

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-Q

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

For the Quarterly Period Ended December 31, 2018

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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.

<u>Class</u>	<u>Outstanding January 31, 2019</u>
Common Stock, no par value	42,489,202

[Table of Contents](#)

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

	<u>Page(s)</u>
<b>PART I. <a href="#">FINANCIAL INFORMATION</a></b>	
Item 1. <a href="#">Financial Statements (Unaudited)</a>	
<a href="#">Condensed Consolidated Statements of Operations Three Months Ended December 31, 2018 and 2017</a>	1
<a href="#">Condensed Consolidated Statements of Comprehensive Income Three Months Ended December 31, 2018 and 2017</a>	2
<a href="#">Condensed Consolidated Statements of Cash Flows Three Months Ended December 31, 2018 and 2017</a>	3
<a href="#">Condensed Consolidated Balance Sheets December 31, 2018 and September 30, 2018</a>	4-5
<a href="#">Condensed Consolidated Statements of Changes in Shareholders' Equity Three Months Ended December 31, 2018 and 2017</a>	6
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	7-15
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	15-22
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	23
Item 4. <a href="#">Controls and Procedures</a>	23
<b>PART II. <a href="#">OTHER INFORMATION</a></b>	
Item 1. <a href="#">Legal Proceedings</a>	23
Item 1A. <a href="#">Risk Factors</a>	23
Item 6. <a href="#">Exhibits</a>	23
<a href="#">Signature</a>	24

## **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 operating results, financial condition and 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, its ability to effectively sell such products and its ability to successfully expand and effectively manage increased sales and marketing operations. While Meridian has introduced a number of internally developed products and acquired products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis or in protecting its intellectual property, and unexpected or costly manufacturing costs associated with its introduction of new products or acquired products could cause actual results to differ from expectations. Meridian relies on proprietary, patented and licensed technologies. As such, 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, as can the uncertainty of regulatory approvals and the regulatory process. 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 outcome of goodwill impairment testing and the impact of possible goodwill impairments on Meridian’s earnings and financial results. 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 initiated by Congress or the presidential administration, 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, trade wars, increased tariffs, and natural disasters and other events could have a materially adverse effect on Meridian’s results of operations and revenues. In the past, the Company has identified a material weakness in our internal control over financial reporting, which has been remediated, but the Company can make no assurances that a material weakness will not be identified in the future, which if identified and not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements. In addition to the factors described in this paragraph, as well as those factors identified from time to time in our filings with the Securities and Exchange Commission, Part I, Item 1A Risk Factors of our most recent Annual Report on Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company. Readers should carefully review these forward-looking statements and risk factors, and not place undue reliance on our forward-looking statements.*

**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>2018</b>	<b>2017</b>
NET REVENUES	\$51,480	\$52,283
COST OF SALES	19,908	20,273
GROSS PROFIT	<u>31,572</u>	<u>32,010</u>
OPERATING EXPENSES		
Research and development	3,967	4,420
Selling and marketing	7,563	8,844
General and administrative	8,902	9,202
Restructuring costs	—	734
Litigation costs	589	749
Total operating expenses	<u>21,021</u>	<u>23,949</u>
OPERATING INCOME	10,551	8,061
OTHER INCOME (EXPENSE)		
Interest income	149	72
Interest expense	(363)	(395)
Other, net	139	(80)
Total other expense	<u>(75)</u>	<u>(403)</u>
EARNINGS BEFORE INCOME TAXES	10,476	7,658
INCOME TAX PROVISION	2,370	1,356
NET EARNINGS	<u>\$ 8,106</u>	<u>\$ 6,302</u>
BASIC EARNINGS PER COMMON SHARE	\$ 0.19	\$ 0.15
DILUTED EARNINGS PER COMMON SHARE	\$ 0.19	\$ 0.15
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC	42,446	42,263
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARE UNITS	459	399
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED	<u>42,905</u>	<u>42,662</u>
ANTI-DILUTIVE SECURITIES:		
Common share options and restricted share units	684	1,034
DIVIDENDS DECLARED PER COMMON SHARE	<u>\$ 0.125</u>	<u>\$ 0.125</u>

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

**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Comprehensive Income (Unaudited)**  
**(dollar amounts in thousands)**

	<b>Three Months Ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>NET EARNINGS</b>	<b>\$ 8,106</b>	<b>\$ 6,302</b>
Other comprehensive income (loss):		
Foreign currency translation adjustment	(716)	291
Unrealized gain (loss) on cash flow hedge	(577)	341
Income taxes related to items of other comprehensive income	145	(112)
Other comprehensive income (loss), net of tax	(1,148)	520
<b>COMPREHENSIVE INCOME</b>	<b><u>\$ 6,958</u></b>	<b><u>\$ 6,822</u></b>

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

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

<b>Three Months Ended December 31,</b>	<b>2018</b>	<b>2017</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 8,106	\$ 6,302
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	1,253	1,146
Amortization of intangible assets	829	938
Amortization of deferred instrument costs	—	201
Stock-based compensation	1,670	1,759
Deferred income taxes	96	(1,624)
Change in:		
Accounts receivable	317	(2,989)
Inventories	(37)	(2,353)
Prepaid expenses and other current assets	539	87
Accounts payable and accrued expenses	(4,081)	1,315
Income taxes payable	991	497
Other, net	(276)	(108)
Net cash provided by operating activities	<u>9,407</u>	<u>5,171</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property, plant and equipment	(1,109)	(1,234)
Net cash used for investing activities	<u>(1,109)</u>	<u>(1,234)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends paid	(5,301)	(5,288)
Payments on term loan	(1,125)	(1,125)
Proceeds and tax benefits from exercises of stock options	145	—
Net cash used for financing activities	<u>(6,281)</u>	<u>(6,413)</u>
Effect of Exchange Rate Changes on Cash and Equivalents and Restricted Cash	<u>(257)</u>	<u>115</u>
Net Increase (Decrease) in Cash and Equivalents and Restricted Cash	1,760	(2,361)
Cash and Equivalents and Restricted Cash at Beginning of Period	60,763	58,072
Cash and Equivalents and Restricted Cash at End of Period	<u>\$62,523</u>	<u>\$55,711</u>
Cash and Equivalents	\$61,523	\$54,711
Restricted Cash	1,000	1,000
Cash and Equivalents and Restricted Cash at End of Period	<u>\$62,523</u>	<u>\$55,711</u>

