MERIDIAN BIOSCIENCE INC Form 10-Q May 10, 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 March 31, 2018

OR

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-14902

MERIDIAN BIOSCIENCE, INC.

**Incorporated under the laws of Ohio** 

31-0888197

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

**3471 River Hills Drive** 

Cincinnati, Ohio 45244

(513) 271-3700

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

Indicate by check mark whether the registrant has submitted electronically 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 April 30, 2018 42,344,282

### MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

## TABLE OF CONTENTS TO QUARTERLY REPORT ON FORM 10-Q

DADTI	EINANCIAL INFORMATION	Page(s)
PART I.	FINANCIAL INFORMATION	
Item 1.	<u>Financial Statements (Unaudited)</u> <u>Condensed Consolidated Statements of Operations Three and Six Months Ended March 31, 2018 and 2017</u>	1
	Condensed Consolidated Statements of Comprehensive Income Three and Six Months Ended March 31, 2018 and 2017	2
	Condensed Consolidated Statements of Cash Flows Six Months Ended March 31, 2018 and 2017	3
	Condensed Consolidated Balance Sheets March 31, 2018 and September 30, 2017	4-5
	Condensed Consolidated Statement of Changes in Shareholders Equity Six Months Ended March 31, 2018	6
	Notes to Condensed Consolidated Financial Statements	7-13
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	14-23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	23
Item 4.	Controls and Procedures	23
PART II.	OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	24
Item 1A.	Risk Factors	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 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. 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 M End Marc	led h 31,	Six Montl Marc	h 31,
	2018	2017	2018	2017
NET REVENUES	\$ 56,451	\$ 54,125	\$ 108,734	\$ 100,934
COST OF SALES	21,882	20,648	42,379	38,418
GROSS PROFIT	34,569	33,477	66,355	62,516
OPERATING EXPENSES				
Research and development	4,222	3,951	8,702	7,548
Selling and marketing	8,648	8,066	17,458	15,684
General and administrative	9,110	7,274	18,062	15,013
Executive transition and realignment costs	3,458	7,274	4,192	13,013
Litigation costs	1,453		2,202	
Litigation costs	1,733		2,202	
Total operating expenses	26,891	19,291	50,616	38,245
OPERATING INCOME	7,678	14,186	15,739	24,271
OTHER INCOME (EXPENSE)				
Interest income	90	29	162	51
Interest expense	(379)	(408)	(774)	(831)
Other, net	(165)	383	(245)	358
Total other income (expense)	(454)	4	(857)	(422)
EARNINGS BEFORE INCOME TAXES	7,224	14,190	14,882	23,849
INCOME TAX PROVISION	1,936	4,878	3,292	8,258
	-,,	1,0,0	-,	-,
NET EARNINGS	\$ 5,288	\$ 9,312	\$ 11,590	\$ 15,591
BASIC EARNINGS PER COMMON SHARE	\$ 0.12	\$ 0.22	\$ 0.27	\$ 0.37
DILUTED EARNINGS PER COMMON SHARE	\$ 0.12	\$ 0.22	\$ 0.27	\$ 0.37
WEIGHTED AVERAGE NUMBER OF COMMON SHARES				
OUTSTANDING - BASIC	42,323	42,202	42,289	42,177
	409	366	404	362

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EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARE UNITS				
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED	42,732	42,568	42,693	42,539
ANTI-DILUTIVE SECURITIES:				
Common share options and restricted share units	1,021	1,001	1,015	871
DIVIDENDS DECLARED PER COMMON SHARE	\$ 0.125	\$ 0.125	\$ 0.250	\$ 0.325

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

Page 1

# MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

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

(dollars in thousands)

	Three Mon Marc		Six Montl Marc	
	2018	2017	2018	2017
NET EARNINGS	\$ 5,288	\$ 9,312	\$11,590	\$ 15,591
Other comprehensive income (loss):				
Foreign currency translation adjustment	926	512	1,217	(911)
Unrealized gain on cash flow hedge	424	128	765	1,688
Income taxes related to items of other comprehensive income	(107)	(24)	(219)	(613)
Other comprehensive income, net of tax	1,243	616	1,763	164
COMPREHENSIVE INCOME	\$ 6,531	\$ 9,928	\$13,353	\$ 15,755

