

MERIDIAN BIOSCIENCE INC  
Form 10-Q  
May 06, 2016  
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, 2016**

**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.

<b>Class</b>	<b>Outstanding April 30, 2016</b>
<b>Common Stock, no par value</b>	<b>42,074,802</b>

**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, 2016 and 2015</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income Three and Six Months Ended March 31, 2016 and 2015</u>	2
<u>Condensed Consolidated Statements of Cash Flows Six Months Ended March 31, 2016 and 2015</u>	3
<u>Condensed Consolidated Balance Sheets March 31, 2016 and September 30, 2015</u>	4-5
<u>Condensed Consolidated Statement of Changes in Shareholders' Equity Six Months Ended March 31, 2016</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>	13-21
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	21
Item 4. <u>Controls and Procedures</u>	21
<b>PART II. <u>OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	22
Item 6. <u>Exhibits</u>	22
<u>Signature</u>	23
<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>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
NET REVENUES	\$ 51,259	\$ 51,545	\$ 98,419	\$ 99,558
COST OF SALES	17,687	19,024	33,264	37,800
GROSS PROFIT	33,572	32,521	65,155	61,758
OPERATING EXPENSES				
Research and development	3,129	3,368	6,510	6,471
Selling and marketing	7,210	6,481	13,653	12,561
General and administrative	6,875	6,940	14,769	14,325
Transaction costs	1,202		1,481	
Total operating expenses	18,416	16,789	36,413	33,357
OPERATING INCOME	15,156	15,732	28,742	28,401
OTHER INCOME (EXPENSE)				
Interest income	3	6	20	12
Interest expense	(43)		(43)	
Other, net	(324)	(211)	(228)	(793)
Total other income (expense)	(364)	(205)	(251)	(781)
EARNINGS BEFORE INCOME TAXES	14,792	15,527	28,491	27,620
INCOME TAX PROVISION	5,701	5,457	10,507	9,649
NET EARNINGS	\$ 9,091	\$ 10,070	\$ 17,984	\$ 17,971
BASIC EARNINGS PER COMMON SHARE	\$ 0.22	\$ 0.24	\$ 0.43	\$ 0.43
DILUTED EARNINGS PER COMMON SHARE	\$ 0.21	\$ 0.24	\$ 0.42	\$ 0.43
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC	42,053	41,707	41,984	41,636
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARES AND UNITS	372	341	376	336

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED	42,425	42,048	42,360	41,972
ANTI-DILUTIVE SECURITIES:				
Common share options and restricted shares and units	444	570	476	546
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.20	\$ 0.20	\$ 0.40	\$ 0.40

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>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>NET EARNINGS</b>	<b>\$ 9,091</b>	<b>\$ 10,070</b>	<b>\$ 17,984</b>	<b>\$ 17,971</b>
Other comprehensive income (loss):				
Foreign currency translation adjustment	(78)	(2,138)	(865)	(3,503)
Unrealized loss on cash flow hedge	(694)		(694)	
Income taxes related to items of other comprehensive income	243		243	
Other comprehensive income (loss), net of tax	(529)	(2,138)	(1,316)	(3,503)
<b>COMPREHENSIVE INCOME</b>	<b>\$ 8,562</b>	<b>\$ 7,932</b>	<b>\$ 16,668</b>	<b>\$ 14,468</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>Six Months Ended March 31,</b>	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 17,984	\$ 17,971
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	1,785	1,832
Amortization of intangible assets	762	900
Amortization of deferred instrument costs	544	754
Stock-based compensation	2,290	1,954
Deferred income taxes	(306)	(257)
Losses on long-lived assets	659	
Change in current assets, net of acquisition	(6,905)	(6,910)
Change in current liabilities, net of acquisition	1,505	3,368
Other, net	143	419
<b>Net cash provided by operating activities</b>	<b>18,461</b>	<b>20,031</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(1,524)	(2,561)
Purchase of equity method investment	(600)	
Acquisition of Magellan, net of cash received	(62,177)	
Purchase of intangible assets	(16)	
<b>Net cash used for investing activities</b>	<b>(64,317)</b>	<b>(2,561)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(16,817)	(16,671)
Proceeds from term loan, net of issuance costs	59,842	
Proceeds and tax benefits from exercises of stock options	1,969	654
<b>Net cash provided by (used for) financing activities</b>	<b>44,994</b>	<b>(16,017)</b>
<b>Effect of Exchange Rate Changes on Cash and Equivalents</b>	<b>(165)</b>	<b>(1,781)</b>
<b>Net Decrease in Cash and Equivalents</b>	<b>(1,027)</b>	<b>(328)</b>
<b>Cash and Equivalents at Beginning of Period</b>	<b>49,973</b>	<b>43,047</b>
<b>Cash and Equivalents at End of Period</b>	<b>\$ 48,946</b>	<b>\$ 42,719</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>March 31, 2016 (Unaudited)</b>	<b>September 30, 2015</b>
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 48,946	\$ 49,973
Accounts receivable, less allowances of \$320 and \$248	32,450	26,254
Inventories	41,934	35,817
Prepaid expenses and other current assets	4,866	7,378
Total current assets	128,196	119,422
<b>PROPERTY, PLANT AND EQUIPMENT, at Cost</b>		
Land	987	986
Buildings and improvements	30,870	30,056
Machinery, equipment and furniture	45,009	41,541
Construction in progress	1,223	1,139
Subtotal	78,089	73,722
Less: accumulated depreciation and amortization	47,906	46,230
Net property, plant and equipment	30,183	27,492
<b>OTHER ASSETS</b>		
Goodwill	64,457	22,349
Other intangible assets, net	32,602	5,931
Restricted cash	1,000	1,000
Deferred instrument costs, net	1,567	1,750
Deferred income taxes		4,954
Other assets	356	384
Total other assets	99,982	36,368
<b>TOTAL ASSETS</b>	<b>\$ 258,361</b>	<b>\$ 183,282</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, 2016 (Unaudited)</b>	<b>September 30, 2015</b>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 7,891	\$ 6,646
Accrued employee compensation costs	5,888	5,132
Other accrued expenses	3,680	2,587
Current portion of long-term debt	3,000	
Income taxes payable	807	886
<b>Total current liabilities</b>	<b>21,266</b>	<b>15,251</b>
<b>NON-CURRENT LIABILITIES</b>		
Acquisition consideration payable	2,198	
Non-current compensation liabilities	2,204	2,158
Interest rate swap liability	694	
Long-term debt	56,842	
Deferred income taxes	5,311	
<b>Total non-current liabilities</b>	<b>67,249</b>	<b>2,158</b>
<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, 42,074,542 and 41,838,399 shares issued, respectively		
Additional paid-in capital	121,273	117,151
Retained earnings	52,219	51,052
Accumulated other comprehensive income	(3,646)	(2,330)
<b>Total shareholders' equity</b>	<b>169,846</b>	<b>165,873</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 258,361</b>	<b>\$ 183,282</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, 2015</b>	41,838	\$ 117,151	\$ 51,052	\$ (2,330)	\$ 165,873
Cash dividends paid			(16,817)		(16,817)
Exercise of stock options	121	1,832			1,832
Conversion of restricted stock units	116				
Stock compensation expense		2,290			2,290
Net earnings			17,984		17,984
Foreign currency translation adjustment				(865)	(865)
Hedging activity, net of tax				(451)	(451)
<b>Balance at March 31, 2016</b>	42,075	\$ 121,273	\$ 52,219	\$ (3,646)	\$ 169,846

