

MERIDIAN BIOSCIENCE INC

Form 10-Q

May 11, 2015

[Table of Contents](#)

**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 March 31, 2015**

**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 April 30, 2015
Common Stock, no par value	41,713,985

**Table of Contents****MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****TABLE OF CONTENTS TO QUARTERLY REPORT ON FORM 10-Q**

	<b>Page(s)</b>
<b>PART I. <u>FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Statements of Operations Three and Six Months Ended March 31, 2015 and 2014</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income Three and Six Months Ended March 31, 2015 and 2014</u>	2
<u>Condensed Consolidated Statements of Cash Flows Six Months Ended March 31, 2015 and 2014</u>	3
<u>Condensed Consolidated Balance Sheets March 31, 2015 and September 30, 2014</u>	4-5
<u>Condensed Consolidated Statement of Changes in Shareholders' Equity Six Months Ended March 31, 2015</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7-12
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12-20
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
<b>PART II. <u>OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	21
Item 6. <u>Exhibits</u>	21
<u>Signature</u>	22
<b><u>FORWARD-LOOKING STATEMENTS</u></b>	

*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*

---

**Table of Contents**

*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 March 31,</b>		<b>Six Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
NET REVENUES	\$ 51,545	\$ 50,134	\$ 99,558	\$ 94,928
COST OF SALES	19,024	18,541	37,800	35,328
GROSS PROFIT	32,521	31,593	61,758	59,600
OPERATING EXPENSES				
Research and development	3,368	3,186	6,471	6,039
Selling and marketing	6,481	6,461	12,561	12,538
General and administrative	6,940	6,280	14,325	13,731
Total operating expenses	16,789	15,927	33,357	32,308
OPERATING INCOME	15,732	15,666	28,401	27,292
OTHER INCOME (EXPENSE)				
Interest income	6	6	12	10
Other, net	(211)	(28)	(793)	(248)
Total other income (expense)	(205)	(22)	(781)	(238)
EARNINGS BEFORE INCOME TAXES	15,527	15,644	27,620	27,054
INCOME TAX PROVISION	5,457	5,344	9,649	9,328
NET EARNINGS	\$ 10,070	\$ 10,300	\$ 17,971	\$ 17,726
BASIC EARNINGS PER COMMON SHARE	\$ 0.24	\$ 0.25	\$ 0.43	\$ 0.43
DILUTED EARNINGS PER COMMON SHARE	\$ 0.24	\$ 0.24	\$ 0.43	\$ 0.42
	41,707	41,471	41,636	41,434

**WEIGHTED AVERAGE NUMBER OF COMMON SHARES  
OUTSTANDING - BASIC**

EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARES AND UNITS	341	676	336	686
---	-----	-----	-----	-----

**WEIGHTED AVERAGE NUMBER OF COMMON SHARES  
OUTSTANDING - DILUTED**

	42,048	42,147	41,972	42,120
--	--------	--------	--------	--------

**ANTI-DILUTIVE SECURITIES:**

Common share options and restricted shares and units	570	168	546	137
--	-----	-----	-----	-----

DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.20	\$ 0.20	\$ 0.40	\$ 0.39
-------------------------------------	---------	---------	---------	---------

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 Comprehensive Income (Unaudited)**

**(in thousands)**

	<b>Three Months Ended March 31,</b>		<b>Six Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
NET EARNINGS	\$ 10,070	\$ 10,300	\$ 17,971	\$ 17,726
Foreign currency translation adjustment	(2,138)	337	(3,503)	1,060
COMPREHENSIVE INCOME	\$ 7,932	\$ 10,637	\$ 14,468	\$ 18,786

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>Six Months Ended March 31,</b>	<b>2015</b>	<b>2014</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 17,971	\$ 17,726
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	1,832	1,756
Amortization of intangible assets	900	1,042
Amortization of deferred <i>illumigene</i> instrument costs	754	864
Stock-based compensation	1,954	2,157
Deferred income taxes	(257)	(31)
Change in current assets	(6,910)	(6,656)
Change in current liabilities	3,368	(3,143)
Other, net	419	(159)
Net cash provided by operating activities	20,031	13,556
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property, plant and equipment	(2,561)	(2,573)
Purchases of intangible assets		(1,677)
Net cash used for investing activities	(2,561)	(4,250)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(16,671)	(16,169)
Proceeds and tax benefits from exercises of stock options	654	540
Net cash used for financing activities	(16,017)	(15,629)
Effect of Exchange Rate Changes on Cash and Equivalents	(1,781)	254
Net Decrease in Cash and Equivalents	(328)	(6,069)
Cash and Equivalents at Beginning of Period	43,047	44,282
Cash and Equivalents at End of Period	\$ 42,719	\$ 38,213

