

Source: Meridian Bioscience Inc.

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# Meridian Bioscience Reports Fourth Quarter and Full-Year Fiscal 2019 Operating Results and Provides Fiscal 2020 Guidance

CINCINNATI, Nov. 07, 2019 (GLOBE NEWSWIRE) -- Meridian Bioscience, Inc. (NASDAQ: VIVO) today announced financial results for the fourth quarter and fiscal year ended September 30, 2019.

# Fourth Quarter 2019 Highlights (Comparison to Fourth Quarter Fiscal 2018):

- Consolidated revenue decreased 4% to \$50.8 million (3% decrease in constant-currency)
- Diagnostics segment revenues decreased 9% to \$33.4 million (also a 9% decrease in constant-currency); note that while Diagnostics segment revenues were down compared to the fourth quarter of fiscal 2018, such revenues were relatively flat with our fiscal 2019 third quarter
- Life Science segment achieved a record quarter, with revenues increasing 7% to \$17.4 million (9% growth in constant-currency)
- Reported GAAP Operating Margin of 11.5% and Adjusted Operating Margin of 14.9% for the quarter, which
  includes a full three months of activities in the Diagnostics segment from the acquisition of the GenePOC
  business
- Reported GAAP EPS of \$0.10 per diluted share and Adjusted EPS of \$0.13 per diluted share
- Adjusted Operating Margin and Adjusted EPS on a diluted basis excludes costs associated with acquisition-related activities, restructuring activities and selected legal matters (see non-GAAP financial measure reconciliation below)

# Full Fiscal Year 2019 Highlights (Comparison to Full Year Fiscal 2018):

- Consolidated revenue decreased 6% to \$201.0 million (5% decrease in constant-currency)
- Diagnostics segment revenues decreased 9% to \$136.7 million (8% decrease in constant-currency)
- Life Science segment revenues increased 2% to \$64.3 million (3% growth in constant-currency)
- Reported GAAP Operating Margin of 16.3% and Adjusted Operating Margin of 19.4%, which includes four months of activities in the Diagnostics segment from the acquisition of the GenePOC business
- Reported GAAP EPS of \$0.57 per diluted share and Adjusted EPS of \$0.68 per diluted share
- Adjusted Operating Margin and Adjusted EPS on a diluted basis excludes costs associated with acquisition-related activities, restructuring activities and selected legal matters (see non-GAAP financial measure reconciliation below)

## Fourth Quarter Fiscal 2019 Results (Comparison to Fourth Quarter Fiscal 2018)

Consolidated revenue for the fourth quarter of fiscal 2019 decreased 4% to \$50.8 million, compared to \$53.1 million last year. Diagnostics segment revenues were down 9%, while Life Science segment revenues were up 7%. Our Diagnostics segment experienced continued competitive pressures in a number of our products, particularly *C. difficile* and foodborne, volume and pricing declines in certain gastrointestinal products, and the effects of initially lighter shipments of respiratory products in advance of the upcoming season. Our Life Science segment revenues for the quarter reflected double-digit growth from IVD customers purchasing immunological reagents in the EMEA region as well as China, but this was offset by softness in the distribution channel in the Americas region.

Reported operating income for the fourth quarter of fiscal 2019 was \$5.8 million, including operating costs of \$3.5 million for the normal activities from the acquisition of the GenePOC business. SG&A expenses were down \$0.9 million, largely due to the effects of last year's organizational stream-lining activities. Research and development expenses increased \$2.0 million for the quarter, primarily due to the addition of costs associated with the acquisition of GenePOC's business and continued development of two revogene™ assays, as well as the completion of clinical trials for our first Curian™ assay, a stool-antigen test for *H. pylori*. Reported operating income for the quarter also included \$1.7 million of costs associated with acquisition-related activities, restructuring activities and selected legal matters. Excluding the effects of such costs, adjusted operating income achieved a margin of 15% (see non-GAAP financial measure reconciliation below).

Jack Kenny, Chief Executive Officer, commented, "We are very pleased with our fourth quarter results, which showed significant progress on our strategic direction for both our Diagnostics and Life Science businesses. For the Diagnostics segment, our overall revenue level stabilized commensurate with our third quarter. Conversion of customers from our alethia™ molecular system to the revogene™ system during the first 120 days exceeded our expectations. Instrument placements were approximately 60 during this time period. The revogene™ platform is helping address competitive pressures and has slowed our account losses. Our new product development efforts on our Diagnostic instrument platforms (revogene™, Curian™ and PediaStat™) continue to make progress, and we submitted our first Curian™ assay, a stool-antigen test for *H. pylori*, to the FDA in September. For the Life Science segment, IVD customer orders for immunological reagents were strong as this segment delivered its best revenue-growth quarter for the year. During the quarter we also made refinements to our organizational structure in both business units in order to improve customer focus and cost efficiencies in fiscal 2020."

