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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 March 31, 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 ☐

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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 April 30, 2021
Common Stock, no par value	43,330,038

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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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
NET REVENUES	$85,264	$57,296	$178,181	$104,717
COST OF SALES	27,492	22,750	58,861	42,520
GROSS PROFIT	57,772	34,546	119,320	62,197
OPERATING EXPENSES				
Research and development	6,065	5,315	11,716	10,078
Selling and marketing	6,540	6,529	13,561	13,257
General and administrative	12,925	10,628	24,863	19,612
Acquisition-related costs	—	1,787	—	1,787
Change in fair value of acquisition consideration	(2,989)	(2,491)	(1,942)	(1,304)
Restructuring costs	—	252	—	527
Selected legal costs	1,030	735	2,257	1,055
Total operating expenses	23,571	22,755	50,455	45,012
OPERATING INCOME	34,201	11,791	68,865	17,185
OTHER INCOME (EXPENSE)				
Interest income	6	23	15	134
Interest expense	(472)	(532)	(1,006)	(1,299)
RADx grant income	200	—	1,000	—
Other, net	(883)	1,365	(1,574)	653
Total other income (expense)	(1,149)	856	(1,565)	(512)
EARNINGS BEFORE INCOME TAXES	33,052	12,647	67,300	16,673
INCOME TAX PROVISION	6,750	3,288	14,219	4,487
NET EARNINGS	$26,302	$ 9,359	$ 53,081	$ 12,186
BASIC EARNINGS PER COMMON SHARE	$ 0.61	$ 0.22	$ 1.23	$ 0.28
DILUTED EARNINGS PER COMMON SHARE	$ 0.60	$ 0.22	$ 1.21	$ 0.28
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING—BASIC	43,244	42,830	43,171	42,810
EFFECT OF DILUTIVE STOCK OPTIONS AND RESTRICTED SHARE UNITS	878	138	789	143
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING—DILUTED	44,122	42,968	43,960	42,953
ANTI-DILUTIVE SECURITIES:				
Common share options and restricted share units	166	1,635	169	1,520

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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
NET EARNINGS	$26,302	$ 9,359	$53,081	$12,186
Other comprehensive income (loss):				
Foreign currency translation adjustment	79	(2,786)	3,380	(18)
Unrealized gain (loss) on cash flow hedge	439	(313)	460	(313)
Reclassification of amortization of gain on cash flow hedge	(77)	(77)	(154)	(154)
Income taxes related to items of other comprehensive income (loss)	(80)	96	(66)	115
Other comprehensive income (loss), net of tax	361	(3,080)	3,620	(370)
COMPREHENSIVE INCOME	$26,663	$ 6,279	$56,701	$11,816

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)

Six Months Ended March 31,	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	$ 53,081	$ 12,186
Non-cash items included in net earnings:		
Depreciation of property, plant and equipment	3,072	2,439
Amortization of intangible assets	4,363	3,449
Stock compensation expense	2,291	1,759
Deferred income taxes	(777)	656
Change in fair value of acquisition consideration	(1,942)	(1,304)
Change in the following:		
Accounts receivable	(5,267)	(4,950)
Inventories	(12,185)	(2,511)
Prepaid expenses and other current assets	1,440	1,278
Accounts payable and accrued expenses	77	1,621
Income taxes payable	(2,698)	400
Other, net	36	692
Net cash provided by operating activities	41,491	15,715
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property, plant and equipment	(11,955)	(1,543)
Payment of acquisition consideration holdback	(5,000)	—
Net cash used in investing activities	(16,955)	(1,543)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment on revolving credit facility	(18,824)	(27,000)
Payment of debt issuance costs	—	(116)
Proceeds from exercise of stock options	2,852	—
Net cash used in financing activities	(15,972)	(27,116)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	1,296	97
Net Increase (Decrease) in Cash and Cash Equivalents	9,860	(12,847)
Cash and Cash Equivalents at Beginning of Period	53,514	62,397
Cash and Cash Equivalents at End of Period	$ 63,374	$ 49,550

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

	March 31, 2021 (Unaudited)	September 30, 2020
CURRENT ASSETS		
Cash and cash equivalents	$ 63,374	$ 53,514
Accounts receivable, less allowances of $505 and $513, respectively	44,895	38,512
Inventories, net	72,534	61,264
Prepaid expenses and other current assets	7,491	8,900
Total current assets	188,294	162,190
PROPERTY, PLANT AND EQUIPMENT, at Cost		
Land	991	991
Buildings and improvements	32,326	32,188
Machinery, equipment and furniture	74,173	69,854
Construction in progress	10,779	1,200
Subtotal	118,269	104,233
Less: accumulated depreciation and amortization	76,303	73,113
Property, plant and equipment, net	41,966	31,120
OTHER ASSETS		
Goodwill	115,296	114,186
Other intangible assets, net	78,834	83,197
Right-of-use assets, net	6,297	6,336
Deferred income taxes	8,017	7,647
Other assets	465	585
Total other assets	208,909	211,951
TOTAL ASSETS	$ 439,169	$ 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

	March 31, 2021 (Unaudited)	September 30, 2020
CURRENT LIABILITIES		
Accounts payable	$ 16,714	$ 11,969
Accrued employee compensation costs	12,634	16,661
Current portion of acquisition consideration	11,296	12,619
Current operating lease obligations	1,892	1,789
Current government grant obligations	608	600
Other accrued expenses	5,664	5,362
Income taxes payable	1,502	3,524
Total current liabilities	50,310	52,524
NON-CURRENT LIABILITIES		
Acquisition consideration	7,671	13,290
Post-employment benefits	2,429	2,493
Fair value of interest rate swaps	254	713
Long-term operating lease obligations	4,555	4,678
Long-term debt	50,000	68,824
Government grant obligations	10,537	10,524
Long-term income taxes payable	374	549
Deferred income taxes	3,389	3,804
Other non-current liabilities	177	233
Total non-current liabilities	79,386	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, 43,329,294 and 43,068,842 shares issued, respectively	—	—
Additional paid-in capital	145,338	140,195
Retained earnings	162,375	109,294
Accumulated other comprehensive income (loss)	1,760	(1,860)
Total shareholders' equity	309,473	247,629
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 439,169	$ 405,261