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>March 31, 2015 (Unaudited)</b>	<b>September 30, 2014</b>
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 42,719	\$ 43,047
Accounts receivable, less allowances of \$220 and \$272	30,298	23,232
Inventories	33,043	35,495
Prepaid expenses and other current assets	6,483	7,058
Deferred income taxes	3,991	3,916
<b>Total current assets</b>	<b>116,534</b>	<b>112,748</b>
<b>PROPERTY, PLANT AND EQUIPMENT, at Cost</b>		
Land	1,150	1,173
Buildings and improvements	29,938	29,146
Machinery, equipment and furniture	40,580	40,192
Construction in progress	895	652
<b>Subtotal</b>	<b>72,563</b>	<b>71,163</b>
Less: accumulated depreciation and amortization	44,541	43,553
<b>Net property, plant and equipment</b>	<b>28,022</b>	<b>27,610</b>
<b>OTHER ASSETS</b>		
Goodwill	22,090	23,193
Other intangible assets, net	6,591	7,813
Restricted cash	1,000	1,000
Deferred <i>illumigene</i> instrument costs, net	2,270	2,740
Deferred income taxes	1,402	1,483
Other assets	403	342
<b>Total other assets</b>	<b>33,756</b>	<b>36,571</b>
<b>TOTAL ASSETS</b>	<b>\$ 178,312</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>March 31, 2015 (Unaudited)</b>	<b>September 30, 2014</b>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 6,110	\$ 4,966
Accrued employee compensation costs	4,899	4,761
Other accrued expenses	3,138	3,149
Income taxes payable	1,079	859
 Total current liabilities	 15,226	 13,735
 <b>NON-CURRENT LIABILITIES</b>	 1,988	 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, 41,713,675 and 41,622,216 shares issued, respectively		
Additional paid-in capital	114,123	111,851
Retained earnings	50,169	48,869
Accumulated other comprehensive income	(3,194)	309
 Total shareholders' equity	 161,098	 161,029
 <b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	 \$ 178,312	 \$ 176,929

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			(16,671)		(16,671)
Exercise of stock options	65	318			318
Conversion of restricted stock units	27				
Stock compensation expense		1,954			1,954
Net earnings			17,971		17,971
Foreign currency translation adjustment				(3,503)	(3,503)
<b>Balance at March 31, 2015</b>	41,714	\$ 114,123	\$ 50,169	\$ (3,194)	\$ 161,098

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

**Table of Contents**

**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 March 31, 2015, the results of its operations for the three and six month periods ended March 31, 2015 and 2014, and its cash flows for the six month periods ended March 31, 2015 and 2014. 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 \$4,650 at March 31, 2015 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.



## **Table of Contents**

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 considered to be 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.

**Table of Contents**

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. 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:

	<b>March 31, 2015</b>		<b>September 30, 2014</b>	
	<b>Cash and Equivalents</b>	<b>Other Assets</b>	<b>Cash and Equivalents</b>	<b>Other Assets</b>
Overnight repurchase agreements	\$ 21,294	\$	\$ 26,407	\$
Cash on hand -				
Restricted		1,000		1,000
Unrestricted	21,425		16,640	
<b>Total</b>	<b>\$ 42,719</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.

**(g) *Reclassifications***

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

**3. Inventories**

Inventories are comprised of the following:

	<b>March 31, 2015</b>	<b>September 30, 2014</b>
Raw materials	\$ 7,005	\$ 5,674
Work-in-process	9,302	10,591
Finished goods - <i>illumigene</i> instruments	1,337	1,710
Finished goods - kits and reagents	15,399	17,520
<b>Total</b>	<b>\$ 33,043</b>	<b>\$ 35,495</b>

