

MERIDIAN BIOSCIENCE INC
Form 10-Q
August 09, 2018

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 June 30, 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 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.

Edgar Filing: MERIDIAN BIOSCIENCE INC - Form 10-Q

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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.

Class	Outstanding July 31, 2018
Common Stock, no par value	42,395,322

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

TABLE OF CONTENTS TO QUARTERLY REPORT ON FORM 10-Q

	Page(s)
PART I. <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements (Unaudited)</u>	
<u>Condensed Consolidated Statements of Operations Three and Nine Months Ended June 30, 2018 and 2017</u>	1
<u>Condensed Consolidated Statements of Comprehensive Income Three and Nine Months Ended June 30, 2018 and 2017</u>	2
<u>Condensed Consolidated Statements of Cash Flows Nine Months Ended June 30, 2018 and 2017</u>	3
<u>Condensed Consolidated Balance Sheets June 30, 2018 and September 30, 2017</u>	4-5
<u>Condensed Consolidated Statement of Changes in Shareholders' Equity Nine Months Ended June 30, 2018</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7-13
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14-23
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4. <u>Controls and Procedures</u>	23
PART II. <u>OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	24
Item 1A. <u>Risk Factors</u>	24
Item 6. <u>Exhibits</u>	24
<u>Signature</u>	25

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, 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 the ramp up of new 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, including legal expenses, 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, compliance with anti-corruption laws, tariffs, trade wars, 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 and natural disasters and other events could have a materially adverse effect on Meridian's results of operations and revenues. Meridian cannot predict the outcome of changes in business strategy or plans, legal proceedings or developments. 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)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
NET REVENUES	\$ 51,737	\$ 50,140	\$ 160,471	\$ 151,074
COST OF SALES	19,781	18,994	62,160	57,412
GROSS PROFIT	31,956	31,146	98,311	93,662
OPERATING EXPENSES				
Research and development	4,259	3,964	13,245	11,512
Selling and marketing	8,504	7,961	25,962	23,645
General and administrative	8,377	8,289	26,155	23,302
Executive transition and realignment costs	913		5,105	
Litigation costs	1,168		3,370	
Goodwill impairment charge		6,628		6,628
Total operating expenses	23,221	26,842	73,837	65,087
OPERATING INCOME	8,735	4,304	24,474	28,575
OTHER INCOME (EXPENSE)				
Interest income	109	51	271	102
Interest expense	(375)	(407)	(1,149)	(1,238)
Other, net	151	(2)	(94)	356
Total other income (expense)	(115)	(358)	(972)	(780)
EARNINGS BEFORE INCOME TAXES	8,620	3,946	23,502	27,795
INCOME TAX PROVISION	1,795	3,706	5,087	11,964
NET EARNINGS	\$ 6,825	\$ 240	\$ 18,415	\$ 15,831
BASIC EARNINGS PER COMMON SHARE	\$ 0.16	\$ 0.01	\$ 0.44	\$ 0.38
DILUTED EARNINGS PER COMMON SHARE	\$ 0.16	\$ 0.01	\$ 0.43	\$ 0.37
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC	42,349	42,203	42,307	42,184
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARE UNITS	409	390	405	372

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED	42,758	42,593	42,712	42,556
ANTI-DILUTIVE SECURITIES:				
Common share options and restricted share units	995	861	1,009	872
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.125	\$ 0.125	\$ 0.375	\$ 0.450

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)**(dollars in thousands)**

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
NET EARNINGS	\$ 6,825	\$ 240	\$ 18,415	\$ 15,831
Other comprehensive income (loss):				
Foreign currency translation adjustment	(1,912)	1,363	(695)	452
Unrealized gain (loss) on cash flow hedge	109	(164)	874	1,524
Income taxes related to items of other comprehensive income	(28)	39	(247)	(574)
Other comprehensive income (loss), net of tax	(1,831)	1,238	(68)	1,402
COMPREHENSIVE INCOME	\$ 4,994	\$ 1,478	\$ 18,347	\$ 17,233

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)**(dollars in thousands)**

Nine Months Ended June 30,	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	\$ 18,415	\$ 15,831
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	3,320	3,255
Amortization of intangible assets	2,732	2,843
Amortization of deferred instrument costs	581	745
Stock-based compensation	2,882	2,891
Goodwill impairment charge		6,628
Deferred income taxes	(71)	1,010
Change in:		
Accounts receivable	(52)	(288)
Inventories	(4,118)	3,899
Prepaid expenses and other current assets	(2,106)	2,153
Accounts payable and accrued expenses	2,967	(5,568)
Income taxes payable	(1,003)	19
Other, net	35	(927)
Net cash provided by operating activities	23,582	32,491
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(3,340)	(3,402)
Net cash used for investing activities	(3,340)	(3,402)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(15,870)	(18,990)
Payments on bank term loan	(3,375)	(2,625)
Proceeds and tax benefits from exercises of stock options	183	303
Net cash used for financing activities	(19,062)	(21,312)
Effect of Exchange Rate Changes on Cash and Equivalents	(322)	250
Net Increase in Cash and Equivalents	858	8,027
Cash and Equivalents at Beginning of Period	57,072	47,226
Cash and Equivalents at End of Period	\$ 57,930	\$ 55,253

