MERIDIAN BIOSCIENCE INC Form 10-Q February 07, 2018 Table of Contents

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, 2017

OR

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

For the transition period from ______ to _____

Commission file number 0-14902

MERIDIAN BIOSCIENCE, INC.

Incorporated under the laws of Ohio

31-0888197

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

3471 River Hills Drive

Cincinnati, Ohio 45244

(513) 271-3700

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 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
Common Stock, no par value

Outstanding January 31, 2018 42,307,742

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

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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 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, and natural disasters and other events could have a materially adverse effect on Meridian s results of operations and revenues. We have identified a material weakness in our internal control over financial reporting that, if 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 N	
	End	
	Decem	,
NEW DEVENTIES	2017	2016
NET REVENUES	\$ 52,283	\$46,809
COST OF SALES	20,497	17,770
GROSS PROFIT	31,786	29,039
OPERATING EXPENSES		
Research and development	4,496	3,597
Selling and marketing	8,842	7,618
General and administrative	8,904	7,739
CEO transition and litigation costs	1,483	
Total operating expenses	23,725	18,954
OPERATING INCOME	8,061	10,085
OTHER INCOME (EXPENSE)		
Interest income	72	22
Interest expense	(395)	(423)
Other, net	(80)	(25)
Total other expense	(403)	(426)
	- (- 0	0.670
EARNINGS BEFORE INCOME TAXES	7,658	9,659
INCOME TAX PROVISION	1,356	3,380
NET EARNINGS	\$ 6,302	\$ 6,279
BASIC EARNINGS PER COMMON SHARE	\$ 0.15	\$ 0.15
DILUTED EARNINGS PER COMMON SHARE	\$ 0.15	\$ 0.15
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC	42,263	42,159
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARE UNITS	399	376
	42,662	42,535

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED

ANTI-DILUTIVE SECURITIES:

Common share options and restricted share units	1,034	715
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.125	\$ 0.20

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Comprehensive Income (Unaudited)

(in thousands)

Three Months Ended

	December 31,		
	2017	2016	
NET EARNINGS	\$ 6,302	\$ 6,279	
Other comprehensive income (loss):			
Foreign currency translation adjustment	291	(1,423)	
Unrealized gain on cash flow hedge	341	1,560	
Income taxes related to items of other comprehensive income	(112)	(589)	
Other comprehensive income (loss), net of tax	520	(452)	
COMPREHENSIVE INCOME	\$ 6,822	\$ 5,827	

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

Three Months Ended December 31,	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	\$ 6,302	\$ 6,279
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	1,146	1,078
Amortization of intangible assets	938	968
Amortization of deferred instrument costs	201	257
Stock-based compensation	1,759	1,884
Deferred income taxes	(1,624)	2,091
Change in:		
Accounts receivable	(2,989)	2,191
Inventories	(2,353)	(169)
Prepaid expenses and other current assets	87	(406)
Accounts payable and accrued expenses	1,315	(913)
Income taxes payable	497	44
Other, net	(108)	(311)
Net cash provided by operating activities	5,171	12,993
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(1,234)	(1,392)
Net cash used for investing activities	(1,234)	(1,392)
CASH ELOWIC EDOM FINANCING ACTIVITIES		
CASH FLOWS FROM FINANCING ACTIVITIES	(5.200)	(9.440)
Dividends paid	(5,288)	(8,440)
Payments on term loan	(1,125)	(750)
Proceeds and tax benefits from exercises of stock options		301
Net cash used for financing activities	(6,413)	(8,889)
Effect of Exchange Rate Changes on Cash and Equivalents	115	(662)
Net (Decrease) Increase in Cash and Equivalents	(2,361)	2,050
Cash and Equivalents at Beginning of Period	57,072	47,226
Cash and Equivalents at End of Period	\$ 54,711	\$49,276

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(in thousands)

