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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended June 30, 2021

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	VIVO	NASDAQ Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date.

Class	Outstanding July 31, 2021
Common Stock, no par value	43,353,741

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
TABLE OF CONTENTS TO QUARTERLY REPORT ON FORM 10-Q

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 "continues", "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "signals", "should", "can" 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 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. 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.

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations (Unaudited)
(dollar and share amounts in thousands, except per share data)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
NET REVENUES	$63,511	$84,797	$241,692	$189,514
COST OF SALES	26,400	28,814	85,261	71,334
GROSS PROFIT	37,111	55,983	156,431	118,180
OPERATING EXPENSES				
Research and development	6,083	6,668	17,799	16,746
Selling and marketing	6,209	6,282	19,770	19,539
General and administrative	11,964	12,624	36,827	32,236
Acquisition-related costs	300	1,641	300	3,428
Change in fair value of acquisition consideration	(3,563)	(6,124)	(5,505)	(7,428)
Restructuring costs	—	93	—	620
Selected legal costs	438	134	2,695	1,189
Total operating expenses	21,431	21,318	71,886	66,330
OPERATING INCOME	15,680	34,665	84,545	51,850
OTHER INCOME (EXPENSE)				
Interest income	—	3	15	137
Interest expense	(444)	(703)	(1,450)	(2,002)
RADx grant income	—	—	1,000	—
Other, net	59	908	(1,515)	1,561
Total other income (expense)	(385)	208	(1,950)	(304)
EARNINGS BEFORE INCOME TAXES	15,295	34,873	82,595	51,546
INCOME TAX PROVISION	3,626	7,366	17,845	11,853
NET EARNINGS	$11,669	$27,507	$ 64,750	$ 39,693
BASIC EARNINGS PER COMMON SHARE	$ 0.27	$ 0.64	$ 1.50	$ 0.93
DILUTED EARNINGS PER COMMON SHARE	$ 0.26	$ 0.64	$ 1.47	$ 0.92
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC	43,334	42,837	43,226	42,819
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARE UNITS	763	436	780	219
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - DILUTED	44,097	43,273	44,006	43,038
ANTI-DILUTIVE SECURITIES:				
Common share options and restricted share units	190	854	180	1,298

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

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Comprehensive Income (Unaudited)
(dollar amounts in thousands)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
NET EARNINGS	$11,669	$27,507	$64,750	$39,693
Other comprehensive income (loss):				
Foreign currency translation adjustment	41	597	3,421	579
Unrealized gain (loss) on cash flow hedge	9	(390)	469	(703)
Reclassification of amortization of gain on cash flow hedge	—	(77)	(154)	(231)
Income taxes related to items of other comprehensive income (loss)	(2)	115	(68)	230
Other comprehensive income (loss), net of tax	48	245	3,668	(125)
COMPREHENSIVE INCOME	$11,717	$27,752	$68,418	$39,568

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

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows (Unaudited)
(dollar amounts in thousands)

Nine Months Ended June 30,	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	$ 64,750	$ 39,693
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	4,729	3,762
Amortization of intangible assets	6,453	5,604
Stock compensation expense	3,170	2,809
Deferred income taxes	(35)	2,214
Change in fair value of acquisition consideration	(5,505)	(7,428)
Change in the following:		
Accounts receivable	(2,363)	(6,352)
Inventories	(11,831)	(17,828)
Prepaid expenses and other current assets	(1,965)	68
Accounts payable and accrued expenses	(2,252)	4,422
Income taxes payable	(2,317)	3,401
Other, net	(448)	1,315
Net cash provided by operating activities	52,386	31,680
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(16,407)	(2,471)
Payment of acquisition consideration holdback	(5,000)	—
Acquisition of Exalenz, net of cash acquired	—	(51,299)
Net cash used in investing activities	(21,407)	(53,770)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment on revolving credit facility	(18,824)	(27,000)
Proceeds from revolving credit facility	—	50,000
Payment of debt issuance costs	—	(116)
Proceeds from exercise of stock options	2,939	—
Net cash (used in) provided by financing activities	(15,885)	22,884
Effect of Exchange Rate Changes on Cash and Cash Equivalents	1,404	254
Net Increase in Cash and Cash Equivalents	16,498	1,048
Cash and Cash Equivalents at Beginning of Period	53,514	62,397
Cash and Cash Equivalents at End of Period	$ 70,012	$ 63,445

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

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(dollar amounts in thousands)

ASSETS

	June 30, 2021 (Unaudited)	September 30, 2020
CURRENT ASSETS		
Cash and cash equivalents	$ 70,012	$ 53,514
Accounts receivable, less allowances of $514 and $513, respectively	42,258	38,512
Inventories, net	71,813	61,264
Prepaid expenses and other current assets	10,896	8,900
Total current assets	194,979	162,190
PROPERTY, PLANT AND EQUIPMENT, at Cost		
Land	993	991
Buildings and improvements	32,372	32,188
Machinery, equipment and furniture	77,429	69,854
Construction in progress	11,555	1,200
Subtotal	122,349	104,233
Less: accumulated depreciation and amortization	77,669	73,113
Property, plant and equipment, net	44,680	31,120
OTHER ASSETS		
Goodwill	115,315	114,186
Other intangible assets, net	76,744	83,197
Right-of-use assets, net	6,384	6,336
Deferred income taxes	8,073	7,647
Other assets	395	585
Total other assets	206,911	211,951
TOTAL ASSETS	$ 446,570	$ 405,261

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

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(dollar amounts in thousands)

LIABILITIES AND SHAREHOLDERS' EQUITY

	June 30, 2021 (Unaudited)	September 30, 2020
CURRENT LIABILITIES		
Accounts payable	$ 13,103	$ 11,969
Accrued employee compensation costs	14,026	16,661
Current portion of acquisition consideration	—	12,619
Current operating lease obligations	2,059	1,789
Current government grant obligations	735	600
Other accrued expenses	4,870	5,362
Income taxes payable	1,909	3,524
Total current liabilities	36,702	52,524
NON-CURRENT LIABILITIES		
Acquisition consideration	15,404	13,290
Post-employment benefits	2,314	2,493
Fair value of interest rate swaps	245	713
Long-term operating lease obligations	4,477	4,678
Long-term debt	50,000	68,824
Government grant obligations	10,512	10,524
Long-term income taxes payable	374	549
Deferred income taxes	4,195	3,804
Other non-current liabilities	191	233
Total non-current liabilities	87,712	105,108
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, 43,352,998 and 43,068,842 shares issued, respectively	—	—
Additional paid-in capital	146,304	140,195
Retained earnings	174,044	109,294
Accumulated other comprehensive income (loss)	1,808	(1,860)
Total shareholders' equity	322,156	247,629
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 446,570	$ 405,261

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

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Shareholders' Equity (Unaudited)
(dollar and share amounts in thousands)

	Common Shares Issued	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
THREE MONTHS ENDED JUNE 30, 2021					
Balance at March 31, 2021	43,329	$145,338	$162,375	$ 1,760	$ 309,473
Conversion of restricted share units and exercise of stock options	24	87	—	—	87
Stock compensation expense	—	879	—	—	879
Net earnings	—	—	11,669	—	11,669
Foreign currency translation adjustment	—	—	—	41	41
Hedging activity, net of tax	—	—	—	7	7
Balance at June 30, 2021	43,353	$146,304	$174,044	$ 1,808	$ 322,156
THREE MONTHS ENDED JUNE 30, 2020					
Balance at March 31, 2020	42,831	$134,584	$ 75,294	$ (5,345)	$ 204,533
Conversion of restricted share units and exercise of stock options	8	—	—	—	—
Stock compensation expense	—	1,050	—	—	1,050
Net earnings	—	—	27,507	—	27,507
Foreign currency translation adjustment	—	—	—	597	597
Hedging activity, net of tax	—	—	—	(352)	(352)
Balance at June 30, 2020	42,839	$135,634	$102,801	$ (5,100)	$ 233,335

	Common Shares Issued	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
NINE MONTHS ENDED JUNE 30, 2021					
Balance at September 30, 2020	43,069	$140,195	$109,294	$ (1,860)	$ 247,629
Conversion of restricted share units and exercise of stock options	284	2,939	—	—	2,939
Stock compensation expense	—	3,170	—	—	3,170
Net earnings	—	—	64,750	—	64,750
Foreign currency translation adjustment	—	—	—	3,421	3,421
Hedging activity, net of tax	—	—	—	247	247
Balance at June 30, 2021	43,353	$146,304	$174,044	$ 1,808	$ 322,156
NINE MONTHS ENDED JUNE 30, 2020					
Balance at September 30, 2019	42,712	$132,834	$ 63,108	$ (4,975)	$ 190,967
Conversion of restricted share units and exercise of stock options	127	(9)	—	—	(9)
Stock compensation expense	—	2,809	—	—	2,809
Net earnings	—	—	39,693	—	39,693
Foreign currency translation adjustment	—	—	—	579	579
Hedging activity, net of tax	—	—	—	(704)	(704)
Balance at June 30, 2020	42,839	$135,634	$102,801	$ (5,100)	$ 233,335

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

MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
Dollars in Thousands, Except Per Share Amounts
(Unaudited)

1. Nature of Business

Meridian Bioscience, Inc. ("Meridian" or "the Company") 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 testing systems and kits, primarily for certain gastrointestinal and respiratory infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, immunoassay blocking reagents, various Polymerase Chain Reaction ("PCR") master mixes, and bioresearch reagents used by other diagnostic manufacturers and researchers.