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

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

	June 30, 2018 (Unaudited)	September 30, 2017
CURRENT ASSETS		
Cash and equivalents	\$ 57,930	\$ 57,072
Accounts receivable, less allowances of \$327 and \$307	28,858	29,106
Inventories	45,154	41,493
Prepaid expenses and other current assets	8,301	6,204
Total current assets	140,243	133,875
PROPERTY, PLANT AND EQUIPMENT, at Cost		
Land	1,161	1,162
Buildings and improvements	32,238	32,207
Machinery, equipment and furniture	48,990	48,836
Construction in progress	2,850	1,895
Subtotal	85,239	84,100
Less: accumulated depreciation and amortization	54,764	53,590
Net property, plant and equipment	30,475	30,510
OTHER ASSETS		
Goodwill	54,776	54,926
Other intangible assets, net	23,975	26,704
Restricted cash	1,000	1,000
Deferred instrument costs, net	1,240	1,368
Fair value of interest rate swap	1,689	815
Deferred income taxes	91	158
Other assets	494	421
Total other assets	83,265	85,392
TOTAL ASSETS	\$ 253,983	\$ 249,777

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

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

	June 30, 2018 (Unaudited)	September 30, 2017
CURRENT LIABILITIES		
Accounts payable	\$ 7,354	\$ 7,719
Accrued employee compensation costs	6,861	4,536
Current portion of acquisition consideration	2,095	2,095
Other accrued expenses	3,162	2,789
Current portion of long-term debt	4,875	4,500
Income taxes payable	118	1,248
Total current liabilities	24,465	22,887
NON-CURRENT LIABILITIES		
Acquisition consideration	235	235
Post-employment benefits	2,513	2,468
Long-term debt	46,422	50,147
Long-term income taxes payable	786	
Deferred income taxes	4,435	4,455
Total non-current liabilities	54,391	57,305
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, 42,358,182 and 42,207,317 shares issued, respectively		
Additional paid-in capital	128,673	125,608
Retained earnings	49,468	46,923
Accumulated other comprehensive loss	(3,014)	(2,946)
Total shareholders' equity	175,127	169,585
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 253,983	\$ 249,777

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

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 Loss	Total Shareholders Equity
Balance at September 30, 2017	42,207	\$ 125,608	\$ 46,923	\$ (2,946)	\$ 169,585
Cash dividends paid			(15,870)		(15,870)
Exercise of stock options	13	183			183
Conversion of restricted share units	138				
Stock compensation expense		2,882			2,882
Net earnings			18,415		18,415
Foreign currency translation adjustment				(695)	(695)
Hedging activity, net of tax				627	627
Balance at June 30, 2018	42,358	\$ 128,673	\$ 49,468	\$ (3,014)	\$ 175,127

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 June 30, 2018, the results of its operations for the three and nine month periods ended June 30, 2018 and 2017, and its cash flows for the nine month periods ended June 30, 2018 and 2017. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company's fiscal 2017 Annual Report on Form 10-K. Financial information as of September 30, 2017 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 2017 Annual Report on Form 10-K.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which supersedes and replaces nearly all currently-existing U.S. GAAP revenue recognition guidance including related disclosure requirements. This guidance, including any clarification guidance thereon, will be effective for the Company beginning October 1, 2018 (fiscal 2019). The Company has prepared an inventory of its existing revenue streams and a preliminary analysis of the revenue recognition criteria applying ASU 2014-09. This analysis is preliminary and our overall assessment is not yet complete. However, based on the analysis completed to date, aside from certain expanded disclosure requirements, the Company does not currently anticipate that its planned adoption of ASU 2014-09 on a modified retrospective basis will have a material impact on its reported revenues.

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 in fiscal 2019.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends the accounting for share-based payment transactions. These changes, which are designed for simplification,

involve several aspects of the accounting for share-based transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted this guidance in the first quarter of fiscal 2018, and as a result recorded \$160 to the income tax provision, which under the previous guidance would have been recorded within additional paid-in capital. While the future effect of the guidance is dependent upon numerous factors (e.g., the market price of the Company's common stock on the equity award grant date, the exercise/lapse dates of equity awards, and the market price of the Company's common stock on such exercise/lapse dates), the effect is not expected to be material. During the first nine months of fiscal 2018, our tax provision included a \$178 charge for application of ASU 2016-09.

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 address adoption of this guidance later in fiscal 2018 in connection with the finalization of other matters related to the recent tax legislation (see Note 6 *Income Taxes*) but does not expect adoption to have a significant impact on the Company's consolidated results of operations, cash flows or financial position.

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:

	June 30, 2018		September 30, 2017	
	Cash and Equivalents	Other Assets	Cash and Equivalents	Other Assets
Institutional money market funds	\$ 20,318	\$	\$ 20,104	\$
Cash on hand -				
Restricted		1,000		1,000
Unrestricted	37,612		36,968	
Total	\$ 57,930	\$ 1,000	\$ 57,072	\$ 1,000

4. Inventories

Inventories are comprised of the following:

	June 30, 2018	September 30, 2017
Raw materials	\$ 7,699	\$ 6,575
Work-in-process	13,756	11,559
Finished goods - instruments	1,342	1,460
Finished goods - kits and reagents	22,357	21,899
Total	\$ 45,154	\$ 41,493

5. Intangible Assets

A summary of our acquired intangible assets subject to amortization, as of June 30, 2018 and September 30, 2017, is as follows:

	June 30, 2018		September 30, 2017	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	\$ 22,314	\$ 13,693	\$ 22,332	\$ 12,807
Trade names, licenses and patents	8,668	5,058	8,689	4,398
Customer lists, customer relationships and supply agreements	24,516	12,772	24,562	11,854
Non-compete agreements	720	720	720	540
	\$ 56,218	\$ 32,243	\$ 56,303	\$ 29,599

The actual aggregate amortization expense for these intangible assets was \$849 and \$939 for the three months ended June 30, 2018 and 2017, respectively, and \$2,732 and \$2,843 for the nine months ended June 30, 2018 and 2017, respectively. The estimated aggregate amortization expense for these intangible assets for each of the fiscal years through fiscal 2023 is as follows: remainder of fiscal 2018 \$844, fiscal 2019 \$3,333, fiscal 2020 \$3,170, fiscal 2021 \$2,561, fiscal 2022 \$2,182, and fiscal 2023 \$2,170.