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

Page 2

# MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

## **Condensed Consolidated Statements of Cash Flows (Unaudited)**

### (dollars in thousands)

Six Months Ended March 31,	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	\$ 11,590	\$ 15,591
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	2,236	2,154
Amortization of intangible assets	1,883	1,904
Amortization of deferred instrument costs	401	500
Stock-based compensation	1,975	2,360
Deferred income taxes	(1,576)	1,982
Change in:		
Accounts receivable	(4,185)	(298)
Inventories	(2,370)	2,248
Prepaid expenses and other current assets	754	2,684
Accounts payable and accrued expenses	3,746	(3,415)
Income taxes payable	(775)	146
Other, net	160	(724)
Net cash provided by operating activities	13,839	25,132
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(2,160)	(2,273)
Net cash used for investing activities	(2,160)	(2,273)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends paid	(10,577)	(13,715)
Payments on term loan	(2,250)	(1,500)
Proceeds and tax benefits from exercises of stock options		303
Net cash used for financing activities	(12,827)	(14,912)
Effect of Exchange Rate Changes on Cash and Equivalents	476	(428)
Net (Decrease) Increase in Cash and Equivalents	(672)	7,519
Cash and Equivalents at Beginning of Period	57,072	47,226
	·	
Cash and Equivalents at End of Period	\$ 56,400	\$ 54,745

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

Page 3

# MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

### **Condensed Consolidated Balance Sheets**

### (dollars in thousands)

### **ASSETS**

	March 31, 2018 (Unaudited)		tember 30, 2017
CURRENT ASSETS			
Cash and equivalents	\$ 56,400	\$	57,072
Accounts receivable, less allowances of \$326 and \$307	33,793		29,106
Inventories	43,794		41,493
Prepaid expenses and other current assets	5,485		6,204
Total current assets	139,472		133,875
PROPERTY, PLANT AND EQUIPMENT, at Cost			
Land	1,169		1,162
Buildings and improvements	32,293		32,207
Machinery, equipment and furniture	50,366		48,836
Construction in progress	2,356		1,895
Subtotal Less: accumulated depreciation and amortization	86,184 55,923		84,100 53,590
Net property, plant and equipment	30,261		30,510
OTHER ASSETS			
Goodwill	55,409		54,926
Other intangible assets, net	24,885		26,704
Restricted cash	1,000		1,000
Deferred instrument costs, net	1,388		1,368
Fair value of interest rate swap	1,580		815
Deferred income taxes	107		158
Other assets	445		421
Total other assets	84,814		85,392
TOTAL ASSETS	\$ 254,547	\$	249,777

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

Page 4

# MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

### **Condensed Consolidated Balance Sheets**

(dollars in thousands)

### LIABILITIES AND SHAREHOLDERS EQUITY

	March 31, 2018 (Unaudited)		Sep	tember 30, 2017
CURRENT LIABILITIES				
Accounts payable	\$	7,564	\$	7,719
Accrued employee compensation costs		8,355		4,536
Current portion of acquisition consideration		2,095		2,095
Other accrued expenses		2,899		2,789
Current portion of long-term debt		4,500		4,500
Income taxes payable		368		1,248
Total current liabilities		25,781		22,887
NON-CURRENT LIABILITIES				
Acquisition consideration		235		235
Post-employment benefits		2,492		2,468
Long-term debt		47,914		50,147
Long-term income taxes payable		854		
Deferred income taxes		2,935		4,455
Total non-current liabilities		54,430		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, 42,344,042 and 42,207,317 shares issued, respectively				
Additional paid-in capital		127,583		125,608
Retained earnings		47,936		46,923
Accumulated other comprehensive loss		(1,183)		(2,946)
Total shareholders equity		174,336		169,585
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$	254,547	\$	249,777

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

Page 5

# MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES

### 

(dollars and shares in thousands)