## **Table of Contents**

### **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, both of which are headquartered in Cincinnati, Ohio, which also serves as the Diagnostics segment's 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 20% and 15% of consolidated accounts receivable at March 31, 2015 and September 30, 2014, respectively. Revenues from these two distributor customers accounted for 32% and 35% of the Diagnostics segment third-party revenues during the three months ended March 31, 2015 and 2014, respectively, and 36% during each of the six months ended March 31, 2015 and 2014. These distributors represented 24% and 26% of consolidated revenues for the fiscal 2015 and 2014 second quarters, respectively, and 27% for each of the respective year-to-date six month periods. In addition, approximately \$2,100 and \$2,700 of our consolidated accounts receivable at March 31, 2015 and September 30, 2014, respectively, was due from Italian hospital customers whose funding ultimately comes from the Italian government, representing 7% and 12% of consolidated accounts receivable in each of the respective periods.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 16% and 23% of the segment's third-party revenues during the three months ended March 31, 2015 and 2014, respectively, and 17% during each of the six months ended March 31, 2015 and 2014.

**Table of Contents**

Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Eliminations(1)	Total
<b>Three Months Ended March 31, 2015</b>				
Net revenues -				
Third-party	\$ 38,662	\$ 12,883	\$	\$ 51,545
Inter-segment	84	226	(310)	
Operating income	11,951	3,728	53	15,732
Goodwill (March 31, 2015)	1,250	20,840		22,090
Other intangible assets, net (March 31, 2015)	2,542	4,049		6,591
Total assets (March 31, 2015)	115,470	63,116	(274)	178,312
<b>Three Months Ended March 31, 2014</b>				
Net revenues -				
Third-party	\$ 37,061	\$ 13,073	\$	\$ 50,134
Inter-segment	154	225	(379)	
Operating income	12,301	3,306	59	15,666
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
<b>Six Months Ended March 31, 2015</b>				
Net revenues -				
Third-party	\$ 75,248	\$ 24,310	\$	\$ 99,558
Inter-segment	189	522	(711)	
Operating income	21,878	6,574	(51)	28,401
<b>Six Months Ended March 31, 2014</b>				
Net revenues -				
Third-party	\$ 71,898	\$ 23,030	\$	\$ 94,928
Inter-segment	263	484	(747)	
Operating income	21,685	5,567	40	27,292

(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.

**Table of Contents****5. Intangible Assets**

A summary of our acquired intangible assets subject to amortization, as of March 31, 2015 and September 30, 2014 is as follows:

	<b>March 31, 2015</b>		<b>September 30, 2014</b>	
	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>
Manufacturing technologies, core products and cell lines	\$ 11,550	\$ 10,677	\$ 11,685	\$ 10,568
Trademarks, licenses and patents	6,280	2,969	6,463	2,766
Customer lists and supply agreements	12,020	9,613	12,378	9,379
	\$ 29,850	\$ 23,259	\$ 30,526	\$ 22,713

The actual aggregate amortization expense for these intangible assets was \$431 and \$516 for the three months ended March 31, 2015 and 2014, respectively, and \$900 and \$1,042 for the six months ended March 31, 2015 and 2014, 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 \$766, fiscal 2016 \$1,326, fiscal 2017 \$1,110, fiscal 2018 \$1,090, fiscal 2019 \$1,049 and fiscal 2020 \$877.

## 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****Quarterly Highlights**

As more fully detailed below, the second quarter of fiscal 2015 was highlighted by our Diagnostics segment's launch of four new products outside of the U.S. and our Life Science segment's continued successful expansion into China and launch of five new RNA tests. The Diagnostics products launched during the quarter include tests for two additional diseases to be performed on our *illumigene*<sup>®</sup> molecular testing platform (*Chlamydia trachomatis* and *Neisseria gonorrhea*) and two new immunoassay products to test for *Streptococcus pneumoniae* (*S. pneumo*) and *H. pylori* TRU STREP PNEUMO<sup>™</sup> and ImmunoCard STAT!<sup>®</sup> HpSA HD, respectively. During the second quarter of fiscal 2015, our Life Science segment's revenue from sales of immunoassay component products into China increased to approximately \$500 compared to less than \$50 in the fiscal 2014 second quarter.

**Three Months Ended March 31, 2015**

Net earnings for the second quarter of fiscal 2015 decreased 2% to \$10,070, or \$0.24 per diluted share, from net earnings for the second quarter of fiscal 2014 of \$10,300, or \$0.24 per diluted share. This decrease reflects the combined effects of increased revenues, slightly increased gross profit margins and increased operating expenses. Consolidated revenues increased 3% to \$51,545 for the second quarter of fiscal 2015 compared to the same period of the prior year, increasing 6% on a constant-currency basis.