ASSETS

	December 31, 2017 (Unaudited)		tember 30, 2017
CURRENT ASSETS			
Cash and equivalents	\$ 54,711	\$	57,072
Accounts receivable, less allowances of \$306 and \$307	32,136		29,106
Inventories	43,644		41,493
Prepaid expenses and other current assets	6,126		6,204
Total current assets	136,617		133,875
PROPERTY, PLANT AND EQUIPMENT, at Cost			
Land	1,164		1,162
Buildings and improvements	32,244		32,207
Machinery, equipment and furniture	49,367		48,836
Construction in progress	2,374		1,895
Subtotal Less: accumulated depreciation and amortization Net property, plant and equipment	85,149 54,749 30,400		84,100 53,590 30,510
OTHER ASSETS			
Goodwill	54,997		54,926
Other intangible assets, net	25,777		26,704
Restricted cash	1,000		1,000
Deferred instrument costs, net	1,415		1,368
Fair value of interest rate swap	1,156		815
Deferred income taxes	146		158
Other assets	443		421
Other ussets	113		721
Total other assets	84,934		85,392
TOTAL ASSETS	\$ 251,951	\$	249,777

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(dollars in thousands)

LIABILITIES AND SHAREHOLDERS EQUITY

	December 31, 2017 (Unaudited)		September 30 2017	
CURRENT LIABILITIES				
Accounts payable	\$	8,507	\$	7,719
Accrued employee compensation costs		4,801		4,536
Current portion of acquisition consideration		2,095		2,095
Other accrued expenses		2,795		2,789
Current portion of long-term debt		4,500		4,500
Income taxes payable		776		1,248
Total current liabilities		23,474		22,887
NON-CURRENT LIABILITIES				
Acquisition consideration		235		235
Post-employment benefits		2,551		2,468
Long-term debt		49,030		50,147
Long-term income taxes payable		854		
Deferred income taxes		2,929		4,455
Total non-current liabilities		55,599		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, 42,307,542 and 42,207,317 shares issued, respectively				
Additional paid-in capital		127,367		125,608
Retained earnings		47,937		46,923
Accumulated other comprehensive loss		(2,426)		(2,946)
Total shareholders equity		172,878		169,585
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$	251,951	\$	249,777

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

(dollars and shares in thousands)

	Common	Additional		Accum	ulated Other	r	Total
	Shares	Paid-In	Retained	l Comprehensive		Sha	areholders
	Issued	Capital	Earnings	Inco	me (Loss)		Equity
Balance at September 30, 2017	42,207	\$ 125,608	\$ 46,923	\$	(2,946)	\$	169,585
Cash dividends paid			(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
Balance at December 31, 2017	42,307	\$ 127,367	\$ 47,937	\$	(2,426)	\$	172,878

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Dollars in Thousands, Except Per Share Amounts

(Unaudited)

1. Basis of Presentation

The interim condensed consolidated financial statements are unaudited and are prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information, and the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of Management, the interim financial statements include all normal adjustments and disclosures necessary to present fairly the Company s financial position as of December 31, 2017, the results of its operations for the three month periods ended December 31, 2017 and 2016, and its cash flows for the three month periods ended December 31, 2017 and 2016. 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 later in fiscal 2018.

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.

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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:

	December :	31, 2017	Septemb 201'	
	Cash and Equivalents	Other Assets	Cash and Equivalents	Other Assets
Institutional money market funds	\$ 20,155	\$	\$ 20,104	\$
Cash on hand -				
Restricted		1,000		1,000
Unrestricted	34,556		36,968	
Total	\$ 54,711	\$1,000	\$ 57,072	\$1,000

4. Inventories

Inventories are comprised of the following:

	ember 31, 2017	-	ember 30, 2017
Raw materials	\$ 7,989	\$	6,575
Work-in-process	12,110		11,559
Finished goods - instruments	1,271		1,460
Finished goods - kits and reagents	22,274		21,899
Total	\$ 43,644	\$	41,493

5. <u>Intangible Assets</u>

A summary of our acquired intangible assets subject to amortization, as of December 31, 2017 and September 30, 2017, is as follows:

