

MERIDIAN BIOSCIENCE INC

Form 10-Q

February 11, 2013

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-Q

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

For the Quarterly Period Ended December 31, 2012

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

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31-0888197

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

3471 River Hills Drive

Cincinnati, Ohio 45244

(513) 271-3700

Indicate by a check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer ☒ Accelerated filer ☐  
Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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

Class	Outstanding January 31, 2013
Common Stock, no par value	41,416,157

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<p><i>The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as estimates, anticipates, projects, plans, seeks, may, will, expects, intends, believes, should and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian's continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Meridian relies on proprietary, patented and licensed technologies, and the Company's ability to protect its intellectual property rights, as well as the potential for intellectual property litigation, would impact its results. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. Costs and difficulties in complying with laws and regulations, including those administered by the United States Food and Drug Administration, can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. The international scope of Meridian's operations, including changes in the relative strength or weakness of the U.S. dollar and general economic conditions in foreign countries, can impact results and make them difficult to predict. One of Meridian's growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses will be successfully integrated into Meridian's operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention and there may be additional risks with respect to Meridian's ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. The Company cannot predict the possible impact of recently-enacted United States healthcare legislation and any similar initiatives in other countries on its results of operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.</i></p>	

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

	<b>Three Months Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
NET SALES	\$ 45,351	\$ 40,075
COST OF SALES	16,555	15,533
GROSS PROFIT	28,796	24,542
OPERATING EXPENSES		
Research and development	2,517	2,273
Selling and marketing	5,693	5,377
General and administrative	7,495	6,643
Plant consolidation costs		444
Total operating expenses	15,705	14,737
OPERATING INCOME	13,091	9,805
OTHER INCOME		
Interest income	7	5
Other, net	128	316
Total other income	135	321
EARNINGS BEFORE INCOME TAXES	13,226	10,126
INCOME TAX PROVISION	4,752	3,548
NET EARNINGS	\$ 8,474	\$ 6,578
BASIC EARNINGS PER COMMON SHARE	\$ 0.21	\$ 0.16
DILUTED EARNINGS PER COMMON SHARE	\$ 0.20	\$ 0.16
AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC	41,148	41,067
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARES AND UNITS	604	420
AVERAGE NUMBER OF COMMON SHARES OUTSTANDING DILUTED	41,752	41,487
ANTI-DILUTIVE SECURITIES:		
Common share options and restricted shares and units	294	343
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.38	\$ 0.19

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

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**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**

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

(in thousands)

	<b>Three Months Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>NET EARNINGS</b>	<b>\$ 8,474</b>	<b>\$ 6,578</b>
Other comprehensive income (loss):		
Foreign currency translation adjustment	339	(1,044)
Income tax benefit related to items of other comprehensive income	(93)	363
Other comprehensive income (loss), net of tax	246	(681)
<b>COMPREHENSIVE INCOME</b>	<b>\$ 8,720</b>	<b>\$ 5,897</b>

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

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

<b>Three Months Ended December 31,</b>	<b>2012</b>	<b>2011</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 8,474	\$ 6,578
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	815	903
Amortization of intangible assets	580	520
Amortization of deferred illumigene instrument costs	381	149
Stock-based compensation	1,146	979
Deferred income taxes	(136)	(679)
(Gain) loss on dispositions of long-lived assets	9	(23)
Change in current assets	5,231	2,718
Change in current liabilities	150	1,452
Other, net	(603)	(100)
<b>Net cash provided by operating activities</b>	<b>16,047</b>	<b>12,497</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property, plant and equipment	(403)	(1,052)
Proceeds from sale of assets		400
Purchases of intangibles and other assets		(1,290)
<b>Net cash used for investing activities</b>	<b>(403)</b>	<b>(1,942)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(15,652)	(7,803)
Proceeds and tax benefits from exercises of stock options	1,390	269
<b>Net cash used for financing activities</b>	<b>(14,262)</b>	<b>(7,534)</b>
<b>Effect of Exchange Rate Changes on Cash and Equivalents</b>	<b>174</b>	<b>(442)</b>
<b>Net Increase in Cash and Equivalents</b>	<b>1,556</b>	<b>2,579</b>
<b>Cash and Equivalents at Beginning of Period</b>	<b>31,593</b>	<b>23,626</b>
<b>Cash and Equivalents at End of Period</b>	<b>\$ 33,149</b>	<b>\$ 26,205</b>