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

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MERIDIAN BIOSCIENCE, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of 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 MARCH 31, 2021					
Balance at December 31, 2020	43,124	$141,395	$136,073	$ 1,399	$ 278,867
Conversion of restricted share units and exercise of stock options	205	2,893	—	—	2,893
Stock compensation expense	—	1,050	—	—	1,050
Net earnings	—	—	26,302	—	26,302
Foreign currency translation adjustment	—	—	—	79	79
Hedging activity, net of tax	—	—	—	282	282
Balance at March 31, 2021	43,329	$145,338	$162,375	$ 1,760	$ 309,473
THREE MONTHS ENDED MARCH 31, 2020					
Balance at December 31, 2019	42,828	$133,622	$ 65,935	$ (2,265)	$ 197,292
Conversion of restricted share units and exercise of stock options	3	(9)	—	—	(9)
Stock compensation expense	—	971	—	—	971
Net earnings	—	—	9,359	—	9,359
Foreign currency translation adjustment	—	—	—	(2,786)	(2,786)
Hedging activity, net of tax	—	—	—	(294)	(294)
Balance at March 31, 2020	42,831	$134,584	$ 75,294	$ (5,345)	$ 204,533

	Common Shares Issued	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
SIX MONTHS ENDED MARCH 31, 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	260	2,852	—	—	2,852
Stock compensation expense	—	2,291	—	—	2,291
Net earnings	—	—	53,081	—	53,081
Foreign currency translation adjustment	—	—	—	3,380	3,380
Hedging activity, net of tax	—	—	—	240	240
Balance at March 31, 2021	43,329	$145,338	$162,375	$ 1,760	$ 309,473
SIX MONTHS ENDED MARCH 31, 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	119	(9)	—	—	(9)
Stock compensation expense	—	1,759	—	—	1,759
Net earnings	—	—	12,186	—	12,186
Foreign currency translation adjustment	—	—	—	(18)	(18)
Hedging activity, net of tax	—	—	—	(352)	(352)
Balance at March 31, 2020	42,831	$134,584	$ 75,294	$ (5,345)	$ 204,533

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 financial position as of March 31, 2021 and the results of its operations, cash flows and shareholders' equity for the three- and six-month periods ended March 31, 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. In December 2019, the SARS-CoV-2 virus emerged in Wuhan, China and spread to other parts of the world. In March 2020, the World Health Organization ("WHO") designated COVID-19 (the disease caused by SARS-CoV-2) a global pandemic. In April 2021, the U.S. Department of Health and Human Services extended the public health emergency declaration for COVID-19. During the past year, governments around the world have implemented lockdown and shelter-in-place orders, requiring many non-essential businesses to shut down operations, many of which remain in effect as of the date of this filing. Our business, however, was deemed "essential" and we have continued to operate, manufacture and distribute products to customers globally.

While revenues within our Life Science segment have been positively impacted by the COVID-19 pandemic, to date, the negative impacts of COVID-19 on the Company have been limited to decreased demand for most of our Diagnostics segment's products and the pausing and/or slowing of clinical trials for new product development programs, as diagnostics testing over the last year has focused primarily on COVID-19 and critical care ailments. For the second half of our fiscal 2021, we expect demand for our Life Science segment's reagent products used in COVID-19 tests will be lower than that experienced during the six months ended March 31, 2021, as health care systems transition to more asymptomatic testing versus the predominant symptomatic testing we have seen over the last year. However, this varies by country based on their individual COVID-19 case statistics. 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. See Management's Discussion and Analysis of Financial Condition and Results of Operations included herein for additional discussion of the effects of the COVID-19 pandemic on the Company and its results of operations.

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 March 31, 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 LIBOR rate. 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 March 31,			Six Months Ended March 31,		
	2021	2020	Inc (Dec)	2021	2020	Inc (Dec)
Diagnostics-						
Americas	$ 25,290	$27,670	(9)%	$ 48,824	$ 55,405	(12)%
EMEA	6,071	6,777	(10)%	12,101	13,277	(9)%
ROW	588	495	19%	1,345	1,051	28%
Total Diagnostics	31,949	34,942	(9)%	62,270	69,733	(11)%
Life Science-						
Americas	13,550	4,612	194%	32,296	8,623	275%
EMEA	21,773	9,946	119%	54,066	14,907	263%
ROW	17,992	7,796	131%	29,549	11,454	158%
Total Life Science	53,315	22,354	139%	115,911	34,984	231%
Consolidated	$ 85,264	$57,296	49%	$178,181	$104,717	70%

Revenue by Product Platform/Type

	Three Months Ended March 31,			Six Months Ended March 31,		
	2021	2020	Inc (Dec)	2021	2020	Inc (Dec)
Diagnostics-						
Molecular assays	$ 4,395	$ 7,238	(39)%	$ 8,985	$14,077	(36)%
Non-molecular assays	27,554	27,704	(1)%	53,285	55,656	(4)%
Total Diagnostics	$ 31,949	$34,942	(9)%	$ 62,270	$69,733	(11)%
Life Science-						
Molecular reagents	$ 37,752	$11,534	227%	$ 83,776	$16,902	396%
Immunological reagents	15,563	10,820	44%	32,135	18,082	78%
Total Life Science	$ 53,315	$22,354	139%	$115,911	$34,984	231%