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, 2016, the results of its operations for the three and six month periods ended March 31, 2016 and 2015, and its cash flows for the six month periods ended March 31, 2016 and 2015. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company's fiscal 2015 Annual Report on Form 10-K. Financial information as of September 30, 2015 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.

The Company's Condensed Consolidated Balance Sheet as of March 31, 2016 includes the condensed balance sheet of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, Inc. (collectively, Magellan), as set forth and more fully described in Note 3. Due to the immateriality of the amounts, revenues and expenses related to Magellan for the period owned by the Company (March 24 – March 31, 2016) are excluded from the Company's Condensed Consolidated Statements of Operations for the three or six months ended March 31, 2016.

**2. Significant Accounting Policies**

A summary of the Company's significant accounting policies is included in Note 1 to the audited consolidated financial statements of the Company's fiscal 2015 Annual Report on Form 10-K.

**(a) Recent Accounting Pronouncements**

In May 2014, the FASB issued 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, 2018 (fiscal 2019). The Company has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which simplifies the financial statement presentation of deferred income taxes by requiring that deferred income tax assets and liabilities be classified as noncurrent within a classified statement of financial position. Adoption and implementation



of the guidance is not required by the Company until issuance of fiscal 2018 first quarter financial statements. However, due to early adoption being permitted and believing the required presentation results in more useful and comparable information related to our net deferred income taxes, the Company has chosen to adopt the guidance as of December 31, 2015 and retrospectively apply the guidance to the prior period presented. This retrospective application results in \$3,431 of deferred income tax assets being reclassified from current assets to non-current assets in the September 30, 2015 balance sheet included herein. Adoption of this guidance did not have an impact on the Company's consolidated results of operations or cash flows.

## **Table of Contents**

In February 2016, the FASB issued ASU 2016-02, *Leases*, which amends the accounting guidance related to leases. These changes, which are designed to increase transparency and comparability among organizations for both lessees and lessors, include, among other things, requiring recognition of lease assets and liabilities on the balance sheet and disclosing key information about leasing arrangements. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2020, although early adoption is permitted. The Company has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends the accounting for share-based payment transactions. These changes, which are designed for simplification, involve several aspects of the accounting for share-based transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2018, although early adoption is permitted. The Company has not yet completed its assessment of the impact that adoption of this guidance will have on its financial statements.

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

### **(b) *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.

### **3. Acquisition of Magellan**

On March 24, 2016, we acquired all of the outstanding common stock of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, Inc. (collectively, "Magellan"), for \$67,800, utilizing the proceeds from a new \$60,000 five-year term loan and cash and equivalents on hand. An amount of the acquisition consideration totaling \$2,198 remains payable to the sellers, pending the realization of tax benefits for certain net operating loss carryforwards in future tax returns. Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S.

As a result of the consideration paid exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of \$42,730 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. This goodwill results largely from the addition of Magellan's complementary customer base and distribution channels, industry reputation in the U.S. as a leader in lead testing, and management talent and workforce. Our Condensed Consolidated Statements of Operations for the three and six months ended March 31, 2016 include \$1,173 of transaction costs related to the Magellan acquisition, which are reflected as Operating Expenses.

