

MERIDIAN BIOSCIENCE INC

Form 10-Q

February 10, 2014

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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, 2013**

**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, 2014
Common Stock, no par value	41,551,153

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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. 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, 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 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. 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 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>2013</b>	<b>2012</b>
NET SALES	\$ 44,794	\$ 45,351
COST OF SALES	16,787	16,555
GROSS PROFIT	28,007	28,796
OPERATING EXPENSES		
Research and development	2,853	2,517
Selling and marketing	5,978	5,693
General and administrative	7,550	7,495
Total operating expenses	16,381	15,705
OPERATING INCOME	11,626	13,091
OTHER INCOME (EXPENSE)		
Interest income	4	7
Other, net	(220)	128
Total other income (expense)	(216)	135
EARNINGS BEFORE INCOME TAXES	11,410	13,226
INCOME TAX PROVISION	3,984	4,752
NET EARNINGS	\$ 7,426	\$ 8,474
BASIC EARNINGS PER COMMON SHARE	\$ 0.18	\$ 0.21
DILUTED EARNINGS PER COMMON SHARE	\$ 0.18	\$ 0.20
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC	41,408	41,148
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARES AND UNITS	691	604
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED	42,099	41,752

ANTI-DILUTIVE SECURITIES:

Common share options and restricted shares and units	110	294
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DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.19	\$ 0.38
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The accompanying notes are an integral part of these condensed consolidated financial statements.

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**

**Condensed Consolidated Statements of Comprehensive Income (Unaudited)**

**(in thousands)**

	<b>Three Months Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>NET EARNINGS</b>	<b>\$ 7,426</b>	<b>\$ 8,474</b>
Foreign currency translation adjustment	723	246
<b>COMPREHENSIVE INCOME</b>	<b>\$ 8,149</b>	<b>\$ 8,720</b>

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

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>2013</b>	<b>2012</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 7,426	\$ 8,474
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	888	815
Amortization of intangible assets	526	580
Amortization of deferred <i>illumigene</i> instrument costs	438	381
Stock-based compensation	1,651	1,146
Deferred income taxes	293	(136)
Loss on disposition and write-down of fixed assets and other assets		9
Change in current assets	1,600	5,231
Change in current liabilities	(3,434)	150
Other, net	(43)	(603)
<b>Net cash provided by operating activities</b>	<b>9,345</b>	<b>16,047</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property, plant and equipment	(899)	(403)
Purchases of intangible assets	(1,638)	
<b>Net cash used for investing activities</b>	<b>(2,537)</b>	<b>(403)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(7,875)	(15,652)
Proceeds and tax benefits from exercises of stock options	407	1,390
<b>Net cash used for financing activities</b>	<b>(7,468)</b>	<b>(14,262)</b>
<b>Effect of Exchange Rate Changes on Cash and Equivalents</b>	<b>107</b>	<b>174</b>
<b>Net Increase (Decrease) in Cash and Equivalents</b>	<b>(553)</b>	<b>1,556</b>
<b>Cash and Equivalents at Beginning of Period</b>	<b>44,282</b>	<b>31,593</b>
<b>Cash and Equivalents at End of Period</b>	<b>\$ 43,729</b>	<b>\$ 33,149</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****(in thousands)****ASSETS**