Revenue by Disease State (Diagnostics segment only)

	Three Months Ended March 31,			Six Months Ended March 31,		
	2021	2020	Inc (Dec)	2021	2020	Inc (Dec)
Diagnostics-						
Gastrointestinal assays	$ 15,666	$ 14,014	12%	$ 31,118	$ 30,060	4%
Respiratory illness assays	3,686	10,863	(66)%	8,492	18,612	(54)%
Blood chemistry assays	4,358	4,194	4%	8,753	9,142	(4)%
Other	8,239	5,871	40%	13,907	11,919	17%
Total Diagnostics	$ 31,949	$ 34,942	(9)%	$ 62,270	$ 69,733	(11)%

Royalty Income

Royalty income received from DiaSorin, which primarily related to sales of *H. pylori* products, totaled approximately $2,845 and $1,280 in the three months ended March 31, 2021 and 2020, respectively, and $3,705 and $2,205 in the six months ended March 31, 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 $900 and $1,125 in the three months ended March 31, 2021 and 2020, respectively, and $1,780 and 2,250 in the six months ended March 31, 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 preliminary 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. 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:

		Fair Value Measurements Using Inputs Considered as		
	Carrying Value	Level 1	Level 2	Level 3
Interest rate swaps -				
As of March 31, 2021	$ (254)	$ —	$ (254)	$ —
As of September 30, 2020	$ (713)	$ —	$ (713)	$ —
Contingent consideration -				
As of March 31, 2021	$(18,967)	$ —	$ —	$ (18,967)
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 preliminary fair value of the net assets acquired, goodwill in the amount of $24,827 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 six months ended March 31, 2021 include the following from Exalenz:

	Three Months Ended March 31, 2021	Six Months Ended March 31, 2021
Net revenues	$ 2,784	$ 5,882
Net loss	$ (947)	$ (1,739)

These results for the three and six months ended March 31, 2021, which are reported as part of the Diagnostics segment, include $720 and $1,520, respectively, of amortization expense related to specific identifiable assets recorded in the preliminary purchase price allocation, including a non-compete agreement, trade name, technology and customer relationships.

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

	PRELIMINARY		
	April 30, 2020 (as initially reported)	Measurement Period Adjustments	April 30, 2020 (as adjusted)
Fair value of assets acquired -			
Cash	$ 5,006	$ —	$ 5,006
Accounts receivable	637	—	637
Inventories	4,329	(296)	4,033
Other current assets	851	1,825	2,676
Property, plant and equipment	544	(16)	528
Goodwill	29,288	(4,461)	24,827
Other intangible assets (estimated useful life):			
Non-compete agreement (5 years)	120	(10)	110
Trade name (10 years)	3,540	320	3,860
Technology (15 years)	5,590	530	6,120
Customer relationships (10 years)	19,370	1,270	20,640
Right-of-use assets	1,358	(47)	1,311
Deferred tax assets, net	5,566	1,178	6,744
	76,199	293	76,492
Fair value of liabilities assumed -			
Accounts payable and accrued expenses (including current portion of lease and government grant obligations)	7,757	251	8,008
Long-term lease obligations	1,054	42	1,096
Long-term government grant obligations	10,792	—	10,792
Other non-current liabilities	291	—	291
	19,894	293	20,187
Total consideration paid (including $8,068 to pay off long-term debt)	$ 56,305	$ —	$ 56,305

As indicated, the allocation of the purchase price is preliminary, pending final completion of valuations. As a result of further refining its estimates and assumptions since the date of the acquisition, the Company recorded measurement period adjustments to the initial opening balance sheet as shown in the table above. Adjustments were primarily made to other current assets, goodwill, other intangible assets, and deferred tax assets. There were no measurement period adjustments materially impacting net earnings that would have been recorded in previous reporting periods if the adjustments had been recognized as of the acquisition date. Currently, we are primarily assessing the results of the valuation of intangible assets and the tax implications thereon. Upon completion of these analyses, any required adjustments are expected to result in an amount being reclassified among goodwill, other intangible assets and deferred taxes, as applicable.

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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Net revenues	$ 85,264	$60,701	$178,181	$111,895
Net earnings	$ 26,302	$ 8,064	$ 53,081	$ 9,246

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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Adjustments to net revenues				
Exalenz pre-acquisition net revenues	$ —	$ 3,405	$—	$ 7,178
Adjustments to net earnings				
Exalenz pre-acquisition net loss	$ —	$ (752)	$—	$(1,504)
Pro forma adjustments:				
Remove net impact of non-continuing personnel, locations or activities	—	490	—	591
Incremental depreciation and amortization	—	(911)	—	(1,824)
Incremental interest costs, net	—	(381)	—	(772)
Tax effects of pro forma adjustments and recognizing benefit on resulting Exalenz losses	—	259	—	569
Total adjustments to net earnings	$ —	$(1,295)	$—	$(2,940)

7. Cash and Cash Equivalents

Cash and cash equivalents include the following:

	March 31, 2021	September 30, 2020
Institutional money market funds	$ 1,017	$ 1,017
Cash on hand, unrestricted	62,357	52,497
Total	$ 63,374	$ 53,514

8. Inventories, Net

Inventories, net are comprised of the following:

	March 31, 2021	September 30, 2020
Raw materials	$ 18,706	$ 11,966
Work-in-process	22,987	19,477
Finished goods - instruments	1,933	1,594
Finished goods - kits and reagents	28,908	28,227
Total	$ 72,534	$ 61,264

9. Leasing Arrangements

The Company is party to a number of 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 six months ended March 31, 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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Lease costs within cost of sales	$ 198	$ 130	$ 356	$ 259
Lease costs within operating expenses	387	292	761	559
Right-of-use assets, net obtained in exchange for operating lease liabilities	612	222	692	222