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of: (i) manufacturing operations for infectious disease products in Cincinnati, Ohio; Quebec City, Canada; and Modi'in, Israel; (ii) manufacturing operations for blood chemistry products in Billerica, Massachusetts (near Boston); and (iii) 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 in blood.

The Life Science segment consists of: (i) manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; and Luckenwalde, Germany; and (ii) the sale and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, and bioresearch reagents domestically and abroad, including a sales and business development facility, with outsourced distribution capabilities, in Beijing, China to pursue 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-generation sequencing, plant genotyping, and mutation detection, among others).

2. Basis of Presentation

The Condensed Consolidated Financial Statements are unaudited and are prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for interim financial information, and the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of Management, the Condensed Consolidated Financial Statements include all normal adjustments and disclosures necessary to present fairly the Company's consolidated financial position as of June 30, 2021, the results of its operations and shareholders' equity for the three- and nine-month periods ended June 30, 2021 and 2020, and cash flows for the nine-month periods ended June 30, 2021 and 2020. These Condensed Consolidated Financial Statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto included in the Company's fiscal 2020 Annual Report on Form 10-K filed with the SEC on November 23, 2020.

It should be noted that the terms revenue and/or revenues are utilized throughout these notes to the Condensed Consolidated Financial Statements to indicate net revenue and/or net revenues.

The results of operations for interim periods are not necessarily indicative of the results to be expected for the year. The preparation of these Condensed Consolidated Financial Statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, at the date of the Condensed Consolidated Financial Statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

3. 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 2020 Annual Report on Form 10-K filed with the SEC on November 23, 2020 and should be referred to for a description of the Company's significant accounting policies.

(a) Recent Accounting Pronouncements –

Pronouncements Adopted

On October 1, 2020, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2016-13, *Measurement of Credit Losses on Financial Instruments*, which changed the impairment model used to measure credit losses for most financial assets. Use of the new forward-looking expected credit loss model for our accounts receivable valuation, rather than the previously utilized incurred credit loss model, resulted in an immaterial impact on the Condensed Consolidated Financial Statements.

Pronouncements Issued but Not Yet Adopted as of June 30, 2021

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, to provide temporary optional guidance relating to reference rate reform, particularly as it relates to easing the potential burden resulting from the expected discontinuation of the London Interbank Offered Rate ("LIBOR"). The guidance provides practical expedients and exceptions for applying GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met, which may be applied through December 31, 2022. The Company continues to evaluate the impacts of this guidance but does not expect its application to have a material impact on the Condensed Consolidated Financial Statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 clarifies and simplifies accounting for income taxes by eliminating certain exceptions for intraperiod tax allocation principles, the methodology for calculating income tax rates in an interim period, and recognition of deferred taxes for outside basis differences in an investment, among other updates. ASU 2019-12 will be effective for the Company's fiscal year beginning on October 1, 2021. The Company is currently evaluating the impact of ASU 2019-12 but does not expect its application to have a material impact on the Condensed Consolidated Financial Statements.

(b) Reclassifications –

Certain reclassifications have been made to the prior year Condensed Consolidated Financial Statements to conform to the current year presentation. Such reclassifications had no impact on net earnings or shareholders' equity.

4. Revenue Recognition

Overview

Revenue from contracts with customers is recognized in an amount that reflects the consideration we expect to receive in exchange for products when obligations under such contracts are satisfied. Revenue is generally recognized at a point-in-time when products are shipped, and control has passed to the customer. Such contracts can include various combinations of products that are generally accounted for as distinct performance obligations. Revenue is reduced in the period of sale for fees paid to distributors, which are inseparable from the distributor's purchase of our product and for which we receive no goods or services in return. Revenue for the Diagnostics segment is reduced at the date of sale for product price adjustments payable to certain distributors under local contracts.

Revenue Disaggregation

The following tables present our revenues disaggregated by major geographic region, major product platform and disease state (Diagnostics segment only):

Revenue by Reportable Segment & Geographic Region

	Three Months Ended June 30,			Nine Months Ended June 30,		
	2021	2020	Inc (Dec)	2021	2020	Inc (Dec)
Diagnostics-						
Americas	$24,543	$17,575	40%	$ 73,367	$ 72,980	1%
EMEA	6,251	3,576	75%	18,352	16,853	9%
ROW	395	447	(12)%	1,740	1,498	16%
Total Diagnostics	31,189	21,598	44%	93,459	91,331	2%
Life Science-						
Americas	7,419	22,007	(66)%	39,661	30,638	29%
EMEA	15,723	26,227	(40)%	70,084	41,305	70%
ROW	9,180	14,965	(39)%	38,488	26,240	47%
Total Life Science	32,322	63,199	(49)%	148,233	98,183	51%
Consolidated	$63,511	$84,797	(25)%	$241,692	$189,514	28%

Revenue by Product Platform/Type

	Three Months Ended June 30,			Nine Months Ended June 30,		
	2021	2020	Inc (Dec)	2021	2020	Inc (Dec)
Diagnostics-						
Molecular assays	$ 4,383	$ 3,182	38%	$ 13,368	$17,259	(23)%
Non-molecular assays	26,806	18,416	46%	80,091	74,072	8%
Total Diagnostics	$31,189	$21,598	44%	$ 93,459	$91,331	2%
Life Science-						
Molecular reagents	$20,385	$38,791	(47)%	$104,016	$55,703	87%
Immunological reagents	11,937	24,408	(51)%	44,217	42,480	4%
Total Life Science	$32,322	$63,199	(49)%	$148,233	$98,183	51%

Revenue by Disease State (Diagnostics segment only)

	Three Months Ended June 30,			Nine Months Ended June 30,		
	2021	2020	Inc (Dec)	2021	2020	Inc (Dec)
Diagnostics-						
Gastrointestinal assays	$17,844	$ 9,584	86%	$48,962	$39,644	24%
Respiratory illness assays	3,742	5,052	(26)%	12,233	23,664	(48)%
Blood chemistry assays	4,254	3,364	26%	13,006	12,508	4%
Other	5,349	3,598	49%	19,258	15,515	24%
Total Diagnostics	$31,189	$21,598	44%	$93,459	$91,331	2%

Royalty Income

Royalty income received from a third party related to sales of *H. pylori* products, totaled approximately $1,380 and $160 in the three months ended June 30, 2021 and 2020, respectively, and $5,085 and $2,365 in the nine months ended June 30, 2021 and 2020, respectively. Such revenue is included as part of Non-molecular assays and Other within the Revenue by Product Platform/Type and Revenue by Disease State tables, respectively, above.

Reagent Rental Arrangements

Revenue allocated to the lease elements of Reagent Rental arrangements totaled approximately $950 and $1,150 in the three months ended June 30, 2021 and 2020, respectively, and $2,730 and $3,400 in the nine months ended June 30, 2021 and 2020, respectively. Such revenue is included as part of net revenues in our Condensed Consolidated Statements of Operations.

5. Fair Value Measurements

Certain assets and liabilities are recorded at fair value in accordance with Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures* ("ASC 820"). ASC 820 defines fair value as the price that would be received to sell an asset or would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a three-level hierarchy, which prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy level assigned to each asset and liability is based on the assessment of the transparency and reliability of the inputs used in the valuation of such items at the measurement date based on the lowest level of input that is significant to the fair value measurement. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

Assets and liabilities measured and reported at fair value are classified and disclosed in one of the following categories based on inputs:

Level 1

Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities

Level 2

Quoted prices in markets that are not active and financial instruments for which all significant inputs are observable, either directly or indirectly

Level 3

Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable

To limit exposure to volatility in the LIBOR interest rate, the Company has entered into interest rate swap agreements, which effectively convert the variable interest rate on $50,000 of the outstanding revolving credit facility discussed in Note 11 to a fixed rate. The fair values of the interest rate swap agreements were determined by reference to a third-party valuation and is considered a Level 2 input within the fair value hierarchy of valuation techniques.

As described in Note 6, we acquired Exalenz Bioscience Ltd. ("Exalenz") in fiscal 2020. The fair values of the acquired accounts receivable, inventories, property, plant and equipment, and other current assets and the fair values of the assumed accounts payable and accrued expenses were valued using Level 2 inputs, which included data points that were observable, such as appraisals or established values of comparable assets (market approach). Intangible assets were valued using Level 3 inputs, which are unobservable by nature, and included internal estimates of future cash flows (income approach). Significant increases (decreases) in any of those unobservable inputs, as of the date of the acquisition, in isolation would result in a significantly lower (higher) fair value measurement. Management engaged a third-party valuation firm to assist in the determination of the purchase accounting fair values, and specifically those considered Level 3 measurements. Management ultimately oversees the third-party valuation firm to ensure that the transaction-specific assumptions are appropriate for the Company.