# Full Fiscal Year 2019 Results (Comparison to Full Year Fiscal 2018)

Consolidated revenue for the fiscal year ended September 30, 2019 decreased 6% to \$201.0 million, compared to \$213.6 million in fiscal 2018. Revenues for our Diagnostics segment decreased 9% (8% on a constant-currency basis) to \$136.7 million, driven largely by declines in gastrointestinal assays, which reflected anticipated pricing declines in our *H. pylori* products and continued competitive pressures in our *C. difficile* and foodborne products. Revenues in our Life Science segment grew 2% (3% on a constant-currency basis), reflecting growth in the EMEA region being partially offset by declines in the Americas and Rest of World. Life Science revenues in China increased by approximately 2% on a full-year basis.

During fiscal 2019, reported operating income was \$32.7 million, including operating costs of \$4.6 million for the normal activities from the acquisition of the GenePOC business. On an adjusted basis (excludes costs associated with acquisition-related activities, restructuring activities and selected legal matters), operating income was \$38.9 million and achieved a margin of 19%, which compares to adjusted operating income of \$44.6 million and a margin of 21% in fiscal 2018 (see non-GAAP financial measure reconciliation below).

# Tax Reform Impact

Our net earnings for both fiscal year-to-date periods include the effects of the tax reform act signed into law during December 2017. The fiscal 2019 year-to-date period reflects the lower U.S. federal tax rate of 21% being fully phased-in, and fiscal 2018 includes: (i) a benefit of \$2.7 million (\$0.06 per diluted share) primarily related to the remeasurement of U.S. net deferred tax liabilities based on the new federal rate; and (ii) a charge of \$0.9 million (\$0.02 per diluted share) for the mandatory U.S. repatriation transition tax. The effective tax rates for both the fourth quarter and full year fiscal 2019 were 23%.

#### Fiscal 2020 Guidance

Our fiscal 2020 guidance reflects significant investments in new product development to continue to refresh our Diagnostics segment's product lines, including beginning clinical trials for six assays across three instrument platforms (revogene<sup>™</sup>, Curian<sup>™</sup> and PediaStat<sup>™</sup>). Our fiscal 2020 guidance noted below for adjusted operating margin and adjusted earnings per share on a diluted basis reflects \$27 million to \$28 million in Research and Development spending, or 13% to 14% of consolidated revenues, compared to approximately \$18 million, or 9% of consolidated revenues in fiscal 2019).

#### Revenues

- Consolidated flat to down 3%
- Diagnostics segment down 3% to 5%
- Life Science segment up 2% to 6%

#### Adjusted Operating Margin

- Consolidated 9% to 10%
- Diagnostics segment mid-single-digits (significant research and development spending)
- Life Science segment 50 to 100 basis-point improvement over 2019

#### Effective Tax Rate

• 23.5% to 24.5%

#### Adjusted Earnings Per Share on a Diluted Basis

• \$0.28 to \$0.34

Adjusted operating margin and adjusted earnings per share on a diluted basis for fiscal 2020 excludes costs associated with restructuring activities and selected legal matters that we expect to continue in fiscal 2020. In addition, our fiscal 2020 guidance for adjusted operating margin and earnings per share on a diluted basis excludes the medical device excise tax, the moratorium for which is due to expire December 31, 2019, unless Congress chooses to extend such moratorium for a third time, or altogether repeals it.

Although we do expect revenues for our Diagnostics segment to be down low to mid-single-digits for the full fiscal year, we expect revenues for our Diagnostics segment to be down high-single-digits during the first quarter, commensurate with the second half of fiscal 2019. Our revenue expectations for our Diagnostics segment for the first quarter, along with current customer order patterns for our Life Science segment, indicate our consolidated revenues for the first quarter could be down mid-single-digits.

#### **Financial Condition**

The Company's financial condition remains sound. At September 30, 2019, cash and equivalents were \$62.4 million and the Company had \$49.2 million of borrowing capacity under its \$125.0 million commercial bank credit facility. The Company's bank-debt obligations under the bank credit facility totaled \$75.8 million as of September 30, 2019.