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

**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
**(dollar amounts in thousands)**

ASSETS

	December 31, 2018 <u>(Unaudited)</u>	September 30, 2018
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 61,523	\$ 59,763
Accounts receivable, less allowances of \$331 and \$310	31,791	32,336
Inventories	41,889	41,993
Prepaid expenses and other current assets	4,411	4,961
Total current assets	<u>139,614</u>	<u>139,053</u>
<b>PROPERTY, PLANT AND EQUIPMENT, at Cost</b>		
Land	1,158	1,160
Buildings and improvements	32,443	32,444
Machinery, equipment and furniture	59,637	50,606
Construction in progress	1,727	1,631
Subtotal	94,965	85,841
Less: accumulated depreciation and amortization	64,108	55,846
Net property, plant and equipment	<u>30,857</u>	<u>29,995</u>
<b>OTHER ASSETS</b>		
Goodwill	54,403	54,637
Other intangible assets, net	22,265	23,113
Restricted cash	1,000	1,000
Deferred instrument costs, net	—	1,239
Fair value of interest rate swap	1,145	1,722
Deferred income taxes	121	130
Other assets	452	488
Total other assets	<u>79,386</u>	<u>82,329</u>
<b>TOTAL ASSETS</b>	<u>\$ 249,857</u>	<u>\$ 251,377</u>

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

**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
**(dollar amounts in thousands)**

LIABILITIES AND SHAREHOLDERS' EQUITY

	December 31, 2018 (Unaudited)	September 30, 2018
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 6,228	\$ 6,260
Accrued employee compensation costs	4,779	7,263
Other accrued expenses	3,035	5,065
Current portion of long-term debt	5,625	5,250
Income taxes payable	1,023	335
Total current liabilities	<u>20,690</u>	<u>24,173</u>
<b>NON-CURRENT LIABILITIES</b>		
Post-employment benefits	2,490	2,646
Long-term debt	43,438	44,930
Long-term income taxes payable	736	441
Deferred income taxes	3,861	3,769
Total non-current liabilities	<u>50,525</u>	<u>51,786</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>SHAREHOLDERS' EQUITY</b>		
Preferred stock, no par value; 1,000,000 shares authorized; none issued	—	—
Common shares, no par value; 71,000,000 shares authorized, 42,488,602 and 42,399,962 shares issued, respectively	—	—
Additional paid-in capital	130,876	129,193
Retained earnings	52,291	49,602
Accumulated other comprehensive loss	(4,525)	(3,377)
Total shareholders' equity	<u>178,642</u>	<u>175,418</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<u>\$ 249,857</u>	<u>\$ 251,377</u>

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



**MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Changes in Shareholders' Equity (Unaudited)**  
**(dollar and share amounts in thousands, except per share data)**

	Common Shares Issued	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
<b>Balance at September 30, 2018</b>	42,400	\$ 129,193	\$49,602	\$ (3,377)	\$ 175,418
Cash dividends paid - \$0.125 per share	—	—	(5,301)	—	(5,301)
Conversion of restricted share units and exercise of stock options	89	13	—	—	13
Stock compensation expense	—	1,670	—	—	1,670
Net earnings	—	—	8,106	—	8,106
Foreign currency translation adjustment	—	—	—	(716)	(716)
Hedging activity, net of tax	—	—	—	(432)	(432)
Adoption of ASU 2014-09	—	—	(116)	—	(116)
<b>Balance at December 31, 2018</b>	<u>42,489</u>	<u>\$ 130,876</u>	<u>\$52,291</u>	<u>\$ (4,525)</u>	<u>\$ 178,642</u>
<b>Balance at September 30, 2017</b>	42,207	\$ 125,608	\$46,923	\$ (2,946)	\$ 169,585
Cash dividends paid - \$0.125 per share	—	—	(5,288)	—	(5,288)
Conversion of restricted share units	100	—	—	—	—
Stock compensation expense	—	1,759	—	—	1,759
Net earnings	—	—	6,302	—	6,302
Foreign currency translation adjustment	—	—	—	291	291
Hedging activity, net of tax	—	—	—	229	229
<b>Balance at December 31, 2017</b>	<u>42,307</u>	<u>\$ 127,367</u>	<u>\$47,937</u>	<u>\$ (2,426)</u>	<u>\$ 172,878</u>

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

**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, 2018, the results of its operations for the three month periods ended December 31, 2018 and 2017, and its cash flows for the three month periods ended December 31, 2018 and 2017. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company's fiscal 2018 Annual Report on Form 10-K. Financial information as of September 30, 2018 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 2018 Annual Report on Form 10-K and should be referred to for a description of the Company's current significant accounting policies, with the exception of Revenue Recognition, which is set forth below.

***Revenue Recognition –***

**Adoption of New Standard**

On October 1, 2018, we adopted ASU No. 2014-09, *Revenue from Contracts with Customers*, using the modified retrospective transition method applied to those contracts that were not completed as of that date. Results for reporting periods beginning on or after October 1, 2018 are presented under the new guidance, while prior period amounts are not adjusted and continue to be reported in accordance with previously applicable guidance.

Upon adoption, we recorded a reduction of \$116 to the opening balance of retained earnings as of October 1, 2018. This adjustment is related to writing off the book value of clinical diagnostic testing instruments located at customers for which there is no contractual arrangement for the instrument to be returned to the Company. Instruments placed with customers under an agreement to return the instrument to the Company were reclassified to machinery and equipment. Prior to adoption of the new guidance, all instruments placed with customers were capitalized and amortized over an estimated three-year utilization period, with the net balance reflected as deferred instrument costs.

## [Table of Contents](#)

The following table summarizes the impact of the new revenue standard on our opening balance sheet:

	<u>Balance at September 30, 2018</u>	<u>New Revenue Standard Adjustment</u>	<u>Balance at October 1, 2018</u>
<b>PROPERTY, PLAN AND EQUIPMENT</b>			
Machinery, equipment and furniture	\$ 50,606	\$ 8,696	\$ 59,302
Accumulated depreciation and amortization	(55,846)	(7,611)	(63,457)
<b>OTHER ASSETS</b>			
Deferred instrument costs, net	1,239	(1,239)	—
<b>NON-CURRENT LIABILITIES</b>			
Deferred income taxes	(3,769)	38	(3,731)
<b>SHAREHOLDERS' EQUITY</b>			
Retained earnings	(49,602)	116	(49,486)

The adoption of this new standard had an immaterial impact on our reported total revenues and operating income, as compared to what would have been reported under the prior standard. We expect the impact of adoption in future periods to continue to be immaterial. Our accounting policies under the new standard were applied prospectively and are noted below following the discussion of Revenue Disaggregation.