In connection with the acquisition of the business of GenePOC, Inc. ("GenePOC") in fiscal 2019 and subsequent amendments to modify certain terms of the agreement related to contingent consideration achievement levels and milestone dates, the Company is required to make contingent consideration payments of up to $64,000 (originally $70,000 at the acquisition date), comprised of up to $14,000 for achievement of product development milestones (originally $20,000 at the acquisition date) and up to $50,000 for achievement of certain financial targets. The fair value for the contingent consideration recognized upon the acquisition as part of the purchase price allocation was $27,202. The fair value of the product development milestone payments is estimated by discounting the probability-weighted contingent payments to present value and is presented on the Condensed Consolidated Balance Sheets based on the Company's anticipated date of payment at each reporting period. Assumptions used in the calculations include probability of success, duration of the earn-out and discount rate, and such calculations were updated for the effect of the previously noted amendments to the contingent consideration achievement levels and milestone dates. The fair value of the financial performance target payments was determined using a Monte Carlo simulation-based model. Assumptions used in these calculations include expected revenues, probability of certain developments, expected expenses and discount rate. The ultimate settlement of contingent consideration could deviate significantly from the current Level 3 measurement estimates, based on the actual results of these financial measures.

The following table provides information by level for financial assets and liabilities that are measured at fair value on a recurring basis:

	Carrying Value	Fair Value Measurements Using Inputs Considered as		
		Level 1	Level 2	Level 3
Interest rate swaps -				
As of June 30, 2021	$ (245)	$ —	$ (245)	$ —
As of September 30, 2020	$ (713)	$ —	$ (713)	$ —
Contingent consideration -				
As of June 30, 2021	$(15,404)	$ —	$ —	$ (15,404)
As of September 30, 2020	$(20,909)	$ —	$ —	$ (20,909)

6. Business Combinations

On April 30, 2020 ("the acquisition date"), we acquired 100% of the outstanding common shares and voting interest of Exalenz, a Modi'in, Israel based provider of the BreathID® Breath Test Systems ("BreathID"), a breath test platform for the detection of *Helicobacter pylori*. Cash consideration totaled 168.6 million New Israeli Shekels ("NIS"), which equated to $48,237 at the date of closing. Including debt assumed and repaid shortly after closing, the total consideration transferred was $56,305. To finance the acquisition, the Company utilized cash and cash equivalents on hand and proceeds drawn from our revolving credit facility (see Note 11). In anticipation of the transaction, we executed forward currency contracts to acquire the NIS required for the acquisition. As a result, the net cash outlay for the transaction prior to the repayment of debt was $47,392.

As a result of total consideration exceeding the fair value of the net assets acquired, goodwill in the amount of $24,798 was recorded in connection with this acquisition, none of which will be deductible for U.S. tax purposes. The goodwill results largely from our ability to market and sell the BreathID platform through our established customer base and distribution channels.

The Company's consolidated results for the three and nine months ended June 30, 2021 and 2020 include the following from Exalenz:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Net revenues	$4,836	$1,308	$10,718	$1,308
Net loss	$ (497)	(932)	(2,236)	(932)

These results, which are reported as part of the Diagnostics segment, include amortization expense related to specific identifiable assets recorded in the purchase price allocation, including a non-compete agreement, trade name, technology and customer relationships, totaling $720 and $2,240 for the three and nine months ended June 30, 2021, respectively; $448 for both the three and nine months ended June 30, 2020.

The recognized amounts of identifiable assets acquired and liabilities assumed in the acquisition of Exalenz are as follows:

	April 30, 2020
Fair value of assets acquired -	
Cash	$ 5,006
Accounts receivable	637
Inventories	4,026
Other current assets	2,676
Property, plant and equipment	528
Goodwill	24,798
Other intangible assets (estimated useful life):	
Non-compete agreement (5 years)	110
Trade name (10 years)	3,860
Technology (15 years)	6,120
Customer relationships (10 years)	20,640
Right-of-use assets	1,311
Deferred tax assets, net	6,780
	76,492
Fair value of liabilities assumed -	
Accounts payable and accrued expenses (including current portion of lease and government grant obligations)	8,008
Long-term lease obligations	1,096
Long-term government grant obligations	10,792
Other non-current liabilities	291
	20,187
Total consideration paid (including $8,068 to pay off long-term debt)	$56,305

During the three months ended June 30, 2021, the purchase price allocation was finalized.

Pro Forma Information

The following table provides the unaudited condensed consolidated pro forma results for the periods presented as if Exalenz had been acquired as of the beginning of fiscal 2020 (October 1, 2019). Pro forma results do not include the effect of any synergies achieved or anticipated to be achieved from the acquisition, and accordingly, are not necessarily indicative of the results that would have occurred if the acquisition had occurred on the date indicated or that may result in the future.

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Net revenues	$63,511	$85,083	$241,692	$196,978
Net earnings	11,669	27,403	64,750	38,433

These unaudited pro forma amounts have been calculated by including the results of Exalenz and adjusting the results to give effect to the following, as if the acquisition had been consummated on October 1, 2019, together with the consequential tax effects thereon:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Adjustments to net revenues				
Exalenz pre-acquisition net revenues	$—	$ 286	$—	$ 7,464
Adjustments to net earnings				
Exalenz pre-acquisition net loss	$—	$(4,919)	$—	$(6,423)
Pro forma adjustments:				
Meridian acquisition-related costs	—	1,641	—	3,428
Exalenz transaction-related costs	—	4,104	—	4,550
Gain on Exalenz purchase price currency contracts	—	(845)	—	(845)
Remove net impact of non-continuing personnel, locations or activities	—	(446)	—	(301)
Incremental depreciation and amortization	—	(240)	—	(2,064)
Interest, net	—	444	—	(328)
Tax effects of pro forma adjustments and recognizing benefit on resulting Exalenz losses	—	157	—	723
Total adjustments to net earnings	$—	$ (104)	$—	$(1,260)

7. Cash and Cash Equivalents

Cash and cash equivalents include the following:

	June 30, 2021	September 30, 2020
Institutional money market funds	$ 1,017	$ 1,017
Cash on hand, unrestricted	68,995	52,497
Total	$70,012	$ 53,514

8. Inventories, Net

Inventories, net are comprised of the following:

	June 30, 2021	September 30, 2020
Raw materials	$18,654	$ 11,966
Work-in-process	23,570	19,477
Finished goods - instruments	1,975	1,594
Finished goods - kits and reagents	27,614	28,227
Total	$71,813	$ 61,264

9. Leasing Arrangements

The Company is party to several operating leases, the majority of which are related to office, warehouse and manufacturing space. The related operating lease assets and obligations are reflected within right-of-use assets, net, current operating lease obligations and long-term operating lease obligations on the Condensed Consolidated Balance Sheets. Lease expense for these leases is recognized on a straight-line basis over the lease term, with variable lease payments recognized in the period those payments are incurred.

The lease costs for these operating leases reflected in our Condensed Consolidated Statements of Operations for the three and nine months ended June 30, 2021 and 2020, as well as the right-of-use assets, net obtained during these periods in exchange for operating lease liabilities, are as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Lease costs within cost of sales	$213	$ 165	$ 569	$ 424
Lease costs within operating expenses	390	330	1,151	889
Right-of-use assets, net obtained in exchange for operating lease liabilities	381	1,394	1,073	1,616

In addition, the Company periodically enters into other short-term operating leases, generally with an initial term of twelve months or less. These leases are not recorded on the Condensed Consolidated Balance Sheets and the related lease expense is immaterial for the three and nine months ended June 30, 2021 and 2020.

The Company often has options to renew lease terms, with the exercise of lease renewal options generally at the Company's sole discretion. In addition, certain lease arrangements may be terminated prior to their original expiration date at our discretion. We evaluate renewal and termination options at the lease commencement date to determine if we are reasonably certain to exercise the option on the basis of economic factors. The discount rate implicit within our leases is generally not determinable and, therefore, the Company uses its incremental borrowing rate as the basis for its discount rate. The weighted average remaining lease term for our operating leases and the weighted average discount rate used to measure our operating leases as of June 30, 2021 and September 30, 2020 were as follows:

	June 30, 2021	September 30, 2020
Weighted average remaining lease term	3.7 years	4.2 years
Average discount rate	3.2%	3.7%

Maturities of lease liabilities by fiscal year for the Company's operating leases were as follows as of June 30, 2021:

2021 (represents remainder of fiscal year)	$ 613
2022	2,202
2023	1,590
2024	1,213
2025	913
Thereafter	385
Total lease payments	6,916
Less amount of lease payments representing interest	(380)
Total present value of lease payments	$6,536

Supplemental cash flow information related to the Company's operating leases are as follows:

Nine Months Ended June 30,	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$1,611	$1,213

10. Goodwill and Other Intangible Assets, Net

During the nine months ended June 30, 2021, goodwill increased $1,129, reflecting: (i) an additional $332 acquisition measurement period adjustment related to Exalenz (see Note 6); (ii) an $80 increase from the currency translation adjustment on goodwill in the Diagnostics segment; and (iii) a $717 increase from the currency translation adjustment on goodwill in the Life Science segment.

The Company has historically performed its annual goodwill impairment assessment as of the last day of the third fiscal quarter of each year (June 30). During the third quarter of fiscal 2021, the Company decided to change the date of its annual impairment assessment from June 30 to July 1. The change was made to more closely align the annual goodwill impairment assessment date with the Company's annual planning and budgeting process, as well as its long-term planning and forecasting process. The Company has determined this change in accounting principle is preferable and will not affect the consolidated financial statements. Pursuant to the authoritative accounting literature, in fiscal 2021 the Company will perform a goodwill impairment assessment as of the last day of its fiscal 2021 third quarter (June 30), as well as July 1, to ensure that the change in goodwill impairment assessment date did not delay or avoid an impairment charge. This change is not applied retrospectively, as it is impracticable to do so because retrospective application would require application of significant estimates and assumptions with the use of hindsight. Accordingly, the change will be applied prospectively.