**Table of Contents**

The recognized preliminary amounts of identifiable assets acquired and liabilities assumed in the acquisition of Magellan are as follows:

	<b>PRELIMINARY</b>
Fair value of assets acquired -	
Cash and equivalents	\$ 3,420
Accounts receivable	1,700
Inventories	1,400
Other current assets	330
Property, plant and equipment	2,790
Goodwill	42,730
Other intangible assets (estimated useful life):	
Customer relationships (15 years)	12,630
Technology (10 years)	10,550
Non-compete agreements (2 years)	740
Trade names (approximate 5 year weighted average)	3,690
	79,980
Fair value of liabilities assumed -	
Accounts payable and accrued expenses	1,610
Deferred income tax liabilities	10,570
Total consideration (including \$2,198 accrued to be paid)	\$ 67,800

As indicated, the allocation of the purchase price and estimated useful lives of property, plant and equipment, and intangible assets shown above is preliminary, pending final completion of valuations. We are currently assessing the amount of tax net operating loss carryforwards available to us. Upon completion of this analysis, an amount will be reclassified from goodwill to deferred taxes.

The consolidated pro forma results of the combined entities of Meridian and Magellan, had the acquisition date been October 1, 2014, are as follows for the periods indicated:

	<b>Three Months</b>		<b>Six Months</b>	
	<b>Ended March 31, 2016</b>	<b>2015</b>	<b>Ended March 31, 2016</b>	<b>2015</b>
Net Revenues	\$ 54,961	\$ 55,073	\$ 106,057	\$ 106,970
Net Earnings	\$ 9,658	\$ 9,537	\$ 18,211	\$ 15,781
Diluted Earnings Per Common Share	\$ 0.23	\$ 0.23	\$ 0.43	\$ 0.38

These pro forma amounts have been calculated by including the results of Magellan, and adjusting the combined results to reflect (i) the transaction costs incurred by the Company; (ii) the additional depreciation and amortization that would have been charged assuming the preliminary fair value adjustments to inventory (\$154), property, plant and equipment (\$550) and identifiable intangible assets (\$27,610) had been applied on October 1, 2014; and (iii) the

interest expense that would have been incurred on the Company's \$60,000 term note had the borrowing occurred on October 1, 2014 together with the consequential tax effects.

**Table of Contents****4. Cash and Equivalents**

Cash and equivalents include the following components:

	March 31, 2016		September 30, 2015	
	Cash and Equivalents	Other Assets	Cash and Equivalents	Other Assets
Overnight repurchase agreements	\$ 21,727	\$	\$ 25,436	\$
Cash on hand -				
Restricted		1,000		1,000
Unrestricted	27,219		24,537	
<b>Total</b>	<b>\$ 48,946</b>	<b>\$ 1,000</b>	<b>\$ 49,973</b>	<b>\$ 1,000</b>

**5. Inventories**

Inventories are comprised of the following:

	March 31, 2016	September 30, 2015
Raw materials	\$ 8,378	\$ 7,095
Work-in-process	11,745	10,096
Finished goods - instruments	2,640	1,890
Finished goods - kits and reagents	19,171	16,736
<b>Total</b>	<b>\$ 41,934</b>	<b>\$ 35,817</b>

**6. Intangible Assets**

A summary of our acquired intangible assets subject to amortization, as of March 31, 2016 and September 30, 2015 is as follows:

	March 31, 2016		September 30, 2015	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	\$ 22,055	\$ 11,012	\$ 11,582	\$ 10,906
Trademarks, licenses and patents	9,965	3,596	6,410	3,296
	24,531	10,081	12,105	9,964

Customer lists and relationships, and supply agreements

Non-compete agreements

740

\$ 57,291	\$	24,689	\$	30,097	\$	24,166
-----------	----	--------	----	--------	----	--------

The actual aggregate amortization expense for these intangible assets was \$374 and \$431 for the three months ended March 31, 2016 and 2015, respectively, and \$762 and \$900 for the six months ended March 31, 2016 and 2015, respectively. The estimated aggregate amortization expense for these intangible assets for each of the fiscal years through fiscal 2021 is as follows: remainder of fiscal 2016 \$2,106, fiscal 2017 \$4,075, fiscal 2018 \$3,869, fiscal 2019 \$3,644, fiscal 2020 \$3,474 and fiscal 2021 \$2,578.

---

**Table of Contents****7. Bank Credit Arrangements**

In connection with the acquisition of Magellan (see Note 3), on March 22, 2016 the Company entered into a \$60,000 five-year term loan with a commercial bank. The term loan requires quarterly principal and interest payments, with interest at a variable rate tied to LIBOR and a balloon principal payment of \$37,500 at the end of five years. Due to the recent execution date of the term loan and interest being determined on a variable rate basis, the fair value of the term loan at March 31, 2016 approximates the current carrying value reflected in the accompanying Condensed Consolidated Balance Sheet.