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	December 31, 2017		December 31, 2017 See		December 31, 2017 Sep		December 31, 2017		December 31, 2017 Sept		ber 3	0, 2017
	Gross		Gross									
	Carrying	Acc	umulated	Carrying	Acc	umulated						
	Value	Am	ortization	Value	Am	ortization						
Manufacturing technologies, core products and cell lines	\$ 22,341	\$	13,117	\$ 22,332	\$	12,807						
Trade names, licenses and patents	8,699		4,632	8,689		4,398						
Customer lists, customer relationships and supply												
agreements	24,586		12,190	24,562		11,854						
Non-compete agreements	720		630	720		540						
	\$ 56,346	\$	30,569	\$ 56,303	\$	29,599						

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The actual aggregate amortization expense for these intangible assets was \$938 and \$968 for the three months ended December 31, 2017 and 2016, 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 \$2,628, fiscal 2019 \$3,343, fiscal 2020 \$3,178, fiscal 2021 \$2,561, fiscal 2022 \$2,182, and fiscal 2023 \$2,170.

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 account 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 first quarter of fiscal 2018, we incurred approximately \$500 in Quality System remediation costs, primarily related to regulatory consultants.

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. In light of these factors and their impacts, 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). 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.

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 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 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 quarter ended December 31, 2017 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 non-current income tax payable in the amount of \$854 related to the repatriation transition tax. 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 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 includes 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%.

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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 - \$3,375, 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 December 31, 2017 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, 2017 and September 30, 2017, the fair value of the interest rate swap was \$1,156 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 December 31, 2017 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 December 31, 2017, 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 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, 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; Magellan s 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).

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Amounts due from two Diagnostics distributor customers accounted for 25% and 11% of consolidated accounts receivable at December 31, 2017 and September 30, 2017, respectively. Revenues from these two distributor customers accounted for 38% and 23% of the Diagnostics segment third-party revenues during the three months ended December 31, 2017 and 2016, respectively, and represented 27% and 17% of consolidated revenues for the fiscal 2018 and 2017 first quarters, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 15% and 19% of the segment s third-party revenues during the three months ended December 31, 2017 and 2016, respectively.

Segment information for the interim periods is as follows:

			Life			
	Dia	agnostics	Science	Elimi	nations(1)	Total
Three Months Ended December 31, 2017						
Net revenues -						
Third-party	\$	37,490	\$ 14,793	\$		\$ 52,283
Inter-segment		121	192		(313)	
Operating income		5,291	2,784		(14)	8,061
Goodwill (December 31, 2017)		35,213	19,784			54,997
Other intangible assets, net (December 31,						
2017)		24,202	1,575			25,777
Total assets (December 31, 2017)		179,943	72,480		(472)	251,951
Three Months Ended December 31, 2016						
Net revenues -						
Third-party	\$	33,808	\$ 13,001	\$		\$ 46,809
Inter-segment		79	125		(204)	
Operating income		6,643	3,267		175	10,085
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

(1) Eliminations consist of inter-segment transactions.

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

9. <u>Legal Matters</u>

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 \$730 of expense related to this matter is included within the accompanying Condensed Consolidated Statement of Operations for the fiscal quarter ended December 31, 2017.

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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. 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 lawsuit underlying plaintiff s class action complaint seeks compensatory damages, injunctive relief and attorneys fees to all members of the proposed class. Because the litigation and related discovery are 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 quarter ended December 31, 2017.

On December 6, 2017, Michael Edelson filed a class action 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. Because the litigation and related discovery are 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 quarter ended December 31, 2017.

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.

QUARTERLY HIGHLIGHTS

The first quarter of fiscal 2018 proved to be a successful quarter; a quarter highlighted by the following, the effects of which are discussed throughout this MD&A:

double-digit percentage revenue growth in both our Diagnostics and Life Science reportable segments compared to the fiscal 2017 first quarter;

significant executive leadership announcements of Mr. Jack Kenny as Meridian s new CEO, and Mr. Jack Kraeutler continuing to serve the Company as Executive Chairman of the Board; and

U.S. Congress passage of the Tax Cuts and Jobs Act (the tax reform act).

