



MERIDIAN BIOSCIENCE REPORTS STRONG FOURTH QUARTER AND RECORD FULL-YEAR FISCAL 2021 OPERATING RESULTS AND PROVIDES FISCAL 2022 GUIDANCE

CINCINNATI, OHIO November 12, 2021 (PRNewswire) -- Meridian Bioscience, Inc. (NASDAQ: VIVO) today announced financial results for the fourth quarter and fiscal year ended September 30, 2021.

Fourth Quarter 2021 Highlights (Comparison to Fourth Quarter Fiscal 2020):

- Consolidated net revenues of \$76.2 million, up 19% year-over-year
- Life Science segment delivered net revenues of \$41.9 million, up 22% year-over-year
- Diagnostics segment net revenues increased 15% year-over-year to \$34.3 million
- Launched Air-Dryable™ sample specific master mixes for stool, blood and urine and Air-Dryable™ LAMP Mix for isothermal amplification
- Received U.S. design patent for Revogene® PIE (Fluidic Centripetal Device)
- Launched new environmentally friendly, REACH compliant, enzymes
- Closed \$20 million acquisition of the BreathTek® Urea Breath Test for *H. pylori*

Full Fiscal Year 2021 Highlights (Comparison to Full Year Fiscal 2020):

- Consolidated net revenues of \$317.9 million, up 25% year-over-year
- Life Science segment delivered record net revenues of \$190.1 million, up 43% year-over-year, with \$111.9 million from COVID-19 related products for immunological and molecular tests
- Diagnostics segment net revenues increased 5% year-over-year to \$127.8 million
- Disrupted molecular reagents market with a comprehensive line of Air-Dryable™ master mixes optimized for specific sample types
- Submitted Curian® Campy 510(k) and Revogene® SARS-CoV-2 Emergency Use Authorization (EUA)
- Awarded \$6.5 million in RADx grants for the Revogene® SARS-CoV-2 assay

Jack Kenny, Chief Executive Officer, commented, "All of our hard work over the previous two years prepared us to both weather the storm in Diagnostics and excel in Life Science as a critical partner to the IVD industry battling the global COVID-19 pandemic. We look forward to Diagnostics making its contribution with the Revogene® SARS-CoV-2 assay receiving Emergency Use Authorization earlier this week. Fiscal 2022 will be an exciting year for Meridian and should provide a foundation for future growth."

Fourth Quarter Fiscal 2021 Results (Comparison to Fourth Quarter Fiscal 2020)

Consolidated net revenues for the fourth quarter of fiscal 2021 increased 19% to \$76.2 million, compared to \$64.2 million last year. Diagnostics segment net revenues increased 15% year-over-year, while Life Science segment net revenues were up 22%. Our Diagnostics segment experienced a 22% increase in net revenues from our molecular products and revenues from our non-molecular assay products increased 14%, despite the impact of the LeadCare® product recall and our pausing of manufacturing and distribution in mid-August. Our Life Science segment net revenues for the quarter included \$23.3 million in net revenues from COVID-19 related products, with \$18.1 million coming from molecular products and \$5.2 million coming from immunological products.

Reported operating income for the fourth quarter of fiscal 2021 was \$8.5 million, a margin of 11%. Operating expenses included: (i) \$5.6 million of LeadCare® product recall expenses; and (ii) a \$4.6 million upward adjustment in the fair value of the earnout obligation for the acquisition of the GenePOC business in 2019, in

arriving at the \$20.0 million fourth quarter settlement of the earnout obligation. On an adjusted basis, operating income was \$13.3 million, a margin of 17% (see non-GAAP financial measure reconciliation below).

Net earnings per diluted share for the fourth quarter of fiscal 2021 on a reported GAAP basis totaled \$0.15 and adjusted net earnings per diluted share totaled \$0.23 (see non-GAAP financial measure reconciliation below).

Full Fiscal Year 2021 Results (Comparison to Full Year Fiscal 2020)

Consolidated net revenues for the fiscal year ended September 30, 2021 increased 25% to \$317.9 million, compared to \$253.7 million in fiscal 2020. Diagnostics segment net revenues were up 5%, while Life Science segment net revenues were up 43%. Our Diagnostics segment experienced a 13% decrease in net revenues from our molecular products, while net revenues from our non-molecular assay products increased 10%. Our Life Science segment net revenues for the fiscal year included \$111.9 million in net revenues from COVID-19 related products, with \$92.55 million coming from molecular products and \$19.35 million coming from immunological products.