	Common	Additional		Accumu	ulated Other	r	Total
	Shares	Paid-In	Retained	Comp	rehensive	Sha	areholders
	Issued	Capital	Earnings	Incor	ne (Loss)		Equity
Balance at September 30, 2017	42,207	\$ 125,608	\$ 46,923	\$	(2,946)	\$	169,585
Cash dividends paid			(10,577)				(10,577)
Conversion of restricted share units	137						
Stock compensation expense		1,975					1,975
Net earnings			11,590				11,590
Foreign currency translation adjustment					1,217		1,217
Hedging activity, net of tax					546		546
Balance at March 31, 2018	42,344	\$ 127,583	\$ 47,936	\$	(1,183)	\$	174,336

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

Page 6

### 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 March 31, 2018, the results of its operations for the three and six month periods ended March 31, 2018 and 2017, and its cash flows for the six month periods ended March 31, 2018 and 2017. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company s fiscal 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 six months of fiscal 2018, our tax provision included a \$170 charge for application of ASU 2016-09.

Page 7

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:

	March 31	l, <b>2018</b>	Septemb 201	
	Cash and Equivalents	Other Assets	Cash and Equivalents	Other Assets
Institutional money market funds	\$ 20,224	\$	\$ 20,104	\$
Cash on hand -				
Restricted		1,000		1,000
Unrestricted	36,176		36,968	
Total	\$ 56,400	\$1,000	\$ 57,072	\$1,000

### 4. <u>Inventories</u>

Inventories are comprised of the following:

	March 31, 2018	Sep	tember 30, 2017
Raw materials	\$ 7,645	\$	6,575
Work-in-process	12,781		11,559
Finished goods - instruments	1,027		1,460
Finished goods - kits and reagents	22,341		21,899
Total	\$ 43,794	\$	41,493

Page 8

### 5. <u>Intangible Assets</u>

A summary of our acquired intangible assets subject to amortization, as of March 31, 2018 and September 30, 2017, is as follows:

	March 31, 2018 Gross			Septem Gross	ber 30	), 2017
	Carrying Value		umulated ortization	Carrying Value		umulated ortization
Manufacturing technologies, core products and						
cell lines	\$22,391	\$	13,469	\$ 22,332	\$	12,807
Trade names, licenses and patents	8,758		4,905	8,689		4,398
Customer lists, customer relationships and						
supply agreements	24,721		12,611	24,562		11,854
Non-compete agreements	720		720	720		540
-						
	\$ 56,590	\$	31,705	\$ 56,303	\$	29,599

The actual aggregate amortization expense for these intangible assets was \$945 and \$936 for the three months ended March 31, 2018 and 2017, respectively, and \$1,883 and \$1,904 for the six months ended March 31, 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 \$1,701, fiscal 2019 \$3,361, fiscal 2020 \$3,193, fiscal 2021 \$2,562, 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 25<sup>th</sup> and June 5<sup>th</sup>. 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 six months ended March 31, 2018, we incurred approximately \$300 and \$800, 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. 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. See Note 10 Subsequent Events .

Page 9

### 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 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 six months ended March 31, 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 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 March 31, 2018. We recorded a one-time tax benefit of \$1,695 in the first quarter 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 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 \$2,250, 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 March 31, 2018 approximates the current carrying value reflected in the accompanying Condensed Consolidated Balance Sheet.

In order to limit exposure to volatility in the LIBOR interest rate, the Company and the commercial bank also entered into an interest rate swap that effectively converts the variable interest rate on the term loan to a fixed rate of 2.76%. With an initial notional balance of \$60,000, the interest rate swap was established with critical terms identical to those of the term loan, including (i) notional reduction amounts and dates; (ii) LIBOR settlement rates; (iii) rate reset dates; and (iv) term/maturity. Due to this, the interest rate swap has been designated as an effective cash flow hedge, with changes in fair value reflected as a separate component of other comprehensive income in the accompanying Condensed Consolidated Statements of Comprehensive Income. At March 31, 2018 and September 30, 2017, the fair value of the interest rate swap was \$1,580 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.

Page 10

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 March 31, 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 March 31, 2018, the Company is in compliance with all covenants. The Company is also required to maintain a compensating cash balance with the bank in the amount of \$1,000, and is in compliance with this requirement.

### 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 25% and 11% of consolidated accounts receivable at March 31, 2018 and September 30, 2017, respectively. Revenues from these two distributor customers accounted for 27% and 28% of the Diagnostics segment third-party revenues during the three months ended March 31, 2018 and 2017, respectively, and 30% and 27% during the six month periods ended March 31, 2018 and 2017, respectively. These distributors represented 19% of consolidated revenues for each of the fiscal 2018 and 2017 second quarters and 21% and 19% for the respective year-to-date six month periods, respectively.