#### **Conference Call Information**

Jack Kenny, Chief Executive Officer, and Bryan Baldasare, Executive Vice President and Chief Financial Officer, will host a conference call on Thursday, November 7, 2019 beginning at 10:00 a.m. Eastern Time to discuss the fourth quarter and full fiscal year financial results and answer questions.

To participate in the live call by telephone from the U.S., dial (866) 443-5802, or from outside the U.S., dial (513) 360-6924, and enter the audience pass code 9471778. A replay will be available for 14 days beginning at 1:00 p.m. Eastern Time on November 7, 2019 by dialing (855) 859-2056 or (404) 537-3406 and entering pass code 9471778.

#### FOURTH QUARTER AND FISCAL 2019 UNAUDITED OPERATING RESULTS

(In Thousands, Except per Share Data)

The following table sets forth the unaudited comparative results of Meridian on a U.S. GAAP basis for the interim and annual periods of fiscal 2019 and fiscal 2018.

		nths Ended	Twelve Months Ended				
		nber 30,	Septen	nber 30,			
	2019	2018	2019	2018			
Net revenues	\$ 50,846	\$ 53,100	\$ 201,014	\$ 213,571			
Cost of sales	21,690	20,944	82,689	82,874			
Gross profit	29,156	32,156	118,325	130,697			
Operating expenses							
Research and development	5,654	3,630	17,948	16,789			
Selling and marketing	7,225	8,505	28,446	34,468			
General and administrative	8,714	8,335	33,002	34,805			
Acquisition-related costs	363	-	1,808	-			
Restructuring costs	1,138	3,601	2,839	8,706			
Selected legal costs	213	975	1,583	4,345			
Total operating expenses	23,307	25,046	85,626	99,113			
Operating income	5,849	7,110	32,699	31,584			
Other expense, net	(493)	(232)	(1,142)	(1,204)			
Earnings before income taxes	5,356	6,878	31,557	30,380			
Income tax provision	1,253	1,444	7,175	6,531			
Net earnings	\$ 4,103	\$ 5,434	\$ 24,382	\$ 23,849			
rect carriings	Ψ,100	Ψ	Ψ 27,002	Ψ 20,0-το			
Net earnings per basic common share	\$ 0.10	\$ 0.13	\$ 0.57	\$ 0.56			
Basic common shares outstanding	42,711	42,391	42,571	42,325			

Net earnings per diluted common share \$ Diluted common shares outstanding	4	0.10 2,916	\$	42	0.13 2,821	\$	0.57 42,899	\$	0.56 42,754	
	Three Months Ended September 30,						Twelve Months Ended September 30,			
		2019		2	2018		2019		2018	
Adjusted Financial Measures										
(see non-GAAP financial measure										
reconciliation below)	_			_				_		
Operating income	\$	•		\$	11,686	\$	38,929	\$	44,635	
Net earnings	_	5,399			8,579	_	29,142	_	31,705	
Net earnings per diluted common share	\$	0.13	3	\$	0.20	\$	0.68	\$	0.74	
Condensed Balance Sheet Data										
							0 1	1	- 00	
							Septe	embe		
Cash and aquivalents						<b>ው</b>	2019	·	2018	
Cash and equivalents						\$	,		59,763	
Working capital							123,847 75,824		114,880 50,180	
Long-term debt Shareholders' equity							190,967		175,418	
Total assets							325,378		251,377	
Total assets							323,370		201,011	
Segment Data The following table sets forth the unaudited revenu 2019 and fiscal 2018 (in thousands).	e ar	nd segmer	nt da	ıta fo	or the interi	im ar	nd annual pe	eriods	s in fiscal	
		Three I	Mon	nthe	Ended	7	Twelve Mo	nthe	Ended	
		Three Months Ended September 30,				Twelve Months Ended September 30,				
	•	2019 2018				2019 2018				
Net Revenues - By Product Platform/Type	•									
Diagnostics										
Molecular assays		\$ 6,0	65	\$	7,727	\$	26,231	\$	33,709	
Immunoassays & blood chemistry assays		27,3		*	29,087		110,451	•	116,745	
Total Diagnostics		33,3		_	36,814	_	136,682		150,454	
Life Science			_	_	· · · · · · · · · · · · · · · · · · ·	_	<u> </u>			
Molecular reagents		5,7	65		6,650		23,261		24,533	
Immunological reagents		11,6	82		9,636		41,071		38,584	
Total Life Science		17,4	47	_	16,286	· <del>-</del>	64,332		63,117	
Total Net Revenues		\$ 50,8	46	\$	53,100	\$	201,014	\$	213,571	
				-		=		_		
		Three M	/ont	tha [	Endod	,	Twelve Mo	ntho	Endod	
		Sept					Septer			
		2019	CIII		2018		2019	TIDCI	2018	
Net Revenues - By Disease State/Geography	_	_010				_	2010			
Diagnostics										
Gastrointestinal assays	\$	16,953	,	\$	19,172	\$	68,977	\$	78,803	
Respiratory illness assays	Ψ	5,380		Ψ	6,132	Ψ	26,622	Ψ	28,911	
Blood chemistry assays		5,572			5,581		19,082		19,109	
Other		5,494			5,929		22,001		23,631	
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Total Diagnostics		33,399		36,814		136,682		150,454
Life Science	_		_		_		_	
Americas		5,094		5,206		19,443		21,080
EMEA		7,318		6,253		29,157		24,715
ROW		5,035		4,827		15,732		17,322
Total Life Science		17,447		16,286		64,332		63,117
Total Net Revenues	\$	50,846	\$	53,100	\$	201,014	\$	213,571
	=				=		=	
OPERATING INCOME								
Diagnostics	\$	1,944	\$	6,773	\$	22,399	\$	32,569
Life Science		5,791		3,479		20,572		13,799
Corporate		(1,923)		(3,203)		(10,373)		(15,076)
Eliminations		37		61		101		292
Total Operating Income	\$_	5,849	\$	7,110	\$	32,699	\$	31,584