Reported operating income for fiscal year ended September 30, 2021 was \$93.0 million, a margin of 29%. Operating expenses included: (i) \$5.6 million of LeadCare[®] product recall expenses; (ii) \$2.8 million of legal expenses related to the ongoing Magellan Department of Justice investigation; and (iii) a \$0.9 million downward adjustment in the fair value of the earnout obligation for the acquisition of the GenePOC business in 2019, in arriving at the \$20.0 million fourth quarter settlement of the earnout obligation. On an adjusted basis, operating income was \$95.3 million, a margin of 30% (see non-GAAP financial measure reconciliation below).

Net earnings per diluted share for the fiscal year ended September 30, 2021 on a reported GAAP basis totaled \$1.62 and adjusted net earnings per diluted share totaled \$1.66 (see non-GAAP financial measure reconciliation below).

Bryan Baldasare, Chief Financial Officer, commented, "Fiscal 2021 was another record year financially. With most of the negative impacts of the COVID-19 pandemic behind us, Meridian is a business expected to be 50% greater than the last pre-pandemic period in fiscal 2019, with opportunities to grow."

Financial Condition

At September 30, 2021, cash and cash equivalents were \$49.8 million and the Company had \$100.0 million of borrowing capacity under its \$160.0 million commercial bank credit facility. The Company's obligations under the commercial bank credit facility totaled \$60.0 million as of September 30, 2021. In October 2021, the Company amended its commercial bank credit facility, increasing the limit to \$200.0 million, leaving the Company with borrowing capacity of \$140.0 million as of November 12, 2021.

Fiscal 2022 Guidance

Net Revenues

- Consolidated – \$285 to \$300 million
- Diagnostics segment – \$145 to \$150 million
- Life Science segment – \$140 to \$150 million

Adjusted Operating Margin

- Consolidated – 21% to 22%

Effective Tax Rate

- 23.5%

Adjusted Earnings Per Share on a Diluted Basis (based on 44.5 million shares)

- \$0.98 to \$1.08

Diagnostics segment net revenues are expected to be higher in the second half of the year, reflecting our assumption that we will begin shipping LeadCare[®] product in April 2022. Life Science segment net revenues contemplate strong double-digit growth for sales of products other than those used in COVID-19 tests, offset by

a reduction in demand for its products due to decreases in COVID-19 testing. COVID-19 has become endemic and as such, we expect the impact from related sales to be higher during the respiratory season, in the first half of our fiscal year. The decline in Life Science net revenues between the first and the second half should be less pronounced than in fiscal 2021 and roughly mirror the increase in Diagnostics net revenues expected in the second half of the year.

Life Science segment operating margins are expected to exceed 50% and the Diagnostics segment is expected to have a break-even to low single-digit operating margin. These estimates, coupled with contribution mix changes between the segments, results in the consolidated operating margin forecast of 21% to 22%.

The higher tax rate compared to 2021 reflects a greater percentage of net revenues and taxable income generated in the United States than in fiscal year 2021.

There are a number of unknowns that make setting guidance challenging including, without limitation, the timing of FDA clearance for the Curian® Campy assay, the resolution of the LeadCare® product recall situation, the anticipated demand for COVID-19 testing globally, the inflationary environment and supply chain interruption considerations. The guidance presented above reflects Meridian's current visibility into these matters and overall market conditions.

Conference Call Information

Jack Kenny, Chief Executive Officer, and Bryan Baldasare, Executive Vice President and Chief Financial Officer, will host a conference call on Friday, November 12, 2021 beginning at 10:00 a.m. Eastern Time to discuss the fourth quarter and full fiscal year financial results and answer questions. A presentation to accompany the quarterly and full fiscal year financial results and related discussion will be made available within the Investor Relations section of the Company's website, www.meridianbioscience.com, prior to the conference call.

The Company is introducing a live webcast for this and future earnings calls, with the link to access the webcast being located at investor.meridianbioscience.com or directly [here](#). The webcast will provide the best experience for tuning into the call; however, if you are unable to join via the webcast, you may still participate by telephone from the U.S. by dialing (877) 407-0890, or from outside the U.S., by dialing (201) 389-0918, and enter the audience pass code 13724028. A replay of the conference call will be available by webcast for one year beginning at 1:00 p.m. Eastern Time on November 12, 2021 using the link provided at investor.meridianbioscience.com.

FOURTH QUARTER AND FISCAL 2021 UNAUDITED CONDENSED OPERATING RESULTS

(In Thousands, Except per Share Data)

The following table sets forth the unaudited comparative results of Meridian on a U.S. generally accepted accounting principles (GAAP) basis for the interim and annual periods of fiscal 2021 and fiscal 2020.