In addition, the Company continues to maintain a \$30,000 credit facility with the same commercial bank, which expires March 31, 2021. As there were no borrowings outstanding on this credit facility at March 31, 2016 or September 30, 2015, available borrowings as of both dates totaled \$30,000. The term loan and the credit facility are collateralized by the business assets of the Company's U.S. subsidiaries, and require compliance with financial covenants that limit the amount of debt obligations and require a minimum level of coverage of fixed charges, as defined in the borrowing agreement. We are in compliance with all covenants.

In order to limit exposure to volatility in the LIBOR interest rate, the Company and the commercial bank also entered into an interest rate swap that effectively converts the variable interest rate on the term loan to a fixed rate. With an initial notional balance of \$60,000, the interest rate swap has been established with critical terms identical to those of the term loan, including (i) notional reduction amounts and dates; (ii) LIBOR settlement rates; (iii) rate reset dates; and (iv) term/maturity. Due to this, the interest swap has been designated as an effective cash flow hedge, with changes in fair value reflected as a separate component of other comprehensive income in the accompanying Condensed Consolidated Statements of Comprehensive Income. At March 31, 2016, the fair value of the interest rate swap was \$694, and is reflected as a non-current liability in the accompanying Condensed Consolidated Balance Sheet. This fair value was determined by reference to a market quote, and is considered a Level 2 input within the fair value hierarchy of valuation techniques.

**8. 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 infectious disease (in vitro) and blood lead diagnostics and life science. Our principal businesses are (i) the development, manufacture and distribution of diagnostic test kits primarily for gastrointestinal, viral, respiratory, parasitic infectious diseases, and elevated blood lead levels; 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 for infectious disease products. The Diagnostics segment includes the Company's recent acquisition of Magellan, which is located in Billerica, Massachusetts (near Boston). Its facility includes research, development, manufacturing, marketing, sales, and distribution operations. The Diagnostics segment has sales and distribution facilities for infectious disease diagnostics 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.

Amounts due from two Diagnostics distributor customers accounted for 18% and 21% of consolidated accounts receivable at March 31, 2016 and September 30, 2015, respectively. Revenues from these two distributor customers accounted for 26% and 32% of the Diagnostics segment third-party revenues during the three months ended March 31, 2016 and 2015, respectively, and 33% and 36% during the six months ended March 31, 2016 and 2015, respectively. These distributors represented 19% and 24% of consolidated revenues for the fiscal 2016 and 2015 second quarters, respectively, and 24% and 27% for the respective year-to-date six month periods.



**Table of Contents**

Within our Life Science segment, two diagnostic manufacturing customers accounted for 18% and 16% of the segment's third-party revenues during the three months ended March 31, 2016 and 2015, respectively, and 18% and 17% during the six months ended March 31, 2016 and 2015, respectively.

Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Eliminations(1)	Total
<b>Three Months Ended March 31, 2016</b>				
Net revenues -				
Third-party	\$ 37,354	\$ 13,905	\$	\$ 51,259
Inter-segment	84	387	(471)	
Operating income	11,196	4,154	(194)	15,156
Goodwill (March 31, 2016)	43,985	20,472		64,457
Other intangible assets, net (March 31, 2016)	29,694	2,908		32,602
Total assets (March 31, 2016)	190,447	68,349	(435)	258,361
<b>Three Months Ended March 31, 2015</b>				
Net revenues -				
Third-party	\$ 38,662	\$ 12,883	\$	\$ 51,545
Inter-segment	85	225	(310)	
Operating income	12,083	3,596	53	15,732
Goodwill (September 30, 2015)	1,250	21,099		22,349
Other intangible assets, net (September 30, 2015)	2,364	3,567		5,931
Total assets (September 30, 2015)	119,939	63,670	(327)	183,282
<b>Six Months Ended March 31, 2016</b>				
Net revenues -				
Third-party	\$ 72,655	\$ 25,764	\$	\$ 98,419
Inter-segment	155	754	(909)	
Operating income	21,526	7,390	(174)	28,742
<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	22,367	6,085	(51)	28,401

(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**

### 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 2016 was highlighted by our March 24, 2016 acquisition of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, Inc. (collectively, Magellan). Headquartered near Boston, Massachusetts, Magellan is a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning in children and adults. Magellan is the leading provider of point-of-care lead testing systems in the U.S. In addition, during the quarter we commercialized our *illumigene*<sup>®</sup> Malaria product outside of the U.S., representing the ninth assay for our *illumigene* molecular platform menu.

### **Three Months Ended March 31, 2016**

Net earnings for the second quarter of fiscal 2016 decreased 10% to \$9,091, or \$0.21 per diluted share, from net earnings for the second quarter of fiscal 2015 of \$10,070, or \$0.24 per diluted share. Reflected within the fiscal 2016 results are transaction costs related to acquisition activity, including the Magellan acquisition (\$1,000, or \$0.02 per diluted share, net of tax). Consolidated revenues decreased 1% to \$51,259 for the second quarter of fiscal 2016 compared to the same period of the prior year, and were flat on a constant-currency basis.

Included within the fiscal 2016 second quarter were revenues from our *illumigene* molecular platform of products totaling \$9,665, representing a 5% decrease from the fiscal 2015 second quarter. Also contributing to the consolidated revenue decrease were decreased revenues in two of our diagnostic focus product families (*C. difficile* and foodborne). Serving to substantially offset these decreases were increased revenues in our *H. pylori*, respiratory and women's health & STD focus product families and both of our Life Science segment's business lines (i.e., molecular components and immunoassay components).