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

**Table of Contents****MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets****(in thousands)****ASSETS**

	<b>December 31, 2012 (Unaudited)</b>	<b>September 30, 2012</b>
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 33,149	\$ 31,593
Accounts receivable, less allowances of \$600 and \$574	23,787	24,183
Inventories	30,269	31,682
Prepaid expenses and other current assets	3,101	6,203
Deferred income taxes	3,019	2,929
<b>Total current assets</b>	<b>93,325</b>	<b>96,590</b>
<b>PROPERTY, PLANT AND EQUIPMENT, at Cost</b>		
Land	1,179	1,175
Buildings and improvements	26,005	25,983
Machinery, equipment and furniture	35,912	34,917
Construction in progress	1,255	1,149
<b>Subtotal</b>	<b>64,351</b>	<b>63,224</b>
Less: accumulated depreciation and amortization	38,524	37,069
<b>Net property, plant and equipment</b>	<b>25,827</b>	<b>26,155</b>
<b>OTHER ASSETS</b>		
Goodwill	23,146	23,146
Other intangible assets, net	9,716	10,264
Restricted cash	1,000	1,000
Deferred illumigene instrument costs, net	3,963	3,958
Deferred income taxes	69	
Other assets	269	268
<b>Total other assets</b>	<b>38,163</b>	<b>38,636</b>
<b>TOTAL ASSETS</b>	<b>\$ 157,315</b>	<b>\$ 161,381</b>

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



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

	<b>December 31, 2012 (Unaudited)</b>	<b>September 30, 2012</b>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 5,521	\$ 5,794
Accrued employee compensation costs	5,767	5,827
Other accrued expenses	4,832	5,247
Income taxes payable	2,887	1,594
Total current liabilities	19,007	18,462
<b>DEFERRED INCOME TAXES</b>		171
<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, 41,416,157 and 41,284,485 shares issued, respectively		
Additional paid-in capital	104,935	102,443
Retained earnings	33,032	40,210
Accumulated other comprehensive income	341	95
Total shareholders' equity	138,308	142,748
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 157,315</b>	<b>\$ 161,381</b>

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

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### 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, 2012</b>	41,284	\$ 102,443	\$ 40,210	\$ 95	\$ 142,748
Cash dividends paid			(15,652)		(15,652)
Exercise of stock options	132	1,346			1,346
Stock compensation expense		1,146			1,146
Net earnings			8,474		8,474
Foreign currency translation adjustment, net of tax				246	246
<b>Balance at December 31, 2012</b>	41,416	\$ 104,935	\$ 33,032	\$ 341	\$ 138,308

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

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### **MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**

#### **Notes to Condensed Consolidated Financial Statements**

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

**(Unaudited)**

#### **1. Basis of Presentation**

The interim condensed consolidated financial statements are unaudited and are prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information, and the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of Management, the interim financial statements include all normal adjustments and disclosures necessary to present fairly the Company's financial position as of December 31, 2012, the results of its operations for the three month periods ended December 31, 2012 and 2011, and its cash flows for the three month periods ended December 31, 2012 and 2011. These statements should be read in conjunction with the financial statements and footnotes thereto included in the Company's fiscal 2012 Annual Report on Form 10-K. Financial information as of September 30, 2012 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 buyer. Revenue for the U.S. Diagnostics segment is reduced at the date of sale for product price adjustments due certain distributors under local contracts. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, estimates of inventories of our products held by distributors, historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Such accruals were \$4,809 at December 31, 2012 and \$3,877 at September 30, 2012, and have been netted against accounts receivable.

Revenue for our Diagnostics segments includes bundled product revenue for our *illumigene*® molecular test system. The bundled product includes an instrument, instrument accessories and test kits. Amounts invoiced for the *illumigene* test kits cover the instrument, accessories and test kits. Revenue is recognized based on test kit sales during the instrument utilization period. Costs for the instruments are recognized in cost of sales over the expected instrument utilization period, generally three years.