Within our Life Science segment, two diagnostic manufacturing customers accounted for 22% and 21% of the segment s third-party revenues during the three months ended March 31, 2018 and 2017, respectively, and 19% and 20% during the six months ended March 31, 2018 and 2017, respectively.

Page 11

Segment information for the interim periods is as follows:

					Co	allocated osts and	
	Dia	agnostics	Life	e Science	Elimi	inations(1)	Total
Three Months Ended March 31, 2018							
Net revenues -							
Third-party	\$	39,782	\$	16,669	\$		\$ 56,451
Inter-segment		80		75		(155)	
Operating income		8,986		3,576		(4,884)	7,678
Goodwill (March 31, 2018)		35,213		20,196			55,409
Other intangible assets, net (March 31,							
2018)		23,430		1,455			24,885
Total assets (March 31, 2018)		179,825		75,288		(566)	254,547
Three Months Ended March 31, 2017							
Net revenues -							
Third-party	\$	37,772	\$	16,353	\$		\$ 54,125
Inter-segment		128		107		(235)	
Operating income		9,595		4,571		20	14,186
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
Six Months Ended March 31, 2018							
Net revenues -							
Third-party	\$	77,272	\$	31,462	\$		\$ 108,734
Inter-segment		201		267		(468)	
Operating income		15,760		6,360		(6,381)	15,739
Six Months Ended March 31, 2017							
Net revenues -							
Third-party	\$	71,580	\$	29,354	\$		\$ 100,934
Inter-segment		207		232		(439)	
Operating income		16,238		7,838		195	24,271

<sup>(1)</sup> Unallocated costs for the three and six months ended March 31, 2018 total \$4,911 and \$6,394, 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.

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 \$925 and \$1,655 of expense for attorneys fees related to this matter is included within the accompanying Condensed Consolidated Statements of Operations for the three and six months ended March 31, 2018, respectively.

Page 12

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. 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 year-to-date period ended March 31, 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. 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 year-to-date period ended March 31, 2018.

Approximately \$500 of expense for attorneys fees related to the above two class action matters is included within the accompanying Condensed Consolidated Statements of Operations for both the three and six months ended March 31, 2018. The Company maintains insurance covering these matters, which has a \$500 deductible.

See Note 10 Subsequent Events .

### 10. Subsequent Events

As discussed in Note 5 Intangible Assets and Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations, Magellan lead tests have been the subject of a series of FDA activities including (i) a Field Safety Notice on May 17, 2017; (ii) product recall notices on May 25, 2017 and June 5, 2017; (iii) an inspection and resulting Form 483, Inspection Observations; and (iv) a Warning Letter on October 23, 2017. 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.

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.

### **OUARTERLY HIGHLIGHTS**

Highlighted by the following, the effects of which are discussed throughout this MD&A, the second quarter of fiscal 2018 continued the success and positive momentum of the first quarter:

achieving a record level of revenue during the quarter of \$56,451; and

announcing a realignment of our business structure 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, both of which will be supported by a global corporate team.

### **RESULTS OF OPERATIONS**

#### Three Months Ended March 31, 2018

Net earnings for the second quarter of fiscal 2018 were \$5,288, or \$0.12 per diluted share. The fiscal 2018 second quarter results include \$4,911 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). These items impacted earnings by \$3,575, or approximately \$0.08 per diluted share on a net basis (see USE OF NON-GAAP MEASURES below). Consolidated revenues increased 4% to \$56,451 for the second quarter of fiscal 2018 compared to the same period of the prior year (3% on a constant-currency basis). On an operating segment basis, revenues increased 5% (3% in constant-currency) and 2% (1% in constant-currency) for Diagnostics and Life Science, respectively.

