

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2020.
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

Commission File No. 0-14902



**MERIDIAN BIOSCIENCE, INC.**

3471 River Hills Drive  
Cincinnati, Ohio 45244

IRS Employer ID No. 31-0888197

State of Incorporation: Ohio

Phone: (513) 271-3700

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Shares, No Par Value	VIVO	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES

NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

YES

NO

Indicate by 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 such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES



NO



Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

YES



NO



Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

YES



NO



The aggregate market value of Common Shares held by non-affiliates as of March 31, 2020 was \$357,822,024 based on a closing sale price of \$8.40 per share on March 31, 2020. As of October 31, 2020, 43,076,077 shares of Common Stock, no par value, were issued and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2021 Annual Meeting of Shareholders, which will be filed within one hundred and twenty days of the fiscal year ended September 30, 2020 (2021 Proxy Statement), are incorporated by reference into Part III of this report to the extent described herein.

MERIDIAN BIOSCIENCE, INC.  
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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This report includes estimates, projections, statements relating to our business plans, objectives, and expected operating results that are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may appear throughout this report, including the following sections: “Business” (Part I, Item 1 of this Form 10-K), “Risk Factors” (Part I, Item 1A of this Form 10-K), and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” (Part II, Item 7 of this Form 10-K). These forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties that may cause actual results to differ materially. We describe risks and uncertainties that could cause actual results and events to differ materially in “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Quantitative and Qualitative Disclosures about Market Risk” (Part II, Item 7A of this Form 10-K) and elsewhere in this Form 10-K. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date they are made. We undertake no obligation to update or revise publicly any forward-looking statements, whether because of new information, future events, the COVID-19 pandemic, or otherwise.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Meridian,” “we,” “us,” “our,” or “our company” refer to Meridian Bioscience, Inc. and its subsidiaries.

In the discussion that follows, all dollar amounts and share amounts are in thousands (both tables and text), except per share data.

This Annual Report on Form 10-K refers to trademarks such as Alethia<sup>®</sup>, BreathID<sup>®</sup>, Curian<sup>®</sup>, ImmunoCard<sup>®</sup>, ImmunoCard STAT!<sup>®</sup>, LeadCare<sup>®</sup>, MyTaq<sup>™</sup>, PediaSTAT<sup>™</sup>, PREMIER<sup>®</sup>, revogene<sup>®</sup> and SensiFAST<sup>™</sup>, which are protected under applicable intellectual property laws and are our property. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the <sup>®</sup> or <sup>™</sup> symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames. Our molecular diagnostic test platform formerly known under the tradenames *illumigene* and *illumipro*, has been rebranded under the tradename Alethia. References to Alethia throughout this Annual Report on Form 10-K refer to our molecular diagnostic tests and instrumentation formerly marketed and sold under the *illumigene* and *illumipro* brands.

## PART I.

### ITEM 1.

#### BUSINESS

##### **Overview**

Meridian is a fully-integrated life science company with principal businesses in: (i) the development, manufacture, sale and distribution of diagnostic test kits, primarily for certain gastrointestinal and respiratory infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, and bioresearch reagents used by in vitro diagnostic (“IVD”) manufacturers and researchers in immunological and molecular tests for human, animal, plant and environmental applications.

Our website is [www.meridianbioscience.com](http://www.meridianbioscience.com). We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements and any amendments thereto, free of charge through this website, as soon as reasonably practicable after such material has been electronically filed with or furnished to the Securities and Exchange Commission (“SEC”). The SEC maintains an internet site containing these filings and other information regarding Meridian at [www.sec.gov](http://www.sec.gov). The information on our website is not and should not be considered part of this Annual Report on Form 10-K.

##### **Reportable Segments**

Our reportable segments are Diagnostics and Life Science, both of which are headquartered in Cincinnati, Ohio. We describe these segments in this “Business” section and in other locations in this report:

<u>Type of Segment Information</u>	<u>Location within Annual Report on Form 10-K</u>
Physical locations and activities	Item 2. “Properties”
Revenue by geographic region	Item 7. “Management’s Discussion and Analysis of Financial Condition & Results of Operations” (hereafter “MD&A”)
Financial information	Note 10 of Consolidated Financial Statements

## **Diagnosics Segment**

### ***Products and Markets***

Prior to the current year effects of the COVID-19 pandemic, our largest source of revenues has been clinical diagnostic products, historically representing approximately two-thirds of our consolidated revenues. However, primarily due to the effects of the pandemic, our Diagnostics segment provided 48% of consolidated net revenues for fiscal 2020.

