

MERIDIAN BIOSCIENCE INC
Form 10-Q
February 09, 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 December 31, 2015

OR

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

For the transition period from _____ to _____

Commission file number 0-14902

MERIDIAN BIOSCIENCE, INC.

Incorporated under the laws of Ohio

31-0888197

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

3471 River Hills Drive

Cincinnati, Ohio 45244

(513) 271-3700

Indicate by a check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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

Class	Outstanding January 31, 2016
Common Stock, no par value	42,051,142

Table of Contents

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

TABLE OF CONTENTS TO QUARTERLY REPORT ON FORM 10-Q

	Page(s)
PART I. FINANCIAL INFORMATION	
Item 1. <u>Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Statements of Operations</u> <u>Three Months Ended December 31, 2015 and 2014</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income</u> <u>Three Months Ended December 31, 2015 and 2014</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u> <u>Three Months Ended December 31, 2015 and 2014</u>	3
<u>Condensed Consolidated Balance Sheets</u> <u>December 31, 2015 and September 30, 2015</u>	4-5
<u>Condensed Consolidated Statement of Changes in Shareholders' Equity</u> <u>Three Months Ended December 31, 2015</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7-10
Item 2. <u>Management's Discussion and Analysis of</u> <u>Financial Condition and Results of Operations</u>	10-17
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	17
Item 4. <u>Controls and Procedures</u>	17
PART II. OTHER INFORMATION	
Item 1A. <u>Risk Factors</u>	18
Item 6. <u>Exhibits</u>	18
<u>Signature</u>	19

Table of Contents**FORWARD-LOOKING STATEMENTS**

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 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)**

	Three Months Ended December 31,	
	2015	2014
NET REVENUES	\$ 47,160	\$ 48,013
COST OF SALES	15,577	18,776
GROSS PROFIT	31,583	29,237
OPERATING EXPENSES		
Research and development	3,381	3,103
Selling and marketing	6,443	6,080
General and administrative	8,173	7,385
Total operating expenses	17,997	16,568
OPERATING INCOME	13,586	12,669
OTHER INCOME (EXPENSE)		
Interest income	17	6
Other, net	96	(582)
Total other income (expense)	113	(576)
EARNINGS BEFORE INCOME TAXES	13,699	12,093
INCOME TAX PROVISION	4,806	4,192
NET EARNINGS	\$ 8,893	\$ 7,901
BASIC EARNINGS PER COMMON SHARE	\$ 0.21	\$ 0.19
DILUTED EARNINGS PER COMMON SHARE	\$ 0.21	\$ 0.19
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC	41,947	41,607
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARES AND UNITS	380	334
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING DILUTED	42,327	41,941

ANTI-DILUTIVE SECURITIES:

Common share options and restricted shares and units	450	566
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.20	\$ 0.20

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)**

	Three Months Ended December 31,	
	2015	2014
NET EARNINGS	\$ 8,893	\$ 7,901
Foreign currency translation adjustment	(787)	(1,365)
COMPREHENSIVE INCOME	\$ 8,106	\$ 6,536

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)**

Three Months Ended December 31,	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	\$ 8,893	\$ 7,901
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	896	927
Amortization of intangible assets	388	469
Amortization of deferred <i>illumigene</i> [®] instrument costs	281	395
Stock-based compensation	1,611	1,428
Deferred income taxes	433	100
Change in current assets	(1,186)	4,878
Change in current liabilities	834	246
Other, net	(58)	(259)
Net cash provided by operating activities	12,092	16,085
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(776)	(1,331)
Purchase of equity method investment	(600)	
Purchases of intangible assets	(16)	
Net cash used for investing activities	(1,392)	(1,331)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(8,407)	(8,330)
Proceeds and tax benefits from exercises of stock options	1,470	499
Net cash used for financing activities	(6,937)	(7,831)
Effect of Exchange Rate Changes on Cash and Equivalents	(314)	(454)
Net Increase in Cash and Equivalents	3,449	6,469
Cash and Equivalents at Beginning of Period	49,973	43,047
Cash and Equivalents at End of Period	\$ 53,422	\$ 49,516