## **Table of Contents**

Included within the second quarter 2015 results were revenues from our *illumigene*® molecular platform of products totaling \$10,192, representing a 5% increase over the fiscal 2014 second quarter. Also contributing to the increase in consolidated revenues were increased revenues in three of our diagnostic focus product families (*H. pylori*, foodborne and respiratory). Serving to partially offset these increases were decreased revenues in our *C. difficile* focus product family and both of our Life Science segment's business lines (i.e., molecular component and immunoassay component).

Revenues for the Diagnostics segment for the second quarter of fiscal 2015 increased 4% compared to the second quarter of fiscal 2014 (7% on a constant-currency basis), reflecting the following for each of our focus product families: 7% growth in our respiratory products, 9% growth in our *H. pylori* products, 27% growth in our foodborne products, and 10% 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 increasing percentage of our respiratory product family revenues. With declines in both its molecular component and immunoassay component business, revenues of our Life Science segment decreased by 1% during the second quarter of fiscal 2015 compared to the second quarter of fiscal 2014, increasing 1% on a constant-currency basis.

## **Six Months Ended March 31, 2015**

For the six month period ended March 31, 2015, net earnings increased 1% to \$17,971, or \$0.43 per diluted share, from net earnings for the comparable fiscal 2014 period of \$17,726, or \$0.42 per diluted share. This increase reflects the combined effects of increased revenues, decreased gross profit margins and increased operating expenses. Consolidated revenues increased 5% to \$99,558 for the first six months of fiscal 2015 compared to the same period of the prior fiscal year, increasing 7% on a constant-currency basis.

Included within the six month year-to-date fiscal 2015 results were revenues from our *illumigene* molecular platform of products totaling \$20,100, representing a 10% increase over the first six months of fiscal 2014. 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.

During the first six months of fiscal 2015, revenues for the Diagnostics segment increased 5% from the comparable fiscal 2014 period (7% on a constant-currency basis), reflecting the following for each of our focus product families: 10% growth in our *H. pylori* products, 16% growth in our foodborne products, 18% 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 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 6% during the six months ended March 31, 2015 over the comparable fiscal 2014 period, increasing 8% 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

**Table of Contents**

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.

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.

	Three Months Ended March 31,			Six Months Ended March 31,		
	2015	2014	Inc (Dec)	2015	2014	Inc (Dec)
Diagnostics-						
Americas	\$ 32,179	\$ 30,312	6%	\$ 63,092	\$ 58,573	8%
EMEA	5,530	5,952	(7)%	10,533	11,325	(7)%
ROW	953	797	20%	1,623	2,000	(19)%
Total Diagnostics	38,662	37,061	4%	75,248	71,898	5%
Life Science-						
Americas	5,910	5,102	16%	11,209	9,415	19%
EMEA	5,002	6,199	(19)%	8,760	10,009	(12)%
ROW	1,971	1,772	11%	4,341	3,606	20%
Total Life Science	12,883	13,073	(1)%	24,310	23,030	6%
Consolidated	\$ 51,545	\$ 50,134	3%	\$ 99,558	\$ 94,928	5%
% of total revenues-						
Diagnostics	75%	74%		76%	76%	
Life Science	25%	26%		24%	24%	
Total	100%	100%		100%	100%	
Ex-Americas	26%	29%		25%	28%	

**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

**Table of Contents**

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

	Three Months Ended March 31,			Six Months Ended March 31,		
	2015	2014	Inc (Dec)	2015	2014	Inc (Dec)
<b>Diagnostics-</b>						
Molecular	\$ 10,192	\$ 9,737	5%	\$ 20,100	\$ 18,287	10%
Immunoassay	28,470	27,324	4%	55,148	53,611	3%
Total Diagnostics	\$ 38,662	\$ 37,061	4%	\$ 75,248	\$ 71,898	5%
<b>Life Science-</b>						
Molecular components	\$ 4,893	\$ 5,023	(3)%	\$ 9,905	\$ 9,893	%
Immunoassay components	7,990	8,050	(1)%	14,405	13,137	10%
Total Life Science	\$ 12,883	\$ 13,073	(1)%	\$ 24,310	\$ 23,030	6%
<b>% of Diagnostics revenues-</b>						
Molecular	26%	26%		27%	25%	
Immunoassay	74%	74%		73%	75%	
Total Diagnostics	100%	100%		100%	100%	
<b>% of Life Science revenues-</b>						
Molecular components	38%	38%		41%	43%	
Immunoassay components	62%	62%		59%	57%	
Total Life Science	100%	100%		100%	100%	