Our clinical diagnostic products provide accuracy, simplicity and speed; enable early diagnosis and treatment of common, acute medical conditions; and provide for better patient outcomes at reduced costs. We target diagnostics for disease states that: (i) are conditions where rapid diagnosis impacts patient outcomes; (ii) have opportunistic demographic and disease profiles; (iii) are underserved by current diagnostic products; and/or (iv) have difficult sample handling requirements (e.g., stool). This approach has allowed us to establish meaningful market share in our target disease states, gastrointestinal and respiratory illnesses, and tests for elevated lead levels in blood.

Our product portfolio includes approximately 150 diagnostic tests and transport media, and is marketed to acute care hospitals, reference laboratories, outpatient clinics and physician office laboratories in over 70 countries around the world. Our testing platforms include: Real-time PCR Amplification (Revogene brand); Isothermal DNA Amplification (Alethia brand); Lateral Flow Immunoassay using fluorescent chemistry (Curian brand); Rapid Immunoassay (ImmunoCard and ImmunoCard STAT! brands); Enzyme-linked Immunoassay (PREMIER brand); Anodic Stripping Voltammetry (LeadCare and PediaSTAT brands); and urea breath testing for *H. pylori* (BreathID brand).

Our research and development programs are focused on menu expansion for our Curian and Revogene instrument platforms, with disease targets in the gastrointestinal and respiratory areas, as well as next generation blood-chemistry testing. Over the next 12 months, we intend to submit to the FDA at least six new products across both the Curian and Revogene instrument platforms. These new products include the following: Curian – Campylobacter, EHEC Shiga Toxins and *C. difficile* combo common antigen and Toxins A and B; Revogene – SARS-CoV-2 (emergency use authorization), gastrointestinal panel and respiratory panel. Although at an earlier stage in our research and development program, we are also exploring the merits and viability of a liver function test on the BreathID system. We are also pursuing opportunities to complement our internal research and development programs by securing rights to finished diagnostics tests. Our arrangement with GenBody for access to its rapid antigen SARS-CoV-2 test is a recent example of this pursuit.

The 2019 acquisition of the GenePOC business and the Revogene platform refreshed our molecular diagnostics product portfolio, stabilized our molecular customer base and provided menu expansion opportunities for RNA-based tests and small-to-mid sized multi-target panels. This year's acquisition of Exalenz Bioscience Ltd. ("Exalenz") and the BreathID system strengthened our position in *H. pylori* testing, as it gives us a second non-invasive test (in addition to stool antigen testing).

### ***Market Trends***

Despite the effects of the global COVID-19 pandemic and the near-term focus on SARS-CoV-2 testing, we believe the global market for infectious disease tests continues to expand as new disease states are identified, new therapies become available, and worldwide standards of living and access to health care improve. There is a continuing shift from conventional testing to more technologically advanced testing, which can be performed by less highly trained personnel and completed in minutes or hours.

The growing global pressures to contain total health care costs have accelerated the increased use of diagnostic testing. Integrated Delivery Networks ("IDNs") in our U.S. market have the goal of increasing the efficiency of health care delivery, reducing spending and improving clinical outcomes. We believe our product portfolio positions us competitively with IDNs and health care systems that are transitioning from fee-for-service compensation models to value-based reimbursement.

We also continue to see aggregation of buying power in our U.S. market via multi-hospital group purchasing organizations and IDNs, consolidation among reference laboratories, hospital laboratories being operated by large reference laboratories, and acquisition of physician practices by hospitals, health systems and for-profit specialty health care companies.

Cost containment pressures have also affected health care systems outside the U.S., particularly in Europe, where the health care systems are generally government-run. The level of government budget deficits can have an adverse effect on the amount of government health care spend.

### ***Sales, Marketing and Distribution***

Our Diagnostics segment relies on direct sales personnel and independent distribution networks. We have a direct sales force in four countries, covering the United States and certain major markets in the EMEA region. We also use independent distributors either in a complementary manner with our direct sales force (e.g., the United States) or solely to supply our products to end-users. Two independent distribution customers in the United States have historically significantly contributed to our revenues, comprising 21% of consolidated revenues as recently as fiscal 2018.

### ***Competition***

Our major competitors in molecular diagnostics are Cepheid (a Danaher business) and Becton Dickinson, both of which have systems with multiple-assay menus. We also face competition in molecular diagnostics, but to a lesser degree, from companies such as Abbott (former Alere business) and Quidel.

Our major competitors in rapid immunoassay diagnostics are primarily Abbott (former Alere business) and Quidel. In recent years, companies such as bioMérieux have captured market share in our gastrointestinal category via its BioFire multi-plex panel tests. However, since their introduction to the market, payors have raised concerns over reimbursement levels relative to clinical utility, particularly for panels with 12 or more targets.