Revenues for the Diagnostics segment for the second quarter of fiscal 2016 decreased 3% compared to the second quarter of fiscal 2015 (also down 3% on a constant-currency basis), reflecting the following for each of our focus product families: 10% decline in our foodborne products, 23% decline in our *C. difficile* products, 8% growth in our *H. pylori* products, 10% growth in our respiratory products, and 21% growth in our women's health & STD products. With growth in both its molecular components and immunoassay components business, revenues of our Life Science segment increased by 8% during the second quarter of fiscal 2016 compared to the second quarter of fiscal 2015, increasing 9% on a constant-currency basis.

### **Six Months Ended March 31, 2016**

For the six month period ended March 31, 2016, net earnings were flat at \$17,984, or \$0.42 per diluted share, compared to net earnings for the comparable fiscal 2015 period of \$17,971, or \$0.43 per diluted share. Reflected within the year-to-date fiscal 2016 results are transaction costs related to acquisition activity, including the Magellan acquisition (\$1,233, or \$0.03 per diluted share, net of tax). Consolidated revenues decreased 1% to \$98,419 for the first six months of fiscal 2016 compared to the same period of the prior year, and were flat on a constant-currency basis.

Included within the six month year-to-date fiscal 2016 results were revenues from our *illumigene* molecular platform of products totaling \$19,501, representing a 3% decrease from the first six months of fiscal 2015. Also contributing to the consolidated revenue decrease were decreased revenues in two of our diagnostic focus product families (*C. difficile* and foodborne) and flat revenues in our respiratory family of products and our

**Table of Contents**

Life Science segment's molecular components business line. Serving to substantially offset these items were increased revenues in our *H. pylori* and women's health & STD focus product families and our Life Science segment's immunoassay components business line.

During the first six months of fiscal 2016, revenues for the Diagnostics segment decreased 3% from the comparable fiscal 2015 period (also down 3% on a constant-currency basis), reflecting the following for each of our focus product families: 11% decline in our foodborne products, 13% decline in our *C. difficile* products, flat revenues in our respiratory products, 13% growth in our *H. pylori* products, and 14% growth in our women's health & STD products. With growth in its immunoassay components business and flat revenue in its molecular components business, revenues of our Life Science segment increased by 6% during the first six months of fiscal 2016, increasing 8% on a constant-currency basis.

**NON-GAAP INFORMATION**

The tables below provide information on net earnings, basic earnings per share and diluted earnings per share, excluding the effect of costs associated with acquisition activity, each of which is a non-GAAP financial measure, as well as reconciliations to amounts reported under U.S. Generally Accepted Accounting Principles. We believe that this information is useful to those who read our financial statements and evaluate our operating results because:

1. These measures help to appropriately evaluate and compare the results of operations from period to period by removing the impact of non-routine costs related to acquisition activity; and
2. These measures are used by our management for various purposes, including evaluating performance against incentive bonus achievement targets, comparing performance from period to period in presentations to our board of directors, and as a basis for strategic planning and forecasting.

	Three Months		Six Months	
	Ended March 31, 2016	2015	Ended March 31, 2016	2015
<b>Net Earnings -</b>				
U.S. GAAP basis	\$ 9,091	\$ 10,070	\$ 17,984	\$ 17,971
Transaction costs (1)	1,000		1,233	
Adjusted earnings	\$ 10,091	\$ 10,070	\$ 19,217	\$ 17,971
<b>Net Earnings per Basic Common Share -</b>				
U.S. GAAP basis	\$ 0.22	\$ 0.24	\$ 0.43	\$ 0.43
Transaction costs (1)	0.02		0.03	
Adjusted Basic EPS	\$ 0.24	\$ 0.24	\$ 0.46	\$ 0.43
<b>Net Earnings per Diluted Common Share -</b>				
U.S. GAAP basis	\$ 0.21	\$ 0.24	\$ 0.42	\$ 0.43

Transaction costs (1)	0.02		0.03	
Adjusted Diluted EPS (2)	\$ 0.24	\$ 0.24	\$ 0.45	\$ 0.43

- (1) These transaction costs are net of income tax effects of \$202 and \$248 for the three and six month periods, respectively, which were calculated using the effective tax rates of the jurisdictions in which the costs were incurred.
- (2) Net Earnings per Diluted Common Share for the three months ended March 31, 2016 does not sum to the total due to rounding.

**Table of Contents****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 for infectious disease products in Cincinnati, Ohio and as a result of our recent acquisition of Magellan, manufacturing operations for products detecting elevated levels of lead in blood in Billerica, Massachusetts (near Boston). These diagnostic test products are sold and distributed in the countries comprising North, Central and South America (the Americas); Europe, Middle East and Africa (EMEA); and other countries outside of the Americas and EMEA (rest of the world, or ROW). The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad, including sales and business development offices in Singapore and Beijing, China to further pursue growing revenue opportunities in Asia.