In light of the factors discussed below and their impacts, during our fiscal 2017 third quarter, it was determined that a potential impairment of goodwill recorded in connection with the acquisition of Magellan had occurred (i.e., a triggering event). With the assistance of an independent valuation firm, Magellan's fair value was calculated via both market (comparable company) and income (discounted cash flows) approaches. Based upon these approaches, it was determined that the carrying value of the Magellan reporting unit did, in fact, exceed its fair value. As a result, an impairment charge of \$6,628, on both a pre-tax and after-tax basis, was recorded during the fiscal 2017 third quarter. Given all of the factors considered, we do not anticipate, at this time, any further goodwill impairment charge from the Magellan acquisition.

On May 17, 2017, the FDA issued a field safety notice advising customers to discontinue use of Magellan's lead testing systems with venous blood samples. This field safety notice was followed by product recall notices on May 25th and June 5th. Magellan's lead testing systems are capable of processing both capillary and venous blood samples. Magellan's LeadCare Plus and LeadCare Ultra systems, which accounted for approximately 10% of Magellan's annual revenues, are used predominantly with venous blood samples. Magellan's LeadCare and LeadCare II systems are predominantly used with capillary blood samples.

Subsequent to the issuances of these field safety and product recall notices, the FDA completed an inspection of Magellan's Quality System, and issued its Form 483, Inspectional Observations, on June 29, 2017, which was expectedly followed by a Warning Letter issued on October 23, 2017. The Warning Letter requires periodic reporting on our remediation progress. To date, we have satisfied our post-Warning Letter reporting requirements with the FDA. During the three and nine months ended June 30, 2018, we incurred approximately \$100 and \$900, respectively, in Quality System remediation costs, primarily related to regulatory consultants and studies required to reinstate our venous blood sample claim.

As a result of these matters, we expect to experience delays in reinstating venous blood sample testing on our LeadCare products, as well as in obtaining 510(k) clearance for new Magellan products. We also expect delays in obtaining export certifications for Magellan products during the remediation period.

6. 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, we followed the guidance in SEC Staff Accounting Bulletin 118 (SAB 118), regarding the application of ASC Topic 740 Income Taxes 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.

We substantially completed the accounting for the effects of the tax reform act during the quarter ended December 31, 2017, except for the effects related to the one-time deemed repatriation transition tax on unrepatriated foreign earnings (the repatriation transition tax). As a result, our financial statements for the nine months ended June 30, 2018 reflect these effects of the tax reform act as provisional based on a reasonable estimate of the income tax effects. We have included a provisional income tax payable in the amount of \$854 related to the repatriation transition tax. Within the accompanying Condensed Consolidated Balance Sheet as of June 30, 2018, \$68 of the provisional amount is reflected within current income taxes payable, with the remaining \$786 reflected as long-term income taxes payable within non-current liabilities. The provisional amount is based on tax attribute information currently available from foreign investments. We continue to gather and analyze information, including historical adjustments to earnings and profits of foreign subsidiaries, in order to complete the accounting for the effects of the estimated repatriation transition tax.

Accounting for the remaining income tax effects of the tax reform act which impact our tax provision has been substantially completed and are included in the accompanying Condensed Consolidated Financial Statements as of June 30, 2018. We recorded a one-time tax benefit of \$2,347 during the nine months ended June 30, 2018 resulting from the tax reform act, including an adjustment from the re-measurement of deferred tax assets and liabilities. Of this adjustment, \$1,695 was recorded during the first quarter and \$652 was recorded in the third quarter, reflecting adjustments resulting from finalization of the fiscal 2017 federal tax return. This re-measurement includes an estimate of the temporary differences expected to be realized during fiscal 2018 at a transitional blended federal rate of 24.5%. The remaining temporary differences were re-measured at the 21% federal rate.

7. Bank Credit Arrangements

In connection with the acquisition of Magellan Biosciences, Inc., and its wholly-owned subsidiary Magellan Diagnostics, Inc. (collectively, Magellan), on March 22, 2016 the Company entered into a \$60,000 five-year term loan with a commercial bank. The term loan requires quarterly principal and interest payments, with interest at a variable rate tied to LIBOR, and a balloon principal payment 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 2018 \$1,125, fiscal 2019 \$5,250, 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 June 30, 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 June 30, 2018 and September 30, 2017, the fair

value of the interest rate swap was \$1,689 and \$815, respectively, and is reflected as a non-current asset in the accompanying Condensed Consolidated Balance Sheets. This fair value was determined by reference to a third party valuation, 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 June 30, 2018 or September 30, 2017.

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 June 30, 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.

8. Reportable Segments 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, viral, respiratory, and parasitic infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, competent cells, and bioresearch reagents used by researchers and other diagnostic manufacturers.

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations for infectious disease products in Cincinnati, Ohio; manufacturing operations for products detecting elevated lead levels in blood 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.

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, business development and distribution facilities in Singapore and 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).

Amounts due from two Diagnostics distributor customers accounted for 15% and 11% of consolidated accounts receivable at June 30, 2018 and September 30, 2017, respectively. Revenues from these two distributor customers accounted for 28% of the Diagnostics segment third-party revenues during each of the three month periods ended June 30, 2018 and 2017, and 29% and 28% during the nine month periods ended June 30, 2018 and 2017, respectively. These distributors represented 19% and 20% of consolidated revenues for the fiscal 2018 and 2017 third quarters, respectively, and 21% and 20% for the respective year-to-date nine month periods, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 17% and 10% of the segment's third-party revenues during the three months ended June 30, 2018 and 2017, respectively, and 18% and 17% during the nine months ended June 30, 2018 and 2017, respectively.

Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Unallocated Costs and Eliminations(1)	Total
Three Months Ended June 30, 2018				
Net revenues -				
Third-party	\$ 36,368	\$ 15,369	\$	\$ 51,737
Inter-segment	80	96	(176)	
Operating income	7,166	3,647	(2,078)	8,735
Goodwill (June 30, 2018)	35,213	19,563		54,776
Other intangible assets, net (June 30, 2018)	22,749	1,226		23,975
Total assets (June 30, 2018)	183,233	71,375	(625)	253,983
Three Months Ended June 30, 2017				
Net revenues -				
Third-party	\$ 35,949	\$ 14,191	\$	\$ 50,140
Inter-segment	71	129	(200)	
Operating income (2)	914	3,388	2	4,304
Goodwill (September 30, 2017)	35,213	19,713		54,926
Other intangible assets, net (September 30, 2017)	24,973	1,731		26,704
Total assets (September 30, 2017)	180,226	69,938	(387)	249,777
Nine Months Ended June 30, 2018				
Net revenues -				
Third-party	\$ 113,640	\$ 46,831	\$	\$ 160,471
Inter-segment	281	363	(644)	
Operating income	22,926	10,007	(8,459)	24,474
Nine Months Ended June 30, 2017				
Net revenues -				
Third-party	\$ 107,529	\$ 43,545	\$	\$ 151,074
Inter-segment	278	361	(639)	
Operating income (2)	17,152	11,226	197	28,575

(1) Unallocated costs for the three and nine months ended June 30, 2018 total \$2,081 and \$8,475, respectively, and are comprised of Executive Transition and Realignment Costs, and Litigation Costs, as set forth within the accompanying Condensed Consolidated Statements of Operations. Eliminations consist of inter-segment transactions.

(2) Diagnostics operating income includes the effect of the Magellan goodwill impairment charge in the amount of \$6,628 during the three and nine month periods ended June 30, 2017.

Transactions between segments are accounted for at established intercompany prices for internal and management purposes, with all intercompany amounts eliminated in consolidation.

9. Litigation Matters

On May 17, 2017, Meridian filed a complaint in the United States District Court for the Southern District of Ohio, Western Division (Cincinnati) naming DiaSorin Inc. (DiaSorin) as a defendant. Meridian's complaint alleges DiaSorin has breached the 2010 Co-Development and License Agreement (the Agreement) between it and Meridian relating to the co-development of certain tests and diagnostic products, pursuant to which Meridian disclosed certain trade secrets and proprietary information. The lawsuit underlying Meridian's complaint alleges that DiaSorin breached the Agreement and used, and is currently using, Meridian's proprietary information and therefore seeks injunctive relief to protect Meridian's intellectual property and information with respect to its diagnostics products. Approximately \$815 and \$2,470 of expense for attorneys' fees related to this matter is included within the accompanying Condensed Consolidated Statements of Operations for the three and nine months ended June 30, 2018, respectively.

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 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. The Complaint seeks compensatory damages, injunctive relief and attorneys' fees to all members of the proposed class. Meridian filed a motion to dismiss the Complaint and that motion remains pending. Because the litigation is in preliminary stages, we do not have sufficient information 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 the accompanying Condensed Consolidated Statement of Operations for the fiscal year-to-date period ended June 30, 2018.

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 lawsuit underlying plaintiff's class action complaint seeks compensatory damages, injunctive relief, equitable relief and attorneys' fees to all members of the proposed class. By agreement of all parties, the derivative action has been stayed pending a decision on the motion to dismiss in the Forman action. Because nothing has occurred in the litigation, we do not have sufficient information 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 the accompanying Condensed Consolidated Statement of Operations for the fiscal year-to-date period ended June 30, 2018.

Approximately \$90 and \$630 of expense for attorneys' fees related to the above two class action matters is included within the accompanying Condensed Consolidated Statements of Operations for the three and nine months ended June 30, 2018, respectively. The Company maintains insurance covering these matters, which it believes to be sufficient, the deductible for which has been met.

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 \$270 of expense for attorneys' fees related to this matter is included within the accompanying Condensed Consolidated Statements of Operations for both the three and nine months ended June 30,

2018.

Page 13

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. Unless otherwise noted, increases or decreases are measured over the corresponding period of the prior fiscal year. This discussion should be read in conjunction with the financial statements and notes thereto beginning on page 1.

QUARTERLY HIGHLIGHTS

Highlighted by the continued implementation of the business structure realignment announced earlier this year, the effects of which are discussed throughout this MD&A, the third quarter of fiscal 2018 continued the progress and positive momentum of the first six months of the fiscal year. The realignment of our business structure is aimed at building a stronger, more sustainable organization and paving the way for future growth, resulting in the Company conducting operations through two business units, Diagnostics and Life Science, supported by a global corporate team.