At June 30, 2021, impairment review of the Company's goodwill consisted of a qualitative assessment for each of our Diagnostics and Life Science reporting units. A qualitative assessment is first performed to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value using qualitative indicators. In the event that the reporting unit does not pass the qualitative assessment, the reporting unit's carrying value is compared to its fair value, with fair value of the reporting unit estimated using market value and discounted cash flow approaches. Both our Diagnostics and Life Science reporting units satisfied the qualitative assessment at June 30, 2021, and no impairment was recognized. The Company will perform its July 1, 2021 goodwill impairment assessment during the fourth quarter of fiscal 2021.

A summary of other intangible assets, net subject to amortization is as follows:

	June 30, 2021		September 30, 2020	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	$ 62,451	$ 21,714	$ 62,363	$ 18,750
Trade names, licenses and patents	18,530	9,225	18,425	7,801
Customer lists, customer relationships and supply agreements	45,305	18,687	45,071	16,210
Non-compete agreements	110	26	110	11
Total	$126,396	$ 49,652	$125,969	$ 42,772

The aggregate amortization expense for these other intangible assets was $2,090 and $2,155 for the three months ended June 30, 2021 and 2020, respectively, and $6,453 and $5,604 for the nine months ended June 30, 2021 and 2020, respectively. The estimated aggregate amortization expense for these other intangible assets for each of the fiscal years through fiscal 2026 is as follows: remainder of fiscal 2021 – $2,000, fiscal 2022 – $7,995, fiscal 2023 – $7,980, fiscal 2024 – $7,975, fiscal 2025 – $7,965, and fiscal 2026 – $7,295.

11. Bank Credit Arrangements

The Company maintains a revolving credit facility with a commercial bank in an aggregate principal amount not to exceed $160,000, which expires in May 2024. Outstanding principal amounts bear interest at a fluctuating rate tied to, at the Company's option, either the federal funds rate or LIBOR, resulting in an effective interest rate of 2.52% and 2.63% on the revolving credit facility during the three months ended June 30, 2021 and 2020, respectively, and 2.55% and 3.45% during the nine months ended June 30, 2021 and 2020, respectively. In light of the interest being determined on a variable rate basis, the fair value of the borrowings under the revolving credit facility at both June 30, 2021 and September 30, 2020, approximates the current carrying value reflected in the Condensed Consolidated Balance Sheets.

The revolving credit facility is collateralized by the business assets of the Company's U.S. subsidiaries and requires 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 revolving credit facility agreement. As of June 30, 2021, the Company was in compliance with all covenants.

12. Contingent Obligations and Non-Current Liabilities

In connection with the acquisition of Exalenz (see Note 6), the Company assumed several Israeli government grant obligations. The repayment of the grants, along with interest incurred at varying stated fixed rates based on LIBOR at the time each grant was received (ranging from 0.58% to 6.60%), is not dictated by an established repayment schedule. Rather, the grants and related interest are required to be repaid using 3% of the revenues generated from the sales of BreathID products, with the timing of repayment contingent upon the level and timing of such revenues. In addition, the grants have no collateral or financial covenant provisions generally associated with traditional borrowing instruments. These obligation amounts total $11,247 and $11,124 as of June 30, 2021 and September 30, 2020, respectively, and are reflected in the Condensed Consolidated Balance Sheets as follows:

	June 30, 2021	September 30, 2020
Current liabilities	$ 735	$ 600
Non-current liabilities	$10,512	$ 10,524

Additionally, the Company has provided certain post-employment benefits to its former Chief Executive Officer, and these obligations total $1,730 and $1,840 at June 30, 2021 and September 30, 2020, respectively. In addition, the Company is required by the governments of certain foreign countries in which we operate to maintain a level of accruals for potential future severance indemnity. These accruals total $756 and $814 at June 30, 2021 and September 30, 2020, respectively.

13. National Institutes of Health Contracts

In December 2020, the Company entered into a sub-award grant contract with the University of Massachusetts Medical School as part of the National Institutes of Health Rapid Acceleration of Diagnostics ("RADx") initiative to support the Company's research and development of its diagnostic test for the SARS-CoV-2 antigen. The Company has received $1,000 under the grant contract for reimbursement of eligible research and development expenditures. These amounts are included within other income (expense) in the Condensed Consolidated Statement of Operations for the nine months ended June 30, 2021.

Effective February 1, 2021, the Company entered into a second grant contract under the RADx initiative, the purpose of which is to support the Company's manufacturing production scale-up and expansion to meet the demand for COVID-19 testing. The contract is a twelve-month term service contract, with payment of up to $5,500 being made based on the Company achieving key milestones related to increasing its capacity to produce COVID-19 tests. No amounts related to this contract are reflected within the Condensed Consolidated Financial Statements.

14. Reportable Segment and Major Customers Information

During the three and nine months ended June 30, 2021, products related to COVID-19 accounted for approximately 45% and 60%, respectively, of Life Science segment revenues, and 23% and 37%, respectively, of consolidated revenues. In addition, on a consolidated basis, two Life Science segment customers (Customers D and E below) represented 17% and 11%, respectively, of consolidated revenues during the three months ended June 30, 2020 (1% and 2%, respectively, during the three months ended June 30, 2021), with no individual Diagnostics or Life Science segment customer accounting for 10% or more of consolidated revenues during the nine months ended June 30, 2021 and 2020.

Individual Diagnostics or Life Science segment customers, including their affiliates, comprising 10% or more of reportable segment revenues during any of the three- and nine-month periods ended June 30, 2021 and 2020 were as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Diagnostics				
Customer A	10%	13%	11%	11%
Customer B	11%	8%	10%	13%
Customer C	14%	5%	12%	5%
Life Science				
Customer D	3%	23%	4%	17%
Customer E	4%	14%	12%	11%

In addition, during the three and nine months ended June 30, 2021, the Life Science segment's ten largest customers, including their affiliates, accounted for approximately 46% and 43%, respectively, of Life Science segment revenues, and 24% and 27%, respectively, of consolidated revenues.

One Life Science segment customer (Customer E above) accounted for 15% of consolidated accounts receivable as of September 30, 2020 (2% as of June 30, 2021).

Reportable segment information for the interim periods is as follows:

	Diagnostics	Life Science	Corporate[1]	Eliminations[2]	Total
Three Months Ended June 30, 2021					
Net revenues -					
Third-party	$ 31,189	$ 32,322	$ —	$ —	$ 63,511
Inter-segment	100	54	—	(154)	—
Operating income	2,510	16,129	(2,998)	39	15,680
Goodwill (June 30, 2021)	95,267	20,048	—	—	115,315
Other intangible assets, net (June 30, 2021)	76,743	1	—	—	76,744
Total assets (June 30, 2021)	329,003	117,564	—	3	446,570
Three Months Ended June 30, 2020					
Net revenues -					
Third-party	$ 21,598	$ 63,199	$ —	$ —	$ 84,797
Inter-segment	86	56	—	(142)	—
Operating income	(1,783)	39,305	(2,849)	(8)	34,665
Goodwill (September 30, 2020)	94,855	19,331	—	—	114,186
Other intangible assets, net (September 30, 2020)	83,179	18	—	—	83,197
Total assets (September 30, 2020)	306,812	98,483	—	(34)	405,261
Nine Months Ended June 30, 2021					
Net revenues -					
Third-party	$ 93,459	$ 148,233	$ —	$ —	$241,692
Inter-segment	285	163	—	(448)	—
Operating income	3,749	92,015	(11,286)	67	84,545
Nine Months Ended June 30, 2020					
Net revenues -					
Third-party	$ 91,331	$ 98,183	$ —	$ —	$189,514
Inter-segment	264	176	—	(440)	—
Operating income	8,087	51,564	(7,832)	31	51,850

(1) Includes selected legal costs of $438 and $2,695 in the three and nine months ended June 30, 2021, respectively, and $134 and $1,189 in the three and nine months ended June 30, 2020, respectively.

(2) Eliminations consist of inter-segment transactions.

A reconciliation of reportable segment operating income to consolidated earnings before income taxes for the interim periods is as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2021	2020	2021	2020
Operating income:				
Diagnostics segment	$ 2,510	$ (1,783)	$ 3,749	$ 8,087
Life Science segment	16,129	39,305	92,015	51,564
Eliminations	39	(8)	67	31
Total segment operating income	18,678	37,514	95,831	59,682
Corporate operating expenses	(2,998)	(2,849)	(11,286)	(7,832)
Interest income	—	3	15	137
Interest expense	(444)	(703)	(1,450)	(2,002)
RADx initiative grant income	—	—	1,000	—
Other, net	59	908	(1,515)	1,561
Consolidated earnings before income taxes	$15,295	$34,873	$ 82,595	$51,546

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

15. Income Taxes

The effective rate for income taxes was 24% and 22% for the three and nine months ended June 30, 2021, respectively, and 21% and 23% for the three and nine months ended June 30, 2020, respectively. The variation in effective tax rates during the three and nine months ended June 30, 2021 and 2020 related primarily to higher allocations of taxable income in the U.S. in the fiscal 2021 reporting periods compared to certain lower-rate foreign jurisdictions, particularly the United Kingdom ("U.K."). Additionally, the nine-month period ended June 30, 2021 was favorably impacted by the effect of current year restricted share unit lapses and stock option exercises occurring on dates when the share price of Company stock was significantly higher than the share price on the date such equity awards were granted, compared to the opposite effect during the prior year period.