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 six months ended March 31, 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 March 31, 2021 and September 30, 2020 were as follows:

	March 31, 2021	September 30, 2020
Weighted average remaining lease term	3.8 years	4.2 years
Average discount rate	3.4%	3.7%

Maturities of lease liabilities by fiscal year for the Company's operating leases were as follows as of March 31, 2021:

2021 (represents remainder of fiscal year)	$1,108
2022	2,016
2023	1,482
2024	1,108
2025	806
Thereafter	331
Total lease payments	6,851
Less amount of lease payments representing interest	(404)
Total present value of lease payments	$6,447

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

Six Months Ended March 31,	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$1,072	$778

10. Goodwill and Other Intangible Assets, Net

During the six months ended March 31, 2021, goodwill increased $1110, reflecting: (i) an additional $361 acquisition measurement period adjustment related to Exalenz (Diagnostics segment; see Note 6); (ii) a $67 increase from the currency translation adjustment on goodwill in the Diagnostics segment; and (iii) a $682 increase from the currency translation adjustment on goodwill in the Life Science segment.

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

	March 31, 2021		September 30, 2020	
	Gross Carrying Value	Accumulated Amortization	Gross Carrying Value	Accumulated Amortization
Manufacturing technologies, core products and cell lines	$ 62,446	$ 20,756	$ 62,363	$ 18,750
Trade names, licenses and patents	18,524	8,813	18,425	7,801
Customer lists, customer relationships and supply agreements	45,287	17,944	45,071	16,210
Government grants	858	858	810	810
Non-compete agreements	110	20	110	11
Total	$127,225	$ 48,391	$126,779	$ 43,582

The aggregate amortization expense for these other intangible assets was $2,142 and $1,727 for the three months ended March 31, 2021 and 2020, respectively, and $4,363 and $3,449 for the six months ended March 31, 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 – $4,210, fiscal 2022 – $8,000, fiscal 2023 – $7,975, fiscal 2024 – $7,975, fiscal 2025 – $7,950, and fiscal 2026 – $7,300.

11. Bank Credit Arrangements

In anticipation of the acquisition of the business of GenePOC, on May 24, 2019, the Company entered into a credit facility agreement with a commercial bank. The Company amended the credit facility agreement on February 19, 2020, in anticipation of the Company's acquisition of Exalenz (see Note 6). The credit facility expires in May 2024, and as amended makes available to the Company a revolving credit facility in an aggregate principal amount not to exceed $160,000 (originally $125,000), with outstanding principal amounts bearing 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 2.60% and 4.15% on the revolving credit facility during the three months ended March 31, 2021 and 2020, respectively, and 2.57% and 4.04% during the six months ended March 31, 2021 and 2020, respectively. Since entering into the revolving credit facility, three draws totaling $125,824 have been made on the credit facility, with principal repayments in January 2020, September 2020, December 2020 and February 2021 of $27,000, $30,000, $10,000 and $8,824, respectively, resulting in an outstanding principal balance of $50,000 and $68,824 at March 31, 2021 and September 30, 2020, respectively. The proceeds from these draws were used to: (i) repay and settle the outstanding principal and interest due on our previously existing $60,000 five-year term loan; and (ii) along with cash on-hand, fund the Exalenz and GenePOC acquisitions. 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 March 31, 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 March 31, 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 $11,145 and $11,124 as of March 31, 2021 and September 30, 2020, respectively, and are reflected in the Condensed Consolidated Balance Sheets as follows:

	March 31, 2021	September 30, 2020
Current liabilities	$ 608	$ 600
Non-current liabilities	$ 10,537	$ 10,524

Additionally, the Company has provided certain post-employment benefits to its former Chief Executive Officer, and these obligations total $1,748 and $1,840 at March 31, 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 $853 and $814 at March 31, 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. During the three and six months ended March 31, 2021, the Company recorded $200 and $1,000, respectively, under the grant contract for reimbursement of eligible research and development expenditures. These amounts are included within other income (expense) in the Condensed Consolidated Statements of Operations.

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 six months ended March 31, 2021, products related to COVID-19 accounted for approximately 58% and 64%, respectively, of Life Science segment revenues, and 37% and 41%, respectively, of consolidated revenues. In addition, during the three and six months ended March 31, 2021 and 2020, no individual Diagnostics or Life Science segment customer accounted for 10% or more of consolidated revenues.

Individual Diagnostics or Life Science segment customers, including their affiliates, comprising 10% or more of reportable segment revenues during any of the three- and six-month periods ended March 31, 2021 and 2020 were as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Diagnostics				
Customer A	10%	9%	11%	11%
Customer B	10%	13%	10%	14%
Customer C	11%	5%	11%	5%
Life Science				
Customer D	9%	13%	6%	11%
Customer E	9%	5%	14%	4%

In addition, during both the three and six months ended March 31, 2021, the Life Science segment's ten largest customers, including their affiliates, accounted for approximately 48% and 30% of Life Science segment revenues and consolidated revenues, respectively.