	Three Months Ended September 30,		Year Ended September 30,	
	2021	2020	2021	2020
Net revenues	\$ 76,204	\$ 64,153	\$ 317,896	\$ 253,667
Cost of sales	31,487	25,822	116,748	97,419
Gross profit	44,717	38,331	201,148	156,248
Operating expenses				
Research and development	6,112	6,983	23,911	23,729
Selling and marketing	7,010	7,210	26,780	26,486
General and administrative	12,714	12,109	49,541	44,345
Product recall costs	5,596	-	5,596	-
Selected legal costs	108	891	2,803	2,080
Acquisition-related costs	92	462	392	3,890
Change in fair value of acquisition consideration	4,596	1,135	(909)	(6,293)
Restructuring costs	-	67	-	687
Total operating expenses	36,228	28,857	108,114	94,924
Operating income	8,489	9,474	93,034	61,324
Other income (expense), net	(633)	(1,727)	(2,583)	(2,031)
Earnings before income taxes	7,856	7,747	90,451	59,293
Income tax provision	1,199	1,254	19,044	13,107
Net earnings	\$ 6,657	\$ 6,493	\$ 71,407	\$ 46,186
Net earnings per basic common share	\$ 0.15	\$ 0.15	\$ 1.65	\$ 1.08
Basic common shares outstanding	43,356	42,940	43,259	42,855
Net earnings per diluted common share	\$ 0.15	\$ 0.15	\$ 1.62	\$ 1.07
Diluted common shares outstanding	44,094	43,642	44,012	43,174

Adjusted Financial Measures (in thousands, except per share data)
(see non-GAAP financial measure reconciliation below)

	Three Months Ended September 30,		Year Ended September 30,	
	2021	2020	2021	2020
Adjusted operating income	\$ 13,285	\$ 12,029	\$ 95,320	\$ 61,688
Adjusted net earnings	10,258	8,289	73,123	46,301
Adjusted net earnings per diluted common share	\$ 0.23	\$ 0.19	\$ 1.66	\$ 1.07

Condensed Consolidated Balance Sheet Data (in thousands)

	September 30,	
	2021	2020
Cash and equivalents	\$ 49,771	\$ 53,514
Working capital	145,650	109,666
Long-term debt	60,000	68,824
Shareholders' equity	328,302	247,629
Total assets	449,722	405,261

Segment Data

The following table sets forth the unaudited net revenues and segment data for the interim and annual periods in fiscal 2021 and fiscal 2020 (in thousands).

	Three Months Ended September 30,		Year Ended September 30,	
	2021	2020	2021	2020
<u>Net Revenues - By Product Platform/Type</u>				
Diagnostics				
Molecular assays	\$ 5,671	\$ 4,648	\$ 19,037	\$ 21,907
Non-molecular assays	28,630	25,153	108,723	99,225
Total Diagnostics	34,301	29,801	127,760	121,132
Life Science				
Molecular reagents	26,399	22,703	130,537	78,431
Immunological reagents	15,504	11,649	59,599	54,104
Total Life Science	41,903	34,352	190,136	132,535
Total Net Revenues	\$ 76,204	\$ 64,153	\$ 317,896	\$ 253,667

	Three Months Ended September 30,		Year Ended September 30,	
	2021	2020	2021	2020
<u>Net Revenues - By Disease State/Geography</u>				
Diagnostics				
Gastrointestinal assays	\$ 19,838	\$ 15,396	\$ 68,890	\$ 55,040
Respiratory illness assays	5,375	3,030	17,608	26,694
Blood chemistry assays	2,391	5,026	15,398	17,534
Other	6,697	6,349	25,864	21,864
Total Diagnostics	34,301	29,801	127,760	121,132
Life Science				
Americas	6,356	6,795	46,063	37,391
EMEA	23,965	17,115	93,655	58,125
ROW	11,582	10,442	50,418	37,019
Total Life Science	41,903	34,352	190,136	132,535
Total Net Revenues	\$ 76,204	\$ 64,153	\$ 317,896	\$ 253,667

OPERATING INCOME

Diagnostics	\$ (11,889)	\$ (4,174)	\$ (8,140)	\$ 3,885
Life Science	23,235	17,234	115,250	68,826
Corporate	(2,878)	(3,605)	(14,164)	(11,437)
Eliminations	21	19	88	50
Total Operating Income	\$ 8,489	\$ 9,474	\$ 93,034	\$ 61,324

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, operating margin, net earnings, basic net earnings per share and diluted net earnings per share, each on an adjusted basis excluding the effects of certain acquisition-related costs, changes in fair value of the acquisition consideration, restructuring costs, and selected legal costs, 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 net earnings per share and diluted net earnings per share amounts reported under GAAP for the three-month period and full year ended September 30, 2021 and 2020.