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RESULTS OF OPERATIONS

Three Months Ended December 31, 2017

Net earnings for the first quarter of fiscal 2018 totaled \$6,302, or \$0.15 per diluted share, relatively flat compared to the net earnings for the first quarter of fiscal 2017 of \$6,279, or \$0.15 per diluted share. The fiscal 2018 first quarter results include \$1,483 of costs associated with the transition to our new CEO and litigation costs (collectively, CEO transition and litigation costs) (see Note 9 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 \$239, or less than \$0.01 per diluted share on a net basis (see USE OF NON-GAAP MEASURES below). Consolidated revenues increased 12% to \$52,283 for the first quarter of fiscal 2018 compared to the same period of the prior year (10% on a constant-currency basis).

Revenues for the Diagnostics segment for the first quarter of fiscal 2018 increased 11% compared to the first quarter of fiscal 2017 (10% on a constant-currency basis), comprised of a 12% increase in molecular assay products and a 10% increase in immunoassay and lead testing products. With a 12% increase in its molecular components business and a 15% increase in its immunoassay components business, revenues of our Life Science segment increased by 14% during the first quarter of fiscal 2018 compared to the first quarter of fiscal 2017, increasing 12% on a constant-currency basis.

Our outlook for Magellan's LeadCare II testing volume continues to be healthy. In the time period since the FDA released its Safety Notification (which pertained to venous blood lead testing performed on the systems produced by Magellan), nearly 700 new LeadCare II systems utilizing capillary blood samples have been placed in physician offices and clinics. Quality System remediation costs in the first quarter of fiscal 2018 associated with the Magellan FDA matter totaled approximately \$500 pre-tax, resulting in a total impact of less than \$0.01 on diluted earnings per share for the quarter. Remediation costs in the remainder of fiscal 2018 are expected to be approximately \$250 pre-tax, or less than \$0.01 impact on diluted earnings per share. Remediation costs relate primarily to professional fees for regulatory consultants and periodic Quality System audits. 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. In addition, at this time, we do not anticipate any further significant impact on our results of operations or financial condition.

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 CEO transition costs, litigation costs and certain one-time tax effects of the tax reform act, 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 fiscal quarters ended December 31, 2017 and December 31, 2016.

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

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.

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	End Decemb	Three Months Ended December 31,	
N . E	2017	2016	
Net Earnings -	Φ. 6.202	Φ. 6. 270	
U.S. GAAP basis	\$ 6,302	\$6,279	
CEO transition and litigation costs (1)	1,080		
One-time benefit from tax law change	(1,695)		
Repatriation transition tax	854		
Adjusted earnings	\$ 6,541	\$ 6,279	
Net Earnings per Basic Common Share -			
U.S. GAAP basis	\$ 0.15	\$ 0.15	
CEO transition and litigation costs (1)	0.03		
One-time benefit from tax law change	(0.04)		
Repatriation transition tax	0.02		
Adjusted Basic EPS (2)	\$ 0.15	\$ 0.15	
Net Earnings per Diluted Common Share -			
U.S. GAAP basis	\$ 0.15	\$ 0.15	
CEO transition and litigation costs (1)	0.03		
One-time benefit from tax law change	(0.04)		
Repatriation transition tax	0.02		
Adjusted Diluted EPS (2)	\$ 0.15	\$ 0.15	

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⁽¹⁾ These CEO transition and litigation costs are net of income tax effects of \$403, which were calculated using the effective tax rates of the jurisdictions in which the costs were incurred.

⁽²⁾ Neither Net Earnings per Basic Common Share nor Net Earnings per Diluted Common Share sum to their respective Adjusted EPS amounts due to rounding.

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 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 Mo	Three Months Ended December 31,				
	2017	2016	Inc (Dec)			
Diagnostics -						
Americas	\$ 31,462	\$ 27,569	14%			
EMEA	5,341	5,662	(6)%			
ROW	687	577	19%			
Total Diagnostics	37,490	33,808	11%			
Life Science -						
Americas	5,351	5,399	(1)%			
EMEA	5,106	4,898	4%			
ROW	4,336	2,704	60%			
Total Life Science	14,793	13,001	14%			
Consolidated	\$ 52,283	\$ 46,809	12%			
% of total revenues -						
Diagnostics	72%	72%				
Life Science	28%	28%				
Total	100%	100%				

Ex-Americas 30% 30%

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