### Six Months Ended March 31, 2018

For the six month period ended March 31, 2018, net earnings were \$11,590, or \$0.27 per diluted share. The year-to-date fiscal 2018 results include \$6,394 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 \$3,814, or approximately \$0.09 per diluted share on a net basis (see USE OF NON-GAAP MEASURES

below). Consolidated revenues increased 8% to \$108,734 for the first six months of fiscal 2018 compared to the same period of the prior year (6% on a constant-currency basis). On an operating segment basis, revenues increased 8% (6% in constant-currency) and 7% (5% in constant-currency) for Diagnostics and Life Science, respectively.

Page 14

### **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 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 25<sup>th</sup> and June 5<sup>th</sup>. 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 six months ended March 31, 2018, we incurred approximately \$300 and \$800, respectively, in remediation costs, primarily related to regulatory consultants and studies required to reinstate our venous blood sample claim. We expect remediation costs in the second half of the year to be in the \$200 to \$400 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 Magellan for the six month period ending March 31, 2018 were \$8,344, compared to \$8,844 in the same period of the prior fiscal year, reflecting reduced revenues as a result of removing the venous blood claim as noted above. Revenues of LeadCare II, utilizing capillary blood samples, increased 7% during the six month period ending March 31, 2018, compared to the same period of the prior fiscal year, reflecting the continued placement of new LeadCare II systems in physician offices.

As set forth in Note 10 Subsequent Events 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

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 second quarters and six month periods ended March 31, 2018 and March 31, 2017.

Page 15

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.

	Three Months Ended		Six M	Six Months			
	Marc 2018	ch 31, 2017	Ended M 2018	larch 31, 2017			
Net Earnings -							
U.S. GAAP basis	\$5,288	\$9,312	\$ 11,590	\$ 15,591			
Executive transition and realignment							
costs (1)	2,517		3,052				
Litigation costs (1)	1,058		1,603				
One-time benefit from tax law change			(1,695)				
Repatriation transition tax			854				
Adjusted earnings	\$8,863	\$9,312	\$ 15,404	\$ 15,591			
Net Earnings per Basic Common Share -							
U.S. GAAP basis	\$ 0.12	\$ 0.22	\$ 0.27	\$ 0.37			
Executive transition and realignment							
costs (1)	0.06		0.07				
Litigation costs (1)	0.02		0.04				
One-time benefit from tax law change			(0.04)				
Repatriation transition tax			0.02				
Adjusted Basic EPS (2)	\$ 0.21	\$ 0.22	\$ 0.36	\$ 0.37			
Net Earnings per Diluted Common Share							
U.S. GAAP basis	\$ 0.12	\$ 0.22	\$ 0.27	\$ 0.37			

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Executive transition and realignment				
costs (1)	0.06		0.07	
Litigation costs (1)	0.02		0.04	
One-time benefit from tax law change			(0.04)	
Repatriation transition tax			0.02	
Adjusted Diluted EPS (2)	\$ 0.21	\$ 0.22	\$ 0.36	\$ 0.37

- (1) These executive transition and realignment costs, and litigation costs are net of income tax effects of \$941 and \$395, respectively, for the three months ended March 31, 2018, and \$1,140 and \$599, 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) Neither Net Earnings per Basic Common Share nor Net Earnings per Diluted Common Share for the fiscal 2018 quarterly period sum to their respective Adjusted EPS amounts due to rounding.

Page 16

### **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

Three Wonths Ended								
	March 31,			Six Months Ended March 31,				
	2018	2017	Inc (Dec)	2018	2017	Inc (Dec)		
Diagnostics -								
Americas	\$ 33,403	\$31,842	5%	\$ 64,865	\$ 59,411	9%		
EMEA	5,736	5,013	14%	11,077	10,675	4%		
ROW	643	917	(30)%	1,330	1,494	(11)%		
Total Diagnostics	39,782	37,772	5%	77,272	71,580	8%		
Life Science - Americas	5,228	5,732	(9)%	10,579	11,131	(5)%		
EMEA	7,440	6,722	11%	12,546	11,620	8%		
ROW	4,001	3,899	3%	8,337	6,603	26%		
Total Life Science	16,669	16,353	2%	31,462	29,354	7%		
Consolidated	\$ 56,451	\$ 54,125	4%	\$ 108,734	\$ 100,934	8%		
% of total revenues - Diagnostics	70%	70%		71%	71%			
Life Science	30%	30%	)	29%	29%			