RESULTS OF OPERATIONS

Three Months Ended June 30, 2018

Net earnings for the third quarter of fiscal 2018 were \$6,825, or \$0.16 per diluted share. The fiscal 2018 third quarter results include \$2,081 of costs associated with the transition to our new CEO and the realignment of other executive positions, and litigation costs (collectively, Executive transition and realignment costs, and litigation costs) (see Note 9 *Litigation Matters* of the accompanying Condensed Consolidated Financial Statements), along with certain one-time tax effects of the recently-enacted U.S. tax reform act. These non-routine items impacted fiscal 2018 third quarter earnings by \$897, or approximately \$0.02 per diluted share on a net of tax basis. The fiscal 2017 third quarter results include an impairment charge against Magellan goodwill (\$6,628, or approximately \$0.16 per diluted share). See **USE OF NON-GAAP MEASURES** below. Consolidated revenues increased 3% to \$51,737 for the third quarter of fiscal 2018 compared to the same period of the prior year (2% on a constant-currency basis). On an operating segment basis, revenues increased 1% (flat in constant-currency) and 8% (7% in constant-currency) for Diagnostics and Life Science, respectively.

Nine Months Ended June 30, 2018

For the nine month period ended June 30, 2018, net earnings were \$18,415, or \$0.43 per diluted share. The year-to-date fiscal 2018 results include \$8,475 of costs associated with the transition to our new CEO and the realignment of other executive positions, and litigation costs (collectively, Executive transition and realignment costs, and litigation costs) (see Note 9 *Litigation Matters* of the accompanying Condensed Consolidated Financial Statements), along with certain one-time tax effects of the recently-enacted U.S. tax reform act. These items impacted earnings by \$4,711, or approximately \$0.12 per diluted share on a net basis. The year-to-date fiscal 2017 results include an impairment charge against Magellan goodwill (\$6,628, or approximately \$0.16 per diluted share). See **USE OF NON-GAAP MEASURES** below. Consolidated revenues increased 6% to \$160,471 for the first nine months of fiscal 2018 compared to the same period of the prior year (5% on a constant-currency basis). On an operating segment basis, revenues increased 6% (4% in constant-currency) and 8% (6% in constant-currency) for Diagnostics and Life Science, respectively.

Update on Magellan Lead Testing

Magellan offers multiple lead testing systems that are capable of processing both capillary and venous blood samples. Magellan's LeadCare Plus and LeadCare Ultra systems, which accounted for approximately 10% of Magellan's annual revenues in fiscal 2016, are used predominantly with venous blood samples. Typically, the Ultra and Plus systems are used in a reference lab setting. Magellan's LeadCare II system is predominantly used with capillary blood samples and is typically used in a physician office setting. LeadCare II system revenue represented approximately 90% of our Magellan lead testing product revenues in fiscal 2016. The LeadCare II system is the only point-of-care system for testing lead exposure, receiving CLIA-waived status. Other methods for testing blood lead levels include Graphite Furnace Atomic Absorption Spectroscopy and Mass Spectrometry, which are typically performed in hospital and reference laboratory settings.

On May 17, 2017, the FDA issued a field safety notice advising customers to discontinue use of Magellan's lead testing systems with venous blood samples. This field safety notice was followed by product recall notices on May 25th and June 5th. Subsequent to the issuances of these field safety and product recall notices, the FDA completed an inspection of Magellan's Quality System, and issued its Form 483, Inspectional Observations, on June 29, 2017, which was expectedly followed by a Warning Letter issued on October 23, 2017. During our 2017 third fiscal quarter, it was determined that a potential impairment of goodwill recorded in connection with the acquisition of Magellan had occurred (i.e., a triggering event). An impairment charge of \$6,628, on both a pre-tax and after-tax basis, was recorded during the fiscal 2017 third quarter as set forth in Note 5 *Intangible Assets* of the accompanying Condensed Consolidated Financial Statements.

The Warning Letter requires periodic reporting on our remediation progress. To date, we have satisfied our post-Warning Letter reporting requirements with the FDA. During the three and nine months ended June 30, 2018, we incurred approximately \$100 and \$900, respectively, in remediation costs, primarily related to regulatory consultants and studies required to reinstate our venous blood sample claim. We expect remediation costs during the balance of the fiscal year to be in the \$100 to \$200 range. In the course of remediation, Magellan may encounter additional matters that warrant notifications to the FDA and/or customers regarding the use of its products. At this time, we do not believe that any such notifications would impact the ability to use the LeadCare systems with capillary blood samples.

Revenues for our blood-lead products for the nine month period ended June 30, 2018 were \$13,250, compared to \$13,174 in the same period of the prior fiscal year. This revenue increase despite the removal of the venous blood claim as noted above, reflects the continued placement of new LeadCare II systems in physician offices. Revenues of LeadCare II, utilizing capillary blood samples, increased approximately 15% during the nine month period ending June 30, 2018, compared to the same period of the prior fiscal year.

As set forth in Note 9 *Litigation Matters* of the accompanying Condensed Consolidated Financial Statements, 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.

USE OF NON-GAAP MEASURES

We have supplemented our reported GAAP financial information with information on net earnings, basic earnings per share and diluted earnings per share excluding the effects of executive transition and realignment costs, litigation costs, certain one-time tax effects of the tax reform act, and the impairment charge against Magellan goodwill, each of which is a non-GAAP measure. We have provided in the tables below reconciliations of net earnings, basic earnings per share and diluted earnings per share, with and without the effects of these non-routine items, for the three and nine month periods ended June 30, 2018 and June 30, 2017.

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.

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.