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 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,		
	2016	2015	Inc (Dec)	2016	2015	Inc (Dec)
<b>Diagnostics-</b>						
Americas	\$ 31,864	\$ 32,179	(1)%	\$ 61,979	\$ 63,092	(2)%
EMEA	4,882	5,530	(12)%	9,531	10,533	(10)%
ROW	608	953	(36)%	1,145	1,623	(29)%
<b>Total Diagnostics</b>	<b>37,354</b>	<b>38,662</b>	<b>(3)%</b>	<b>72,655</b>	<b>75,248</b>	<b>(3)%</b>
<b>Life Science-</b>						
Americas	6,356	5,910	8%	11,459	11,209	2%
EMEA	4,614	5,002	(8)%	9,150	8,760	4%
ROW	2,935	1,971	49%	5,155	4,341	19%

Edgar Filing: MERIDIAN BIOSCIENCE INC - Form 10-Q

Total Life Science	13,905	12,883	8%	25,764	24,310	6%
Consolidated	\$ 51,259	\$ 51,545	(1)%	\$ 98,419	\$ 99,558	(1)%
% of total revenues-						
Diagnostics	73%	75%		74%	76%	
Life Science	27%	25%		26%	24%	
Total	100%	100%		100%	100%	
Ex-Americas	25%	26%		25%	25%	

Page 15

**Table of Contents****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 on multiple technology platforms

**Life Science**

- 1) Molecular components
- 2) Immunoassay components

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,		
	2016	2015	Inc (Dec)	2016	2015	Inc (Dec)
<b>Diagnostics-</b>						
Molecular	\$ 9,665	\$ 10,192	(5)%	\$ 19,501	\$ 20,100	(3)%
Immunoassay	27,689	28,470	(3)%	53,154	55,148	(4)%
Total Diagnostics	\$ 37,354	\$ 38,662	(3)%	\$ 72,655	\$ 75,248	(3)%
<b>Life Science-</b>						
Molecular components	\$ 5,116	\$ 4,893	5%	\$ 9,865	\$ 9,905	%
Immunoassay components	8,789	7,990	10%	15,899	14,405	10%
Total Life Science	\$ 13,905	\$ 12,883	8%	\$ 25,764	\$ 24,310	6%
<b>% of Diagnostics revenues-</b>						
Molecular	26%	26%		27%	27%	
Immunoassay	74%	74%		73%	73%	
Total Diagnostics	100%	100%		100%	100%	
<b>% of Life Science revenues-</b>						
Molecular components	37%	38%		38%	41%	
Immunoassay components	63%	62%		62%	59%	



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*

We have over 1,500 customer account placements. Of these account placements, over 1,300 accounts have completed evaluations and validations and are regularly purchasing product, with the balance of our account placements being in some stage of product evaluation and/or validation. Of our account placements, we have over 400 accounts that are regularly purchasing, evaluating and/or validating two or more assays.

We continue to invest in new product development for our molecular testing platform, *illumigene*. This platform now has the following commercialized tests:

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

**Table of Contents**

4. *illumigene*<sup>®</sup> Mycoplasma (*M. pneumoniae*; walking pneumonia) commercialized in June 2013
5. *illumigene*<sup>®</sup> *Bordetella pertussis* (whooping cough) commercialized in March 2014
6. *illumigene*<sup>®</sup> *Chlamydia trachomatis* commercialized outside of U.S. in February 2015
7. *illumigene*<sup>®</sup> *Neisseria gonorrhoea* commercialized outside of U.S. in February 2015
8. *illumigene*<sup>®</sup> HSV 1&2 (Herpes Simplex Virus Type 1 & Type 2) commercialized outside of U.S. in May 2015; commercialized in U.S. in July 2015
9. *illumigene*<sup>®</sup> Malaria commercialized outside of U.S. in February 2016

We have several additional *illumigene* tests in development and have a robust pipeline of *illumigene* opportunities. We continue to add new assays to our *illumigene* platform menu, with our latest being malaria, which was launched in the EMEA region in February 2016.

We believe that the diagnostic testing market is continuing to selectively 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 others such as Quidel, Great Basin, Nanosphere, and Alere, 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**

Revenues from our Diagnostics segment's immunoassay products decreased 3% in the second quarter of fiscal 2016 and decreased 4% on a six month year-to-date basis. As described in the product discussions below, the quarterly and year-to-date decreases result primarily from the decline in revenues of our foodborne, *C. difficile* and respiratory immunoassay products, partially offset by the revenue increase in our *H. pylori* products.

**Life Science Products**

During the second quarter of fiscal 2016, revenues from our Life Science segment increased 8%, with revenues from molecular component sales increasing 5% from the comparable fiscal 2015 quarter and revenues from immunoassay component sales increasing 10%. For the first six months of fiscal 2016, revenues from our Life Science segment increased 6%, with flat revenues from molecular component sales compared to the year-to-date fiscal 2015 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 fiscal 2015 periods, with revenues increasing 8% and 4% on a constant-currency basis over the second quarter and first six months of fiscal 2015, respectively. Our Life Science segment continued to benefit from increased sales into China, with such sales totaling approximately \$1,000 and \$1,500 during the fiscal 2016 second quarter and year-to-date periods, respectively,

primarily in the immunoassay components business.