Total	100%	100%	100%	100%	
Ex-Americas	32%	31%	31%	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
- 2) Immunoassays and lead tests on multiple technology platforms

### Life Science

- 1) Molecular reagents
- 2) Immunological reagents

Page 17

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

	Three	Six Months Ended March 31,					
		1arch 31,	Ina (Daa)		•		
Diagnostics	2018	2017	Inc (Dec)	2018	2017	Inc (Dec)	
Diagnostics-	Φ 0.674	Φ 0 477	201	ф 10 24 <b>2</b>	ф <b>17</b> 100	701	
Molecular assays	\$ 9,674	\$ 9,477	2%	\$ 18,342	\$ 17,188	7%	
Immunoassays & lead	20.100	20.205	6.04	<b>5</b> 0.020	54.202	0.64	
tests	30,108	28,295	6%	58,930	54,392	8%	
Total Diagnostics	\$ 39,782	\$ 37,772	5%	\$ 77,272	\$71,580	8%	
Life Science-							
Molecular reagents	\$ 6,245	\$ 5,339	17%	\$ 11,950	\$ 10,455	14%	
Immunological reagents	10,424	11,014	(5)%	19,512	18,899	3%	
	- ,	, -	(-)	- ,-	-,		
Total Life Science	\$ 16,669	\$ 16,353	2%	\$31,462	\$ 29,354	7%	
% of Diagnostics							
revenues-							
Molecular assays	24%	25%	)	24%	24%		
Immunoassays & lead							
tests	76%	75%		76%	76%		
Total Diagnostics	100%	100%	)	100%	100%		
% of Life Science							
revenues-							
Molecular reagents	37%	33%	)	38%	36%		
Immunological reagents	63%	67%		62%	64%		
		2770		5376	5.70		
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, were strong performers during the first half of fiscal 2018, up \$1,333 (18%) during the second quarter and \$3,173 (26%) during the first half of the year.

# <u>H. pylori</u>

Reflecting the ongoing conversion of serology testing to our antigen tests and buying patterns of certain customers, our *H. pylori* products also showed solid revenue growth for the first half of fiscal 2018, up \$273 (4%) during the second quarter and \$1,977 (13%) during the first half of the fiscal year. 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 partnering the ability to diagnose *H. pylori* and identify resistance provides a competitive advantage.

Page 18

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 also performed well in the aggregate during the first half of fiscal 2018, increasing \$713 (3%) during the second quarter and \$1,024 (2%) during the first half of the year.

### **Life Science Products**

During the second quarter of fiscal 2018, revenues from our Life Science segment increased 2%, with revenues from molecular reagent sales increasing 17% and revenues from immunological reagent sales decreasing 5%. For the first six months of fiscal 2018, revenues from our Life Science segment increased 7%, with revenues from molecular reagent sales increasing 14% and revenues from immunological reagent sales increasing 3%. Our molecular reagent products revenue growth was impacted by the movement in currency exchange rates since the fiscal 2017 periods, with revenues increasing 12% and 8% on a constant-currency basis over the second quarter and first six months of fiscal 2017, respectively. Comparisons of our immunological reagents products revenue to the prior year quarter 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 \$2,100 during second quarter of fiscal 2018 and approximately \$3,600 during the year-to-date period representing increases of approximately 60% and 80% 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 Mor	nths Ended M	Iarch 31,	Six Months Ended March 31,			
	2018	2017	Change	2018	2017	Change	
Gross Profit	\$ 34,569	\$ 33,477	3%	\$ 66,355	\$62,516	6%	
Gross Profit Margin	61%	62%	-1 point	61%	62%	-1 point	

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

Page 19

# **Operating Expenses Segment Detail**

	Three Months Ended March 31, 2018								
	Research & Development		lling & arketing		neral & inistrative	Other		Operating penses	
Fiscal 2017:	•		J					•	
Diagnostics	\$3,377	\$	5,625	\$	5,486	\$	\$	14,488	
Life Science	574		2,441		1,788			4,803	
<b>Total Expenses (2017 Quarter)</b>	\$ 3,951	\$	8,066	\$	7,274	\$	\$	19,291	
Fiscal 2018:									
Diagnostics	\$3,530	\$	6,101	\$	6,795	\$	\$	16,426	
Life Science	692		2,547		2,315			5,554	
Unallocated Expenses						4,911		4,911	
Total Expenses (2018 Quarter)	\$4,222	\$	8,648	\$	9,110	\$4,911	\$	26,891	