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

	December 31, 2015 (Unaudited)	September 30, 2015
CURRENT ASSETS		
Cash and equivalents	\$ 53,422	\$ 49,973
Accounts receivable, less allowances of \$222 and \$248	27,617	26,254
Inventories	38,778	35,817
Prepaid expenses and other current assets	3,414	7,378
Total current assets	123,231	119,422
PROPERTY, PLANT AND EQUIPMENT, at Cost		
Land	981	986
Buildings and improvements	30,119	30,056
Machinery, equipment and furniture	42,363	41,541
Construction in progress	938	1,139
Subtotal	74,401	73,722
Less: accumulated depreciation and amortization	46,952	46,230
Net property, plant and equipment	27,449	27,492
OTHER ASSETS		
Goodwill	22,064	22,349
Other intangible assets, net	5,465	5,931
Restricted cash	1,000	1,000
Deferred <i>illumigene</i> instrument costs, net	1,671	1,750
Deferred income taxes	4,566	4,954
Other assets	989	384
Total other assets	35,755	36,368
TOTAL ASSETS	\$ 186,435	\$ 183,282

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

	December 31, 2015 (Unaudited)	September 30, 2015
CURRENT LIABILITIES		
Accounts payable	\$ 7,208	\$ 6,646
Accrued employee compensation costs	4,990	5,132
Other accrued expenses	2,601	2,587
Income taxes payable	933	886
Total current liabilities	15,732	15,251
NON-CURRENT LIABILITIES	2,129	2,158
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Preferred stock, no par value; 1,000,000 shares authorized; none issued		
Common shares, no par value; 71,000,000 shares authorized; 42,044,388 and 41,838,399 shares issued, respectively		
Additional paid-in capital	120,153	117,151
Retained earnings	51,538	51,052
Accumulated other comprehensive income (loss)	(3,117)	(2,330)
Total shareholders' equity	168,574	165,873
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 186,435	\$ 183,282

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
Balance at September 30, 2015	41,838	\$ 117,151	\$ 51,052	\$ (2,330)	\$ 165,873
Cash dividends paid			(8,407)		(8,407)
Exercise of stock options	91	1,391			1,391
Conversion of restricted stock units	115				
Stock compensation expense		1,611			1,611
Net earnings			8,893		8,893
Foreign currency translation adjustment				(787)	(787)
Balance at December 31, 2015	42,044	\$ 120,153	\$ 51,538	\$ (3,117)	\$ 168,574

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 December 31, 2015, the results of its operations for the three month periods ended December 31, 2015 and 2014, and its cash flows for the three month periods ended December 31, 2015 and 2014. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company's fiscal 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.

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 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, in light of early adoption being permitted and believing the required presentation results in more useful and comparable information related to our net deferred income tax assets, 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.

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.

Table of Contents**3. Cash and Equivalents**

Cash and equivalents include the following components:

	December 31, 2015		September 30, 2015	
	Cash and Equivalents	Other Assets	Cash and Equivalents	Other Assets
Overnight repurchase agreements	\$ 25,147	\$	\$ 25,436	\$
Cash on hand				
Restricted		1,000		1,000
Unrestricted	28,275		24,537	
Total	\$ 53,422	\$ 1,000	\$ 49,973	\$ 1,000

4. Inventories

Inventories are comprised of the following:

	December 31, 2015	September 30, 2015
Raw materials	\$ 7,351	\$ 7,095
Work-in-process	12,297	10,096
Finished goods <i>illumigene</i> instruments	2,260	1,890
Finished goods kits and reagents	16,870	16,736
Total	\$ 38,778	\$ 35,817

5. Reportable Segment and Major Customers Information

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

Our reportable segments are Diagnostics and Life Science, both of which are headquartered in Cincinnati, Ohio, which also serves as the Diagnostics segment's base of manufacturing operations and research and development. The Diagnostics segment has sales and distribution facilities in the United States, Europe and Australia. The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR

reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad, including sales and business development offices in Singapore and Beijing, China to further pursue growing revenue opportunities in Asia.

Amounts due from two Diagnostics distributor customers accounted for 26% and 21% of consolidated accounts receivable at December 31, 2015 and September 30, 2015, respectively. Revenues from these two distributor customers accounted for 39% and 41% of the Diagnostics segment third-party revenues during the three months ended December 31, 2015 and 2014, respectively; and represented 29% and 31% of consolidated revenues for the fiscal 2016 and 2015 first quarters, respectively.

Table of Contents

Within our Life Science segment, two diagnostic manufacturing customers accounted for 18% of the segment's third-party revenues during each of the three months ended December 31, 2015 and 2014.

Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Eliminations(1)	Total
Three Months Ended December 31, 2015				
Net revenues				
Third-party	\$ 35,301	\$ 11,859	\$	\$ 47,160
Inter-segment	71	367	(438)	
Operating income	10,330	3,236	20	13,586
Goodwill (December 31, 2015)	1,250	20,814		22,064
Other intangible assets, net (December 31, 2015)	2,236	3,229		5,465
Total assets (December 31, 2015)	120,780	65,927	(272)	186,435
Three Months Ended December 31, 2014				
Net revenues				
Third-party	\$ 36,586	\$ 11,427	\$	\$ 48,013
Inter-segment	104	297	(401)	
Operating income	10,284	2,489	(104)	12,669
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

(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.

6. Intangible Assets

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

	December 31, 2015		September 30, 2015	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	\$ 11,547	\$ 10,963	\$ 11,582	\$ 10,906
Trademarks, licenses and patents	6,349	3,450	6,410	3,296
Customer lists and supply agreements	12,012	10,030	12,105	9,964

\$ 29,908 \$ 24,443 \$ 30,097 \$ 24,166

Table of Contents

The actual aggregate amortization expense for these intangible assets was \$388 and \$469 for the three months ended December 31, 2015 and 2014, 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 \$1,009, fiscal 2017 \$1,106, fiscal 2018 \$1,085, fiscal 2019 \$1,045, fiscal 2020 \$873 and fiscal 2021 \$313.

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

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

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

Results of Operations

Net earnings for the first quarter of fiscal 2016 increased 13% to \$8,893, or \$0.21 per diluted share, from net earnings for the first quarter of fiscal 2015 of \$7,901, or \$0.19 per diluted share. Consolidated revenues decreased 2% to \$47,160 for the first quarter of fiscal 2016 compared to the same period of the prior year and were flat on a constant-currency basis.

Included within the first quarter of fiscal 2016 were revenues from our *illumigene*[®] molecular platform of products totaling \$9,836, representing a 1% decrease from the fiscal 2015 first quarter (flat on a constant-currency basis). Also contributing to the consolidated revenues decrease were decreased revenues in three of our diagnostic focus product families (*C. difficile*, foodborne and respiratory) and our Life Science segment's molecular component business line. Serving to substantially offset these decreases were increased revenues in our *H. pylori* and women's health & STD focus product families and our Life Science segment's immunoassay components business.

Revenues for the Diagnostics segment for the first quarter of fiscal 2016 decreased 4% compared to the first quarter of fiscal 2015 (decreased 2% on a constant-currency basis), reflecting the following for each of our focus product families: 2% decline in our *C. difficile* products, 9% decline in our respiratory products, 11% decline in our foodborne products, 7% growth in our women's health & STD products, and 19% growth in our *H. pylori* products. With growth in its immunoassay component business and a decline in its molecular components business, revenues of our Life Science segment increased by 4% during the first quarter of fiscal 2016 compared to the first quarter of fiscal 2015, increasing 6% on a constant-currency basis.

Additionally, during November 2015, we made a minority investment in Oasis Diagnostics[®] Corporation (Oasis), with the right to acquire 100% ownership interest in the future. Located in Vancouver, Washington, Oasis designs, develops, manufactures and sells pre-analytic tools for the collection, preservation, and transportation of saliva/oral fluids and our investment was made to explore our interest in saliva diagnostics and collection devices. Our investment in Oasis has been accounted for as an equity method investment and is included within other assets in the accompanying Condensed Consolidated Balance Sheet as of December 31, 2015.

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 in Cincinnati, Ohio, and the sale and distribution of diagnostic test kits in the countries comprising North, Central and South America (the Americas); Europe, Middle East and Africa (EMEA); and other countries outside of the Americas and EMEA (rest of the world, or ROW). The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; and Sydney, Australia, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells and bioresearch reagents domestically and abroad, including 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 December 31,		
	2015	2014	Inc (Dec)
Diagnostics-			
Americas	\$ 30,115	\$ 30,913	(3)%
EMEA	4,649	5,003	(7)%
ROW	537	670	(20)%
Total Diagnostics	35,301	36,586	(4)%
Life Science-			
Americas	5,103	5,299	(4)%
EMEA	4,536	3,758	21 %
ROW	2,220	2,370	(6)%
Total Life Science	11,859	11,427	4 %
Consolidated	\$ 47,160	\$ 48,013	(2)%