	<b>December 31, 2013 (Unaudited)</b>	<b>September 30, 2013</b>
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 43,729	\$ 44,282
Accounts receivable, less allowances of \$206 and \$233	22,495	26,183
Inventories	37,674	34,835
Prepaid expenses and other current assets	3,083	4,643
Deferred income taxes	4,240	4,145
<b>Total current assets</b>	<b>111,221</b>	<b>114,088</b>
<b>PROPERTY, PLANT AND EQUIPMENT, at Cost</b>		
Land	1,186	1,183
Buildings and improvements	26,868	26,848
Machinery, equipment and furniture	38,928	38,502
Construction in progress	1,027	554
<b>Subtotal</b>	<b>68,009</b>	<b>67,087</b>
Less: accumulated depreciation and amortization	41,886	40,996
<b>Net property, plant and equipment</b>	<b>26,123</b>	<b>26,091</b>
<b>OTHER ASSETS</b>		
Goodwill	23,389	23,115
Other intangible assets, net	9,279	8,057
Restricted cash	1,000	1,000
Deferred <i>illumigene</i> instrument costs, net	2,852	3,270
Deferred income taxes	679	823
Other assets	316	304
<b>Total other assets</b>	<b>37,515</b>	<b>36,569</b>
<b>TOTAL ASSETS</b>	<b>\$ 174,859</b>	<b>\$ 176,748</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, 2013 (Unaudited)</b>	<b>September 30, 2013</b>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 5,044	\$ 5,592
Accrued employee compensation costs	4,268	9,670
Other accrued expenses	5,463	5,462
Income taxes payable	2,714	979
Total current liabilities	17,489	21,703
<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, 41,544,709 and 41,517,839 shares issued, respectively		
Additional paid-in capital	109,463	107,412
Retained earnings	46,439	46,888
Accumulated other comprehensive income	1,468	745
Total shareholders' equity	157,370	155,045
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 174,859</b>	<b>\$ 176,748</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, 2013</b>	41,518	\$ 107,412	\$ 46,888	\$ 745	\$ 155,045
Cash dividends paid			(7,875)		(7,875)
Exercise of stock options	26	400			400
Conversion of restricted stock units	1				
Stock compensation expense		1,651			1,651
Net earnings			7,426		7,426
Foreign currency translation adjustment				723	723
<b>Balance at December 31, 2013</b>	41,545	\$ 109,463	\$ 46,439	\$ 1,468	\$ 157,370

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, 2013, the results of its operations for the three month periods ended December 31, 2013 and 2012, and its cash flows for the three month periods ended December 31, 2013 and 2012. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company's fiscal 2013 Annual Report on Form 10-K. Financial information as of September 30, 2013 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 our products held by distributors, historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Such accruals were \$3,974 at December 31, 2013 and \$3,866 at September 30, 2013, 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 (i.e., the United States, Australia, Belgium, France, Holland and Italy), the cost of the instrument and instrument accessories are 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 (i.e., countries other than the United States, Australia, Belgium, France, Holland and Italy), 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. In some cases, customers may request that we store on their behalf, clinical grade biologicals that we produce under contract manufacturing agreements. These cases arise when customers do not have clinical grade storage facilities or do not want to risk contamination during transport. For such cases, revenue may be recognized on a bill-and-hold basis. No such bill-and-hold arrangements existed at December 31, 2013 or September 30, 2013.

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. 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 Australian dollar, British pound, Euro and Singapore dollar currencies. 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.

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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. The Company is currently assessing the impact of the final regulations on its financial statements.

**(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, 2013		September 30, 2013	
	Cash and Equivalents	Other	Cash and Equivalents	Other
Overnight repurchase agreements	\$ 30,107	\$	\$ 32,103	\$
Cash on hand -				
Restricted		1,000		1,000
Unrestricted	13,622		12,179	
Total	\$ 43,729	\$ 1,000	\$ 44,282	\$ 1,000

**(f) *Recent Accounting Pronouncements***

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, to improve the transparency of reporting reclassifications out of accumulated other comprehensive income. Specifically, the new amendments to ASU No. 2013-02 required, depending upon the items being reclassified, the (i) presentation (either on the face of the statement where net income is presented or in the notes) of the effects on the line items of net income of significant amounts reclassified out of accumulated other comprehensive income; and/or (ii) the cross-reference to other disclosures currently required under U.S. GAAP that provide additional detail about such items. These requirements were effective prospectively for the Company beginning October 1, 2013, and their adoption 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 Company's 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.

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

Inventories are comprised of the following:

	December 31, 2013	September 30, 2013
Raw materials	\$ 7,007	\$ 7,170
Work-in-process	6,943	8,585
Finished goods - <i>illumigene</i> instruments	2,981	1,980
Finished goods - kits and reagents	20,743	17,100
Total	\$ 37,674	\$ 34,835

**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.

In the fourth quarter of fiscal 2013, we aggregated our Diagnostics operating segments into a single reportable segment, thereby resulting in our reportable segments being Diagnostics and Life Science. The prior period information reflected herein has been conformed to the current period presentation.