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

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

Following our launch outside the U.S. of *illumigene*® *Chlamydia trachomatis* and *illumigene*® *Neisseria gonorrhea* during the second quarter of fiscal 2015, we now have just over 1,400 customer account placements. Of these account placements, approximately 1,240 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 approximately 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 seven commercialized tests, with one additional test 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. pneumonia*; walking pneumonia) commercialized in June 2013
  5. *illumigene*<sup>®</sup> *Bordetella pertussis* (whooping cough) commercialized in March 2014
  6. *illumigene*<sup>®</sup> *Chlamydia trachomatis* commercialized outside of U.S. in February 2015
  7. *illumigene*<sup>®</sup> *Neisseria gonorrhea* commercialized outside of U.S. in February 2015
  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.

**Table of Contents**

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 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 that runs moderately-complex tests.

**Immunoassay Products**

Having launched our TRU STREP PNEUMO™ and ImmunoCard STAT!® HpSA HD products outside the U.S. during the second quarter of fiscal 2015, our Diagnostics segment's revenues from immunoassay products increased 4% for the quarter and increased 3% on a six month, year-to-date basis. As described in the product discussions below, the quarterly and year-to-date increases both result primarily from the revenue growth of our *H. pylori*, foodborne and respiratory products, partially offset by the decline in revenues from our *C. difficile* products.

**Life Science Products**

During the second quarter of fiscal 2015, revenues from our Life Science segment decreased 1%, with revenues from molecular component sales decreasing 3% from the comparable fiscal 2014 quarter and revenues from immunoassay component sales decreasing 1%. For the first six months of fiscal 2015, revenues from our Life Science segment increased 6%, with revenues from molecular component sales increasing less than 1% over the comparable prior year period and revenues from immunoassay component sales increasing 10%. Our molecular component business' growth was negatively impacted by the movement in currency exchange rates since the 2014 second quarter, with revenues increasing 5% and 6% on a constant-currency basis for the quarterly and year-to-date periods, respectively. The revenue level of our immunoassay component business faced a difficult prior year comparison (i.e., in fiscal 2014, certain shipments were delayed and shifted from the first quarter to the second quarter). The effects of the timing of these prior year shipments were partially offset by the sales into China of approximately \$500 for the quarter (approximately \$1,100 for the year-to-date period).

**Diagnostic Revenue Overview- By Disease Family**

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

***C. difficile* Products**

Revenues for our *C. difficile* product family decreased 10% to \$8,200 for the fiscal 2015 second quarter, and decreased 11% to \$15,800 for the six month, year-to-date period. This decrease reflects the combined effects of revenue from new *illumigene* customers, the loss of several larger *illumigene* customers in fiscal 2014 and reduced revenues from our immunoassay products, which now represent less than 25% of this product category. The *C. difficile* test market continues to be highly competitive, with over 10 suppliers in the United States, certain of which choose to compete solely on price. We believe that the following factors will help us respond to these challenging market conditions: (i) 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; (ii) our *illumigene* molecular platform, with its expanding differentiated menu, affords both an opportunity to grow the

platform utilization within the hospital, as well as protect against competitive threats; and (iii) our *illumigene* molecular platform 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 for our foodborne products (Enterohemorrhagic *E. coli* ( EHEC ) and *Campylobacter*), all of which are immunoassay products, totaled \$6,900 during the fiscal 2015 second quarter, a 27% increase from the fiscal 2014 second quarter. During the six months ended March 31, 2015, foodborne revenues totaled \$12,800, a 16% increase from the fiscal 2014 year-to-date period. These quarterly and year-to-date increases reflect the positive effects of a large distributor order made in connection with our inside and field sales programs designed to protect and expand upon our current customer base through the addition of new customers adopting rapid tests and competitive



---

**Table of Contents**

takeaways. Excluding the effects of this order, fiscal 2015 second quarter and first six month revenues increased 17% and 11%, respectively, over the comparable fiscal 2014 periods. 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 second quarter of fiscal 2015, revenues from our *H. pylori* products, all of which are immunoassay products, grew 9% to \$7,700. These revenues grew 10% to \$15,000 during the first six months of fiscal 2015. These increases continue to reflect the benefits of our partnerships with managed care companies in promoting (i) the health and economic benefits of a test and treat strategy; (ii) changes in policies that discourage the use of traditional serology methods and promote the utilization of active infection testing methods; and (iii) moving physician behavior away from serology-based testing and toward direct antigen testing. A significant amount of the *H. pylori* product revenues are to reference labs, whose buying patterns may not be consistent period to period.