Life Science revenue for contract services may come from research and development services or manufacturing services, including process development work, or a combination of both. Revenue is recognized based on each of the deliverables in a given arrangement having distinct and separate customer pricing. Depending on the nature of the arrangement, revenue is recognized as services are performed and billed, upon completion and acceptance by the customer, or upon delivery of product and acceptance by the customer. In some cases, customers may request that we store on their behalf, clinical grade biologicals that we produce under contract manufacturing agreements. These cases arise when customers do not have clinical grade storage facilities or do not want to risk contamination during transport. For such cases, revenue may be recognized on a bill-and-hold basis. No such bill-and-hold arrangements existed at December 31, 2012 or September 30, 2012.

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

**Table of Contents****(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, foreign currency translation and the related income tax effects.

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

**(c) Income Taxes**

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

We account for uncertain tax positions using a benefit recognition model with a two-step approach: (i) a more-likely-than-not recognition criterion; and (ii) a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being ultimately realized upon settlement. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. We recognize accrued interest and penalties related to unrecognized tax benefits as a portion of our income tax provision in the Condensed Consolidated Statements of Operations.

**(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 period.

**(e) Cash and Cash Equivalents**

Cash and cash equivalents include the following components:

	December 31, 2012		September 30, 2012	
	Cash and Equivalents	Other	Cash and Equivalents	Other
Overnight repurchase agreements	\$ 15,084	\$	\$ 13,492	\$
Cash on hand				
Restricted		1,000		1,000
Unrestricted	18,065		18,101	
<b>Total</b>	<b>\$ 33,149</b>	<b>\$ 1,000</b>	<b>\$ 31,593</b>	<b>\$ 1,000</b>

**Table of Contents****(f) Recent Accounting Pronouncements**

In June 2011, FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*, which amended the disclosure and presentation requirements of Comprehensive Income. Specifically, FASB ASU No. 2011-05 required that all nonowner changes in shareholders' equity be presented either in 1) a single continuous statement of comprehensive income or 2) two separate but consecutive statements, in which the first statement presents total net income and its components, and the second statement presents total other comprehensive income and its components. The Company adopted these new presentation requirements effective October 1, 2012 and has presented herein Condensed Consolidated Statements of Comprehensive Income for the three month periods ended December 31, 2012 and 2011 that are compliant with the requirements. Adoption of these requirements had no impact on the Company's consolidated results of operations, cash flows or financial position.

In September 2011, FASB issued ASU No. 2011-08, *Testing Goodwill for Impairment*, which amended goodwill impairment guidance to provide an option for entities to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. After assessing the totality of events and circumstances, if an entity determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, performance of the two-step impairment test is no longer required. The Company's adoption of this guidance effective October 1, 2012 had no impact on the Company's consolidated results of operations, cash flow or financial position.

**(g) Reclassifications**

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

**3. Inventories**

Inventories are comprised of the following:

	December 31, 2012	September 30, 2012
Raw materials	\$ 7,169	\$ 6,916
Work-in-process	9,294	9,540
Finished goods - illumigene instruments	1,973	2,326
Finished goods - kits and reagents	11,833	12,900
Total	\$ 30,269	\$ 31,682

**4. Major Customers and Segment 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; (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bio research reagents used by researchers and other diagnostic manufacturers; and (iii) 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.

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Our reportable segments are U.S. Diagnostics, European Diagnostics and Life Science. Initial segmentation between Diagnostics and Life Science has been determined based upon products and customers, with further segmentation of Diagnostics between U.S. and European being based upon geographic regions served and management responsibility. The U.S. Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the U.S. and countries outside of Australia, Europe, Africa and the Middle East. The European Diagnostics segment consists of the sale and distribution of diagnostic test kits in Australia, Europe, Africa and the Middle East. The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Two distributor customers accounted for 55% and 50% of the U.S. Diagnostics segment third-party sales during the three months ended December 31, 2012 and 2011, respectively. Two diagnostic manufacturing customers accounted for 18% and 27% of the Life Science segment third-party sales during the three months ended December 31, 2012 and 2011, respectively.