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 a sales and business development location in Singapore. 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 14% and 17% of consolidated accounts receivable at December 31, 2013 and September 30, 2013, respectively. Sales to these two distributor customers accounted for 38% and 47% of the Diagnostics segment third-party sales during the three months ended December 31, 2013 and 2012, respectively. In addition, approximately \$3,100 and \$3,500 of our accounts receivable at December 31, 2013 and September 30, 2013, respectively, is due from Italian hospital customers whose funding ultimately comes from the Italian government, representing 14% and 13% of consolidated accounts receivable in each of the respective periods.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 10% and 18% of the segment's third-party sales during the three months ended December 31, 2013 and 2012, 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, 2013</b>				
Net sales -				
Third-party	\$ 34,837	\$ 9,957	\$	\$ 44,794
Inter-segment	109	259	(368)	
Operating income	9,384	2,261	(19)	11,626
Goodwill (December 31, 2013)	1,250	22,139		23,389
Other intangible assets, net (December 31, 2013)	3,064	6,215		9,279
Total assets (December 31, 2013)	109,721	111,028	(45,890)	174,859
<b>Three Months Ended December 31, 2012</b>				
Net sales -				
Third-party	\$ 35,669	\$ 9,682	\$	\$ 45,351
Inter-segment	98	158	(256)	
Operating income	11,340	1,634	117	13,091
Goodwill (September 30, 2013)	1,250	21,865		23,115
Other intangible assets, net (September 30, 2013)	1,561	6,496		8,057
Total assets (September 30, 2013)	112,054	110,111	(45,417)	176,748

(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, 2013 and September 30, 2013 is as follows:

	December 31, 2013		September 30, 2013	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	\$ 11,709	\$ 10,254	\$ 11,676	\$ 10,097
Trademarks, licenses and patents	6,430	2,300	4,748	2,130
Customer lists and supply agreements	12,442	8,748	12,353	8,493
	\$ 30,581	\$ 21,302	\$ 28,777	\$ 20,720

During the first quarter of fiscal 2014, we acquired the remaining licensing rights related to our *illumigene* molecular technology for \$1,638. These rights will be amortized over a weighted average period of approximately 8.5 years.

The actual aggregate amortization expense for these intangible assets was \$526 and \$580 for the three months ended December 31, 2013 and 2012, respectively. The estimated aggregate amortization expense for these intangible assets for each of the fiscal years through fiscal 2019 is as follows: remainder of fiscal 2014 \$1,474, fiscal 2015 \$1,767, fiscal 2016 \$1,422, fiscal 2017 \$1,156, fiscal 2018 \$1,132 and fiscal 2019 \$1,092.

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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 2014 decreased 12% to \$7,426, or \$0.18 per diluted share, from net earnings for the first quarter of fiscal 2013 of \$8,474, or \$0.20 per diluted share. This decrease reflects the combined effects of decreased sales, slightly decreased gross profit margins and modestly increased operating expenses, along with the negative effect of \$400 (pre-tax) of medical device tax that did not exist during the first quarter of fiscal 2013 (see discussion in Medical Device Tax below). Consolidated sales decreased 1% to \$44,794 for the first quarter of fiscal 2014 compared to the same period of the prior year. Contributing to this decrease were decreased sales in our largest diagnostic focus product family (*C. difficile*), our respiratory product family and our Life Science segment's immunoassay component business. Serving to partially offset these sales decreases were increased sales in our *H. pylori* focus product family, as well as our Life Science segment's molecular component business. Included within the first quarter 2014 results were sales of our *illumigene*® molecular platform of products totaling \$8,495, representing a 15% increase over the fiscal 2013 first quarter.