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.

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 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 RECONCILIATION TABLES**
(In Thousands, Except per Share Data)

	Three Months		Year	
	Ended September 30,		Ended September 30,	
	2021	2020	2021	2020
Operating Expenses -				
GAAP basis	\$ 36,228	\$ 28,857	\$ 108,114	\$ 94,924
Selected legal costs	(108)	(891)	(2,803)	(2,080)
Acquisition-related costs	(92)	(462)	(392)	(3,890)
Change in fair value of acquisition consideration	(4,596)	(1,135)	909	6,293
Restructuring costs	-	(67)	-	(687)
Adjusted Operating Expenses	<u>\$ 31,432</u>	<u>\$ 26,302</u>	<u>\$ 105,828</u>	<u>\$ 94,560</u>
Operating Income -				
GAAP basis	\$ 8,489	\$ 9,474	\$ 93,034	\$ 61,324
Selected legal costs	108	891	2,803	2,080
Acquisition-related costs	92	462	392	3,890
Change in fair value of acquisition consideration	4,596	1,135	(909)	(6,293)
Restructuring costs	-	67	-	687
Adjusted Operating Income	<u>\$ 13,285</u>	<u>\$ 12,029</u>	<u>\$ 95,320</u>	<u>\$ 61,688</u>
Net Earnings -				
GAAP basis	\$ 6,657	\$ 6,493	\$ 71,407	\$ 46,186
Selected legal costs *	81	667	2,105	1,562
Acquisition-related costs *	69	212	294	2,751
Change in fair value of acquisition consideration *	3,451	867	(683)	(4,726)
Restructuring costs *	-	50	-	528
Adjusted Net Earnings	<u>\$ 10,258</u>	<u>\$ 8,289</u>	<u>\$ 73,123</u>	<u>\$ 46,301</u>
Basic Earnings per Common Share -				
GAAP basis	\$ 0.15	\$ 0.15	\$ 1.65	\$ 1.08
Selected legal costs	-	0.02	0.05	0.04
Acquisition-related costs	-	-	0.01	0.06
Change in fair value of acquisition consideration	0.08	0.02	(0.02)	(0.11)
Restructuring costs	-	-	-	0.01
Adjusted Basic EPS **	<u>\$ 0.24</u>	<u>\$ 0.19</u>	<u>\$ 1.69</u>	<u>\$ 1.08</u>

	Three Months		Year	
	Ended September 30, 2021	2020	Ended September 30, 2021	2020
Diluted Earnings per Common Share -				
GAAP basis	\$ 0.15	\$ 0.15	\$ 1.62	\$ 1.07
Selected legal costs	-	0.02	0.05	0.04
Acquisition-related costs	-	-	0.01	0.06
Change in fair value of acquisition consideration	0.08	0.02	(0.02)	(0.11)
Restructuring costs	-	-	-	0.01
Adjusted Diluted EPS	<u>\$ 0.23</u>	<u>\$ 0.19</u>	<u>\$ 1.66</u>	<u>\$ 1.07</u>

* Net of tax, as applicable.

** Three months ended September 30, 2021 does not sum to total due to rounding.

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”, “can”, “guidance” 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 Bioscience, Inc. (“Meridian” or “the Company”) expects or anticipates will occur in the future, including, but not limited to, statements relating to per share diluted net earnings, sales, product demand, net revenues, operating margin, other guidance and the impact of COVID-19 on its business and prospects, 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 the Company’s 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 future 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 net revenues. The Company can make no assurances that a material weakness in its internal control over financial reporting will not be identified in the future, which if identified and not properly corrected, could materially and adversely affect its operations and result in material misstatements in its consolidated financial statements. Meridian also is subject to risks and uncertainties related to disruptions to or reductions in business operations or prospects due to pandemics, epidemics, widespread health emergencies, or outbreaks of infectious diseases such as COVID-19, including, without limitation, related supply chain interruptions. In addition to the factors described in this paragraph, as well as those factors identified from time to time in the Company's filings with the Securities and Exchange Commission, Part I, Item 1A Risk Factors of the Company's 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 the Company's forward-looking statements.

Revogene® SARS-CoV-2 assay disclaimer

The Revogene® SARS-CoV-2 assay has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated, or authorization is revoked sooner.

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 www.meridianbioscience.com.

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