16. Litigation and Regulatory Matters

On April 17, 2018, the Company's wholly owned subsidiary Magellan received a subpoena from the U.S. 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, including responding to additional information requests that have followed receipt of the subpoena in April 2018. The Company has executed tolling agreements to extend the statute of limitations. In March and April 2021, DOJ issued two subpoenas calling for witnesses to testify before a federal grand jury related to this matter. The March 2021 subpoena was issued to a former employee of Magellan, and the April subpoena was issued to a current employee of Magellan. The Company cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on the Company. Approximately $438 and $134 of expense for attorneys' fees related to this matter is included within the Condensed Consolidated Statements of Operations for the three months ended June 30, 2021 and 2020, respectively, and approximately $2,695 and $1,145 for the nine months ended June 30, 2021 and 2020, respectively.

Magellan submitted 510(k) applications in December 2018, seeking to reinstate venous blood sample-types for its LeadCare II, LeadCare Plus and LeadCare Ultra testing systems. In the second fiscal quarter of 2019 the U.S. Food and Drug Administration ("FDA") informed Magellan that each of these 510(k) applications had been put on Additional Information hold. On July 15, 2019, we provided responses to the FDA's requests for Additional Information. These 510(k) applications have since expired and are no longer under FDA review. Further, while Magellan's LeadCare testing systems remain cleared for marketing by the FDA and permitted for use with capillary blood samples, the FDA advised that it has commissioned a third-party study of the Company's LeadCare testing systems using both venous and capillary blood samples. According to the FDA, the results of the field study will be used in conjunction with other information to determine whether further action by the FDA or the Centers for Disease Control and Prevention ("CDC") is necessary to protect the public health. The Company intends to fully cooperate with the FDA or CDC on any follow-up based on the third-party study.

During October 2019, the FDA performed a follow-up inspection of Magellan's manufacturing facility. The FDA issued five Form FDA 483 observations. On March 18, 2020, we participated in a regulatory meeting with the FDA at the FDA's request to further discuss the Form FDA 483 observations and our remediation efforts. Since the inspection, we have submitted a number of written responses to the FDA regarding the five Form FDA 483 observations issued in the October 2019 inspection, and have worked diligently to execute a remediation plan. During October 2020, the FDA issued Establishment Inspection Reports which closed out the inspections from June 2017 and October 2019 under 21 C.F.R.20.64(d)(3).

During June 2021, the FDA performed an inspection of Magellan's manufacturing facility. The inspection followed a voluntary recall, initiated in May 2021, involving certain manufactured lots of its LeadCare II, LeadCare Plus and LeadCare Ultra products. As a result of this inspection, the FDA issued one Form 483 observation. The FDA has identified this recall, which remains ongoing, as a Class I recall, and the Company is working closely with the FDA in its execution of the recall activities. Magellan is also responding to ongoing information requests from the FDA regarding issues related to the recall. Based upon information known at this time, the recall's impact on the Company's consolidated financial statements is not believed to be material and no related costs are included within the Condensed Consolidated Statements of Operations for the three and nine months ended June 30, 2021. On August 3, 2021, FDA sent Magellan a close-out letter for the Warning Letter that FDA issued to Magellan on October 23, 2017. FDA's close-out letter notified Magellan that FDA has completed an evaluation of Magellan's corrective actions in response to FDA's Warning Letter, and based on FDA's evaluation, Magellan has addressed the issues identified in the Warning Letter. FDA's close-out letter also stated that future FDA inspections of Magellan and regulatory activities will further assess the adequacy and sustainability of Magellan's corrections.

17. Subsequent Event

On July 22, 2021, the Company signed a definitive agreement to acquire from Otsuka America Pharmaceutical, Inc. ("OAPI") its BreathTek® business in the U.S. and Mexico for $20,000 in cash. BreathTek is an FDA approved urea breath test for the detection of *H. pylori*. Assets to be acquired include test kit inventory, customer relationships and rights to the BreathTek trade name. In addition, the Company and OAPI have entered into a transition services agreement, which is designed to allow the Company to integrate the BreathTek business in a manner that provides appropriate customer support. This transaction closed on July 31, 2021. The purchase price was funded with cash and cash equivalents on hand and this acquisition will be included in our Diagnostics segment.

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.

The purpose of Management's Discussion and Analysis is to provide an understanding of the financial condition, changes in financial condition and results of operations of Meridian Bioscience, Inc. ("Meridian", the "Company", "We"). This discussion should be read in conjunction with the Condensed Consolidated Financial Statements and notes. It should be noted that the terms revenue and/or revenues are utilized throughout the Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") to indicate net revenue and/or net revenues. In addition, throughout the MD&A, we refer to certain product tradenames and trademarks, which are protected under applicable intellectual property laws and are our property. Solely for convenience, these tradenames and trademarks are referred to without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent of the law, our rights to these tradenames and trademarks.

Reportable Segments

Our reportable segments are Diagnostics and Life Science. The Diagnostics segment consists of manufacturing operations for infectious disease products in Cincinnati, Ohio; Quebec City, Canada; and Modi'in, Israel; and manufacturing operations for blood chemistry products in Billerica, Massachusetts (near Boston). These diagnostic test products are 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"). The Life Science segment consists of manufacturing operations in Memphis, Tennessee; Boca Raton, Florida; London, England; and Luckenwalde, Germany, and the sale and distribution of bulk antigens, antibodies, immunoassay blocking reagents, various Polymerase Chain Reaction ("PCR") master mixes, and bioresearch reagents domestically and abroad, including a sales and business development facility, with outsourced distribution capabilities, in Beijing, China to further pursue growing revenue opportunities in Asia.

Recent Developments

During the latter half of fiscal 2020 and the first half of fiscal 2021, the COVID-19 pandemic has had both positive and negative effects on our businesses. The third quarter of fiscal 2021 represents the first quarter since the early stages of the COVID-19 pandemic that our Diagnostics segment has shown positive revenue growth versus the same quarter in fiscal 2020. Conversely for our Life Science segment, the third quarter of fiscal 2021 represents the first quarter since the early stages of the COVID-19 pandemic that its revenues have shown a decline compared to the same quarter in fiscal 2020.

Our Life Science segment's products have been well positioned to respond to in-vitro device ("IVD") manufacturers' needs for reagents for molecular, rapid antigen and serology tests. Consequently, our Life Science segment grew its revenues over 100% in fiscal 2020 and delivered record operating income and margin, demonstrating what this segment could achieve at a much larger scale. This higher-than-historical level of growth continued into the first half of fiscal 2021 for the Life Science segment before declining during the three months ended June 30, 2021. In recent months, we have experienced a decline in the demand for our Life Science segment's reagent products used in COVID-19 tests and as a result, our Life Science segment's revenues during the three months ended June 30, 2021 decreased 49% from the prior year period, while the segment's revenues during the fiscal 2021 year-to-date nine-month period increased 51% over the comparable fiscal 2020 period.

Our Diagnostics segment, on the other hand, reported increased year-over-year revenues of 44% and 2% for the three- and nine-month periods ended June 30, 2021, respectively. Following decreasing year-over-year revenues in the last two quarters of fiscal 2020 and first two quarters of fiscal 2021, these results indicate signs of a return to more normal pre-pandemic levels of revenue in all product areas except for respiratory illness products. Revenue from sales of respiratory illness assays continues to compare unfavorably to fiscal 2020, down 26% and 48% for the three and nine months ended June 30, 2021, respectively.

Despite these recent COVID-19 pandemic related trends, due to the many uncertainties surrounding the COVID-19 pandemic, we can provide no assurances with respect to our views of the longevity, severity or impacts to our financial condition of the COVID-19 pandemic.

Employee Safety

While our employee base in the U.S. has returned to working on-site at our facilities, we continue to utilize a work-from-home process as needed on a site-by-site basis outside the U.S. for those employees whose on-site presence has been deemed to be non-essential. We have also implemented enhanced cleaning and sanitizing procedures and provided additional personal hygiene supplies at all our sites. We have implemented policies for employees to adhere to CDC guidelines on social distancing, and similar guidelines by authorities outside the U.S. To date, we have been able to manufacture and distribute products globally, and all our sites have continued to operate with little, if any, impact on shipments to customers to date. As the COVID-19 pandemic continues, along with continuing governmental restrictions which vary by locale and jurisdiction, there is an increased risk of employee absenteeism, which could materially impact our operations at one or more sites. To date, the steps we have taken, including our work-from-home processes, have not materially impacted the Company's financial reporting systems, internal controls over financial reporting or disclosure controls.

Supply Chains

Supply chains supporting our products have generally remained intact, providing access to sufficient inventory of the key materials needed for manufacturing. To date, delays and allocations for raw materials have been limited and have not had a material impact on our results of operations. From time to time, we identify alternative suppliers to address the risk of a current supplier's inability to deliver materials in volumes sufficient to meet our manufacturing needs; or we may choose to purchase certain materials in bulk volumes where we have supply chain scarcity concerns. It remains possible that we may experience some sort of interruption to our supply chains, and such an interruption could materially affect our ability to timely manufacture and distribute our products and unfavorably impact our results of operations.