The patents for our *H. pylori* products are owned by us and expire in 2016 in the U.S. and in 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase upon the expiration of these patents in 2016 and 2017 as we currently market the only FDA-cleared test to detect *H. pylori* antigen in stool samples. Such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. In order to mitigate any loss in revenues upon patent expiration, among other things, we are researching and experimenting with new products (e.g., detection of *H. pylori* in samples other than stool and detection of *H. pylori* on molecular platforms). We are unable to provide any assurances that we will be successful with any mitigation strategy or that any mitigation strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

***Respiratory Products***

Total respiratory revenues from our Diagnostics segment increased 7% to \$5,800 during the fiscal 2015 second quarter; and increased 18% to \$12,000 for the six month year-to-date period. 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 94% and 149% growth during the second quarter of fiscal 2015 and the six months ended March 31, 2015, respectively. Serving to partially offset these increases were declines in our immunoassay respiratory products of 15% and 11% for the quarterly and six month year-to-date periods, respectively, reflecting both 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 and lower influenza sales.

***Foreign Currency***

During the second quarter of fiscal 2015, currency exchange rates had a \$1,400 unfavorable impact on revenue; \$1,000 unfavorable within the Diagnostics segment and \$400 unfavorable within the Life Science segment. On a six month year-to-date basis, currency exchange rates had a \$2,000 unfavorable impact on revenue; \$1,400 unfavorable within the Diagnostics segment and \$600 unfavorable within the Life Science segment.

***Significant Customers***

Two U.S. distributors accounted for 32% and 35% of our Diagnostics segment's total revenues for the second quarter of fiscal 2015 and 2014, respectively, and 36% during each of the six months ended March 31, 2015 and 2014, respectively. These distributors represented 24% and 26% of consolidated revenues for the fiscal 2015 and 2014 second quarters, respectively, and 27% for each of the respective year-to-date six month periods.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 16% and 23% of the segment's total revenues for the second quarter of fiscal 2015 and 2014, respectively, and 17% during each of the six months ended March 31, 2015 and 2014, respectively.

**Table of Contents****Gross Profit**

	Three Months Ended March 31,			Six Months Ended March 31,		
	2015	2014	Change	2015	2014	Change
Gross Profit	\$ 32,521	\$ 31,593	3%	\$ 61,758	\$ 59,600	4%

Gross Profit Margin 63% 63% None 62% 63% -1 point

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.

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.

**Operating Expenses**

	Three Months Ended March 31, 2015			
	Research & Development	Selling & Marketing	General & Administrative	Total Operating Expenses
<b>2014 Expenses</b>	\$ 3,186	\$ 6,461	\$ 6,280	\$ 15,927
% of Revenues	6%	13%	13%	32%
Fiscal 2015 Increases (Decreases):				
Diagnostics	4	178	874	1,056
Life Science	178	(158)	(214)	(194)
<b>2015 Expenses</b>	\$ 3,368	\$ 6,481	\$ 6,940	\$ 16,789
% of Revenues	7%	13%	13%	33%
% Increase (Decrease)	6%	%	11%	5%

	Six Months Ended March 31, 2015			
	Research & Development	Selling & Marketing	General & Administrative	Total Operating Expenses
<b>2014 Expenses</b>	\$ 6,039	\$ 12,538	\$ 13,731	\$ 32,308
% of Revenues	6%	13%	14%	34%
Fiscal 2015 Increases (Decreases):				

Edgar Filing: MERIDIAN BIOSCIENCE INC - Form 10-Q

Diagnostics	185	298	889	1,372
Life Science	247	(275)	(295)	(323)

<b>2015 Expenses</b>	\$ 6,471	\$ 12,561	\$ 14,325	\$ 33,357
----------------------	----------	-----------	-----------	-----------

% of Revenues	6%	13%	14%	34%
% Increase (Decrease)	7%	%	4%	3%

Page 18

## **Table of Contents**

Overall, total operating expenses increased during both the second quarter and first six months of fiscal 2015 relative to the comparable prior fiscal year periods, increasing slightly as a percentage of quarterly consolidated revenues and remaining relatively flat as a percentage of year-to-date consolidated revenues. These levels of operating expenses result 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; (ii) overall increased compensation-related expenses; and (iii) favorable effects of currency rates.