	Six Months Ended March 31, 2018								
	Research &	Selling &	General &		Total	Operating			
	Development	Marketing	Administrative	Other	Ex	xpenses			
Fiscal 2017:									
Diagnostics	\$6,350	\$ 11,119	\$ 11,291	\$	\$	28,760			
Life Science	1,198	4,565	3,722			9,485			
Total Expenses (2017 Year-to-Date)	\$7,548	\$ 15,684	\$ 15,013	\$	\$	38,245			
Fiscal 2018:									
Diagnostics	\$7,251	\$ 12,514	\$ 13,615	\$	\$	33,380			
Life Science	1,451	4,944	4,447			10,842			
Unallocated Expenses				6,394		6,394			
<b>Total Expenses (2018 Year-to-Date)</b>	\$8,702	\$ 17,458	\$ 18,062	\$6,394	\$	50,616			

# Operating Expenses Comparisons to Prior Year Periods

	Three Months Ended March 31, 2018									
	Research & Development	Selling &	General & Administrative	Other		Operating xpenses				
2017 Expenses	\$ 3,951	\$ 8,066	\$ 7,274	\$	\$	19,291				
% of Revenues	7%	15%	13%	%		36%				
Fiscal 2018 Increases:										

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Diagnostics	153	476	1,309		1,938
Life Science	118	106	527		751
Unallocated Expenses				4,911	4,911
2018 Expenses	\$4,222	\$ 8,648	\$ 9,110	\$4,911	\$ 26,891
% of Revenues	7%	15%	16%	9%	48%
% Increase	7%	7%	25%	NMF	39%

Page 20

Six Months Ended March 31, 2018							
Research & Development		O			Other		Operating xpenses
\$7,548	\$	15,684	\$	15,013	\$	\$	38,245
7%		16%		15%	9	6	38%
901		1,395		2,324			4,620
253		379		725			1,357
					6,394		6,394
\$8,702	\$	17,458	\$	18,062	\$6,394	\$	50,616
8%		16%		17%	6%		47%
15%		11%		20%	NMF		32%
	Development \$7,548 7% 901 253 \$8,702	Development     Management       \$ 7,548     \$       7%     \$       901     253       \$ 8,702     \$       8%     \$	Research & Development         Selling & Marketing           \$ 7,548         \$ 15,684           7%         16%           901         1,395           253         379           \$ 8,702         \$ 17,458           8%         16%	Research & Development         Selling & Adm           \$ 7,548         \$ 15,684           \$ 16%           901         1,395           253         379           \$ 8,702         \$ 17,458           8%         16%	Research & Development         Selling & Administrative Administrative           \$ 7,548         \$ 15,684         \$ 15,013           7%         16%         15%           901         1,395         2,324           253         379         725           \$ 8,702         \$ 17,458         \$ 18,062           8%         16%         17%	Research & Development         Selling & Administrative         Other           \$7,548         \$ 15,684         \$ 15,013         \$           7%         16%         15%         9           901         1,395         2,324         253         379         725         6,394           \$8,702         \$ 17,458         \$ 18,062         \$6,394           8%         16%         17%         6%	Research & Development         Selling & Administrative         General & Other         Total Examples           \$7,548         \$ 15,684         \$ 15,013         \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$

Total operating expenses increased during both the second quarter and first six 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 \$3,458 and \$4,192 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 termination related expenses incurred in the second quarter of fiscal 2018 in connection with realigning our business structure.

Litigation costs (reflected within Other in the above tables), which totaled \$1,453 and \$2,202 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 decreased 46% to \$7,678 for the second quarter of fiscal 2018, and decreased 35% to \$15,739 for the first six months of fiscal 2018, as a result of the factors discussed above.

Page 21

## **Income Taxes**

The effective rate for income taxes was 27% and 22% for the fiscal 2018 second quarter and six month year-to-date periods, respectively, compared to 34% and 35% during the corresponding fiscal 2017 periods. These lower fiscal 2018 taxes primarily result from the combined net impact of the following effects of the recently-enacted 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 \$1,695 tax benefit during the first quarter of fiscal 2018, including the re-measurement of deferred tax balances at the lower rate; 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 26%-27%.