% of total revenues-

Edgar Filing: MERIDIAN BIOSCIENCE INC - Form 10-Q

Diagnostics	75 %	76 %
Life Science	25 %	24 %
Total	100 %	100 %
Ex-Americas	25 %	25 %

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 December 31,		
	2015	2014	Inc (Dec)
Diagnostics-			
Molecular	\$ 9,836	\$ 9,908	(1)%
Immunoassay	25,465	26,678	(5)%
Total Diagnostics	\$ 35,301	\$ 36,586	(4)%
Life Science-			
Molecular components	\$ 4,749	\$ 5,012	(5)%
Immunoassay components	7,110	6,415	11 %
Total Life Science	\$ 11,859	\$ 11,427	4 %
% of Diagnostics revenues-			
Molecular	28 %	27 %	
Immunoassay	72 %	73 %	
Total Diagnostics	100 %	100 %	
% of Life Science revenues-			
Molecular components	40 %	44 %	
Immunoassay components	60 %	56 %	
Total Life Science	100 %	100 %	

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

Diagnostics Products

illumigene Molecular Platform Products

We have approximately 1,490 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*[®] *C. difficile* commercialized in August 2010
2. *illumigene*[®] Group B *Streptococcus* (Group B Strep or GBS) commercialized in December 2011
3. *illumigene*[®] Group A *Streptococcus* (Group A Strep) commercialized in September 2012
4. *illumigene*[®] Mycoplasma (*M. pneumoniae*; walking pneumonia) commercialized in June 2013

Table of Contents

5. *illumigene*[®] *Bordetella pertussis* (whooping cough) commercialized in March 2014
6. *illumigene*[®] *Chlamydia trachomatis* commercialized outside of U.S. in February 2015
7. *illumigene*[®] *Neisseria gonorrhoea* commercialized outside of U.S. in February 2015
8. *illumigene*[®] 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*[®] 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 5% in the first quarter of fiscal 2016. As described in the product discussions below, the current year decrease results 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 first quarter of fiscal 2016, revenues from our Life Science segment increased 4%, with revenues from molecular component sales decreasing 5% from the comparable fiscal 2015 quarter and revenues from immunoassay component sales increasing 11%. Our molecular component business' growth was negatively impacted by the movement in currency exchange rates since the fiscal 2015 first quarter, with the revenues increasing less than 1% on a constant-currency basis over the fiscal 2015 first quarter. Our Life Science segment continued to benefit from increased sales into China, with such sales totaling approximately \$500 during the fiscal 2016 first quarter (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 81% and 78% of our Diagnostics segment's revenues during the first quarter of fiscal 2016 and 2015, respectively. Following is a discussion of the revenues generated by each product family:

***C. difficile* Products**

During the fiscal 2016 first quarter, revenues for our *C. difficile* product family decreased 2% to \$7,400 from the first quarter of fiscal 2015 (flat in constant-currency). Our molecular products now represent over 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. During the first quarter of fiscal 2016, the amount and rate of decline in constant-currency revenues has continued to decrease. We believe this is due largely to the expansion of our *illumigene* molecular platform menu having a positive effect on defending our *C. difficile* business.

Foodborne Products

Revenues from our foodborne products (Enterohemorrhagic *E. coli* (EHEC) and *Campylobacter*), all of which are immunoassay products, totaled \$5,300 during the first quarter of fiscal 2016, an 11% decrease from the fiscal 2015 first quarter (also 11% in constant-currency). Revenues for our foodborne products during the first quarter of fiscal 2016 were affected by distributor ordering patterns. We are continuing to re-emphasize the benefits of increased sensitivity and faster turnaround time versus culture methods in our marketing programs. The primary competition

Table of Contents

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 first quarter, revenues from our *H. pylori* products, all of which are immunoassay products, increased 19% (22% in constant-currency) to \$8,700. This increase continues 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 begun to increase 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 decreased 9% to \$5,600 during the first quarter of fiscal 2016 (decreased 8% in constant-currency). This decline was largely due to 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 \$1,700 during the first quarter of fiscal 2016, a 7% increase from the fiscal 2015 first quarter (also 7% 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

Two U.S. distributors accounted for 39% and 41% of our Diagnostics segment's total revenues for the first quarter of fiscal 2016 and 2015, respectively. These revenues represented 29% and 31% of consolidated revenues for the fiscal 2016 and 2015 first quarters, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 18% of the segment's total revenues for each of the first quarters of fiscal 2016 and 2015.