**Diagnostics Revenue Overview- By Disease Family**

Revenues from our focus families (*C. difficile*, foodborne, *H. pylori*, respiratory and women's health & STD) comprised 78% of our Diagnostics segment's revenues during both the second quarter of fiscal 2016 and fiscal 2015, comprising 80% and 78% during the first six months of fiscal 2016 and 2015, respectively. Following is a discussion of the revenues generated by each product family:

***C. difficile* Products**

Revenues for our *C. difficile* product family decreased 23% to \$6,300 for the fiscal 2016 second quarter (22% in constant-currency), and decreased 13% to \$13,700 for the six month year-to-date period (12% in constant-currency). Our molecular products now represent approximately 80% 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.

---

**Table of Contents*****Foodborne Products***

Revenues from our foodborne products (Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*), all of which are immunoassay products, totaled \$6,100 during the fiscal 2016 second quarter, a 10% decrease from the fiscal 2015 second quarter (also 10% in constant-currency). During the six months ended March 31, 2016, foodborne revenues totaled \$11,400, an 11% decrease from the fiscal 2015 year-to-date period (also 11% in constant-currency). Revenues for our foodborne products during fiscal 2016 have been affected by distributor ordering patterns and increased competition. The primary competition for our foodborne products is laboratory culture methods and an immunoassay EHEC 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. More recently, multi-plex gastro-intestinal panels are introducing new competition in this product category.

***H. pylori Products***

During the fiscal 2016 second quarter, revenues from our *H. pylori* products, all of which are immunoassay products, increased 8% (also 8% in constant-currency) to \$8,300. These revenues grew 13% to \$17,000 during the first six months of fiscal 2016 (15% in constant-currency). 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) physician behavior movement away from serology-based testing and toward direct antigen testing. A significant amount of the *H. pylori* product revenues are sales to reference labs, whose buying patterns may not be consistent from period to period. In addition to our managed care strategy, we have also employed bulk-buy sales promotions into selected distribution and laboratory channels as a defensive strategy against potential new competitive product introductions later in the year.

The patents for our *H. pylori* products are owned by us and expire in May 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* on molecular platforms) and attempting to secure significant customers under long-term contracts. 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 for our Diagnostics segment increased 10% to \$6,500 during the second quarter of fiscal 2016 (also 10% in constant-currency) and remained flat on a six month year-to-date basis (increased 1% in constant-currency), totaling \$12,100 in fiscal 2016. The quarterly growth was primarily experienced in our molecular respiratory products (*illumigene* Group A Strep, *illumigene* Mycoplasma and *illumigene* Pertussis), while our year-to-date results were significantly impacted by the success of promotional stock-and-block programs in the third (influenza) and fourth (Group A strep) quarters of fiscal 2015 that affected buying patterns in the first quarter of fiscal 2016.

***Women's Health & STD Products***

Revenues from our women's health & STD products, all of which are molecular products, totaled \$1,900 during the second quarter of fiscal 2016, a 21% increase from the fiscal 2015 second quarter (also 21% in constant-currency). During the six months ended March 31, 2016, revenues from these products totaled \$3,600, an increase of 14% (also 14% in constant-currency). This growth primarily reflects the results of our commercialization during fiscal 2015 of three *illumigene* tests for sexually transmitted diseases (Chlamydia, Gonorrhea and HSV).

***Significant Customers***

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 8 of the accompanying Condensed Consolidated Financial Statements.

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

On January 1, 2013, the medical device tax established as part of the U.S. health care reform legislation became effective, and as a result, the Company made its first required tax deposit near the end of January 2013. During the first six months of fiscal 2016 and fiscal 2015, the Company recorded approximately \$500 and \$1,000, respectively, of medical device tax expense (\$0 and \$500 in the second quarters of fiscal 2016 and 2015, respectively), which is reflected as a component of cost of sales in the accompanying Condensed Consolidated Statements of Operations. During December 2015, the Consolidations Appropriations Act of 2016 imposed a two-year moratorium on this excise tax effective January 1, 2016. During calendar years 2016 and 2017, this moratorium would result in approximately \$2,000 of savings each year. We are unable to predict any future legislative changes or developments related to this moratorium or excise tax.

**Gross Profit**

	Three Months Ended March 31,			Six Months Ended March 31,		
	2016	2015	Change	2016	2015	Change
Gross Profit	\$ 33,572	\$ 32,521	3%	\$ 65,155	\$ 61,758	6%
Gross Profit Margin	65%	63%	+2 points	66%	62%	+4 points

The overall gross profit increases experienced in fiscal 2016 primarily result from the combined effects of (i) mix of products sold, particularly the higher revenue contribution from *H. pylori* products; (ii) realization of manufacturing facility efficiencies for our *illumigene* products as a result of bringing in-house certain reagent dispensing operations that were previously outsourced; (iii) manufacturing efficiencies in our Life Science segment; and (iv) favorable effects of currency rates related to products where the purchase cost is denominated in Euros but the customer sales are billed in U.S. dollars.