For blood lead testing, we believe we have the only FDA-cleared, CLIA-waived point-of-care test available commercially. Other blood lead testing systems in use, marketed by our competitors, include Graphite Furnace Atomic Absorption Spectroscopy, which requires a highly skilled technician and larger laboratory space to operate, in addition to not being portable or suitable for point-of-care use.

Our major competitor for urea breath testing for *H. pylori* is Otsuka, a pharmaceutical company that also markets and sells a urea breath testing system. We believe that our BreathID system has a competitive advantage in that it: (i) has substantially higher sensitivity and specificity; (ii) has a shorter processing time; (iii) offers full automation; and (iv) connects directly to lab information systems.

We believe that with the breadth and depth of our product portfolio, we are well positioned for the clinical laboratory.

### ***Research and Development***

Our Diagnostics segment's research and development personnel are organized into three pre-clinical teams: immunoassay, PCR-based molecular and blood-chemistry. We have a separate team responsible for execution of clinical trials across all three pre-clinical programs. Our research and development activities are focused on new product and new technology development, new applications for our existing technologies, and improvements to existing products, including assay-menu expansion. Research and development efforts may occur in-house or with collaborative partners. We believe that new product development is a key source for sustaining revenue growth. The products within our Revogene and Alethia molecular platforms, *H. pylori* product family and blood lead testing family were developed in-house. See "Operating Expenses" section within MD&A on page 31.

### ***Manufacturing***

Our Diagnostics tests are manufactured at four principal sites in Billerica, Massachusetts (blood-chemistry); Cincinnati, Ohio (immunoassays and molecular tests); Modi'in, Israel, (urea breath tests for *H. pylori*); and Quebec City, Quebec, Canada (molecular tests). Our immunoassay and molecular assay products require the production of highly specialized reagents, primers and enzymes, and our BreathID system requires the production of urea in pharmaceutical-grade form. We produce the vast majority of our own immunoassay requirements. Reagents, primers and enzymes for our Revogene molecular assay products, primers for our Alethia molecular assay products, and urea for our BreathID system are purchased from outside vendors. Our blood lead testing products require the production of electrical chemical sensors, which we manufacture using critical raw materials purchased from outside vendors.

### ***Intellectual Property, Patents and Licenses***

We own or license U.S. and foreign patents, most of which are for select products manufactured by our Diagnostics segment. These patents are used in our manufacturing processes for select products (e.g., method patents) or may relate to the design of the test device technology format (e.g., design patents). In the absence of patent protection, we may be vulnerable to competitors who successfully replicate our production and manufacturing technologies and processes. Our employees are required to sign confidentiality and non-disclosure agreements designed to protect our proprietary products.

The patents for our Alethia products, which represented 9%, 13% and 16% of consolidated revenues for fiscal 2020, 2019 and 2018, respectively, are licensed from a third party, Eiken Chemical Co., Ltd., under a non-exclusive license agreement and expire between 2020 and 2022. These patents were issued in the U.S., European Union and other countries. The term of our license agreement runs until the last patent expires in 2022, at which point we will be free to practice the patents without any restriction or royalty obligation.

The patents for the Revogene platform and related products acquired as part of the GenePOC business are either wholly owned or licensed from two third parties, Laval University and The Regents of California, under an exclusive license agreement. These patents are issued in the U.S., European Union and other countries. The term of our exclusive license agreement and the related patents currently runs through June 15, 2034, after which we will be free to practice the patents without any restriction or royalty obligation. For a description of our acquisition of the GenePOC business, see Note 2 of the accompanying Consolidated Financial Statements.

The patents for the BreathID system and related urea breath test for *H. pylori* are either wholly owned or licensed from a third party, Oridion Medical 1987 Ltd., under an exclusive, royalty free, license agreement. The licensed and wholly owned patents are issued in the U.S., European Union, Israel, Japan, Australia and China. The wholly owned patents have varying expiration dates, with the last being in 2033.

The patents for our stool antigen *H. pylori* products, owned by us and which represented approximately 10%, 16% and 16% of consolidated revenues for fiscal 2020, 2019 and 2018, respectively, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our stool antigen *H. pylori* products to continue to increase, and such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. We have executed on a number of measures to address competitive pressures in coming off patent including: (i) in October 2018, we entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests; (ii) we have executed multi-year 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, we launched Curian HpSA, our first assay on the new 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, allowing 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.