Product Development and Clinical Trials

Our clinical trials are progressing at a slower pace than normal, as the prevalence of certain infectious diseases (e.g., bacterial gastrointestinal) has been much lower than normal during the pandemic. In addition, the relative lack of a respiratory illness season in 2020-2021 has significantly impacted the availability of influenza samples, thereby affecting the pace of development of our molecular respiratory panel for the Revogene system. These matters continue to impact our timing for filing applications for product clearances with the FDA, as well as related timing of FDA clearances of such filings. Additionally, the ongoing COVID-19 pandemic has slowed and could continue to slow down our efforts to expand our product portfolio through acquisitions and distribution opportunities, impacting the speed with which we are able to bring additional products to market.

Product Demand

Our Life Science segment manufactures, markets and sells a number of molecular and immunological reagents to IVD customers, including those who are making both molecular and immunoassay COVID-19 tests. Since late in the second quarter of fiscal 2020, we have experienced unprecedented demand for certain of our molecular reagents (e.g., ribonucleic acid ("RNA") master mixes and nucleotides). However, as expected, to date during the second half of our fiscal 2021, we have experienced a decline in the demand for our Life Science segment's reagent products used in COVID-19 tests, as health care systems transition to more asymptomatic testing versus the predominant symptomatic testing we saw during the peak of the COVID-19 pandemic. While we expect a continuation of this trend throughout the remainder of our fiscal year ending September 30, 2021, this expectation could be impacted by the recent resurgence in COVID-19 infection rates, particularly those associated with the COVID-19 strain commonly known as the "Delta variant", with infection rates and the responses to such levels of infection varying by country based on their individual COVID-19 case statistics, infection rates and vaccine programs. We believe that our reagent products for COVID-19 have applications in many alternative, non-hospital-based channels (e.g., airports, schools, etc.). Our products are used in over 100 regulatory agency approved COVID-19 related assays around the world. COVID-19 related reagent revenues totaled approximately $14,500 and $88,500 in the three and nine months ended June 30, 2021, respectively, compared to approximately $48,000 and $53,000 in the three and nine months ended June 30, 2020, respectively, and approximately $71,500 during full year fiscal 2020.

Our Diagnostics segment manufactures, markets and sells a number of molecular, immunoassay, blood chemistry and urea breath tests for various infectious diseases and blood-lead levels. Sales volumes for a number of these assays have been adversely affected by the COVID-19 pandemic over the past year and half, as such assays are often used in non-critical care settings. However, as previously noted, during the three months ended June 30, 2021, we have begun to see signs of a return to more normal pre-pandemic levels for most of our Diagnostics segment product lines, with respiratory illness assays being the exception. The COVID-19 pandemic also has affected instrument orders and placements for our BreathID and Revogene platforms. Recently, we are seeing higher levels of order activity for our BreathID platform. However, order activity for our Revogene platform continues to be affected by our pending SARS-CoV-2 assay emergency use authorization ("EUA") application, which we voluntarily withdrew from the FDA on February 23, 2021 and resubmitted on June 25, 2021. We believe customers have taken a "wait and see" approach with our EUA application resubmission. Despite the situation with our EUA application for the SARS-CoV-2 assay, we are in the process of increasing our capacity to produce these tests, as well as other tests on the Revogene system, at our sites in Quebec and Cincinnati. Specifically, we are: (i) adding a second production line at our Quebec manufacturing facility; and (ii) installing two additional production lines in a leased facility near our corporate headquarters in Cincinnati. It is expected that these expansion efforts will be completed during calendar 2021 at a total cost of approximately $18,000, which is expected to be partially offset by the $5,500 RADx grant entered into on February 1, 2021 (see Note 13 of the Condensed Consolidated Financial Statements).

Critical Accounting Estimates

Aside from the change in the Company's annual goodwill impairment assessment discussed in Note 10 of the Condensed Consolidated Financial Statements, for the three and nine months ended June 30, 2021, there were no significant changes to our critical accounting estimates, as outlined in our Annual Report on Form 10-K as of and for the year ended September 30, 2020.

Impact of Brexit

The U.K. left the European Union ("EU") on January 31, 2020. While all EU rules and laws continued to apply to the U.K. through the transition period, which ended December 31, 2020, the U.K. and the EU reached a free trade agreement on December 24, 2020, which was ratified on April 28, 2021 and went into effect on May 1, 2021. The agreement includes regulatory and customs cooperation mechanisms, as well as provisions supporting open and fair competition. Under the trade agreement, the U.K. is free to set its own trade policy and can negotiate with other countries that do not currently have free trade deals with the EU. Although the full impact of the trade agreement is uncertain, it is possible that the recent changes to the trading relationship between the U.K. and the EU due to the trade agreement could result in increased cost of goods imported into and exported from the U.K., which may decrease the profitability of our operations. Additional currency volatility could drive a weaker British pound, which could increase the cost of goods imported into the U.K. and may decrease the profitability of our operations. A weaker British pound versus the U.S. dollar may also cause local currency results of our operations to be translated into fewer U.S. dollars during a reporting period. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the trade agreement will have on our business; however, Brexit and its related effects could potentially have an adverse impact on our consolidated financial position and results of operations.

The U.K.'s withdrawal from the EU could also adversely impact the operations of our vendors and of our other partners. Our management team has evaluated a range of possible outcomes, identified areas of concern, and implemented strategies to help mitigate these concerns. It is possible that these strategies may not be adequate to mitigate any adverse impacts of Brexit, and that these impacts could further adversely affect our business and results of operations.

RESULTS OF OPERATIONS

Three Months Ended June 30, 2021

Net earnings for the three months ended June 30, 2021 decreased 58% to $11,669, or $0.26 per diluted share, from net earnings for the third quarter of fiscal 2020 of $27,507, or $0.64 per diluted share. The level of net earnings in the third quarter of fiscal 2021 was affected predominantly by the decline in revenues and operating income in our Life Science segment, stemming from the softening in demand for COVID-19 related reagents during the quarter.

Consolidated revenues for the third quarter of fiscal 2021 totaled $63,511, a decrease of 25% compared to the third quarter of fiscal 2020 (29% decrease on a constant-currency basis).

Revenues from the Diagnostics segment for the third quarter of fiscal 2021 increased 44% compared to the third quarter of fiscal 2020 (42% increase on a constant-currency basis), comprised of a 38% increase in molecular assay products and a 46% increase in non-molecular assay products. The third quarter of fiscal 2021 represents the first quarter since the early stages of the COVID-19 pandemic that our Diagnostics segment has shown positive revenue growth versus the same quarter in fiscal 2020. Our Diagnostics segment generated $2,500 in operating income for the third quarter of fiscal 2021, an increase of $4,300 over the third quarter of fiscal 2020.

With a 47% decrease in revenues from molecular reagent products and a 51% decrease in revenues from immunological reagent products, revenues for our Life Science segment decreased 49% during the third quarter of fiscal 2021 compared to the third quarter of fiscal 2020. On a constant-currency basis, revenues for the Life Science segment decreased 52%. Life Science segment revenues reflect a significant decrease in the demand from diagnostic test manufacturers for the reagents utilized in COVID-19 related tests, as the demand for such tests has declined. However, revenue from sales of our core Life Science segment products (other than COVID-19 contributions) experienced growth of over $2,000, or approximately 15%, compared to the third quarter of 2020. This growth resulted in large part from obtaining business from COVID-19 customers who are now using our products for other non-COVID-19 related purposes, as well as a rebound in volumes in core immunological products. Our Life Science segment generated $16,100 of operating income for the third quarter of fiscal 2021, a decline of $23,200 from the third quarter of fiscal 2020.

Nine Months Ended June 30, 2021

Net earnings for the nine-month period ended June 30, 2021 increased 63% to $64,750, or $1.47 per diluted share, from net earnings for the comparable fiscal 2020 period of $39,693, or $0.92 per diluted share. The level of net earnings in the first nine months of fiscal 2021 was affected predominantly by the strong first half increase in revenues and operating income in our Life Science segment, stemming from the demand for COVID-19 related reagents.

Consolidated revenues increased 28% to $241,692 for the first nine months of fiscal 2021 compared to the same period of the prior year (24% increase on a constant-currency basis).

Diagnostics segment revenues increased 2% (1% on a constant-currency basis), comprised of a 23% decrease in molecular assay products and an 8% increase in non-molecular assay products. Our Diagnostics segment generated operating income of $3,700 for the first nine months of fiscal 2021, a decline of $4,300 compared to the first nine months of fiscal 2020.

With an 87% increase in revenues from molecular reagent products and a 4% increase in revenues from immunological reagent products, revenues for our Life Science segment increased 51% during the first nine months of fiscal 2021 compared to the same period of the prior year. On a constant-currency basis, revenues for the Life Science segment increased 44%. Life Science segment revenues during the first nine months of fiscal 2021 reflect a significant increase in sales of key molecular components such as RNA master mixes and deoxyribonucleotide triphosphates (“dNTPs”) to diagnostic test manufacturers for use in COVID-19 related PCR tests. Also contributing to the increased revenue levels during the fiscal 2021 year-to-date period were sales of monoclonal antibody pairs used in COVID-19 antigen tests and, to a lesser degree, recombinant antigens used in COVID-19 antibody tests. In addition, revenue from sales of our core Life Science segment products (other than COVID-19 contributions) experienced growth of approximately $14,500, or approximately 33%, during the first nine months of fiscal 2021 compared to the same period of the prior year. This growth resulted in large part from obtaining business from COVID-19 customers who are now using our products for other non-COVID-19 related purposes, as well as a rebound in volumes in core immunological products. Our Life Science segment generated $92,000 of operating income for the first nine months of fiscal 2021, an increase of over $40,000 compared to the first nine months of fiscal 2020.