## **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 \$13,839 for the first six months of fiscal 2018, a 45% decrease from the \$25,132 provided during the first six 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 the net effects of (i) increased customer receivables from higher sales levels; and (ii) increased inventory levels during the first half of fiscal 2018, largely related to continued expansion in Asia; partially offset by the effects of increased accrued employee compensation costs during the fiscal 2018 period largely as a result of executive realignment activities, coupled with 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.

Page 22

During fiscal 2017, the indicated annual cash dividend rate was established at \$0.50 per share (down from \$0.80 per share) in order to align it with the stated policy guidelines of the payout ratio to range between 75% and 85% of each fiscal year s non-GAAP net earnings. Consistent with this annual indicated dividend rate, a cash dividend of \$0.125 per share was declared for each of the first and second quarters of fiscal 2018, representing 104% and 93% of the second quarter and first six months diluted earnings per share, respectively; 60% and 69% of the periods diluted earnings per share on a non-GAAP basis (see USE OF NON-GAAP MEASURES above).

## 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 April 30, 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 six 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 March 31, 2018. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company s disclosure controls and procedures were effective as of March 31, 2018.

### Remediation of the Prior Year Material Weakness

As previously disclosed in the Company s Annual Report on Form 10-K for the fiscal year ended September 30, 2017, a material weakness was identified in the design and operating effectiveness of the Company s internal control over financial reporting. Specifically, deficiencies were identified related to Information Technology General Controls (ITGC) intended to restrict access to certain data and applications, resulting in inappropriate access at both the Information Technology and end user levels within an application impacting financial reporting functions and controls. As a result, we concluded that the Company s disclosure controls and procedures were not effective in providing reasonable assurance that information required to be disclosed in our reports filed under the Exchange Act

was recorded, processed, summarized and reported within the time periods prescribed by SEC rules and regulations, and that such information was accumulated and communicated to our management to allow timely decisions regarding required disclosure.

In response to this material weakness, the Company implemented changes to its internal control over financial reporting to remediate the control deficiencies that gave rise to the material weakness originally identified as of September 30, 2017. Those changes included, but were not limited to, taking steps to strengthen information technology security and user access controls. We have tested the newly implemented controls and found them to be effective and therefore, have concluded that as of March 31, 2018, the previously identified material weakness has been remediated.

Page 23

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

Except as described above, 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 March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

See Note 9 Litigation Matters and Note 10 Subsequent Events 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 to Part I of Form 10-K.

### ITEM 6. EXHIBITS

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

- 10.1 <u>Separation Agreement and Release of Claims dated February 20, 2018 between the Company and Richard L. Eberly (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on February 26, 2018)</u>
- 10.2 <u>Separation Agreement and Release of Claims dated February 20, 2018 between the Company and Vecheslav A. Elagin (Incorporated by reference to Meridian s Form 8-K filed with the Securities and Exchange Commission on February 26, 2018)</u>
- 10.3 <u>April 2018 Revision to Fiscal 2018 Cash-Based Incentive Compensation Plan</u> <u>Officers and Selected Executives</u>
- 31.1 Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
- 31.2 <u>Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)</u>
- 32 <u>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</u>
- The following financial information from Meridian Bioscience Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 filed with the SEC on May 10, 2018, formatted in XBRL includes: (i) Condensed Consolidated Statements of Operations for the three and six months ended March 31, 2018 and 2017; (ii) Condensed Consolidated Statements of Comprehensive Income for the three and six months ended March 31, 2018 and 2017; (iii) Condensed Consolidated Statements of Cash Flows for the six months ended March 31, 2018 and 2017; (iv) Condensed Consolidated Balance Sheets as of March 31, 2018 and September 30, 2017; (v) Condensed Consolidated Statement of Shareholders Equity for the six months ended March 31, 2018; and (vi) the Notes to Condensed Consolidated Financial Statements

Page 24

# **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: May 10, 2018

By: /s/ Melissa A. Lueke

Melissa A. Lueke

Executive Vice President and Chief Financial

Officer

(Principal Financial and Accounting Officer)

Page 25