research & Development for our molecular platform products and increased investment in Sales and Marketing personnel and programs; and (ii) overall increased incentive compensation expense in light of the corporate-wide operating profit levels.

Operating expenses for the Diagnostics segment increased \$316 for the first quarter of fiscal 2015 compared to the fiscal 2014 first quarter. These overall increases result largely from the combined effects of the following:

**Research & Development**

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

**Selling & Marketing**

Increased sales commission expenses on increased revenues.

**General & Administrative**

An increase in bonus and profit sharing expense as a result of the previously noted year-to-date increase in corporate-wide operating profits, substantially offset by a decrease in stock-based compensation resulting in large part from the decline in our stock price relative to the fiscal 2014 first quarter.

**Operating Income**

Operating income increased 9% to \$12,669 for the first quarter of fiscal 2015, as a result of the factors discussed above.

**Income Taxes**

The effective rate for income taxes remained stable at 35% for the first quarters of fiscal 2015 and fiscal 2014. For the fiscal year ending September 30, 2015, we expect the effective tax rate to approximate 34%-35%.

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In September 2013, the Internal Revenue Service issued Treasury Decision 9636, which enacted final tax regulations regarding the capitalization and expensing of amounts paid to acquire, produce, or improve tangible property. The regulations also include guidance regarding the retirement of depreciable property. The regulations are required to be effective in taxable years beginning on or after January 1, 2014, although taxpayers may choose to apply them in taxable years beginning on or after January 1, 2012. Our adoption of these regulations on October 1, 2014 did not have a significant impact on the Company's consolidated results of operations, cash flows or financial position.

## **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.

We have an investment policy that guides the holdings of our investment portfolio. Our objectives in managing the investment portfolio are to (i) preserve capital; (ii) provide sufficient liquidity to meet working capital requirements and fund strategic objectives such as acquisitions; and (iii) capture a market rate of return commensurate with market conditions and our policy's investment eligibility criteria. As we look forward, we will continue to manage the holdings of our investment portfolio with preservation of capital being the primary objective.

We do not expect current conditions in the financial markets, or overall economic conditions, to have a significant impact on our liquidity needs, financial condition, or results of operations, although no assurances can be made in this regard. We intend to continue to fund our working capital requirements and dividends from current cash flows from operating activities and cash on hand. If needed, we also have an additional source of liquidity through our \$30,000 bank credit facility. Approximately \$2,100 of our consolidated accounts receivable at December 31, 2014 is due from Italian hospital customers whose funding ultimately comes from the Italian government, which is down from approximately \$2,700 at September 30, 2014. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets tightens for an extended period of time, and such conditions impact the collectibility of our customer accounts receivable or impact credit terms with our vendors, or disrupt the supply of raw materials and services.

Net cash provided by operating activities increased 72% for the first quarter of fiscal 2015 to \$16,085, reflecting the 6% increase in net earnings, along with the effects of the payment of incentive bonus payments related to fiscal 2013 made in the first quarter of fiscal 2014, the timing of federal income tax payments, and the timing of payments from and to customers and suppliers, respectively. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and dividends during the next 12 months.

### ***Capital Resources***

We have a \$30,000 credit facility with a commercial bank that expires on September 15, 2015. As of January 31, 2015, there were no borrowings outstanding on this facility and we had 100% borrowing capacity available to us. We have had no borrowings outstanding under this facility during the first three months of fiscal 2015 or during the full year of fiscal 2014.

Our capital expenditures are estimated to be approximately \$4,000 for fiscal 2015, 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.

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

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**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

There have been no material changes in the Company's exposure to market risk since September 30, 2014.

**ITEM 4. CONTROLS AND PROCEDURES**

As of December 31, 2014, 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 December 31, 2014. 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 first fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, or in other factors that could materially affect internal control subsequent to December 31, 2014.

**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

There have been no material changes from risk factors as previously disclosed in the Registrant's Form 10-K in response to Item 1A to Part I of Form 10-K.

**ITEM 6. EXHIBITS**

The following exhibits are being filed or furnished as a part of this Quarterly Report on Form 10-Q.

- 31.1 Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
- 31.2 Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
- 32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101 The following financial information from Meridian Bioscience Inc.'s Quarterly Report on Form 10-Q for the quarter ended December 31, 2014 filed with the SEC on February 9, 2015, formatted in XBRL includes:
  - (i) Condensed Consolidated Statements of Operations for the three months ended December 31, 2014 and 2013;
  - (ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended December 31, 2014 and 2013;
  - (iii) Condensed Consolidated Statements of Cash Flows for the three months ended December 31, 2014 and 2013;
  - (iv) Condensed Consolidated Balance Sheets as of December 31, 2014 and September 30, 2014;
  - (v) Condensed Consolidated Statement of Shareholders' Equity for the three months ended December 31, 2014; and
  - (vi) the Notes to Condensed Consolidated Financial Statements

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SIGNATURE

Pursuant to the requirements 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.**

Date: February 9, 2015

By: /s/ Melissa A. Lueke  
Melissa A. Lueke  
Executive Vice President and  
Chief Financial Officer

(Principal Financial and Accounting Officer)

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