Operating expenses for the Diagnostics segment increased \$1,056 for the second quarter of fiscal 2015 compared to the fiscal 2014 second quarter, and in the first six months of fiscal 2015, increased \$1,372 over the comparable prior year period. These overall Diagnostics segment increases result largely from the combined effects of the following:

### **Research & Development**

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

### **Selling & Marketing**

Increased personnel costs resulting from increased Sales and Marketing headcount, and increased sales commission expenses on increased revenues.

### **General & Administrative**

An increase in profit sharing expense as a result of the previously noted increases in operating profits, partially offset by a decrease in stock-based compensation resulting in large part from the decline in our stock price relative to the fiscal 2014 periods. In addition to these compensation-related factors, legal spending increased over the prior year related largely to a foreign distributor matter.

### **Operating Income**

Operating income increased less than 1% to \$15,732 for the second quarter of fiscal 2015, and increased 4% to \$28,401 for the first six months of fiscal 2015, as a result of the factors discussed above.

### **Income Taxes**

The effective rate for income taxes remained stable at 35% for both the second quarter and first six months of fiscal 2015, increasing slightly from the 34% effective rate in each of the comparable fiscal 2014 periods. For the fiscal year ending September 30, 2015, 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. 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.

## **Table of Contents**

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, which has been renewed through April 21, 2018. Approximately \$2,100 of our consolidated accounts receivable at March 31, 2015 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 totaled \$20,031 for the first six months of fiscal 2015, a 48% increase over the \$13,556 provided during the first six months of fiscal 2014. While reflecting the effects of the timing of federal income tax payments, and the timing of payments from and to customers and suppliers, respectively, this \$6,475 increase primarily results from approximately \$5,500 of incentive bonus payments related to fiscal 2013 being made in the first quarter of fiscal 2014, with no such payments having been made during the fiscal 2015 year-to-date period. 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 April 21, 2018. As of April 30, 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 six 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.

### **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 March 31, 2015, 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 March 31, 2015. 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 second fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, or in other factors that could materially affect internal control

subsequent to March 31, 2015.

Page 20



**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

The following information regarding factors that could affect the Company's results of operations, financial condition and liquidity is being expanded in the risk factors discussion provided under Part I, Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2014:

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

Our patents related to our *H. pylori* products expire in 2016 in the U.S. and in 2017 in countries outside the U.S. Revenues from our *H. pylori* products were \$15,000 during the first six months of fiscal 2015. We expect competition with respect to our *H. pylori* products to increase upon the expiration of these patents in 2016 and 2017 as we currently market the only FDA-cleared test to detect *H. pylori* antigen in stool samples. Such competition may have an adverse impact on our selling prices for these products or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. In order to mitigate any loss in revenues upon patent expiration, among other things, we are researching and experimenting with new products (e.g., detection of *H. pylori* in samples other than stool and detection of *H. pylori* on molecular platforms). We are unable to provide any assurances that we will be successful with any mitigation strategy or that any mitigation strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

**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 March 31, 2015 filed with the SEC on May 11, 2015, formatted in XBRL includes: (i) Condensed Consolidated Statements of Operations for the three and six months ended March 31, 2015 and 2014; (ii) Condensed Consolidated Statements of Comprehensive Income for the three and six months ended March 31, 2015 and 2014; (iii) Condensed Consolidated Statements of Cash Flows for the six months ended March 31, 2015 and 2014; (iv) Condensed Consolidated Balance Sheets as of March 31, 2015 and September 30, 2014; (v) Condensed Consolidated Statement of Shareholders' Equity for the six months ended March 31, 2015; and (vi) the Notes to Condensed Consolidated Financial Statements

**Table of Contents**

**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: May 11, 2015

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

(Principal Financial and Accounting Officer)

Page 22