Sales for the Diagnostics segment for the first quarter of fiscal 2014 decreased 2% compared to the first quarter of fiscal 2013, reflecting the following for each of our focus product families: 11% decline in our *C. difficile* products, 8% growth in our *H. pylori* products, and 1% growth in our foodborne products. In addition, we experienced a 19% decline in sales of our respiratory products compared to the prior year fiscal first quarter. With 16% growth in its molecular component business being partially offset by a 7% decline in its immunoassay component businesses, sales of our Life Science segment increased by 3% during the first quarter of fiscal 2014 compared to the first quarter of fiscal 2013.

### **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 is headquartered in Cincinnati, Ohio, which also serves as the base of manufacturing operations and research and development. The Diagnostics segment sells diagnostic test kits in the U.S. and Canada ( North America ); Europe, Middle East and Africa ( EMEA ); and other countries outside of North America 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. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Revenues for the Diagnostics segment, in the normal course of business, may be affected from quarter to quarter by buying patterns of major distributors, seasonality and strength of certain diseases, and foreign currency exchange rates. Revenues for the Life Science segment, in the normal course of business, may be affected from quarter to

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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.

	<b>Three Months Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>Inc(Dec)</b>
Diagnostics -			
North America	\$ 27,943	\$ 28,814	(3)%
EMEA	5,373	5,129	5%
ROW	1,521	1,726	(12)%
Total Diagnostics	34,837	35,669	(2)%
Life Science -			
North America	4,306	4,251	1%
EMEA	3,810	4,126	(8)%
ROW	1,841	1,305	41%
Total Life Science	9,957	9,682	3%
Consolidated	\$ 44,794	\$ 45,351	(1)%
% of total sales -			
Diagnostics	78%	79%	
Life Science	22%	21%	
Total	100%	100%	
Ex-North America	28%	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

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

	<b>Three Months Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>Inc(Dec)</b>
<b>Diagnostics -</b>			
Molecular	\$ 8,495	\$ 7,394	15%
Immunoassay	26,342	28,275	(7)%
Total Diagnostics	\$ 34,837	\$ 35,669	(2)%
<b>Life Science -</b>			
Molecular components	\$ 4,870	\$ 4,196	16%
Immunoassay components	5,087	5,486	(7)%
Total Life Science	\$ 9,957	\$ 9,682	3%

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% of Diagnostics sales -		
Molecular	24%	21%
Immunoassay	76%	79%
Total Diagnostics	100%	100%
% of Life Science sales -		
Molecular components	49%	43%
Immunoassay components	51%	57%
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 just over 1,200 customer account placements. Of these account placements, over 1,000 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 200 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 four commercialized tests, with one additional test expected to be available for sale later in fiscal 2014 and three additional tests in fiscal 2015:

1. *illumigene*® *C. difficile* commercialized in August 2010
2. *illumigene*® Group B *Streptococcus* (Group B Strep or GBS) commercialized in December 2011
3. *illumigene*® Group A *Streptococcus* (Group A Strep) commercialized in September 2012
4. *illumigene*® Mycoplasma (*M. pneumonia*; walking pneumonia) commercialized in June 2013
5. *illumigene*® *Bordetella pertussis* (whooping cough) expected fiscal 2014
6. *illumigene*® *Chlamydia trachomatis* expected fiscal 2015
7. *illumigene*® *Neisseria gonorrhea* expected fiscal 2015

8. *illumigene*® Herpes Simplex Virus I & II expected fiscal 2015  
Additional *illumigene* tests in early-stage research or development include enteric parasites such as Giardia, foodborne pathogens such as *E. coli*, and bloodborne pathogens such as 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 healthcare. While this market is competitive, with molecular companies such as Cepheid and Becton Dickinson and new 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. These features, along with its small footprint and the performance of the *illumigene* assays, make *illumigene* an attractive molecular platform to any size hospital.

#### Immunoassay Products

Sales of our Diagnostic segment's immunoassay products decreased 7% in the first quarter of fiscal 2014. This current quarter decrease results primarily from the decline in sales of our *C. difficile* and respiratory products, partially offset by the revenue growth of our *H. pylori* products, as described below.