### Revenue Disaggregation

The following tables present our revenues disaggregated by major geographic region, major product platform and disease state (Diagnostics only):

### Revenue by Reportable Segment & Geographic Region

	<u>Three Months Ended December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>Inc (Dec)</u>
<b>Diagnostics-</b>			
Americas	\$ 31,147	\$ 31,575	(1)%
EMEA	5,085	5,415	(6)%
ROW	433	500	(13)%
Total Diagnostics	<u>36,665</u>	<u>37,490</u>	<u>(2)%</u>
<b>Life Science-</b>			
Americas	4,534	5,250	(14)%
EMEA	7,455	5,185	44%
ROW	2,826	4,358	(35)%
Total Life Science	<u>14,815</u>	<u>14,793</u>	<u>— %</u>
Consolidated	<u>\$ 51,480</u>	<u>\$ 52,283</u>	<u>(2)%</u>

**Revenue by Product Platform/Type**

	Three Months Ended December 31,		
	2018	2017	Inc (Dec)
<b>Diagnostics-</b>			
Molecular assays	\$ 7,298	\$ 8,717	(16)%
Immunoassays & blood chemistry assays	29,367	28,773	2%
Total Diagnostics	<u>\$ 36,665</u>	<u>\$ 37,490</u>	<u>(2)%</u>
<b>Life Science-</b>			
Molecular reagents	\$ 6,589	\$ 5,688	16%
Immunological reagents	8,226	9,105	(10)%
Total Life Science	<u>\$ 14,815</u>	<u>\$ 14,793</u>	<u>— %</u>

**Revenue by Disease State (Diagnostics only)**

	Three Months Ended December 31,		
	2018	2017	Inc (Dec)
<b>Diagnostics-</b>			
Gastrointestinal assays	\$ 18,633	\$ 20,270	(8)%
Respiratory illness assays	7,977	7,486	7%
Blood chemistry assays	4,466	4,266	5%
Other	5,589	5,468	2%
Total Diagnostics	<u>\$ 36,665</u>	<u>\$ 37,490</u>	<u>(2)%</u>

**Revenue Policies***Product Sales*

Revenue from contracts with customers is recognized in an amount that reflects the consideration we expect to receive in exchange for products when obligations under such contracts are satisfied. Revenue is generally recognized at a point-in-time when products are shipped and title has passed to the customer. Such contracts can include various combinations of products that are generally accounted for as distinct performance obligations.

Revenue is reduced in the period of sale for fees paid to distributors, which are inseparable from the distributor's purchase of our product and for which we receive no goods or services in return. Revenue for the Diagnostics segment is reduced at the date of sale for product price adjustments due to certain distributors under local contracts. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Such accruals are netted against accounts receivable.

Shipping and handling costs incurred after control of the product is transferred to our customers are treated as fulfillment costs and not a separate performance obligation.

Our payment terms differ by jurisdiction and customer but payment is generally required in a term ranging from 30 to 90 days from the date of shipment or satisfaction of the performance obligation. Trade accounts receivable are recorded in the accompanying Consolidated Balance Sheets at invoiced amounts less provisions for distributor price adjustments under local contracts and doubtful accounts. The allowance for doubtful accounts represents our estimate of probable credit losses and is based on historical write-off experience and known conditions that would likely lead to non-payment. Customer invoices are charged off against the allowance when we believe it is probable that the invoices will not be paid.

## [Table of Contents](#)

### *Practical Expedients and Exemptions*

Revenue is recognized net of any taxes collected from customers (sales tax, value added tax, etc.), which are subsequently remitted to government authorities.

Our products are generally not subject to a customer right of return except for product recall events under the rules and regulations of the Food and Drug Administration or equivalent agencies outside the United States. In this circumstance, the costs to replace affected products would be accrued at the time a loss was probable and estimable.

We expense as incurred the costs to obtain contracts, as the amortization period would have been one year or less. These costs, recorded within selling and marketing expense, include our internal sales force compensation programs and certain partner sales incentive programs, as we have determined that annual compensation is commensurate with annual selling activities.

### *Reagent Rental Arrangements*

Our Alethia and LeadCare product platforms require the use of instruments for the tests to be processed. In many cases a customer is given use of the instrument, provided they continue purchasing the associated tests, also referred to as “consumables” or “reagents”. If a customer stops purchasing the consumables, the instrument must be returned to Meridian. Such arrangements are common practice in the diagnostics industry and are referred to as “Reagent Rental” agreements. These agreements may also include instrument related services such as a limited replacement warranty, training and installation. We concluded that the use of the instrument and related services (collectively known as “lease elements”) are not within the scope of ASU No. 2014-09 but rather ASU 2016-02, *Leases*. Accordingly, we first allocate the transaction price between the lease elements and the non-lease elements based on estimates of relative standalone selling prices. Lease revenue is derived solely from the sale of consumables and is therefore recognized monthly as earned, which coincides with the transfer of control of the non-lease elements.

For the portion of the transaction price allocated to the non-lease elements, which are principally the test kits, the related revenue will be recognized at a point-in-time when control transfers.

Revenue allocated to the lease elements of these Reagent Rental arrangements represent less than 1% of total revenue and are included as part of net revenues in our Condensed Consolidated Statements of Income.

### *Recent Accounting Pronouncements –*

In February 2016, the FASB issued ASU 2016-02, *Leases*, which amends the accounting guidance related to leases. These changes, which are designed to increase transparency and comparability among organizations for both lessees and lessors, include, among other things, requiring recognition of lease assets and liabilities on the balance sheet and disclosing key information about leasing arrangements. Adoption and implementation of the guidance is not required by the Company until the beginning of fiscal 2020, although early adoption is permitted. The Company expects to begin its assessment of the impact that adoption of this guidance will have on its financial statements during the second quarter of fiscal 2019.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The update addresses certain specific cash flows and their treatment, with the objective being to reduce the existing diversity in how the items are presented and classified within the statement of cash flows. The Company adopted this guidance in the first quarter of fiscal 2019, with the Condensed Consolidated Statements of Cash Flows reflecting such adoption, including the information related to restricted cash.

In February 2018, the FASB issued ASU 2018-02, *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, to address certain of the recent U.S. federal income tax legislation’s impact on Accumulated Other Comprehensive Income (“AOCI”). The guidance specifically provides the option of reclassifying “stranded tax effects” related to the tax legislation from AOCI to retained earnings. Adoption and implementation of the optional guidance is not effective for the Company until the beginning of fiscal 2020, although early adoption is permitted. The Company plans to adopt this guidance in fiscal 2020 as required but does not expect adoption to have a significant impact on the Company’s consolidated results of operations, cash flows or financial position.