Segment information for the interim periods is as follows:

	U.S. Diagnostics	European Diagnostics	Life Science	Eliminations(1)	Total
<b>Three Months Ended December 31, 2012</b>					
Net sales					
Third-party	\$ 30,366	\$ 5,303	\$ 9,682	\$	\$ 45,351
Inter-segment	2,086	3	158	(2,247)	
Operating income	11,243	229	1,634	(15)	13,091
Goodwill (December 31, 2012)	1,250		21,896		23,146
Other intangible assets, net (December 31, 2012)	2,073		7,643		9,716
Total assets (December 31, 2012)	82,800	15,353	99,813	(40,651)	157,315
<b>Three Months Ended December 31, 2011</b>					
Net sales					
Third-party	\$ 25,009	\$ 5,505	\$ 9,561	\$	\$ 40,075
Inter-segment	2,228		336	(2,564)	
Operating income (2)	8,473	643	698	(9)	9,805
Goodwill (September 30, 2012)	1,250		21,896		23,146
Other intangible assets, net (September 30, 2012)	2,239		8,025		10,264
Total assets (September 30, 2012)	82,654	15,443	101,706	(38,422)	161,381

(1) Eliminations consist of inter-segment transactions.

(2) Life Science includes \$444 of costs related to consolidation of the Maine operations into the Tennessee facility.

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 December 31, 2012 and September 30, 2012 is as follows:

	December 31, 2012		September 30, 2012	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	\$ 11,678	\$ 9,519	\$ 11,678	\$ 9,327
Trademarks, licenses and patents	4,704	1,732	4,704	1,616
Customer lists and supply agreements	12,360	7,775	12,360	7,535
	\$ 28,742	\$ 19,026	\$ 28,742	\$ 18,478

The actual aggregate amortization expense for these intangible assets was \$580 and \$520 for the three months ended December 31, 2012 and 2011, respectively. The estimated aggregate amortization expense for these intangible assets for each of the fiscal years through fiscal 2018 is as follows: remainder of fiscal 2013 \$1,616, fiscal 2014 \$1,771, fiscal 2015 \$1,523, fiscal 2016 \$1,179, fiscal 2017 \$930 and fiscal 2018 \$908.

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

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

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

**Results of Operations**

Net earnings for the first quarter of fiscal 2013 increased 29% to \$8,474, or \$0.20 per diluted share, from net earnings for the first quarter of fiscal 2012 of \$6,578, or \$0.16 per diluted share. This increase reflects the combined effects of both increased sales and increased operating expense. Additionally, the fiscal 2012 first quarter included \$444 of costs associated with the consolidation of the Saco, Maine operations into the Memphis, Tennessee facility (impact on earnings of \$289, or \$0.01 per diluted share). Consolidated sales increased 13% to \$45,351 for the first quarter of fiscal 2013 compared to the same period of the prior year. Increased sales across all of our diagnostic focus product families (*C. difficile*, Foodborne and *H. pylori*) as well as in our Life Science segment, contributed to this increase. In addition, an early and strong start to the influenza season resulted in an increase in sales of our Respiratory family of products compared to the fiscal 2012 first quarter.

Sales for the U.S. Diagnostics segment for the first quarter of fiscal 2013 increased 21% compared to the first quarter of fiscal 2012, reflecting growth across all of our focus product families 14% growth in *H. pylori* products, 16% growth in foodborne products, and 17% growth in *C. difficile* products. Sales of our influenza respiratory products increased 211%, or approximately \$1,000. First quarter fiscal 2013 sales for our European Diagnostics segment decreased 4% compared to the first quarter of fiscal 2012 due primarily to a negative currency effect. On an organic basis, which excludes the effects of currency translation, sales of our European Diagnostics segment were flat compared to the 2012 first quarter, with growth in *C. difficile* and *H. pylori* product sales offset by a decline in sales of our foodborne product family. Reflecting growth in its molecular reagent business being largely offset by a decline in its bulk immunoassay reagent business, sales of our Life Science segment increased by 1% during the first quarter of fiscal 2013 compared to the first quarter of fiscal 2012.

**Table of Contents****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 the consolidation of our Saco, Maine operations into our Memphis, Tennessee facility (Q1 fiscal 2012), 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 consolidating the Maine operations (Q1 fiscal 2012); 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.

	<b>Three Months Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Net Earnings</b>		
U.S. GAAP basis	\$ 8,474	\$ 6,578
Facility consolidation costs (1)		289
Adjusted earnings	\$ 8,474	\$ 6,867
<b>Net Earnings per Basic Common Share</b>		
U.S. GAAP basis	\$ 0.21	\$ 0.16
Facility consolidation costs (1)		0.01
Adjusted Basic EPS	\$ 0.21	\$ 0.17
<b>Net Earnings per Diluted Common Share</b>		
U.S. GAAP basis	\$ 0.20	\$ 0.16
Facility consolidation costs (1)		0.01
Adjusted Diluted EPS	\$ 0.20	\$ 0.17

- (1) These facility consolidation costs are net of an income tax effect of \$155, which was calculated using the effective tax rates of the jurisdictions in which the costs were incurred.