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Net Earnings -				
U.S. GAAP basis	\$ 6,825	\$ 240	\$ 18,415	\$ 15,831
Executive transition and realignment costs (1)	685		3,737	
Litigation costs (1)	864		2,467	
Goodwill impairment charge		6,628		6,628
One-time benefit from tax law change	(652)		(2,347)	
Repatriation transition tax			854	
Adjusted earnings	\$ 7,722	\$ 6,868	\$ 23,126	\$ 22,459
Net Earnings per Basic Common Share -				
U.S. GAAP basis	\$ 0.16	\$ 0.01	\$ 0.44	\$ 0.38
Executive transition and realignment costs (1)	0.02		0.09	
Litigation costs (1)	0.02		0.06	
Goodwill impairment charge		0.16		0.16
One-time benefit from tax law change	(0.02)		(0.06)	
Repatriation transition tax			0.02	
Adjusted Basic EPS (2)	\$ 0.18	\$ 0.16	\$ 0.55	\$ 0.53
Net Earnings per Diluted Common Share				
U.S. GAAP basis	\$ 0.16	\$ 0.01	\$ 0.43	\$ 0.37
Executive transition and realignment costs (1)	0.02		0.09	
Litigation costs (1)	0.02		0.06	
Goodwill impairment charge		0.16		0.16
One-time benefit from tax law change	(0.02)		(0.05)	
Repatriation transition tax			0.02	
Adjusted Diluted EPS (2)	\$ 0.18	\$ 0.16	\$ 0.54	\$ 0.53

- (1) These executive transition and realignment costs, and litigation costs are net of income tax effects of \$228 and \$304, respectively, for the three months ended June 30, 2018, and \$1,368 and \$903, respectively for the fiscal 2018 year-to-date period. These tax effects were calculated using the effective tax rates of the jurisdictions in

which the costs were incurred.

- (2) Due to rounding, the Net Earnings per Common Share for the following do not sum to their respective Adjusted EPS amounts: Net Earnings per Basic Common Share (fiscal 2017 quarterly and year-to-date periods); Net Earnings per Diluted Share (fiscal 2017 quarterly period and fiscal 2018 year-to-date period).

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 8 *Reportable Segments and Major Customers Information* 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.

	Three Months Ended			Nine Months Ended June 30,		
	2018	June 30, 2017	Inc (Dec)	2018	2017	Inc (Dec)
Diagnostics -						
Americas	\$ 30,653	\$ 30,810	(1)%	\$ 95,518	\$ 90,221	6%
EMEA	5,053	4,232	19%	16,130	14,907	8%
ROW	662	907	(27)%	1,992	2,401	(17)%
Total Diagnostics	36,368	35,949	1%	113,640	107,529	6%
Life Science -						
Americas	5,663	5,550	2%	16,242	16,681	(3)%
EMEA	5,653	4,633	22%	18,199	16,253	12%
ROW	4,053	4,008	1%	12,390	10,611	17%
Total Life Science	15,369	14,191	8%	46,831	43,545	8%
Consolidated	\$ 51,737	\$ 50,140	3%	\$ 160,471	\$ 151,074	6%
% of total revenues -						
Diagnostics	70%	72%		71%	71%	
Life Science	30%	28%		29%	29%	
Total	100%	100%		100%	100%	

Ex-Americas	30%	27%	30%	29%
-------------	-----	-----	-----	-----

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 *illumigene* platform
- 2) Immunoassays and lead tests on multiple technology platforms

Life Science

- 1) Molecular reagents
- 2) Immunological reagents

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

	Three Months Ended			Nine Months Ended June 30,		
	2018	2017	Inc (Dec)	2018	2017	Inc (Dec)
Diagnostics-						
Molecular assays	\$ 7,532	\$ 8,006	(6)%	\$ 26,227	\$ 25,194	4%
Immunoassays & lead tests	28,836	27,943	3%	87,413	82,335	6%
Total Diagnostics	\$ 36,368	\$ 35,949	1%	\$ 113,640	\$ 107,529	6%
Life Science-						
Molecular reagents	\$ 5,961	\$ 5,541	8%	\$ 17,911	\$ 15,996	12%
Immunological reagents	9,408	8,650	9%	28,920	27,549	5%
Total Life Science	\$ 15,369	\$ 14,191	8%	\$ 46,831	\$ 43,545	8%
% of Diagnostics revenues-						
Molecular assays	21%	22%		23%	23%	
Immunoassays & lead tests	79%	78%		77%	77%	
Total Diagnostics	100%	100%		100%	100%	
% of Life Science revenues-						
Molecular reagents	39%	39%		38%	37%	
Immunological reagents	61%	61%		62%	63%	
Total Life Science	100%	100%		100%	100%	

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

Diagnostics Products

Respiratory

The 2017-2018 flu season was particularly strong, as measured by the rate of laboratory-confirmed influenza hospitalizations (published by the CDC). Our respiratory products, which include tests for flu, RSV, Group A Strep, Pertussis, and Mycoplasma pneumonia, among others, have been strong performers in fiscal 2018, up \$600 (12%) during the third quarter and \$3,700 (20%) during the first nine months of the year.

H. pylori

Reflecting the ongoing conversion of serology testing to our antigen tests and buying patterns of certain customers, our *H. pylori* products have shown solid revenue growth thus far in fiscal 2018, up \$500 (6%) during the third quarter

and \$2,400 (10%) during the first nine months. 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. 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. We have introduced capabilities to identify resistance to Clarithromycin, the antibiotic commonly used to treat *H. pylori*. This is currently available in an Analyte Specific Reagent (ASR) format. We believe that identifying Clarithromycin resistance in conjunction with diagnosis enables better treatment decisions and patient outcomes. We continue to work on our *H. pylori*/Clarithromycin resistance assay and have identified improvements that we believe will enhance the workflow and the cost effectiveness of the test for the customer. In light of these changes, we are re-evaluating our clinical trial dates.

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, which represent approximately 15% of our total revenues, 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. In order to mitigate competition, our product development pipeline includes multiple new product initiatives for the detection of *H. pylori*. We are unable to provide 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. See Note 9 *Litigation Matters* of the accompanying Condensed Consolidated Financial Statements regarding related litigation.