Lead Testing Matters

During the past three fiscal years, various regulatory matters have arisen related to Magellan and the Company’s blood lead test manufacturing facility. See Note 16 of the Condensed Consolidated Financial Statements for discussion of these matters.

While we remain committed to strengthening Magellan’s quality system and ensuring that all aspects of the system are in full compliance, we do not expect that the FDA will reinstate our venous blood claims. We can provide no assurance that the ongoing investigation and regulatory activity of the DOJ and FDA discussed in Note 16 of the Condensed Consolidated Financial Statements, or future exercise of their respective enforcement, regulatory, discretionary or other powers will not result in findings or alleged violations of federal laws that could lead to enforcement actions, proceedings or litigation, and/or the imposition of damages, fines, penalties, restitution, other monetary liabilities, sanctions, injunctions, settlements or changes to our business practices, product offerings or operations that could have a material adverse effect on our business, consolidated financial condition or results of operations; or eliminate altogether our ability to operate our lead testing business on terms substantially similar to those on which we currently operate.

REVENUE OVERVIEW

Below are analyses of the Company's revenues, provided for each of the following:

- By Reportable Segment & Geographic Region
- By Product Platform/Type

Revenue Overview- By Reportable Segment & Geographic Region

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 severity of seasonal diseases and outbreaks (including the COVID-19 pandemic), 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 IVD manufacturing customers, severity of disease outbreaks and foreign currency exchange rates. The severity of the COVID-19 pandemic contributed approximately $71,500 of new revenue for our Life Science segment during fiscal 2020 including approximately $48,000 and $53,000 in the three and nine months ended June 30, 2020, respectively. This compares to approximately $14,500 and $88,500 of such revenue during the three and nine months ended June 30, 2021, respectively.

See the "Revenue Disaggregation" section of Note 4, *"Revenue Recognition"* of the Condensed Consolidated Financial Statements for detailed revenue disaggregation information.

Following is a discussion of the revenues generated by these product platforms/types and/or disease states:

Diagnostics Segment Products

The acquisitions of the Revogene molecular diagnostics platform and the BreathID breath test system, the development of the Curian immunoassay platform, and the expansion of the related assay-menu for each of these platforms are important steps in addressing competitive pressures in our gastrointestinal and respiratory illness assay families.

In March 2020, we received clearance from the FDA for the Curian immunoassay diagnostics instrument and its first assay, a test for *H. pylori* antigen in stool. We began clinical trials for the Curian *C. difficile* Common Antigen and Toxins A and B test during the second quarter of fiscal 2021 and submitted a 510(k) pre-market notification to the FDA for marketing clearance of Curian Campylobacter on March 31, 2021. We believe the advantages of the Curian analyzer will help protect our existing rapid test accounts, and in the case of the *C. difficile* test, provide meaningful revenue growth opportunities.

Gastrointestinal, Respiratory Illness and Blood Chemistry Assays

As previously noted, the ongoing COVID-19 pandemic has had a negative impact on revenue levels from sales of our gastrointestinal, respiratory illness and blood chemistry products. Comprised of tests for Group A Strep, Mycoplasma pneumonia, Influenza, and Pertussis, among others, the respiratory illness category in particular continues to experience significantly lower sales activity relative to the prior year, with revenues from sales of such products decreasing 26% and 48% during the third quarter and first nine months of fiscal 2021, respectively. However, during the third quarter of fiscal 2021, we experienced an increase in sales activity for gastrointestinal and blood chemistry products for the second consecutive quarter, with revenues from each of these product categories increasing as follows compared to the third quarter of fiscal 2020: (i) gastrointestinal products, which include tests for *C. difficile*, *H. pylori* and certain foodborne pathogens, among others, increased 86% to $17,844; and (ii) blood chemistry products, which test for elevated levels of lead in blood, increased 26% to $4,254. During the first nine months of fiscal 2021, gastrointestinal product revenues increased 24% over the prior year period to $48,962, and blood chemistry product revenues increased 4% to $13,006. The increases in the *H. pylori* component of our gastrointestinal family of products include contributions from the BreathID urea breath platform acquired in the Exalenz acquisition on April 30, 2020.

In order to combat certain of the pricing and volume pressures we face within the gastrointestinal product category, we have executed on a number of measures including: (i) operating under a strategic collaboration with DiaSorin to sell *H. pylori* tests; (ii) executing long-term supply agreements with reference laboratory customers for *H. pylori* tests to secure volume, albeit at lower selling prices; and (iii) upon FDA clearance in March 2020, launching Curian HpSA, our first assay on the Curian platform, which we expect will help protect our existing customer base using lateral flow tests. We also expect the BreathID platform to combat competitive pressures, as we believe that we are now the only company with FDA-cleared, non-invasive assays for both stool antigen and urea breath samples, providing physicians a choice in test format from a single supplier. We are unable to provide assurances that we will be successful with any strategy or that any strategy will prevent an adverse effect on our future results of operations and liquidity, including revenues and gross profit.

Life Science Segment Products

During the third quarter of fiscal 2021, revenues from our Life Science segment decreased 49%, with revenues from molecular reagent sales decreasing 47% from the comparable fiscal 2020 quarter and revenues from immunological reagent sales decreasing 51%. Life Science segment revenues increased 51% for the first nine months of fiscal 2021, reflecting an 87% increase from molecular reagent sales and a 4% increase in immunological reagent sales. The quarterly decrease in Life Science segment revenue results primarily from the continued reduction in diagnostic test manufacturers' demand for reagents associated with COVID-19. It is this demand from diagnostic test manufacturers throughout the peak of the COVID-19 pandemic that resulted in the increase in fiscal year-to-date revenues. The increase resulted specifically from demand for key molecular components such as RNA master mixes and dNTPs to diagnostic test manufacturers for use in COVID-19 related PCR tests, as well as sales of monoclonal antibody pairs used in antigen tests and to a lesser degree, recombinant antigens used in COVID-19 antibody tests. COVID-19-related reagent revenues totaled approximately $14,500 and $88,500 during the third quarter and first nine months of fiscal 2021, respectively, compared to approximately $48,000 and $53,000 in the three and nine months ended June 30, 2020, respectively.

During the third quarter of fiscal 2021, revenue from sales of our core Life Science segment products (other than COVID-19 contributions) grew approximately 15% over the third quarter of fiscal 2020 to approximately $17,500. During the first nine months of fiscal 2021, such revenue grew approximately 33% over the comparable fiscal 2020 period to approximately $59,000. This growth resulted in large part from obtaining business from COVID-19 customers who are now using our products for non-COVID-19 related purposes, as well as a rebound in volumes of core immunological product sales.

Significant Customers

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 14 of the Condensed Consolidated Financial Statements.

Gross Profit

	Three Months Ended June 30,			Nine Months Ended June 30,		
	2021	2020	Change	2021	2020	Change
Gross profit	$37,111	$55,983	(34)%	$156,431	$118,180	32%
Gross profit margin	58%	66%	-8 points	65%	62%	+3 points

The movements in gross profit margins during both the third quarter and first nine months of fiscal 2021 are primarily attributable to the overall shifts in sales mix the Company has experienced in connection with the COVID-19 pandemic. During the nine-month period ended June 30, 2021, which included the peak of the COVID-19 pandemic, approximately 43% of consolidated revenues related to sales of molecular reagent products, which are some of our higher margin products. This compares to approximately 29% during the first nine months of fiscal 2020.

As the demand for such molecular reagent products for use in COVID-19 test manufacturing declined during the fiscal 2021 third quarter, such products comprised a smaller relative percentage of consolidated revenue; approximately 32% in the third quarter of fiscal 2021 compared to approximately 46% in the third quarter of fiscal 2020. Additionally, the current period margins have been unfavorably impacted by production capacity ramp-up costs for our Quebec facility, where Revogene instruments and test devices are made.