**Revenue Overview**

Our Diagnostics segments provide the largest share of our consolidated revenues, 79% and 76% for the first quarters of fiscal 2013 and fiscal 2012, respectively. Sales from our focus families (*C. difficile*, Foodborne and *H. pylori*) comprised 60% and 62% of our Diagnostics segments revenues during the first quarters of fiscal 2013 and fiscal 2012, respectively. During the fiscal 2013 first quarter, 21% of our Diagnostic segments' revenues came from sales of our *illumigen*® molecular platform, which now consists of three FDA-cleared products: *illumigene C. difficile*, *illumigene* Group B Strep and *illumigene* Group A Strep.

The global revenue change for our Diagnostics segments during the fiscal 2013 first quarter was an increase of 17%, reflecting growth in all of our focus product families—10% growth in *H. pylori* products, 13% growth in *C. difficile* products, and 15% in foodborne products.





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### ***illumigene Molecular Platform Products***

Sales from our *illumigene* molecular platform products increased 66% to \$7,400 in the first quarter of fiscal 2013 compared to the first quarter of the prior fiscal year, with nearly 975 clinical laboratories now using this innovative molecular platform. Our *illumigene* molecular *C. difficile* product was cleared by the FDA in July 2010, followed by our *illumigene* GBS (Group B *Streptococcus*), which was cleared by the FDA in December 2011, and our *illumigene* Group A Strep (Group A *Streptococcus*; Strep Throat), which was cleared in September 2012.

Additional *illumigene* molecular products are in development. These include a test for *Mycoplasma pneumoniae* (Walking Pneumonia), which was recently submitted to the FDA for marketing clearance and is expected to be available for sale in the U.S. during the third quarter of fiscal 2013. Our fifth test, for *Bordetella pertussis* (Whooping Cough), is expected to be available for sale in the U.S. during the third or fourth quarter of fiscal 2013. Our most recently announced tests, for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, are expected to be available for sale during the first half of 2014.

We believe that the diagnostic testing market is moving away from culture and immunoassay testing to molecular testing for diseases where there is a favorable cost/benefit position for the total cost of healthcare. While this market is competitive, with molecular companies such as Cepheid and Becton Dickinson and new entrants such as Quidel, Great Basin and Quest, we believe we are well positioned to capitalize on the migration to molecular testing. Our simple, easy to use, *illumigene* platform, with its expanding menu, requires no expensive equipment purchase and little to no maintenance cost. These features, along with its small footprint and the performance of the *illumigene* assays, make *illumigene* an attractive molecular platform to any size hospital.

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

Our *C. difficile* family grew 17% for our U.S. Diagnostics segment and 1% for our European Diagnostics segment on an organic basis. This growth is largely driven by the growth of our *illumigene C. difficile* product, which now represents nearly 70% of total *C. difficile* revenues. While the *C. difficile* market continues to be highly competitive, we are the only company that can offer a full range of high performing *C. difficile* testing formats, including toxin, GDH and molecular tests.

### ***Foodborne Products***

Although our foodborne products are marketed and sold on a global basis, most of our sales volume is within the U.S. Diagnostics segment. We continue to see demand increases in the United States, as laboratories realize the benefits of increased sensitivity and faster turnaround time with our tests for Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*, compared to traditional culture methods. Sales increases for these products within the U.S. Diagnostics segment were 16% for the first quarter of fiscal 2013.

The primary competition for our foodborne products is laboratory culture methods. We believe that our products have two principal advantages versus culture methods: 1) test accuracy, and 2) improved work flow, resulting in a significantly shortened time to test result (20 minutes vs. 24-48 hours for culture).

### ***H. pylori Products***

During the first quarter of fiscal 2013, sales of *H. pylori* products grew 14% for our U.S. Diagnostics segment; continuing to reflect the benefits of our partnerships with managed care companies in promoting the health and economic benefits of a test and treat strategy, and the ongoing effects of such strategy moving physician behavior away from serology-based testing toward direct antigen testing. Compared to the first quarter of fiscal 2012, sales of *H. pylori* products for our European Diagnostics segment increased 2% on an organic basis for the first quarter of fiscal 2013.