Other Product Families

Revenues for our other diagnostic products have also maintained their aggregate levels relatively well during fiscal 2018 in the face of increased competition and the FDA notices described above in RESULTS OF OPERATIONS and in Note 5 *Intangible Assets* of the accompanying Condensed Consolidated Financial Statements. Revenues for such products decreased \$300 (1%) during the third quarter and increased \$500 (1%) during the first nine months, with *C. difficile* competition continuing to impact overall molecular product growth.

Life Science Products

During the third quarter of fiscal 2018, revenues from our Life Science segment increased 8%, with revenues from molecular reagent sales increasing 8% and revenues from immunological reagent sales increasing 9%. For the first nine months of fiscal 2018, revenues from our Life Science segment increased 8%, with revenues from molecular reagent sales increasing 12% and revenues from immunological reagent sales increasing 5%. Our molecular reagent products revenue growth was impacted by the movement in currency exchange rates since the fiscal 2017 periods, with revenues increasing 4% and 7% on a constant-currency basis over the third quarter and first nine months of fiscal 2017, respectively. Comparisons of our immunological reagent products fiscal 2017 year-to-date period was impacted by the fact that the 2017 second quarter revenue for such products was extraordinarily high due to a high level of contract manufacturing activity and the timing of orders from certain large customers. Overall, our Life Science segment continued to benefit from increased sales into China, with such sales totaling approximately \$2,400 during third quarter of fiscal 2018 and approximately \$6,000 during the year-to-date period representing increases of approximately 20% and 50% over the comparable periods of fiscal 2017.

Significant Customers

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

Gross Profit

	Three Months Ended June 30,			Nine Months Ended June 30,		
	2018	2017	Change	2018	2017	Change
Gross Profit	\$ 31,956	\$ 31,146	3%	\$ 98,311	\$ 93,662	5%
Gross Profit Margin	62%	62%	NONE	61%	62%	-1 point

The gross profit margin decreases experienced during the first nine months of fiscal 2018 primarily result from the combined effects of mix of products sold and operating segment mix.

Operating Expenses Segment Detail

	Three Months Ended June 30, 2018				Total Operating Expenses
	Research & Development	Selling & Marketing	General & Administrative	Other	
Fiscal 2017:					
Diagnostics	\$ 3,220	\$ 5,769	\$ 6,309	\$	\$ 15,298
Life Science	744	2,192	1,980		4,916
Unallocated Expenses				6,628	6,628
Total Expenses (2017 Quarter)	\$ 3,964	\$ 7,961	\$ 8,289	\$ 6,628	\$ 26,842
Fiscal 2018:					
Diagnostics	\$ 3,473	\$ 6,013	\$ 6,214	\$	\$ 15,700
Life Science	786	2,491	2,163		5,440
Unallocated Expenses				2,081	2,081
Total Expenses (2018 Quarter)	\$ 4,259	\$ 8,504	\$ 8,377	\$ 2,081	\$ 23,221

	Nine Months Ended June 30, 2018				Total Operating Expenses
	Research & Development	Selling & Marketing	General & Administrative	Other	
Fiscal 2017:					
Diagnostics	\$ 9,570	\$ 16,888	\$ 17,600	\$	\$ 44,058
Life Science	1,942	6,757	5,702		14,401
Unallocated Expenses				6,628	6,628
Total Expenses (2017 Year-to-Date)	\$ 11,512	\$ 23,645	\$ 23,302	\$ 6,628	\$ 65,087
Fiscal 2018:					
Diagnostics	\$ 10,937	\$ 18,527	\$ 19,616	\$	\$ 49,080
Life Science	2,308	7,435	6,539		16,282
Unallocated Expenses				8,475	8,475
Total Expenses (2018 Year-to-Date)	\$ 13,245	\$ 25,962	\$ 26,155	\$ 8,475	\$ 73,837

Operating Expenses Comparison to Prior Year Periods

	Three Months Ended June 30, 2018				Total Operating Expenses
	Research & Development	Selling & Marketing	General & Administrative	Other	

Edgar Filing: MERIDIAN BIOSCIENCE INC - Form 10-Q

2017 Expenses	\$ 3,964	\$ 7,961	\$ 8,289	\$ 6,628	\$ 26,842
% of Revenues	8%	16%	17%	13%	54%
Fiscal 2018 Increases (Decreases):					
Diagnostics	253	244	(95)		402
Life Science	42	299	183		524
Executive transition and realignment costs				913	913
Litigation costs				1,168	1,168
Goodwill impairment charge				(6,628)	(6,628)
2018 Expenses	\$ 4,259	\$ 8,504	\$ 8,377	\$ 2,081	\$ 23,221
% of Revenues	8%	16%	16%	4%	45%
% Increase (Decrease)	7%	7%	1%	(69)%	(13)%

	Nine Months Ended June 30, 2018				Total Operating
	Research & Development	Selling & Marketing	General & Administrative	Other	Expenses
2017 Expenses	\$ 11,512	\$ 23,645	\$ 23,302	\$ 6,628	\$ 65,087
% of Revenues	8%	16%	15%	4%	43%
Fiscal 2018 Increases (Decreases):					
Diagnostics	1,367	1,639	2,016		5,022
Life Science	366	678	837		1,881
Executive transition and realignment costs				5,105	5,105
Litigation costs				3,370	3,370
Goodwill impairment charge				(6,628)	(6,628)
2018 Expenses	\$ 13,245	\$ 25,962	\$ 26,155	\$ 8,475	\$ 73,837
% of Revenues	8%	16%	16%	5%	46%
% Increase	15%	10%	12%	28%	13%