**Geographic Regions** 

Americas = North and Latin America EMEA = Europe, Middle East and Africa

ROW = Rest of World

# **NON-GAAP FINANCIAL MEASURES**

In this press release, we have supplemented our reported GAAP financial information with information on operating expenses, operating income, net earnings, basic earnings per share and diluted earnings per share excluding the effects of acquisition-related costs, restructuring costs, selected legal 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 to the operating expenses, operating income, net earnings, basic earnings per share and diluted earnings per share amounts reported under U.S. Generally Accepted Accounting Principles for the fourth quarters and fiscal years ended September 30, 2019 and September 30, 2018.

We believe this information is useful to an investor in evaluating our performance because:

- 1. These measures help investors to more meaningfully evaluate and compare the results of operations from period to period by removing the impacts of these non-routine items; and
- 2. These measures are used by our management for various purposes, including evaluating performance against incentive bonus achievement targets, comparing performance from period to period in presentations to our board of directors, and as a basis for strategic planning and forecasting.

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

These non-GAAP measures may be different from non-GAAP measures used by other companies. In addition, the 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.

# FOURTH QUARTER AND FISCAL YEAR GAAP TO NON-GAAP RECONCILATION TABLES

(In Thousands, Except per Share Data)

		I welve Months							
		Ended September 30,				Ended September 3			
		2019	2018		2019		2018		
Operating Expenses U.S. GAAP basis	\$	23,307	\$	25,046	\$	85,626	\$	99,113	

Acquisition-related costs		(363)		-		(1,808)		-
Restructuring costs		(1,138)		(3,601)		(2,839)		(8,706)
Selected legal costs		(213)		(975)		(1,583)		(4,345)
Adjusted Operating Expenses	\$	21,593	\$	20,470	\$	79,396	\$	86,062
Operating Income -								
U.S. GAAP basis	\$	5,849	\$	7,110	\$	32,699	\$	31,584
Acquisition-related costs	Ψ	363	Ψ	-	Ψ	1,808	Ψ	-
Restructuring costs		1,138		3,601		2,839		8,706
Selected legal costs		213		975		1,583		4,345
Adjusted Operating Income	\$	7,563	\$	11,686	\$	38,929	\$	44,635
Net Famina								
Net Earnings U.S. GAAP basis	\$	4 402	<b>ው</b>	E 121	Φ	24 202	\$	22 040
	Ф	4,103 273	\$	5,434	\$	24,382	Ф	23,849
Acquisition-related costs *		273 864		2 602		1,381		6 420
Restructuring costs *				2,693		2,169		6,430
Selected legal costs *		159		738		1,210		3,205
One-time benefit from tax law change		-		(308)		-		(2,655)
Repatriation transition tax				22				876
Adjusted Earnings	\$	5,399	\$	8,579	\$	29,142	\$	31,705

<sup>\*</sup> Net of tax.