### ***Government Regulation***

Our diagnostic products are regulated by the FDA as “devices” pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”). Under the FDCA, medical devices are classified into one of three classes (i.e., Class I, II or III). Class I and II devices are not expressly approved by the FDA, but, instead, are “cleared” for marketing. Class III devices generally must receive “pre-market approval” from the FDA as to safety and effectiveness. Our diagnostics manufacturing facilities are subject to periodic inspection by the FDA. See page 28 within MD&A for discussion regarding the FDA’s inspection of our Billerica facility.

Each of the diagnostic products currently marketed by us in the United States has been cleared by the FDA pursuant to the 510(k) clearance process or is exempt from such requirements. We believe that most, but not all (e.g., liver function test on the BreathID system in development, a Class III medical device), products under development will be classified as Class I or II medical devices and, in the case of most of our Class I and all Class II devices, will be eligible for 510(k) clearance; however, we can make no assurances in this regard. Our urea breath test for *H. pylori* on the BreathID system was cleared as a Class I medical device since the urea drug component was

approved by the FDA separately via the New Drug Application process. Our SARS-CoV-2 test on the Revogene platform is expected to be submitted to the FDA under its emergency use authorization program in late November or early December 2020. We notified the FDA of our intent to submit for emergency use authorization on November 13, 2020.

Sales of our diagnostic products in foreign countries are subject to foreign government regulation, which is similar to that of the FDA. Our Diagnostics facilities are certified to ISO 13485:2016.

Following a five-year transition period, sales of our diagnostic tests in the European Union will be subject to new regulations under the In Vitro Diagnostics Regulation of 2017 (“IVDR”) beginning in May 2022. IVDR replaces the previous IVD Regulation (98/79/EC). We have begun our assessment regarding which products will not be sellable under IVDR and the revenue associated with these products is not expected to be material.

Our principal business is the sale of a broad range of clinical diagnostic test kits for common gastrointestinal and respiratory infectious diseases, and elevated blood lead levels. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as foodborne illnesses or pandemics such as an influenza outbreak or the current COVID-19 pandemic. While we believe that the breadth of our diagnostic product lines normally reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, the current COVID-19 pandemic did result in a significant decline in our Diagnostics revenues during the second half of fiscal 2020. Accordingly, we can make no assurance that revenues will not be impacted period over period by such factors.

## **Life Science Segment**

### ***Products and Markets***

Our Life Science segment develops, manufactures, sells and distributes bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, and bioresearch reagents used predominantly by IVD manufacturing companies, and to a lesser degree, by researchers and non-human clinical customers. The COVID-19 pandemic has provided the opportunity for our Life Science segment to showcase the breadth of its reagent products across not only SARS-CoV-2 testing platforms (molecular, rapid antigen and serology), but also RNA and DNA based molecular tests for nearly any infectious disease. For fiscal 2020, approximately 85% of Life Science revenues were generated from the industrial market, defined as IVD manufacturers, and reagents for use in SARS-CoV-2 tests contributed approximately \$71,500 in new revenues. We engage direct sales teams in the U.S., the U.K., France, Germany, China and Australia. During fiscal 2020, 27% of third-party revenues for this segment were from three IVD manufacturing customers.

Our Life Science products are marketed to IVD manufacturing customers as a source of raw materials for their human clinical diagnostics tests, or as an outsourced step in their manufacturing processes. We seek and maintain multi-year supply arrangements to provide stability in volumes and pricing. Independent distributors market our molecular biology products to academic/research customers. These products are used in measuring DNA and RNA in human, animal, plant and environmental applications.

### ***Market Trends***

Major IVD manufacturing customers often have global footprints, where we are supplying reagents to specific manufacturing sites around the world. IVD manufacturers in specific countries of the Asia-Pacific region (e.g., China) are increasing their efforts in the development and manufacturing of infectious disease tests. We intend to use the breadth of our product portfolio, particularly molecular reagents, to increase the penetration of our products in IVD manufacturing customers’ tests, regardless of customer class (large multi-national companies or regional companies).

### ***Competition***

The market for bulk biomedical reagents is highly competitive with respect to product quality, price, customer service and reputation. Our competitors often have greater financial, research and development, sales and marketing, and manufacturing resources. Customers also may choose to manufacture their biomedical reagents in-house rather than purchase from us.



### **Research and Development**

Our research and development activities for the Life Science segment focus on improving molecular reagents, including DNA and RNA master mixes. For example, our Life Science segment introduced a family of lyophilization-ready reagents that have a number of advantages over prior generation “wet” reagents (e.g., room-temperature shipping and storage and longer shelf-life). See “Operating Expenses” section within MD&A on page 31.