## [Table of Contents](#)

### **Reclassifications –**

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

### **3. Cash and Equivalents**

Cash and equivalents include the following components:

	<u>December 31, 2018</u>		<u>September 30, 2018</u>	
	<u>Cash and Equivalents</u>	<u>Other Assets</u>	<u>Cash and Equivalents</u>	<u>Other Assets</u>
Institutional money market funds	\$ 20,540	\$ —	\$ 20,421	\$ —
Cash on hand -				
Restricted	—	1,000	—	1,000
Unrestricted	40,983	—	39,342	—
<b>Total</b>	<b>\$ 61,523</b>	<b>\$ 1,000</b>	<b>\$ 59,763</b>	<b>\$ 1,000</b>

### **4. Inventories**

Inventories are comprised of the following:

	<u>December 31, 2018</u>	<u>September 30, 2018</u>
Raw materials	\$ 7,123	\$ 6,689
Work-in-process	12,037	12,098
Finished goods - instruments	1,224	1,191
Finished goods - kits and reagents	21,505	22,015
<b>Total</b>	<b>\$ 41,889</b>	<b>\$ 41,993</b>

### **5. Intangible Assets**

A summary of our acquired intangible assets subject to amortization, as of December 31, 2018 and September 30, 2018, is as follows:

	<u>December 31, 2018</u>		<u>September 30, 2018</u>	
	<u>Gross Carrying Value</u>	<u>Accumulated Amortization</u>	<u>Gross Carrying Value</u>	<u>Accumulated Amortization</u>
Manufacturing technologies, core products and cell lines	\$22,268	\$ 14,243	\$22,297	\$ 13,974
Trade names, licenses and patents	8,613	5,463	8,647	5,267
Customer lists, customer relationships and supply agreements	24,385	13,295	24,461	13,051
Non-compete agreements	720	720	720	720
<b>Total</b>	<b>\$55,986</b>	<b>\$ 33,721</b>	<b>\$56,125</b>	<b>\$ 33,012</b>

## Table of Contents

The actual aggregate amortization expense for these intangible assets was \$829 and \$938 for the three months ended December 31, 2018 and 2017, respectively. The estimated aggregate amortization expense for these intangible assets for each of the fiscal years through fiscal 2024 is as follows: remainder of fiscal 2019 – \$2,487, fiscal 2020 – \$3,156, fiscal 2021 – \$2,560, fiscal 2022 – \$2,182, fiscal 2023 – \$2,170, and fiscal 2024 – \$2,166.

### **6. Restructuring**

During the second quarter of fiscal 2018, the Company began implementation of a plan to realign its business structure into two business units, Diagnostics and Life Science, supported by a global corporate team. As part of this plan, certain functions and locations within both business units were streamlined, including: (i) the elimination of certain executive management and commercial sales positions; (ii) the closing of Life Science locations in Taunton, Massachusetts and Singapore, the operations of which were transferred to locations in Memphis, Tennessee and London, England, respectively; and (iii) the transfer of certain functions performed in the Billerica, Massachusetts Diagnostics facility to the corporate headquarters in Cincinnati, Ohio. As a result of these activities, restructuring costs totaling \$6,332 were recorded during the fiscal year ended September 30, 2018.

A summary of the accrued liability associated with the restructuring costs as of December 31, 2018 and September 30, 2018, is as follows:

	<u>December 31,</u> <u>2018</u>	<u>September 30,</u> <u>2018</u>
Severance, other termination benefits and related costs	\$ 368	\$ 987
Lease and other contract termination fees	8	33
Other	5	6
Total	<u>\$ 381</u>	<u>\$ 1,026</u>

### **7. Income Taxes**

On December 22, 2017, the United States enacted tax reform legislation commonly known as the Tax Cuts and Jobs Act (the “tax reform act”). In applying the tax reform act during the three months ended December 31, 2017, we followed the guidance in SEC Staff Accounting Bulletin 118 (“SAB 118”), regarding the application of ASC Topic 740 in situations where a company does not have the necessary information available, prepared or analyzed in reasonable detail to complete the accounting for certain income tax effects of the tax reform act for the reporting period in which the tax reform act was enacted. SAB 118 provides for a measurement period beginning in the reporting period that includes the tax reform act’s enactment date and ending when a company has obtained, prepared and analyzed the information needed in order to complete the accounting requirements, but in no circumstances should the measurement period extend beyond one year from the enactment date.

As a result, our financial statements for the three months ended December 31, 2017 reflected the effects of the tax reform act as provisional based on a reasonable estimate of the income tax effects and included a provisional noncurrent income tax payable in the amount of \$854 related to the repatriation transition tax. Subsequent to the quarter ended December 31, 2017 and prior to September 30, 2018, we completed the accounting for the effects of the tax reform act. As a result, our repatriation transition tax liability was increased to \$876, which is reflected as follows in the accompanying Condensed Consolidated Balance as of December 31, 2018: \$140 of current income taxes payable and \$736 long-term income taxes payable.

In addition, during the three months ended December 31, 2017 we recorded a one-time tax benefit of \$1,695 resulting from the tax reform act, including an adjustment from the re-measurement of deferred tax assets and liabilities. This re-measurement included an estimate of the temporary differences expected to be realized during fiscal 2018 at a transitional blended rate of 24.5%. The remaining temporary differences were re-measured at 21%.

## **8. Bank Credit Arrangements**

In March 2016, the Company entered into a \$60,000 five-year term loan with a commercial bank. The term loan requires quarterly principal and interest payments, with interest at a variable rate tied to LIBOR, and a balloon principal payment due March 31, 2021. The required principal payments on the term loan for each of the remaining fiscal years are as follows: remainder of fiscal 2019 – \$4,125, fiscal 2020 – \$6,000, and fiscal 2021 – \$39,000. In light of the term loan’s interest being determined on a variable rate basis, the fair value of the term loan at December 31, 2018 approximates the current carrying value reflected in the accompanying Condensed Consolidated Balance Sheet.