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

**Operating Expenses**

	Three Months Ended March 31, 2016					Total Operating Expenses
	Research & Development	Selling & Marketing	General & Administrative	Transaction Costs		
<b>2015 Expenses</b>	\$ 3,368	\$ 6,481	\$ 6,940	\$		\$ 16,789
% of Revenues	7%	13%	13%		%	33%
Fiscal 2016 Increases (Decreases):						
Diagnosics	(117)	302	(223)	1,202		1,164
Life Science	(122)	427	158			463
<b>2016 Expenses</b>	\$ 3,129	\$ 7,210	\$ 6,875	\$ 1,202		\$ 18,416
% of Revenues	6%	14%	13%	2%		36%

% Increase (Decrease)	(7)%	11%	(1)%	NMF	10%
-----------------------	------	-----	------	-----	-----

**Table of Contents**

	<b>Six Months Ended March 31, 2016</b>				
	<b>Research &amp; Development</b>	<b>Selling &amp; Marketing</b>	<b>General &amp; Administrative</b>	<b>Transaction Costs</b>	<b>Total Operating Expenses</b>
<b>2015 Expenses</b>	\$ 6,471	\$ 12,561	\$ 14,325	\$	\$ 33,357
% of Revenues	6%	13%	14%	%	34%
<b>Fiscal 2016 Increases (Decreases):</b>					
Diagnostics	278	331	191	1,481	2,281
Life Science	(239)	761	253		775
<b>2016 Expenses</b>	\$ 6,510	\$ 13,653	\$ 14,769	\$ 1,481	\$ 36,413
% of Revenues	7%	14%	15%	2%	37%
% Increase	1%	9%	3%	NMF	9%

Total operating expenses increased during both the second quarter of fiscal 2016 and the first six months of fiscal 2016 compared to the corresponding fiscal 2015 periods. These levels of operating expenses result primarily 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 new product development in our Diagnostics segment (concentrated during the first three months of the year), and increased investment in Sales and Marketing personnel and programs; (ii) favorable effects of currency rates; and (iii) transaction costs incurred in connection with acquisition activities, most notably related to the acquisition of Magellan.

**Operating Income**

Operating income decreased 4% to \$15,156 for the second quarter of fiscal 2016, and increased 1% to \$28,742 for the first six months of fiscal 2016, as a result of the factors discussed above.

**Income Taxes**

The effective rate for income taxes increased to 39% and 37% during the fiscal 2016 second quarter and six month year-to-date periods, respectively, compared to 35% in both of the corresponding fiscal 2015 periods. These increases primarily result from the non-deductibility of certain expenses incurred in connection with the Company's acquisition activities. For the fiscal year ending September 30, 2016, we expect the effective tax rate to approximate 36%-37%.

**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.

We have an investment policy that guides the holdings of our investment portfolio, which presently consist of overnight repurchase agreements, bank savings accounts and institutional money market mutual funds (beginning in April). Our objectives 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 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. Our liquidity needs may

## **Table of Contents**

change if overall economic conditions change 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 \$18,461 for the first six months of fiscal 2016, an 8% decrease from the \$20,031 provided during the first six months of fiscal 2015. While reflecting the effects of the timing of payments from and to customers and suppliers, respectively, this decrease also largely results from the timing of tax payments. 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.

As described in Notes 3 and 7 of the accompanying Condensed Consolidated Financial Statements, on March 24, 2016, the Company acquired all of the outstanding common stock of Magellan for \$67,800, utilizing the proceeds from a new \$60,000 five-year term loan and cash and equivalents on hand. An amount of the acquisition consideration totaling \$2,198 remains payable to the sellers, pending the realization of tax benefits for certain net operating loss carryforwards in future tax returns.

### ***Capital Resources***

We have a \$30,000 credit facility with a commercial bank that expires on March 31, 2021. As of April 30, 2016, 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 2016 or during the full year of fiscal 2015.

Our capital expenditures are estimated to range between approximately \$3,000 to \$4,000 for fiscal 2016, 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, 2015.

### **ITEM 4. CONTROLS AND PROCEDURES**

As of March 31, 2016, 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, 2016. 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, 2016. We routinely refine our internal controls over financial reporting in the normal course of business as new business activities arise or risks change. These refinements are made under a program of continuous improvement.



**Table of Contents**

**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.

- 10.1 Agreement and Plan of Merger among Meridian Bioscience, Inc. and Mariner Merger Sub, Inc. and Magellan Biosciences, Inc. and Ampersand 2006 Limited Partnership as the Stockholder Representative dated as of March 24, 2016
- 10.2 Term Note with Fifth Third Bank dated March 22, 2016
- 10.3 Amended and Restated Revolving Note with Fifth Third dated March 22, 2016
- 10.4 Sixth Amendment to Loan and Security Agreement among Meridian Bioscience, Inc., Meridian Bioscience Corporation, Omega Technologies, Inc., Meridian Life Science, Inc., Bioline USA, Inc. and Fifth Third Bank dated March 22, 2016
- 10.5 Executive Employment Agreement between Meridian and Amy Winslow dated March 21, 2016
- 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, 2016 filed with the SEC on May 6, 2016, formatted in XBRL includes: (i) Condensed Consolidated Statements of Operations for the three and six months ended March 31, 2016 and 2015; (ii) Condensed Consolidated Statements of Comprehensive Income for the three and six months ended March 31, 2016 and 2015; (iii) Condensed Consolidated Statements of Cash Flows for the six months ended March 31, 2016 and 2015; (iv) Condensed Consolidated Balance Sheets as of March 31, 2016 and September 30, 2015; (v) Condensed Consolidated Statement of Shareholders' Equity for the six months ended March 31, 2016; 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 6, 2016

By: /s/ Melissa A. Lueke  
Melissa A. Lueke  
Executive Vice President and Chief Financial Officer  
  
(Principal Financial and Accounting Officer)

Page 23