	Three Months Ended September 30,				Twelve Months Ended Septembe			
	2019		2018		2019		20	018
Net Earnings per Basic Common Share -								
U.S. GAAP basis	\$	0.10	\$	0.13	\$	0.57	\$	0.56
Acquisition-related costs		0.01		-		0.03		-
Restructuring costs		0.02		0.06		0.05		0.15
Selected legal costs		-		0.02		0.03		0.08
One-time benefit from tax law change		-		(0.01)		-		(0.06)
Repatriation transition tax		-		-		-		0.02
Adjusted Basic EPS	\$	0.13	\$	0.20	\$	0.68	\$	0.75
Net Earnings per Diluted Common Share -								
U.S. GAAP basis	\$	0.10	\$	0.13	\$	0.57	\$	0.56
Acquisition-related costs		0.01		-		0.03		-
Restructuring costs		0.02		0.06		0.05		0.15
Selected legal costs		-		0.02		0.03		0.07
One-time benefit from tax law change		-		(0.01)		-		(0.06)
Repatriation transition tax		-		-		-		0.02
Adjusted Diluted EPS	\$	0.13	\$	0.20	\$	0.68	\$	0.74

## 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 "continues", "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes",

"signals", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. All statements that address operating performance or events or developments that Meridian expects or anticipates will occur in the future, including, but not limited to, statements relating to per share diluted earnings and revenue, are forward-looking statements. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. Specifically, Meridian's forward-looking statements are, and will be, based on management's then-current views and assumptions regarding future events and operating performance. Meridian assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following:

Meridian's operating results, financial condition and continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition, its ability to effectively sell such products and its ability to successfully expand and effectively manage increased sales and marketing operations. While Meridian has introduced a number of internally developed products and acquired products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis or in protecting its intellectual property, and unexpected or costly manufacturing costs associated with its introduction of new products or acquired products could cause actual results to differ from expectations. Meridian relies on proprietary, patented and licensed technologies. As such, the Company's ability to protect its intellectual property rights, as well as the potential for intellectual property litigation, would impact its results. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers, can change expected results. Costs and difficulties in complying with laws and regulations, including those administered by the United States Food and Drug Administration, can result in unanticipated expenses and delays and interruptions to the sale of new and existing products, as can the uncertainty of regulatory approvals and the regulatory process (including the currently ongoing study and other FDA actions regarding the Company's LeadCare products). The international scope of Meridian's operations, including changes in the relative strength or weakness of the U.S. dollar and general economic conditions in foreign countries, can impact results and make them difficult to predict. One of Meridian's growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses will be successfully integrated into Meridian's operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention, and there may be additional risks with respect to Meridian's ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. Meridian cannot predict the outcome of goodwill impairment testing and the impact of possible goodwill impairments on Meridian's earnings and financial results. Meridian cannot predict the possible impact of U.S. health care legislation enacted in 2010 – the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act – and any modification or repeal of any of the provisions thereof initiated by Congress or the presidential administration, and any similar initiatives in other countries on its results of operations. Efforts to reduce the U.S. federal deficit, breaches of Meridian's information technology systems, trade wars, increased tariffs, and natural disasters and other events could have a materially adverse effect on Meridian's results of operations and revenues. In the past, the Company has identified a material weakness in our internal control over financial reporting, which has been remediated, but the Company can make no assurances that a material weakness will not be identified in the future, which if identified and not properly corrected, could materially adversely affect our operations and result in material misstatements in our financial statements. In addition to the factors described in this paragraph, as well as those factors identified from time to time in our filings with the Securities and Exchange Commission, Part I, Item 1A Risk Factors of our most recent Annual Report on Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company. Readers should carefully review these forward-looking statements and risk factors, and not place undue reliance on our forward-looking statements.

#### About Meridian Bioscience, Inc.

Meridian is a fully integrated life science company that develops, manufactures, markets and distributes a broad range of innovative diagnostic products. We are dedicated to developing and delivering better solutions that give answers with speed, accuracy and simplicity that are redefining the possibilities of life from discovery to diagnosis. Through discovery and development, we provide critical life science raw materials used in immunological and molecular tests for human, animal, plant, and environmental applications. Through diagnosis, we provide diagnostic solutions in areas including gastrointestinal and upper respiratory infections and blood lead level testing. We build relationships and provide solutions to hospitals, reference laboratories, research centers, veterinary testing centers, physician offices, diagnostics manufacturers, and biotech companies in more than 70 countries around the world.

Meridian's shares are traded on the NASDAQ Global Select Market, symbol VIVO. Meridian's website address is <a href="https://www.meridianbioscience.com">www.meridianbioscience.com</a>.

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