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 each of the first quarters of fiscal 2016 and fiscal 2015, the Company recorded approximately \$500 of medical device tax expense, which is reflected as a component of cost of sales in the accompanying Condensed Consolidated

Table of Contents

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 December 31,		
	2015	2014	Change
Gross Profit	\$ 31,583	\$ 29,237	8 %
Gross Profit Margin	67 %	61 %	+6 points

The overall gross profit increase for the three months ended December 31, 2015 primarily results 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

	Changes for the Three Months Ended December 31, 2015			
	Research & Development	Selling & Marketing	General & Administrative	Total Operating Expenses
2015 Expenses	\$ 3,103	\$ 6,080	\$ 7,385	\$ 16,568
% of Revenues	6 %	13 %	15 %	35 %
Fiscal 2016 Increases (Decreases):				
Diagnostics	395	29	693	1,117
Life Science	(117)	334	95	312
2016 Expenses	\$ 3,381	\$ 6,443	\$ 8,173	\$ 17,997
% of Revenues	7 %	14 %	17 %	38 %
% Increase	9 %	6 %	11 %	9 %

Total operating expenses increased during the first quarter of fiscal 2016 compared to the first quarter of fiscal 2015. This level of operating expenses results 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, and increased investment in Sales and

Marketing personnel and programs, particularly in our Life Science segment; and (ii) favorable effects of currency rates.

Table of Contents

Operating expenses for the Diagnostics segment increased \$1,117 for the first quarter of fiscal 2016 compared to the first quarter of fiscal 2015. These overall Diagnostics segment increases result primarily from the combined effects of the following:

Research & Development

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

General & Administrative

Increase in incentive bonus and stock-based compensation expense as a result of the increase in corporate-wide operating profits, along with expenses incurred in connection with completing the Company's investment in Oasis.

Operating Income

Operating income increased 7% to \$13,586 for the first quarter of fiscal 2016, as a result of the factors discussed above.

Other Income and Expense

First quarter of fiscal 2016 other income and expense included approximately \$100 of foreign currency gains. This compares to \$600 of foreign currency losses in the first quarter of fiscal 2015, which related primarily to foreign currency exchange transaction losses on a subsidiary intercompany loan.

Income Taxes

The effective rate for income taxes remained stable at 35% for the first quarters of fiscal 2016 and fiscal 2015. For the fiscal year ending September 30, 2016, 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.

We have an investment policy that guides the holdings of our investment portfolio, which at present consist of overnight repurchase agreements and bank savings accounts. 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 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 \$12,092 for the first quarter of fiscal 2016, a 25% decrease from the \$16,085 provided during the first quarter of fiscal 2015. While reflecting the effects of the timing of payments from and to customers and suppliers, respectively, this decrease reflects the approximate \$3,000 increase in inventory during the quarter ended December 31, 2015, compared to the approximate \$1,100 decrease in inventory during the quarter ended December 31, 2014. 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.

Table of Contents

Capital Resources

We have a \$30,000 credit facility with a commercial bank that expires on April 21, 2018. As of January 31, 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 three 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 December 31, 2015, an evaluation was completed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) promulgated under the Securities Exchange Act of 1934, as amended. Based on that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective as of December 31, 2015. There have been no changes in our internal control over financial reporting identified in connection with the evaluation of internal control that occurred during the first fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, or in other factors that could materially affect internal control subsequent to December 31, 2015.

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.

- 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, 2015 filed with the SEC on February 9, 2016, formatted in XBRL includes:
 - (i) Condensed Consolidated Statements of Operations for the three months ended December 31, 2015 and 2014;
 - (ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended December 31, 2015 and 2014;
 - (iii) Condensed Consolidated Statements of Cash Flows for the three months ended December 31, 2015 and 2014;
 - (iv) Condensed Consolidated Balance Sheets as of December 31, 2015 and September 30, 2015;
 - (v) Condensed Consolidated Statement of Shareholders' Equity for the three months ended December 31, 2015; and
 - (vi) the Notes to Condensed Consolidated Financial Statements

Table of Contents

SIGNATURE

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

MERIDIAN BIOSCIENCE, INC.

Date: February 9, 2016

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

(Principal Financial and Accounting Officer)

Page 19