#### **Life Science Products**

During the first quarter of fiscal 2014, sales of our Life Science segment increased 3%, with sales of our molecular component business increasing 16% over the comparable fiscal 2013 quarter and sales of our immunoassay component business decreasing 7%. Our molecular component business continues to benefit from new product launches and advancements most notably SensiFAST and MyTaq PCR components. The first quarter sales level of our bulk immunoassay component business reflects the effect of certain customer shipments being delayed until the fiscal 2014 second quarter.

**Table of Contents****Diagnostic Revenue Overview- By Disease Family**

Sales from our focus families (*C. difficile*, foodborne and *H. pylori*) comprised 60% of our Diagnostics segment's revenue during each of the first quarter of fiscal 2014 and 2013. Following is a discussion of the revenues generated by each product family:

***C. difficile Products***

During the fiscal 2014 first quarter our *C. difficile* product family sales totaled \$8,600, representing a decline of 11% from the first quarter of fiscal 2013. Due to factors including reduced hospital admissions and declining *C. difficile* incidence rates in hospitals putting further pressure on an already competitive market, sales decreases were experienced in both our *illumigene C. difficile* product, which represents approximately 75% of total *C. difficile* revenues, and our immunoassay *C. difficile* product. While the *C. difficile* market continues to be highly competitive, 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.

***Foodborne Products***

With first quarter fiscal 2014 sales totaling \$5,700, or 1% growth over the fiscal 2013 first quarter, we continue to see demand for our foodborne products, all of which are immunoassay products. Despite these sales results reflecting the negative impact of buying patterns for these products, laboratories continue to realize the benefits of increased sensitivity and faster turnaround time with our fully CDC compliant rapid immunoassay tests for Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*, compared to traditional culture methods. While historically the primary competition for our foodborne products has been laboratory culture methods, during 2012 one of our competitors, Alere, cleared through the FDA a shiga toxin test that competes with our EHEC test. We believe that our products have two principal advantages versus culture methods: (i) test accuracy; and (ii) improved work flow, resulting in a significantly shortened time to test result (20 minutes vs. 24-48 hours for culture).

***H. pylori Products***

During the fiscal 2014 first quarter, sales of our *H. pylori* products, all of which are immunoassay products, grew 8% to \$6,500. 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 sales are to reference labs, whose buying patterns may not be consistent period to period.

***Respiratory Products***

Total respiratory sales for our Diagnostics segment decreased 19% to \$4,800 during the fiscal 2014 first quarter. Contributing to this volume were decreased sales of influenza products, reflecting the relative late start of this year's influenza season, compared to last year's. Partially offsetting the impact of lower influenza product sales was growth in our *illumigene* Group A Strep and *illumigene* Mycoplasma products, which received FDA approval in September 2012 and June 2013, respectively.

***Foreign Currency***

During the first quarter of fiscal 2014, currency exchange rates had a \$150 favorable impact on revenue; \$200 favorable within the Diagnostics segment and \$50 unfavorable in the Life Science segment.

***Significant Customers***

Two U.S. distributors accounted for 38% and 47% of our Diagnostics segment's total sales for first quarter of fiscal 2014 and 2013, respectively. These sales represented 29% and 37% of consolidated sales for the fiscal 2014 and 2013 first quarters, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 10% and 18% of the segment's total sales for the first quarter of fiscal 2014 and 2013, respectively.

**Table of Contents*****Medical Device Tax***

On January 1, 2013, the medical device tax established as part of the U.S. healthcare 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 2014, the Company recorded approximately \$400 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>2013</b>	<b>2012</b>	<b>Change</b>
Gross Profit	\$ 28,007	\$ 28,796	(3)%
Gross Profit Margin	63%	64%	-1 point

The overall slight gross profit margin decrease for the three months ended December 31, 2013 primarily results from the combined effects of (i) mix of sales from the Company's segments; (ii) mix of products sold; and (iii) the medical device tax, which did not exist during the first quarter of fiscal 2013 (see discussion in Medical Device Tax above).

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 sales mix shifts, in the normal course of business, can cause the consolidated gross profit margin to fluctuate by several points.