In order to limit exposure to volatility in the LIBOR interest rate, the Company and the commercial bank also entered into an interest rate swap that effectively converts the variable interest rate on the term loan to a fixed rate of 2.76%. With an initial notional balance of \$60,000, the interest rate swap was established with critical terms identical to those of the term loan, including: (i) notional reduction amounts and dates; (ii) LIBOR settlement rates; (iii) rate reset dates; and (iv) term/maturity. Due to this, the interest rate swap has been designated as an effective cash flow hedge, with changes in fair value reflected as a separate component of other comprehensive income in the accompanying Condensed Consolidated Statements of Comprehensive Income. At December 31, 2018 and September 30, 2018, the fair value of the interest rate swap was \$1,145 and \$1,722, respectively, and is reflected as a non-current asset in the accompanying Condensed Consolidated Balance Sheets. This fair value was determined by information provided by the counterparty, and is considered a Level 2 input within the fair value hierarchy of valuation techniques.

In addition, the Company maintains a \$30,000 revolving credit facility with a commercial bank, which expires March 31, 2021. There were no borrowings outstanding on this credit facility at December 31, 2018 or September 30, 2018.

The term loan and the revolving credit facility are collateralized by the business assets of the Company’s U.S. subsidiaries and require compliance with financial covenants that limit the amount of debt obligations and require a minimum level of coverage of fixed charges, as defined in the borrowing agreement. As of December 31, 2018, the Company is in compliance with all covenants. The Company is also required to maintain a compensating cash balance with the bank in the amount of \$1,000, and is in compliance with this requirement.

## **9. Reportable Segment and Major Customers Information**

Meridian was formed in 1976 and functions as a fully-integrated life science company with principal businesses in: (i) the development, manufacture, sale and distribution of diagnostic test kits, primarily for certain gastrointestinal and respiratory infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents used by researchers and other diagnostic manufacturers.

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations for infectious disease products in Cincinnati, Ohio, and manufacturing operations for blood chemistry products in Billerica, Massachusetts (near Boston), and the sale and distribution of diagnostics products domestically and abroad. This segment’s products are used by hospitals, reference labs and physician offices to detect infectious diseases and elevated lead levels in blood.

The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; and Luckenwalde, Germany, and the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents domestically and abroad, including a sales and business development facility in Beijing, China to further pursue growing revenue opportunities in Asia. This segment’s products are used by manufacturers and researchers in a variety of applications (e.g., in-vitro medical device manufacturing, microRNA detection, next-gen sequencing, plant genotyping, and mutation detection, among others).



## [Table of Contents](#)

Amounts due from two Diagnostics distributor customers accounted for 14% and 12% of consolidated accounts receivable at December 31, 2018 and September 30, 2018, respectively. Revenues from these two distributor customers accounted for 34% and 32% of the Diagnostics segment third-party revenues during the three months ended December 31, 2018 and 2017, respectively, and represented 24% and 23% of consolidated revenues for the fiscal 2019 and 2018 first quarters, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 28% and 15% of the segment's third-party revenues during the three months ended December 31, 2018 and 2017, respectively.

Segment information for the interim periods is as follows:

	<u>Diagnostics</u>	<u>Life Science</u>	<u>Corporate(1)</u>	<u>Eliminations(2)</u>	<u>Total</u>
<b>Three Months Ended December 31, 2018</b>					
Net revenues -					
Third-Party	\$ 36,665	\$ 14,815	\$ —	\$ —	\$ 51,480
Inter-segment	163	176	—	(339)	—
Operating income	8,786	5,129	(3,391)	27	10,551
Goodwill (December 31, 2018)	35,213	19,190	—	—	54,403
Other intangible assets, net (December 31, 2018)	21,386	879	—	—	22,265
Total assets (December 31, 2018)	178,863	71,283	—	(289)	249,857
<b>Three Months Ended December 31, 2017</b>					
Net revenues -					
Third-Party	\$ 37,490	\$ 14,793	\$ —	\$ —	\$ 52,283
Inter-segment	121	192	—	(313)	—
Operating income	8,569	2,943	(3,555)	104	8,061
Goodwill (September 30, 2018)	35,213	19,424	—	—	54,637
Other intangible assets, net (September 30, 2018)	22,068	1,045	—	—	23,113
Total assets (September 30, 2018)	180,978	70,341	—	58	251,377

(1) Includes Restructuring and Litigation Costs of \$589 and \$1,483 in the quarters ended December 31, 2018 and 2017, respectively.

(2) 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.

### **10. Litigation Matters**

On November 15, 2017, Barbara Forman filed a class action complaint in the United States District Court for the Southern District of Ohio naming Meridian, its Chief Executive Officer and Chief Financial Officer (in their capacities as such) as defendants. An amended complaint was filed on April 16, 2018 and the Company believes the essential elements of the amended complaint are the same. The complaint and the amended complaint are hereafter referred to as the "Complaint". The Complaint seeks compensatory damages and attorneys' fees. Meridian has filed a motion to dismiss the Complaint, to which the plaintiff responded on August 14, 2018. The motion has been fully briefed and remains pending before the court. We are unable to determine or predict the ultimate outcome or estimate the range of possible losses, if any. Accordingly, no provision for litigation losses has been included within either of the accompanying Condensed Consolidated Statements of Operations for the three months ended December 31, 2018 or December 31, 2017.

## [Table of Contents](#)

On December 6, 2017, Michael Edelson filed a derivative complaint in the United States District Court for the Southern District of Ohio naming Meridian, its Chief Executive Officer, Chief Financial Officer and certain members of Meridian's Board of Directors and Audit Committee (in their capacities as such) as defendants. The complaint alleges that Meridian made false and misleading representations concerning certain of Magellan's lead test systems at or around the time of Meridian's acquisition of Magellan and subsequent thereto, and the complaint alleges that certain members of the Board of Directors and Audit Committee breached their fiduciary duties in their oversight of the Company's public disclosures and corporate governance matters. The complaint seeks compensatory damages, equitable relief relating to corporate governance matters and attorneys' fees. The case has been stayed by agreement of the parties pending resolution of the motion to dismiss the class action described above. We are unable to determine or predict the ultimate outcome or estimate the range of possible losses, if any. Accordingly, no provision for litigation losses has been included within either of the accompanying Condensed Consolidated Statements of Operations for the three months ended December 31, 2018 or December 31, 2017. The Company maintains an insurance policy covering these matters, which has a \$500 deductible.

On April 17, 2018, Magellan received a subpoena from the United States Department of Justice ("DOJ") regarding its LeadCare product line. The subpoena outlines documents to be produced, and the Company is cooperating with the DOJ in this matter. The Company maintains rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements, and is working with the DOJ to promptly respond to the subpoena. However, the Company cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on the Company. Approximately \$540 and \$0 of expense for attorneys' fees related to this matter is included within the accompanying Condensed Consolidated Statements of Operations for the three months ended December 31, 2018 and December 31, 2017, respectively.