Two Life Science segment customers accounted for the following significant percentages of consolidated accounts receivable:

	March 31, 2021	September 30, 2020
Customer D	10%	8%
Customer E	3%	15%

Reportable segment information for the interim periods is as follows:

	Diagnostics	Life Science	Corporate[1]	Eliminations[2]	Total
Three Months Ended March 31, 2021					
Net revenues -					
Third-party	$ 31,949	$ 53,315	$ —	$ —	$ 85,264
Inter-segment	116	91	—	(207)	—
Operating income	2,421	36,089	(4,325)	16	34,201
Goodwill (March 31, 2021)	95,283	20,013	—	—	115,296
Other intangible assets, net (March 31, 2021)	78,832	2	—	—	78,834
Total assets (March 31, 2021)	313,271	125,947	—	(49)	439,169
Three Months Ended March 31, 2020					
Net revenues -					
Third-party	$ 34,942	$ 22,354	$ —	$ —	$ 57,296
Inter-segment	81	55	—	(136)	—
Operating income	4,729	9,931	(2,896)	27	11,791
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
Six Months Ended March 31, 2021					
Net revenues -					
Third-party	$ 62,270	$ 115,911	$ —	$ —	$178,181
Inter-segment	185	109	—	(294)	—
Operating income	1,239	75,886	(8,288)	28	68,865
Six Months Ended March 31, 2020					
Net revenues -					
Third-party	$ 69,733	$ 34,984	$ —	$ —	$104,717
Inter-segment	178	120	—	(298)	—
Operating income	9,870	12,259	(4,983)	39	17,185

(1) Includes selected legal costs of $1,030 and $2,257 in the three and six months ended March 31, 2021, respectively, and restructuring costs and selected legal costs of $685 and $1,055 in the three and six months ended March 31, 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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Operating income:				
Diagnostics segment	$ 2,421	$ 4,729	$ 1,239	$ 9,870
Life Science segment	36,089	9,931	75,886	12,259
Eliminations	16	27	28	39
Total operating income	38,526	14,687	77,153	22,168
Corporate operating expenses	(4,325)	(2,896)	(8,288)	(4,983)
Interest income	6	23	15	134
Interest expense	(472)	(532)	(1,006)	(1,299)
RADx initiative grant income	200	—	1,000	—
Other, net	(883)	1,365	(1,574)	653
Consolidated earnings before income taxes	$33,052	$12,647	$67,300	$16,673

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

15. IncomeTaxes

The effective rate for income taxes was 20% and 21% for the three and six months ended March 31, 2021, respectively, and 26% and 27% for the three and six months ended March 31, 2020. The lower fiscal 2021 effective tax rates result primarily from the combined effects of the following: (i) a significantly higher percentage of earnings before income taxes being generated in foreign jurisdictions with tax rates lower than the U.S., particularly the United Kingdom (“U.K.”); (ii) the non-deductibility of a significant portion of the acquisition-related costs related to Exalenz; and (iii) the tax impact of 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.

16. LitigationMatters

On April 17, 2018, 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. The Company has executed tolling agreements to extend the statute of limitations. The Company cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on the Company. Approximately $1,030 and $725 of expense for attorneys’ fees related to this matter is included within the Condensed Consolidated Statements of Operations for the three months ended March 31, 2021 and 2020, respectively, and approximately $2,257 and $1,005 for the six months ended March 31, 2021 and 2020, respectively.

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.

Impact of COVID-19 Pandemic

In December 2019, the SARS-CoV-2 virus emerged in Wuhan, China and spread to other parts of the world. In March 2020, the World Health Organization ("WHO") designated COVID-19 (the disease caused by SARS-CoV-2) a global pandemic. In April 2021, the United States ("U.S.") Department of Health and Human Services extended the public health emergency declaration for COVID-19. During the past year, governments around the world have implemented lockdown and shelter-in-place orders, requiring many non-essential businesses to shut down operations, many of which remain in effect as of the date of this filing. Our business, however, was deemed "essential" and we have continued to operate, manufacture and distribute products to customers globally. We have developed a comprehensive plan that enables us to maintain operational continuity with an emphasis on manufacturing, product distribution and new product development during this crisis. We continually assess COVID-19 related developments and adjust risk mitigation planning and business continuity activities in real-time as needed.

The COVID-19 pandemic has had both positive and negative effects on our businesses. Our Life Science segment's products were 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, with revenue for the three and six months ended March 31, 2021 exceeding the comparable fiscal 2020 periods by approximately 140% and 230%, respectively. Our Diagnostics segment, on the other hand, reported decreased year-over-year revenues in the both the first and second quarters of fiscal 2021, a continuation of the trends experienced in the third and fourth quarters of fiscal 2020, as health systems focus on SARS-CoV-2 testing over traditional infectious disease and blood-chemistry testing. Following signs of a recovery in our Diagnostics segment late in fiscal 2020, as evidenced by a 38% sequential quarter increase in the fourth quarter of fiscal 2020, and which continued throughout the early part of the first quarter of fiscal 2021, the recent volatility in COVID-19 infection rates has resulted in sequential quarter growth in Diagnostic segment revenues of only 2% and 5% in the first and second quarters of fiscal 2021, respectively.

Employee Safety

We have implemented work-from-home processes on a site-by-site basis for employees whose on-site presence is designated as non-essential to the ongoing functions of our manufacturing sites, distribution centers, and new product development facilities. We continue to utilize this work-from-home process as needed on a site-by-site basis. We also implemented enhanced cleaning and sanitizing procedures and provided additional personal hygiene supplies at all our sites. We implemented policies for employees to adhere to the Centers for Disease Control and Prevention ("CDC") guidelines on social distancing, and similar guidelines by authorities outside the U.S., and any employees experiencing any symptoms of COVID-19 are required to stay home and encouraged to seek medical attention. Any employee who tests positive for COVID-19 is required to quarantine and is not allowed to return to our facilities without a physician's release, including a negative active infection test result. Access to our facilities by outside persons not critical to continuing our operations continues to be limited. To date, we have been able to manufacture and distribute products globally, and all our sites continue to operate with little, if any, impact on shipments to customers to date. As the 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 remain intact, providing access to sufficient inventory of the key materials needed for manufacturing. To date, delays and allocations for certain raw materials of higher demand have been limited and have not had a material impact on our results of operations. We regularly communicate with suppliers, third-party partners, customers, health care providers and government officials in order to respond rapidly to issues as they arise. The longer the current situation continues, it is more likely 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.