Excluding the impact of the \$6,628 non-cash goodwill impairment in the third quarter of fiscal 2017 (reflected within Other in the above tables), total operating expenses increased during both the third quarter and first nine months of fiscal 2018, relating primarily to (i) executive transition and realignment costs; (ii) litigation costs; (iii) overall impact of the weakening of the U.S. dollar relative to the foreign currencies in which the Company's foreign operations incur expenses; and (iv) overall increases in spending in our Diagnostics segment, with such increased Diagnostics spending reflecting the following:

Increased R&D costs in connection with instrumentation development programs for Curian and *H. pylori* Clarithromycin resistance in an FDA-cleared IVD format, and clinical trials for our *illumigene* CMV test;

Increased sales and marketing headcount, coupled with increased commission and bonus payments made in connection with increased sales levels;

Increased Quality System remediation costs related to Magellan; and

Increased accrual of cash incentive compensation expenses (also for the Life Science segment).

Executive transition and realignment costs (reflected within Other in the above tables) totaled \$913 and \$5,105 for the quarterly and year-to-date periods, respectively. These costs reflect compensation and benefits for our Executive Chairman (formerly Chairman and CEO) during 2018, while we also have the compensation and benefits costs of a new CEO, along with executive terminations and related expenses incurred in the second and third quarters of fiscal 2018 in connection with realigning our business structure.

Litigation costs (reflected within Other in the above tables), which totaled \$1,168 and \$3,370 for the quarterly and year-to-date periods, respectively, relate to the matters discussed in Note 9 *Litigation Matters* of the accompanying Condensed Consolidated Financial Statements and Part II. Item 1 of this Quarterly Report on Form 10-Q.

Operating Income

Operating income increased 103% to \$8,735 for the third quarter of fiscal 2018, and decreased 14% to \$24,474 for the first nine months of fiscal 2018, as a result of the factors discussed above.

Income Taxes

The effective rate for income taxes was 21% and 22% for the fiscal 2018 third quarter and nine month year-to-date periods, respectively, compared to 94% and 43% during the corresponding fiscal 2017 periods (35% for both fiscal 2017 periods, excluding the effects of the Magellan goodwill impairment charge). These lower fiscal 2018 tax rates primarily result from the combined net impact of the following effects of the recently-enacted U.S. tax reform act (see Note 6 *Income Taxes* of the accompanying Condensed Consolidated Financial Statements):

Application of an approximate 24.5% blended federal rate due to the lowering of the applicable federal rate from 35% to 21%;

Recognizing a one-time \$2,347 tax benefit during fiscal 2018, including the re-measurement of deferred tax balances at the lower rate \$1,695 of which was recorded during the first quarter of fiscal 2018 and \$652 of which was recorded in the third quarter, reflecting adjustments resulting from the finalization of the fiscal 2017 federal tax return; and

Recording during the first quarter of fiscal 2018 a provisional one-time \$854 tax expense related to the estimated repatriation transition tax on foreign earnings.

Excluding the effects of these one-time tax effects, we expect the overall effective tax rate for the fiscal year ending September 30, 2018 to approximate 27%-28%.

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 (including Brexit), 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 collectibility of our customer accounts receivable, impact credit terms with our vendors, or disrupt the supply of raw materials and services.

Net cash provided by operating activities totaled \$23,582 for the first nine months of fiscal 2018, a 27% decrease from the \$32,491 provided during the first nine months of fiscal 2017. While reflecting the timing of payments from customers, and to suppliers and taxing authorities, this decrease also results in large part from (i) increased inventory levels during fiscal 2018, largely related to continued expansion in Asia; and (ii) increased prepaid U.S. federal tax payments as of June 30, 2018. The effect of these cash-decreasing items was partially offset by the effects of increased accrued employee compensation costs during the fiscal 2018 period largely as a result of executive realignment activities and accrued incentive compensation, coupled with the impact of such accruals decreasing during the fiscal 2017 period, reflecting the payment of discretionary bonuses and the timing of regularly scheduled payroll payments. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and dividends during the next 12 months.

The indicated annual cash dividend rate for fiscal 2018 was established at \$0.50 per share in accordance with the stated policy guidelines of the payout ratio to range between 75% and 85% of each fiscal year's net earnings. Consistent with this annual indicated dividend rate, a cash dividend of \$0.125 per share was declared for each of the first three quarters of fiscal 2018.

Capital Resources

As described in Note 7 *Bank Credit Arrangements* of the accompanying Condensed Consolidated Financial Statements, in connection with the acquisition of Magellan, 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. In addition, we have a \$30,000 revolving credit facility with a commercial bank that expires March 31, 2021. As of July 31, 2018, 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 nine months of fiscal 2018 or during the full year of fiscal 2017.

Our capital expenditures are estimated to range between approximately \$4,000 to \$5,000 for fiscal 2018, 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 special-purpose financing vehicles or have 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, 2017.

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 June 30, 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 June 30, 2018.

Changes in Internal Control over Financial Reporting

There were no 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 June 30, 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 9 *Litigation Matters* 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 2017 Annual Report on Form 10-K in response to Item 1A of 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 June 30, 2018 filed with the SEC on August 9, 2018, formatted in XBRL includes:
(i) Condensed Consolidated Statements of Operations for the three and nine months ended June 30, 2018 and 2017; (ii) Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended June 30, 2018 and 2017; (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended June 30, 2018 and 2017; (iv) Condensed Consolidated Balance Sheets as of June 30, 2018 and September 30, 2017; (v) Condensed Consolidated Statement of Shareholders' Equity for the nine months ended June 30, 2018; 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: August 9, 2018

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

(Principal Financial and Accounting Officer)