On October 9, 2018, the Company and DiaSorin Inc. entered into a strategic collaboration to sell DiaSorin's *Helicobacter pylori* stool antigen test to detect *H. pylori* for use on its automated LIAISON platform under the Meridian brand name worldwide. The new collaboration results in the termination of all pending legal disputes between the two parties and will expand the previous agreement between DiaSorin and Meridian, which focused on the sale, by DiaSorin, of co-developed products in major countries in continental Europe. Approximately \$50 and \$730 of expense for attorneys' fees related to this matter is included within the accompanying Condensed Consolidated Statements of Operations for the three months ended December 31, 2018 and December 31, 2017, respectively.

## 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**

### **Three Months Ended December 31, 2018**

Net earnings for the first quarter of fiscal 2019 increased 29% to \$8,106, or \$0.19 per diluted share, from net earnings for the first quarter of fiscal 2018 of \$6,302, or \$0.15 per diluted share. The fiscal 2019 first quarter results include \$589 of litigation costs, while the fiscal 2018 first quarter results include \$1,483 of restructuring and litigation costs, along with certain one-time tax effects of the U.S. tax reform act enacted in December 2017. These items had a combined impact on net earnings of \$452, or \$0.01 per diluted share, in the fiscal 2019 quarter and \$239, or less than \$0.01 per diluted share, in the fiscal 2018 quarter (see “USE OF NON-GAAP MEASURES” below). Consolidated revenues for the first quarter of fiscal 2019 totaled \$51,480, a decrease of 2% compared to the first quarter of fiscal 2018 (1% decrease on a constant-currency basis).

Revenues for the Diagnostics segment for the first quarter of fiscal 2019 decreased 2% compared to the first quarter of fiscal 2018 (also 2% on a constant-currency basis), comprised of a 16% decrease in molecular assay products and a 2% increase in immunoassay and blood chemistry assay products. With a 16% increase in its molecular reagents products and a 10% decrease in its immunological reagents products, revenues for our Life Science segment were flat during the first quarter of fiscal 2019 compared to the first quarter of fiscal 2018. On a constant-currency basis, revenues for the Life Science segment increased 1%.

The first quarter Diagnostics revenues reflect improvement in our respiratory illness and blood chemistry assay product lines being more than offset by decreased revenues for our gastrointestinal assays. Life Science revenues reflect inconsistent buying patterns with a number of our multi-national IVD manufacturing customers and general market softness in North America and China.

### **USE OF NON-GAAP MEASURES**

We have supplemented our reported GAAP financial information with information on operating expenses, operating income, net earnings, basic earnings per share and diluted earnings per share excluding the effects of: (i) restructuring costs (fiscal 2018); (ii) litigation costs (fiscal 2019 and 2018); and (iii) certain one-time tax effects of the tax reform act (fiscal 2018) – each of which is a non-GAAP measure. We have provided in the tables below reconciliations to the operating expenses, operating income, net earnings, basic earnings per share and diluted earnings per share 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 impacts of these non-routine items; 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.

Revenue reported on a constant-currency basis is also a non-GAAP measure and is calculated by applying current period average foreign currency exchange rates to each of the prior comparable periods. Management analyzes revenue on a constant-currency basis to better measure the comparability of results between periods. Because changes in foreign currency exchange rates have a non-operating impact on revenue, management believes that evaluating revenue changes on a constant-currency basis provides an additional and meaningful assessment of revenue to both management and investors.

These non-GAAP measures may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP measures have limitations, in that they do not reflect all amounts associated with our results as determined in accordance with U.S. GAAP. Therefore, these measures should only be used to evaluate our results in conjunction with corresponding GAAP measures.

[Table of Contents](#)

	Three Months Ended December 31,	
	2018	2017
<b>Operating Expenses -</b>		
U.S. GAAP basis	\$ 21,021	\$ 23,949
Restructuring costs	—	(734)
Litigation costs	(589)	(749)
Adjusted Operating Expenses	<u>\$ 20,432</u>	<u>\$ 22,466</u>
<b>Operating Income -</b>		
U.S. GAAP basis	\$ 10,551	\$ 8,061
Restructuring costs	—	734
Litigation costs	589	749
Adjusted Operating Income	<u>\$ 11,140</u>	<u>\$ 9,544</u>
<b>Net Earnings -</b>		
U.S. GAAP basis	\$ 8,106	\$ 6,302
Restructuring costs (1)	—	535
Litigation costs (1)	452	545
One-time benefit from tax law change	—	(1,695)
Repatriation transition tax	—	854
Adjusted Net Earnings	<u>\$ 8,558</u>	<u>\$ 6,541</u>
<b>Net Earnings per Basic Common Share -</b>		
U.S. GAAP basis	\$ 0.19	\$ 0.15
Restructuring costs (1)	—	0.01
Litigation costs (1)	0.01	0.01
One-time benefit from tax law change	—	(0.04)
Repatriation transition tax	—	0.02
Adjusted Basic EPS	<u>\$ 0.20</u>	<u>\$ 0.15</u>
<b>Net Earnings per Diluted Common Share -</b>		
U.S. GAAP basis	\$ 0.19	\$ 0.15
Restructuring costs (1)	—	0.01
Litigation costs (1)	0.01	0.01
One-time benefit from tax law change	—	(0.04)
Repatriation transition tax	—	0.02
Adjusted Diluted EPS	<u>\$ 0.20</u>	<u>\$ 0.15</u>

- (1) These restructuring costs and litigation costs are net of income tax effects of \$137 and \$403 in the three months ended December 31, 2018 and 2017, respectively, which were calculated using the effective tax rates of the jurisdictions in which the costs were incurred.

**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

**Revenue Overview- By Reportable Segment & Geographic Region**

Our reportable segments are Diagnostics and Life Science, with products sold and distributed in the countries comprising North and Latin America (the “Americas”); Europe, Middle East and Africa (“EMEA”); and other countries outside of the Americas and EMEA (rest of the world, or “ROW”). A full description of our segments is set forth in Note 9 of the accompanying Condensed Consolidated Financial Statements.

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 the severity of seasonal diseases and outbreaks, 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.