**Operating Expenses**

	<b>Three Months Ended December 31, 2013</b>			
	<b>Research &amp; Development</b>	<b>Selling &amp; Marketing</b>	<b>General &amp; Administrative</b>	<b>Total Operating Expenses</b>
<b>2013 Expenses</b>	\$ 2,517	\$ 5,693	\$ 7,495	\$ 15,705
% of Sales	6%	13%	17%	35%
<b>Fiscal 2014 Increases (Decreases):</b>				
Diagnostics	281	219	247	747
Life Science	55	66	(192)	(71)
<b>2014 Expenses</b>	\$ 2,853	\$ 5,978	\$ 7,550	\$ 16,381
% of Sales	6%	13%	17%	37%
% Increase (Decrease)	13%	5%	1%	4%

Overall, total operating expense increased during the first quarter of fiscal 2014 relative to the comparable prior fiscal year quarter and as a percentage of consolidated sales. 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 (ii) overall decreased incentive compensation expense in light of the decline in corporate-wide operating profits. We expect to continue to have higher levels of Research & Development spending during the remainder of fiscal 2014 related to clinical trials for our *illumigene Chlamydia trachomatis* and *Neisseria gonorrhea* products.

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Operating expenses for the Diagnostics segment increased \$747 for the first quarter of fiscal 2014 compared to the fiscal 2013 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**

Addition of field sales force personnel, including the filling of open territorial positions, since the prior year quarter, resulting in an approximate \$200 increase in personnel-related expenses.

### **General & Administrative**

An approximate \$500 increase in stock-based compensation during the first quarter of fiscal 2014, along with other less significant general operating expense increases, partially offset by a decrease in bonus and profit sharing expenses as a result of the previously noted year-to-date decline in corporate-wide operating profits.

Operating expenses for the Life Science segment decreased \$71 for the first quarter of fiscal 2014 compared to the fiscal 2013 first quarter. This activity reflects in large part the decreased bonus expenses resulting from the decline in corporate-wide operating profits.

## **Operating Income**

Operating income decreased 11% to \$11,626 for the first quarter of fiscal 2014, as a result of the factors discussed above.

## **Income Taxes**

The effective rate for income taxes was 35% for the first quarter of fiscal 2014, and 36% for the first quarter of fiscal 2013. For the fiscal year ending September 30, 2014, we expect the effective tax rate to approximate 34%-35%.

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. The Company is currently assessing the impact of the final regulations on its financial statements.

## **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

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\$30,000 bank credit facility. Approximately \$3,100 of our accounts receivable at December 31, 2013 is due from Italian hospital customers whose funding ultimately comes from the Italian government, which is down from approximately \$3,500 at September 30, 2013. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets remains tight for an extended period of time, and such conditions impact the collectibility of our customer accounts receivable or impact credit terms with our vendors, or disrupt the supply of raw materials and services.

Net cash provided by operating activities decreased 42% for the first quarter of fiscal 2014 to \$9,345, reflecting the 12% decrease in net earnings, along with the effects of the payment of incentive bonus payments related to fiscal 2013, 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, 2014, 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 2014 or during the full year of fiscal 2013.

Our capital expenditures are estimated to range between approximately \$7,500 to \$9,000 for fiscal 2014, 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. This range of capital expenditures includes approximately \$4,000 related to an expansion of our molecular diagnostic manufacturing capacity in Cincinnati, Ohio.

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

**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, 2013.

**ITEM 4. CONTROLS AND PROCEDURES**

As of December 31, 2013, 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, 2013. 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, 2013.



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**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, 2013 filed with the SEC on February 10, 2014, formatted in XBRL includes:  
(i) Condensed Consolidated Statements of Operations for the three months ended December 31, 2013 and 2012,  
(ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended December 31, 2013 and 2012, (iii) Condensed Consolidated Statements of Cash Flows for the three months ended December 31, 2013 and 2012, (iv) Condensed Consolidated Balance Sheets as of December 31, 2013 and September 30, 2013, (v) Condensed Consolidated Statement of Shareholders' Equity for the three months ended December 31, 2013, 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 10, 2014

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

Chief Financial Officer

(Principal Financial and Accounting Officer)

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