Clinical Trial Delays

As a result of the pandemic, certain of our clinical trials which were underway or scheduled to begin were temporarily placed on hold. While we are continuing to see "re-starts" for certain clinical trials, the trials are being conducted 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. Such delays 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 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). For the second half of our fiscal 2021, we expect demand for reagent products used in COVID-19 tests will be lower than we experienced in our second quarter of fiscal 2021, as health care systems transition to more asymptomatic testing versus the predominant symptomatic testing we have seen over the last year. However, this varies 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 approved COVID-19 related assays around the world. COVID-19 related reagent revenues totaled approximately $31,000 and $74,000 in the three and six months ended March 31, 2021, respectively, following 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, as such assays are often used in non-critical care settings. The COVID-19 pandemic also has continued to affect our instrument placements. The launch of our Curian platform has been slower than expected, as diagnostic testing sites have turned their attention to critical care testing. On the other hand, as a result of announcing the development of a SARS-CoV-2 assay (the "Revogene

COVID-19 assay") and subsequently submitting an application for the test to the FDA on December 7, 2020 under its emergency use authorization ("EUA") program, beginning in our fiscal 2020 fourth quarter and continuing through the first quarter of fiscal 2021, we experienced an acceleration in Revogene instrument orders and placements. However, based upon a mid-February 2021 discussion with the FDA related to certain information contained within the EUA application, on February 23, 2021, we announced our withdrawal of the EUA application and our intention to conduct a Limit-of-Detection bridging study and an updated clinical validation study, with the intention of re-submitting an EUA application for the Revogene COVID-19 assay, which we expect to occur in June 2021. We will not resume shipments of the Revogene COVID-19 assay until FDA EUA clearance. Understandably, these events resulted in a slow-down in orders for the Revogene system that were related to the anticipated COVID-19 assay. We believe this slow-down to be temporary, as potential customers take a "wait and see" approach while we work toward re-submission of our EUA application. In response to the high level of demand we have experienced since announcing development of the test, we are in the process of increasing our capacity to produce these tests, as well as other tests on the Revogene system. Specifically, we are: (i) adding a second production line at our Quebec City, Canada manufacturing facility; and (ii) installing two additional production lines in a leased facility near our corporate headquarters in Cincinnati, Ohio. It is expected that these expansion efforts will be completed during fiscal 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

For the three and six months ended March 31, 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 United Kingdom ("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 goes 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 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 concerns, and implemented strategies to help mitigate these concern. 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 and Six Months Ended March 31, 2021

Net earnings for the second quarter of fiscal 2021 increased 181% to $26,302, or $0.60 per diluted share, from net earnings for the second quarter of fiscal 2020 of $9,359, or $0.22 per diluted share. Net earnings for the six-month period ended March 31, 2021 increased 336% to $53,081, or $1.21 per diluted share, from net earnings for the comparable fiscal 2020 period of $12,186, or $0.28 per diluted share. The level of net earnings in the second quarter ("QTD") and first six months ("YTD") of fiscal 2021 were affected by several factors, including most notably the combined effects of the following (amounts presented on a pre-tax basis) and a lower effective tax rate resulting in large part from a greater percentage of pre-tax earnings being generated in lower tax jurisdictions:

(i) significantly higher revenue in the Life Science segment, due to supplying key reagents to diagnostic test manufacturers for use in COVID-19 related PCR and immunoassay tests (up $30,961 QTD; up $80,927 YTD);

(ii) higher research and development spending in the Diagnostics segment (up $745 QTD; up $1,640 YTD) under new product development programs;

(iii) increased intangible asset amortization, primarily resulting from intangible amortization related to the acquisition of Exalenz in April 2020 (up $491 QTD; up $990 YTD);

(iv) decreased acquisition-related costs, as compared to those related to the Exalenz transaction in April 2020 (down $1,787 both QTD and YTD);

(v) increased legal expenses related primarily to the DOJ matter at the Billerica, Massachusetts facility (up $295 QTD; up $1,202 YTD);

(vi) the fiscal 2021 periods including grant income related to the National Institutes of Health RADx initiative ($200 QTD; $1,000 YTD) (see Note 13 of the Condensed Consolidated Financial Statements); and

(vii) the change from net currency gains in the fiscal 2020 periods to net currency losses in the fiscal 2021 periods ($2,286 change QTD; $2,250 change YTD), resulting primarily from movement in the British pound exchange rate.

Consolidated revenues for the second quarter of fiscal 2021 totaled $85,264, an increase of 49% compared to the second quarter of fiscal 2020 (45% increase on a constant-currency basis).

Revenues from the Diagnostics segment for the second quarter of fiscal 2021 decreased 9% compared to the second quarter of fiscal 2020 (10% decrease on a constant-currency basis), comprised of a 39% decrease in molecular assay products and a 1% decrease in non-molecular assay products. Reflecting the factors noted in the Product Demand section above, our Revogene system installed based totaled 325 at March 31, 2021, as compared to 288 at December 31, 2020.

With a 227% increase in revenues from molecular reagents products and a 44% increase in revenues from immunological reagents products, revenues for our Life Science segment increased 139% during the second quarter of fiscal 2021 compared to the second quarter of fiscal 2020. On a constant-currency basis, revenues for the Life Science segment increased 129%. Life Science segment revenues reflect a significant increase in the 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 second quarter of fiscal 2021 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, our core Life Science segment business (other than COVID-19 contributions) experienced growth of approximately $5,000, or approximately 32%, compared to the second quarter of 2020. This growth, including an approximate 83% increase in revenues from sales into China, resulted in large part from obtaining business from COVID-19 customers who are now using our products for other non-COVID related purposes, as well as a rebound in volumes in core immunological products.