	<b>Three Months Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>Inc (Dec)</b>
<b>Diagnostics -</b>			
Americas	\$31,147	\$31,575	(1)%
EMEA	5,085	5,415	(6)%
ROW	433	500	(13)%
Total Diagnostics	<u>36,665</u>	<u>37,490</u>	<u>(2)%</u>
<b>Life Science -</b>			
Americas	4,534	5,250	(14)%
EMEA	7,455	5,185	44%
ROW	2,826	4,358	(35)%
Total Life Science	<u>14,815</u>	<u>14,793</u>	<u>— %</u>
Consolidated	<u>\$51,480</u>	<u>\$52,283</u>	<u>(2)%</u>
<b>% of total revenues -</b>			
Diagnostics	71%	72%	
Life Science	29%	28%	
Total	<u>100%</u>	<u>100%</u>	
Ex-Americas	<u>31%</u>	<u>30%</u>	

**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 assays that operate on our Alethia platform (formerly branded as *illumigene*)
- 2) Immunoassays and blood chemistry assays on multiple technology platforms

Life Science

- 1) Molecular reagents
- 2) Immunological reagents

## Table of Contents

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

	Three Months Ended December 31,		
	2018	2017	Inc (Dec)
<b>Diagnostics-</b>			
Molecular assays	\$ 7,298	\$ 8,717	(16)%
Immunoassays & blood chemistry assays	29,367	28,773	2%
Total Diagnostics	<u>\$36,665</u>	<u>\$37,490</u>	<u>(2)%</u>
<b>Life Science-</b>			
Molecular reagents	\$ 6,589	\$ 5,688	16%
Immunological reagents	8,226	9,105	(10)%
Total Life Science	<u>\$14,815</u>	<u>\$14,793</u>	<u>— %</u>
<b>% of Diagnostics revenues-</b>			
Molecular assays	20%	23%	
Immunoassays & blood chemistry assays	80%	77%	
Total Diagnostics	<u>100%</u>	<u>100%</u>	
<b>% of Life Science revenues-</b>			
Molecular reagents	44%	38%	
Immunological reagents	56%	62%	
Total Life Science	<u>100%</u>	<u>100%</u>	

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

### Diagnosics Products

#### Gastrointestinal Assays

During the first quarter of fiscal 2019, revenues from our gastrointestinal products, which include tests for *C. difficile*, *H. pylori* and certain foodborne pathogens, among others, totaled \$18,633. This represents an 8% decrease from the first quarter of fiscal 2018. This decrease results in large part from the pricing and volume pressures we continue to face within this product category. In an effort to combat these pressures, we have executed multi-year supply agreements with our two largest reference laboratory customers for *H. pylori* tests to secure volume, albeit at lower selling prices. We continue to believe there are ongoing benefits to be realized from 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.

Contributing to the competitive pressures being faced in this product category, the patents for our *H. pylori* products, owned by us, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our *H. pylori* products to increase in the near future, and 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. Our product development pipeline includes new product initiatives for the detection of *H. pylori*, and early in the first quarter of fiscal 2019 we entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests (see Note 10, "Litigation Matters" of the accompanying Condensed Consolidated Financial Statements). We are unable to provide assurances that we will be successful with any strategy or that any strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

## [Table of Contents](#)

### Respiratory Illness Assays

Including tests for influenza, RSV, Group A Strep, Pertussis, and Mycoplasma pneumonia, among others, our respiratory illness product revenues increased 7% in the fiscal 2019 first quarter.

### Blood Chemistry Assays

Revenues from our sale of products to test for elevated levels of lead in blood increased 5% during the first quarter of fiscal 2019 to a total of \$4,466. In late December 2018, the documents to reinstate our venous blood claims removed in fiscal 2017 were submitted to the FDA. See Note 10, "Litigation Matters" of the accompanying Condensed Consolidated Financial Statements for additional information related to the Company's LeadCare product line.

### **Life Science Products**

During the first quarter of fiscal 2018, revenues from our Life Science segment were flat, with revenues from molecular reagent sales increasing 16% from the comparable fiscal 2018 quarter and revenues from immunological reagent sales decreasing 10%. Our Life Science segment's growth was slightly impacted by the movement in currency exchange rates since the first quarter of fiscal 2018, with revenues increasing 1% on a constant-currency basis over the first quarter of fiscal 2018. Our Life Science segment was also impacted by buying patterns of certain IVD manufacturer customers including sales into China, with such sales totaling approximately \$1,000 during first quarter of fiscal 2019 – representing an approximate 28% decrease from the first quarter of fiscal 2018.

### **Significant Customers**

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 9 of the accompanying Condensed Consolidated Financial Statements.

### **Gross Profit**

	<b>Three Months Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>Change</b>
Gross Profit	\$31,572	\$32,010	(1)%
Gross Profit Margin	61%	61%	—

### **Operating Expenses – Segment Detail**

	<b>Research &amp; Development</b>	<b>Selling &amp; Marketing</b>	<b>General &amp; Administrative</b>	<b>Other</b>	<b>Total Operating Expenses</b>
Fiscal 2018 First Quarter:					
Diagnostics	\$ 3,705	\$ 6,456	\$ 5,114	\$ —	\$ 15,275
Life Science	715	2,388	2,016	—	5,119
Corporate	—	—	2,072	1,483	3,555
<b>Total 2018 First Quarter Expenses</b>	<b>\$ 4,420</b>	<b>\$ 8,844</b>	<b>\$ 9,202</b>	<b>\$1,483</b>	<b>\$ 23,949</b>
Fiscal 2019 First Quarter:					
Diagnostics	\$ 3,196	\$ 6,041	\$ 4,609	\$ —	\$ 13,846
Life Science	771	1,522	1,491	—	3,784
Corporate	—	—	2,802	589	3,391
<b>Total 2019 First Quarter Expenses</b>	<b>\$ 3,967</b>	<b>\$ 7,563</b>	<b>\$ 8,902</b>	<b>\$ 589</b>	<b>\$ 21,021</b>

**Operating Expenses – Comparison to Prior Year Periods**

	<u>Research &amp; Development</u>	<u>Selling &amp; Marketing</u>	<u>General &amp; Administrative</u>	<u>Other</u>	<u>Total Operating Expenses</u>
<b>2018 First Quarter Expenses</b>	<b>\$ 4,420</b>	<b>\$ 8,844</b>	<b>\$ 9,202</b>	<b>\$1,483</b>	<b>\$ 23,949</b>
% of Revenues	8%	17%	18%	3%	46%
<b>Fiscal 2019 Increases (Decreases):</b>					
Diagnostics	(509)	(415)	(505)	—	(1,429)
Life Science	56	(866)	(525)	—	(1,335)
Corporate	—	—	730	(894)	(164)
<b>2019 First Quarter Expenses</b>	<b>\$ 3,967</b>	<b>\$ 7,563</b>	<b>\$ 8,902</b>	<b>\$ 589</b>	<b>\$ 21,021</b>
% of Revenues	8%	15%	17%	1%	41%
% Increase (Decrease)	(10)%	(14)%	(3)%	(60)%	(12)%