### ***Respiratory Products***

During the first quarter of fiscal 2013, total respiratory sales for our Diagnostics segments increased 42% compared to the fiscal 2012 first quarter, with our influenza product contributing approximately \$1,800 in sales. This increase reflects the impact of the strong and early start to this year's influenza season, compared to a relatively mild season in fiscal 2012. In the U.S. we continue to see strong customer orders for our influenza product during January 2013. Influenza sales were negligible in Europe during the quarter.



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### ***Life Science Segment***

Sales for our Life Science segment increased 1% for the first quarter of fiscal 2013, reflecting a 9% increase in our molecular reagent business being largely offset by a 4% decrease in our bulk immunoassay reagent business. Our molecular reagent business, operated through our Bioline Group, continues to benefit from its new product launches and advancements during recent months – most notably its SensiFAST and MyTaq PCR components. The decrease in our bulk immunoassay reagent business, on the other hand, largely results from the timing and size of certain large customers' orders, along with the timing of contract manufacturing work.

### ***Foreign Currency***

During the first quarter of fiscal 2013, currency exchange rates had an approximate \$150 unfavorable impact on revenue; \$175 unfavorable within the European Diagnostics segment and \$25 favorable in the Life Science segment. This compares to currency exchange having an approximate \$50 unfavorable impact on revenue in the first quarter of fiscal 2012.

### ***Significant Customers***

Two national distributors in our U.S. Diagnostics segment accounted for 55% and 50% of total sales for this segment for the first quarters of fiscal 2013 and 2012, respectively.

Our Life Science segment's sales of purified antigens and reagents to two diagnostic manufacturing customers accounted for 18% and 27% of the segment's total sales during the first quarters of fiscal 2013 and 2012, respectively. The fluctuation in the percentage of sales during the quarter reflects the inherent volatility in the buying patterns of these customers.

### ***Medical Device Tax***

On January 1, 2013, the medical device tax established as part of the U.S. healthcare reform legislation became effective and as a result, the Company made its first required tax deposit near the end of January. As previously disclosed, we currently anticipate that this legislation will result in an excise tax for the Company of approximately \$2,000 in fiscal 2013, of which little, if any, can be passed on to the customer.

## **Segment Revenues**

Our reportable segments are U.S. Diagnostics, European Diagnostics and Life Science. The U.S. Diagnostics segment consists of manufacturing operations in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the U.S. and countries outside of Australia, Europe, Africa and the Middle East. The European Diagnostics segment consists of the sale and distribution of diagnostic test kits in Australia, Europe, Africa and the Middle East. The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad. The Life Science segment also includes the contract development and manufacture of cGMP clinical grade proteins and other biologicals for use by biopharmaceutical and biotechnology companies engaged in research for new drugs and vaccines.

Revenues for the Diagnostics segments, 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.

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Revenues for each of our segments are shown below.

	Three Months Ended December 31,		
	2012	2011	Inc (Dec)
U.S. Diagnostics	\$ 30,366	\$ 25,009	21%
European Diagnostics	5,303	5,505	(4)%
Life Science	9,682	9,561	1%
Consolidated	\$ 45,351	\$ 40,075	13%
International			
U.S. Diagnostics	\$ 1,773	\$ 1,485	19%
European Diagnostics	5,303	5,505	(4)%
Life Science	5,354	5,720	(6)%
Total	\$ 12,430	\$ 12,710	(2)%
% of total sales	27%	32%	

**Gross Profit**

	Three Months Ended December 31,		
	2012	2011	Change
Gross Profit	\$ 28,796	\$ 24,542	17%
Gross Profit Margin	64 %	61 %	+3 points

The overall gross profit margin increase for the first quarter of fiscal 2013 primarily results from the combined effects of 1) mix of sales from the Company's segments; 2) the lower overall cost structure from the consolidation of our U.S. Life Science manufacturing facilities; and 3) mix of products sold.