Operating Expenses – Segment Detail

	Three Months Ended June 30,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2020:					
Diagnostics	$ 6,129	$ 5,009	$ 6,279	$(4,387)	$ 13,030
Life Science	539	1,273	3,630	(3)	5,439
Corporate	—	—	2,715	134	2,849
Total Expenses (2020 Quarter)	$ 6,668	$ 6,282	$ 12,624	$(4,256)	$ 21,318
Fiscal 2021:					
Diagnostics	$ 5,463	$ 4,966	$ 6,140	$(3,263)	$ 13,306
Life Science	620	1,243	3,264	—	5,127
Corporate	—	—	2,560	438	2,998
Total Expenses (2021 Quarter)	$ 6,083	$ 6,209	$ 11,964	$(2,825)	$ 21,431

	Nine Months Ended June 30,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2020:					
Diagnostics	$ 15,037	$ 15,806	$ 16,853	$(3,575)	$ 44,121
Life Science	1,709	3,733	8,740	195	14,377
Corporate	—	—	6,643	1,189	7,832
Total Expenses (2020 Year-to-Date)	$ 16,746	$ 19,539	$ 32,236	$(2,191)	$ 66,330
Fiscal 2021:					
Diagnostics	$ 16,011	$ 15,914	$ 18,441	$(5,205)	$ 45,161
Life Science	1,788	3,856	9,795	—	15,439
Corporate	—	—	8,591	2,695	11,286
Total Expenses (2021 Year-to-Date)	$ 17,799	$ 19,770	$ 36,827	$(2,510)	$ 71,886

Operating Expenses – Comparisons to Prior Year Periods

	Three Months Ended June 30,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2020 Expenses	$ 6,668	$ 6,282	$ 12,624	$(4,256)	$ 21,318
% of Revenues	8%	7%	15%	(5)%	25%
Fiscal 2021 Increases/(Decreases):					
Diagnostics	(666)	(43)	(139)	1,124	276
Life Science	81	(30)	(366)	3	(312)
Corporate	—	—	(155)	304	149
2021 Expenses	$ 6,083	$ 6,209	$ 11,964	$(2,825)	$ 21,431
% of Revenues	10%	10%	19%	(4)%	34%
% Increase (Decrease)	(9)%	(1)%	(5)%	34%	1%

Total operating expenses for the third quarter of fiscal 2021 show a net increase of 1%, This net increase primarily includes two components. The change in the fair value of contingent consideration was a decline of $3,563 in the 2021 quarter compared to a decline of $6,124 in the 2020 quarter, which results in an increase in net expense of $2,561 between periods. This is increase is largely offset by decreases in other operating expenses, predominantly Diagnostics segment research and development spending and corporate-wide general and administrative expenses.

	Nine Months Ended June 30,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2020 Expenses	$ 16,746	$ 19,539	$ 32,236	$(2,191)	$ 66,330
% of Revenues	9%	10%	17%	(1)%	35%
Fiscal 2021 Increases/(Decreases):					
Diagnostics	974	108	1,588	(1,630)	1,040
Life Science	79	123	1,055	(195)	1,062
Corporate	—	—	1,948	1,506	3,454
2021 Expenses	$ 17,799	$ 19,770	$ 36,827	(2,510)	$ 71,886
% of Revenues	7%	8%	15%	(1)%	30%
% Increase (Decrease)	6%	1%	14%	(15)%	8%

Total operating expenses for the first nine months of fiscal 2021 show a net increase of 8%, This increase primarily includes three components. The change in the fair value of contingent consideration was a decline of $5,505 in fiscal 2021 year-to-date period compared to a decline of $7,428 in the comparable fiscal 2020 period, which results in an increase in net expense of $1,923 between periods. Other operating expenses in 2021 include a full nine months of costs related to the Exalenz business acquired in April 2020, including purchase accounting amortization, and selected legal costs increased $1,506 related to our on-going DOJ matter.

Operating Income

Compared to the prior year periods, operating income decreased 55% to $15,680 for the third quarter of fiscal 2021 and increased 63% to $84,545 for the first nine months of fiscal 2021, as a result of the factors discussed above.

Income Taxes

The effective rate for income taxes was 24% and 22% for the three and nine months ended June 30, 2021, respectively, and 21% and 23% for the three and nine months ended June 30, 2020, respectively. The variation in effective tax rates during the three and nine months ended June 30, 2021 and 2020 related primarily to higher allocations of taxable income in the U.S. in the fiscal 2021 reporting periods compared to certain lower-rate foreign jurisdictions, particularly the U.K. Additionally, the nine-month period ended June 30, 2021 was favorably impacted by the effect of current year restricted share unit lapses and stock option exercises occurring on dates when the share price of Company stock was significantly higher than the share price on the date such equity awards were granted, compared to the opposite effect during the prior year period.

Liquidity and Capital Resources

Liquidity

Our cash flow and financing requirements are determined by analyses of operating and capital spending budgets and debt service. 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.

We intend to continue to fund our working capital requirements from current cash flows from operating activities and cash on hand. If needed, we also have an additional source of liquidity through the amount remaining available on our $160,000 bank revolving credit facility, which totaled $110,000 as of June 30, 2021. Our liquidity needs may change if overall economic conditions worsen and/or liquidity and credit within the financial markets tightens for an extended period, and such conditions impact the collectability of our customer accounts receivable, impact credit terms with our vendors, or disrupt the supply of raw materials and services.

During the first nine months of fiscal 2021, we generated cash flow from operations totaling $52,386. This represents a 65% increase over the comparable prior year period, reflecting a higher level of net earnings.

Our levels of inventories increased $10,549 to $71,813 between September 30, 2020 and June 30, 2021. This increase was largely attributable to inventory builds in our Life Science segment to protect against future supply interruptions. For our Diagnostics segment, we also have continued to maintain relatively consistent inventory levels in anticipation of a return to pre-pandemic diagnostic testing activity. We are continuing to actively manage our inventory levels.

As of June 30, 2021, our cash and cash equivalents balance was $70,012 or $16,498 higher than at the end of fiscal 2020. As a result of the cash generated from operations during the third quarter and first nine months of fiscal 2021, our balance of net debt (defined as bank debt, government grant obligations and total contingent obligations related to the acquisition of the GenePOC business, net of cash and cash equivalents on-hand) decreased approximately $46,700 to approximately $6,600 at June 30, 2021. Net cash flows from operating activities and cash on hand are anticipated to be adequate to fund working capital requirements, capital expenditures and debt service during the next twelve months.

Capital Resources

As described in Note 11, *"Bank Credit Arrangements"* of the Condensed Consolidated Financial Statements, the Company maintains a $160,000 revolving credit facility, which is secured by substantially all our U.S. assets and includes certain restrictive financial covenants. The Company also maintains a shelf registration statement on file with the SEC.

Our capital expenditures are estimated to range between approximately $18,000 and $24,000 during fiscal 2021. Our Diagnostics segment capital expenditures could be as high as $21,000, depending upon the level and timing of the previously noted Revogene COVID-19 assay production capacity expansion and scale-up efforts, and our Life Science segment capital expenditures could be as high as $3,000, reflecting manufacturing capacity expansion at various locations. Such expenditures may be funded with cash and cash equivalents on hand, operating cash flows and/or availability under the $160,000 revolving credit facility discussed above. In addition, a portion of the Diagnostics segment expansion may be funded by the previously noted $5,500 RADx grant entered into on February 1, 2021 (see Note 13 of the Condensed Consolidated Financial Statements).

We do not utilize any special-purpose financing vehicles or have any material undisclosed off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of June 30, 2021, there were no material changes to the information provided under Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” in the Company’s Form 10-K for the year ended September 30, 2020, filed with the SEC on November 23, 2020.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of the Company’s management, including the Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of the Company’s disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of June 30, 2021. 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 the period covered by this report.

Control systems, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that control objectives are met. Because of inherent limitations in all control systems, no evaluation of controls can provide assurance that all control issues and instances of fraud, if any, within a company will be detected. Additionally, controls can be circumvented by individuals, by collusion of two or more people or by management override. Over time, controls can become inadequate because of changes in conditions or the degree of compliance may deteriorate. Further, the design of any system of controls is based in part upon assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Because of the inherent limitations in any cost-effective control system, misstatements due to errors or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

In the ordinary course of business, we routinely enhance our information systems by either upgrading current systems or implementing new ones. There were no changes in our internal control over financial reporting (as that term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2021 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

Information with respect to legal proceedings can be found in Note 16, *“Litigation and Regulatory Matters”* of the Condensed Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q and is incorporated herein by reference.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, careful consideration should be given to the factors discussed in Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the SEC on November 23, 2020, as may be supplemented by our Quarterly Reports on Form 10-Q, any or all of which could materially affect our business, financial condition or future results. The risks described therein are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial condition and/or operating results. There have been no material changes with respect to the risk factors disclosed in our Annual Report on Form 10-K for the year ended September 30, 2020, filed with the SEC on November 23, 2020, as may be supplemented by our Quarterly Reports on Form 10-Q.

ITEM 6. EXHIBITS

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

31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
31.2	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a)
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Instance Extension Schema
101.CAL	Inline XBRL Instance Extension Calculation Linkbase
101.DEF	Inline XBRL Instance Extension Definition Linkbase
101.LAB	Inline XBRL Instance Extension Label Linkbase
101.PRE	Inline XBRL Instance Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MERIDIAN BIOSCIENCE, INC.

Date: August 6, 2021

By: /s/ Bryan T. Baldasare
Bryan T. Baldasare
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a)

I, Jack Kenny, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Meridian Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2021

/s/ Jack Kenny
Jack Kenny
Chief Executive Officer

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a)

I, Bryan T. Baldasare, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Meridian Bioscience, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2021

/s/ Bryan T. Baldasare
Bryan T. Baldasare
Executive Vice President and Chief Financial Officer

Exhibit 32

Meridian Bioscience, Inc.

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

In connection with the filing with the Securities and Exchange Commission of the Quarterly Report of Meridian Bioscience, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 (the "Report"), the undersigned officers of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of their knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jack Kenny
Jack Kenny
Chief Executive Officer
August 6, 2021

/s/ Bryan T. Baldasare
Bryan T. Baldasare
Executive Vice President and Chief Financial Officer
August 6, 2021