Total operating expenses decreased during the first quarter of fiscal 2019 compared to the first quarter of fiscal 2018, with overall decreases in spending in all of our segments, reflecting the following:

- Decreased Research & Development costs due to the timing of product development projects and the clinical trials for our cCMV test in the first quarter of fiscal 2018;
- Decreased Selling & Marketing costs due to: (i) lower sales commissions resulting from the decrease in sales levels; and (ii) the effects of the fiscal 2018 organization streamlining initiatives;
- Decreased General & Administrative costs due to: (i) lower Quality System remediation costs related to our blood-lead manufacturing facility; and (ii) the effects of the fiscal 2018 organization streamlining initiatives; and
- Decreased restructuring & litigation costs (reflected with “Other” in the above tables), noting that the only such costs incurred during the fiscal 2019 first quarter were litigation costs related to the matters discussed in Note 10 of the accompanying Condensed Consolidated Financial Statements.

**Operating Income**

Operating income increased 31% to \$10,551 for the first quarter of fiscal 2019, as a result of the factors discussed above, including the restructuring and litigation costs.

**Income Taxes**

The effective rate for income taxes was 23% for the first quarter of fiscal 2019, compared to 18% for the first quarter of 2018. This higher fiscal 2019 tax results from the fact that the fiscal 2019 first quarter reflects the lower U.S. federal tax rate of 21% being fully phased-in, while the fiscal 2018 first quarter reflects the combined net impact of the following effects of the tax reform act (see Note 7 of the accompanying Condensed Consolidated Financial Statements):

- Application of an approximate 24.5% blended rate due to the lowering of the applicable rate from 35% to 21% on a phased-in basis;
- Recognizing a one-time \$1,695 tax benefit, including the re-measurement of deferred tax balances at the lower rate; and
- Recording a provisional one-time \$854 tax expense related to the estimated repatriation transition tax on foreign earnings.



## **Liquidity and Capital Resources**

### ***Comparative Cash Flow Analysis***

Our cash flow and financing requirements are determined by analyses of operating and capital spending budgets, debt service, consideration of acquisition plans, and consideration of common share dividends. We have historically maintained a credit facility to augment working capital requirements and to respond quickly to acquisition opportunities.

We have an investment policy that guides the holdings of our investment portfolio, which presently consists of bank savings accounts and institutional money market mutual funds. 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.

Considering the various worldwide geo-political and geo-economic conditions, we do not expect macroeconomic 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 revolving credit facility. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets tightens for an extended period of time, and such conditions impact the collectability of our customer accounts receivable, impact credit terms with our vendors, or disrupt the supply of raw materials and services.

As of December 31, 2018, our cash and equivalents balance is \$61,523 or \$6,812 higher than at the end of the fiscal 2018 first quarter, and \$1,760 higher than at September 30, 2018. This increase results in large part from the cash flows from operating activities being more than sufficient to cover capital expenditures, shareholder dividends and debt service. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and shareholder dividends during the next 12 months.

The indicated annual cash dividend rate for fiscal 2019 was established at \$0.50 per share. Consistent with this annual indicated dividend rate, a cash dividend of \$0.125 was declared for the first quarter of fiscal 2019.

### ***Capital Resources***

In 2016, the Company entered into a \$60,000 five-year term loan and related interest rate swap agreement with a commercial bank, the details of which are set forth in Note 8 of the accompanying Condensed Consolidated Financial Statements. In addition, we have a \$30,000 revolving credit facility (discussed above) with a commercial bank that expires March 31, 2021. As of January 31, 2019, 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 revolving credit facility during the first three months of fiscal 2019 or during the full year of fiscal 2018.

Our capital expenditures are estimated to range between approximately \$4,000 to \$5,000 for fiscal 2019, with the actual amount dependent 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 revolving credit facility discussed above.

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

## [Table of Contents](#)

### 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, 2018.

### ITEM 4. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of the Company's disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2018. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of December 31, 2018.

#### **Changes in Internal Control over Financial Reporting**

During the quarter ended December 31, 2018, the Company enacted additional controls associated with the adoption of ASU 2014-09, *Revenue from Contracts with Customers*. There were no other changes in our internal control over financial reporting (as that term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### ITEM 1. LEGAL PROCEEDINGS

See Note 10 of the accompanying Condensed Consolidated Financial Statements.

### ITEM 1A. RISK FACTORS

There have been no material changes from risk factors as previously disclosed in the Company's fiscal 2018 Annual Report on 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, 2018 filed with the SEC on February 11, 2019, formatted in XBRL includes: (i) Condensed Consolidated Statements of Operations for the three months ended December 31, 2018 and 2017; (ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended December 31, 2018 and 2017; (iii) Condensed Consolidated Statements of Cash Flows for the three months ended December 31, 2018 and 2017; (iv) Condensed Consolidated Balance Sheets as of December 31, 2018 and September 30, 2018; (v) Condensed Consolidated Statements of Shareholders' Equity for the three months ended December 31, 2018 and 2017; and (vi) the Notes to Condensed Consolidated Financial Statements

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, 2019

By: /s/ Bryan T. Baldasare  
Bryan T. Baldasare  
Senior Vice President, Corporate Controller, Treasurer and Chief  
Accounting Officer  
(Principal Accounting Officer)

**Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)**

I, Jack Kenny, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Meridian Bioscience, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 11, 2019

/s/ Jack Kenny

\_\_\_\_\_  
Jack Kenny  
Chief Executive Officer

**Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)**

I, Eric S. Rasmussen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Meridian Bioscience, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 11, 2019

/s/ Eric S. Rasmussen

---

Eric S. Rasmussen

Executive Vice President and Chief Financial Officer

**Meridian Bioscience, Inc.****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**

In connection with the filing with the Securities and Exchange Commission of the Quarterly Report of Meridian Bioscience, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2018 (the "Report"), the undersigned officers of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jack Kenny

Jack Kenny  
Chief Executive Officer  
February 11, 2019

/s/ Eric S. Rasmussen

Eric S. Rasmussen  
Executive Vice President and  
Chief Financial Officer  
February 11, 2019