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

**Operating Expenses**

	Research & Development	Selling & Marketing	General & Administrative	Plant Consolidation	Total Operating Expenses
Q1 2012 Expenses	\$ 2,273	\$ 5,377	\$ 6,643	\$ 444	\$ 14,737
% of Sales	6%	13%	17%	1%	37%
Fiscal 2013 Increases (Decreases):					
U.S. Diagnostics	208	24	540		772
European Diagnostics		294	102		396
Life Science	36	(2)	210	(444)	(200)
Q1 2013 Expenses	\$ 2,517	\$ 5,693	\$ 7,495	\$	\$ 15,705

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% of Sales	6%	13%	17%	%	35%
% Increase (Decrease)	11%	6%	13%	(100)%	7%

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Overall, total operating expense increased during the first quarter of fiscal 2013 relative to the comparable prior fiscal year quarter, while declining as percentage of consolidated sales. The increase results in large part from the combined effects of our (i) ongoing efforts to control spending in each of our segments while investing the necessary resources in our strategic areas of growth, including increased investment in Research & Development for our molecular platform products; (ii) continuing to realize cost savings from the consolidation of our Core Life Science operations into one facility; (iii) increased sales personnel costs in Europe in connection with filling open positions and upgrading talent; (iv) increasing incentive compensation expense compared to the prior year quarter based upon improved year-to-date operating results; and (v) incurring costs in connection with the consolidation of our Saco, Maine operations into our Memphis, Tennessee location during the three months ended December 31, 2011 of approximately \$444.

## **Operating Income**

Operating income increased 34% to \$13,091 for the first quarter of fiscal 2013, as a result of the factors discussed above.

## **Income Taxes**

The effective rate for income taxes was 36% for the first quarter of fiscal 2013, and 35% for the first quarter of fiscal 2012. The increase in the rate for the first quarter of fiscal 2013 primarily reflects the effect of no tax benefit being provided on losses experienced in certain foreign jurisdictions during the first quarter of fiscal 2013. For the fiscal year ending September 30, 2013, we expect the effective tax rate to approximate 34% - 35%.

## **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.

At the present time, 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. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets remains tight for an extended period of time, and such conditions impact the collectability of our customer accounts receivable or credit terms with our vendors, or disrupt the supply of raw materials and services.

Net cash provided by operating activities increased 28% for the first quarter of fiscal 2013 to \$16,047, reflecting the 29% increase in net earnings, along with the effects of the timing of federal income tax payments, and the timing of payments from and to customers and suppliers, respectively. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and dividends during the next 12 months.

Net cash used for financing activities increased 89% to \$14,262 for the first quarter of fiscal 2013. This increase results primarily from the acceleration of the declaration and payment of the fiscal 2013 first quarter cash dividend; thus resulting in two quarterly dividends actually being disbursed during the three months ended December 31, 2012 (i.e., dividends for both fiscal 2012 fourth quarter and fiscal 2013 first quarter). This accelerated payment, believed to be in the best interest of the Company's shareholders, was made in anticipation of potential tax law changes at the beginning of the 2013 calendar year. The next regular quarterly cash dividend is expected to be declared in April 2013 and paid in May 2013.

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### ***Capital Resources***

We have a \$30,000 credit facility with a commercial bank that expires on September 15, 2015. As of January 31, 2013, there were no borrowings outstanding on this facility and we had 100% borrowing capacity available to us. We have had no borrowings outstanding under this facility during the first three months of fiscal 2013 or during the full year of fiscal 2012.

Our capital expenditures are estimated to range between approximately \$3,500 to \$5,000 for fiscal 2013, 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, 2012.

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

As of December 31, 2012, an evaluation was completed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) promulgated under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective as of December 31, 2012. There have been no changes in our internal control over financial reporting identified in connection with the evaluation of internal control that occurred during the first quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, or in other factors that could materially affect internal control subsequent to December 31, 2012.



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**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

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

**ITEM 6. EXHIBITS**

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

31.1 Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)

31.2 Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)

32 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 The following financial information from Meridian Bioscience Inc.'s Quarterly Report on Form 10-Q for the quarter ended December 31, 2012 filed with the SEC on February 11, 2013, formatted in XBRL includes: (i) Condensed Consolidated Statements of Operations for the three months ended December 31, 2012 and 2011, (ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended December 31, 2012 and 2011, (iii) Condensed Consolidated Statements of Cash Flows for the three months ended December 31, 2012 and 2011, (iv) Condensed Consolidated Balance Sheets as of December 31, 2012 and September 30, 2012, (v) Condensed Consolidated Statement of Shareholders' Equity for the three months ended December 31, 2012, and (vi) the Notes to Condensed Consolidated Financial Statements

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**MERIDIAN BIOSCIENCE, INC.**

Date: February 11, 2013

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

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