Consolidated revenues increased 70% to $178,181 for the first six months of fiscal 2021 compared to the same period of the prior year (67% increase on a constant-currency basis). On a reportable segment basis, Diagnostics segment revenues decreased 11% (12% decrease on a constant-currency basis) and Life Science segment revenues increased 231% (222% increase on a constant-currency basis). The drivers of the fiscal year-to-date revenue levels are consistent with the drivers that resulted in the quarterly revenue levels, as detailed above and within the Revenue Overview section below.

Lead Testing Matters

On April 17, 2018, Magellan received a subpoena from the U.S. Department of Justice (“DOJ”) regarding its LeadCare product line, which outlined documents to be produced. Since that time, we have received and responded to additional related information requests and 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 2021 subpoena was issued to a current employee of Magellan. At this time, we do not know the outcome of this matter, however, we continue to cooperate with the DOJ.

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 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 Magellan'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 CDC is necessary to protect the public health. Meridian intends to fully cooperate with the FDA as the third-party study is completed.

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. Over the last year, 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). The Warning Letter issued in October 2017 remains outstanding, pending a future FDA inspection. While we remain committed to strengthening Magellan's quality system and ensuring that all aspects of the system are in full compliance, we can provide no assurance that our remediation efforts will be successful to a degree acceptable by the FDA.

In the course of remediation, we may encounter additional matters that warrant notifications to the FDA and/or customers regarding the use of our products. At this time, we do not believe that any such notifications would impact the ability to use the LeadCare systems with capillary blood samples. While we remain confident in the performance of the Magellan LeadCare testing systems using capillary samples, we do not expect that the FDA will reinstate our venous blood claims. We can provide no assurance that the ongoing investigation and study of the DOJ and FDA, respectively, 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, 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, and approximately $31,000 and $74,000 during the second quarter and first six months of fiscal 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. We continue to convert our existing Alethia install base to the Revogene platform for the *C. difficile*, Group A *Streptococcus* ("Group A Strep") and Group B *Streptococcus* ("Group B Strep") assays. Reflecting the factors noted in the Product Demand section above, our Revogene system installed based totaled 325 at March 31, 2021, as compared to 288 at December 31, 2020.

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 66% and 54% during the second quarter and first six months of fiscal 2021, respectively. However, during the second quarter of fiscal 2021, we began to experience an increase in sales activity for gastrointestinal and blood chemistry products, with revenues from each of these product categories increasing as follows compared to the second quarter of fiscal 2020: (i) gastrointestinal products, which include tests for *C. difficile*, *H. pylori* and certain foodborne pathogens, among others, increased 12% to $15,666; and (ii) blood chemistry products, which test for elevated levels of lead in blood, increased 4% to $4,358. During the first six months of fiscal 2021, gastrointestinal product revenues increased 4% over the prior year period to $31,118, and blood chemistry product revenues decreased 4% to $8,753. 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) entering into a strategic collaboration with DiaSorin to sell *H. pylori* tests; (ii) executing supply agreements with our two largest 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 acquisition of the Exalenz 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 second quarter of fiscal 2021, revenues from our Life Science segment increased 139%, with revenues from molecular reagent sales increasing 227% from the comparable fiscal 2020 quarter and revenues from immunological reagent sales increasing 44%. Life Science segment revenues increased 231% for the first six months of fiscal 2021, reflecting a 396% increase from molecular reagent sales and a 78% increase in immunological reagent sales. Our Life Science segment's revenue performance was nominally impacted by the movement in currency exchange rates since the fiscal 2020 reporting periods, with revenues increasing 129% and 222% on a constant-currency basis over the second quarter and first six months of fiscal 2020, respectively. The increase in revenues was primarily attributable to sales of 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-related reagent revenues totaled approximately $31,000 and $74,000 during the second quarter and first six months of fiscal 2021, respectively.

During the second quarter of fiscal 2021, revenue from our core Life Science segment business (other than COVID-19 contributions) grew approximately 32% over the second quarter of fiscal 2020 to approximately $22,000. During the first six months of fiscal 2021, such revenue grew approximately 42% over the comparable fiscal 2020 period to approximately $41,600. This growth, including an approximate 83% and 85% increase in revenue from sales into China during the quarter and fiscal year-to-date period, respectively, resulted in large part from obtaining business from COVID-19 customers who are now using our products for non-COVID 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 March 31,			Six Months Ended March 31,		
	2021	2020	Change	2021	2020	Change
Gross profit	$57,772	$34,546	67%	$119,320	$62,197	92%
Gross profit margin	68%	60%	8 points	67%	59%	8 points

The increase in gross profit margin during the second quarter and first six months of fiscal 2021 results primarily from the overall shift in sales mix the Company has experienced, largely as a result of the COVID-19 pandemic. During the second quarter and first six months of fiscal 2021, approximately 44% and 47%, respectively, of consolidated revenues relate to sales of molecular reagent products by our Life Science segment, which are some of our higher margin products, as compared to sales of such products comprising approximately 20% and 16% of consolidated revenues during the second quarter and first six months of fiscal 2020, respectively.

Operating Expenses – Segment Detail

	Three Months Ended March 31,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2020:					
Diagnostics	$ 4,733	$ 5,401	$ 5,645	$ (505)	$ 15,274
Life Science	582	1,128	2,772	103	4,585
Corporate	—	—	2,211	685	2,896
Total Expenses (2020 Quarter)	$ 5,315	$ 6,529	$ 10,628	$ 283	$ 22,755
Fiscal 2021:					
Diagnostics	$ 5,478	$ 5,220	$ 6,553	$(2,989)	$ 14,262
Life Science	587	1,320	3,077	—	4,984
Corporate	—	—	3,295	1,030	4,325
Total Expenses (2021 Quarter)	$ 6,065	$ 6,540	$ 12,925	$(1,959)	$ 23,571

	Six Months Ended March 31,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2020:					
Diagnostics	$ 8,908	$ 10,797	$ 10,574	$ 812	$ 31,091
Life Science	1,170	2,460	5,110	198	8,938
Corporate	—	—	3,928	1,055	4,983
Total Expenses (2020 Year-to-Date)	$ 10,078	$ 13,257	$ 19,612	$ 2,065	$ 45,012
Fiscal 2021:					
Diagnostics	$ 10,548	$ 10,948	$ 12,301	$(1,942)	$ 31,855
Life Science	1,168	2,613	6,531	—	10,312
Corporate	—	—	6,031	2,257	8,288
Total Expenses (2021 Year-to-Date)	$ 11,716	$ 13,561	$ 24,863	$ 315	$ 50,455

Operating Expenses – Comparisons to Prior Year Periods

	Three Months Ended March 31,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2020 Expenses	$ 5,315	$ 6,529	$ 10,628	$ 283	$ 22,755
% of Revenues	9%	11%	19%	-%	40%
Fiscal 2021 Increases/(Decreases):					
Diagnostics	745	(181)	908	(2,484)	(1,012)
Life Science	5	192	305	(103)	399
Corporate	—	—	1,084	345	1,429
2021 Expenses	$ 6,065	$ 6,540	$ 12,925	$(1,959)	$ 23,571
% of Revenues	7%	8%	15%	(2)%	28%
% Increase (Decrease)	14%	-%	22%	NMF	4%

	Six Months Ended March 31,				
	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
2020 Expenses	$ 10,078	$ 13,257	$ 19,612	$ 2,065	$ 45,012
% of Revenues	10%	13%	19%	2%	43%
Fiscal 2021 Increases/(Decreases):					
Diagnostics	1,640	151	1,727	(2,754)	764
Life Science	(2)	153	1,421	(198)	1,374
Corporate	—	—	2,103	1,202	3,305
2021 Expenses	$ 11,716	$ 13,561	$ 24,863	315	$ 50,455
% of Revenues	7%	8%	14%	—%	28%
% Increase (Decrease)	16%	2%	27%	(85)%	12%

The changes in operating expenses primarily reflect the combined effects of the following:

1) Increased Research & Development costs, primarily reflecting the development of the molecular SARS-CoV-2 assay and molecular gastrointestinal and respiratory panel assays for the Diagnostics segment, and the addition of research and development expenses related to Exalenz, acquired in April 2020;

2) Increased Selling & Marketing costs, primarily reflecting increased bonus and commissions paid early in fiscal 2021 to sustain the Diagnostics segment sales force during the downturn caused by the COVID-19 pandemic, substantially offset by the effects of reduced travel from restrictions imposed during the pandemic and the effect such restrictions have had on general sales and marketing activities;

3) Increased General & Administrative costs, primarily reflecting the addition of expenses related to Exalenz, including purchase accounting amortization, along with additional investment in incentive compensation; and

4) Decreased Acquisition and Restructuring Costs and a decrease in the effect of changes in the fair value of the contingent consideration obligation for the GenePOC business, partially offset by increased Selected Legal Costs (reflected within “Other” in the above tables).

Operating Income

Compared to the prior year periods, operating income increased 190% to $34,201 for the second quarter of fiscal 2021 and increased 301% to $68,865 for the first six months of fiscal 2021, as a result of the factors discussed above.

Income Taxes

The effective rate for income taxes was 20% and 21% for the three and six months ended March 31, 2021, respectively, compared to 26% and 27% for the three and six months ended March 31, 2020, respectively. These lower fiscal 2021 effective tax rates result primarily from the combined effects of the following: (i) a significantly higher percentage of earnings before income taxes being generated in foreign jurisdictions with tax rates lower than the U.S., particularly the U.K.; (ii) the non-deductibility of a significant portion of the acquisition-related costs related to Exalenz; and (iii) the tax impact of 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.

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 March 31, 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 of time, 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 six months of fiscal 2021, we generated cash flow from operations totaling $41,491. This level of cash resulted from the achievement of record fiscal year-to-date revenues, along with well-managed accounts receivable balances, including the requirement of advance payments in certain instances, as illustrated by an approximate 33% increase in second quarter fiscal 2021 consolidated revenues over the fourth quarter of fiscal 2020 and only an approximate 17% increase in accounts receivable balances since September 30, 2020.

Our levels of inventories increased approximately $11,000 to $72,534 between September 30, 2020 and March 31, 2021. This increase was largely attributable to inventory builds in our Life Science segment to protect against future supply interruptions and to meet COVID-19 related demand. For our Diagnostics segment, we also have maintained inventory levels in anticipation of a return to pre-pandemic diagnostic testing activity. We are continuing to actively manage our inventory levels.

As of March 31, 2021, our cash and cash equivalents balance was $63,374 or $9,860 higher than at the end of fiscal 2020. As a result of the cash generated from operations during the second quarter and first six 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 $35,600 to approximately $16,700 at March 31, 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. 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 undisclosed off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in the Company's exposure to market risk since September 30, 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 March 31, 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 March 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as that term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 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

See Note 16, *"Litigation Matters"* of the Condensed Consolidated Financial Statements.

ITEM 1A. RISK FACTORS

There have been no material changes from risk factors as previously disclosed in the Company's fiscal 2020 Annual Report on Form 10-K in response to Item 1A to Part I of Form 10-K.

ITEM 6. EXHIBITS

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

10.1	Meridian Bioscience, Inc. 2021 Omnibus Award Plan (incorporated by reference to Exhibit 10 to the Company's Registration Statement on Form S-8 (File No. 333-252538) filed with the Securities and Exchange Commission on January 29, 2021)
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: May 7, 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: May 7, 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: May 7, 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 March 31, 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
May 7, 2021

/s/ Bryan T. Baldasare
Bryan T. Baldasare
Executive Vice President and Chief Financial Officer
May 7, 2021