### **Manufacturing and Government Regulation**

Our Life Science facilities are ISO 13485:2016 certified. Additionally, where appropriate, our Life Science facilities comply with Regulation EC 1069:2009.

### **International Markets**

International markets are an important source of revenues and future growth opportunities for both of our segments. For both segments combined, revenues from customers located outside of the United States and its territories approximated \$122,000 or 48% of consolidated fiscal 2020 revenues, \$74,000 or 37% of consolidated fiscal 2019 revenues, and \$71,000 or 33% of consolidated fiscal 2018 revenues. For our Life Science segment, the COVID-19 pandemic resulted in the significantly higher percentage of international revenues for fiscal 2020. We expect to continue to look to key European markets as a source of revenue growth in the future for both business units. For the Life Science segment, we have also focused resources on IVD manufacturing customers in China. To date, we have not experienced any adverse effects from the trade tensions between the United States and China, but we cannot be sure that we will not experience any adverse effects in the future.

Fluctuations in foreign currency exchange rates since fiscal 2019 had an approximate \$1,250 unfavorable impact on fiscal 2020 revenues; \$150 within the Diagnostics segment and \$1,100 within the Life Science segment. This compares to year-to-year currency exchange rates having an approximate \$2,200 unfavorable impact on revenues in fiscal 2019; \$1,150 within the Diagnostics segment and \$1,050 within the Life Science segment.

### **Environmental**

We are in compliance with applicable portions of the federal and state hazardous waste regulations and have never been a party to any environmental proceeding.

### **Human Capital**

As of September 30, 2020, our Diagnostics segment had approximately 560 employees in ten countries and our Life Science segment had approximately 190 employees in seven countries. Approximately 58% of our employees are women. In addition, of our U.S. based employees, which represents approximately 60% of our total worldwide workforce, approximately 23% are ethnically diverse.

Below is additional demographic information about our current employee base as of September 30, 2020.

<b>Meridian Employees</b>	<b>2020</b>
Salaried workforce	537
Managers and above	157
Part-time employees	27
Average age	43
Average length of service in years	7
Employee turnover rate (voluntary)	13%
Fiscal 2020 revenues per employee (in thousands)	\$340

Equal Employment Opportunity Table (by number of employees) U.S. Employee Diversity as of September 30, 2020								
Job category	Gender	White	Black/African American	Hispanic/Latino	Asian	American Indian/Alaskan Native	Two or more races	Total
Executive/senior level officials and managers	Male	11	-	-	-	-	-	11
	Female	2	-	1	-	-	-	3
First/mid-level officials and managers	Male	38	3	2	3	-	-	46
	Female	38	4	-	2	-	1	45
Professionals	Male	56	2	2	4	1	2	67
	Female	67	6	4	8	-	2	87
All other	Male	48	9	5	4	-	1	67
	Female	84	13	7	10	-	4	118
<b>Total</b>	Male	153	14	9	11	1	3	191
	Female	191	23	12	20	-	7	253

We believe that developing a diverse, equitable and inclusive culture is critical to continuing to attract and retain the top talent necessary to deliver on our growth strategy. As such, we are investing in the creation of a work environment where our employees can feel inspired to deliver their workplace best every day. All employees are responsible for upholding the Meridian Values and Meridian Code of Conduct, which form the foundation of our policies and practices. We continue to expand our Human Resources Information System (“HRIS”) and other systems to track key human capital metrics, including workforce demographics, diversity, turnover, engagement and training data.

#### ***Diversity, Equity and Inclusion***

A diverse and inclusive workforce is a business imperative and key to our long-term success. To champion our efforts in this area, we have recently initiated the “One Meridian Inclusion Diversity and Equity Team,” which is comprised of a group of employees around the world and led by Dr. Lourdes Weltzien, Executive Vice President, Life Science. This team will be developing a mission and a strategy that will look to identify gaps and present suggestions on how we can encourage and enforce an environment in which all employees feel included and empowered to achieve their best. Though we are proud of our efforts in these areas to date, we realize that the voice and ongoing feedback of this newly established team is critical for Meridian to achieve its full potential.

#### ***Compensation and Benefits***

We strive to provide pay, benefits, and services that are competitive to market and create incentives to attract and retain employees globally. Our compensation package includes market-competitive pay, broad-based stock grants and bonuses, health care and retirement benefits, paid time off and family leave, among others, depending upon locale. We are focused on pay equity globally and are striving to close the gap in pay among similar roles and responsibilities throughout our organization, after accounting for legitimate business factors that can explain differences, such as performance, time at grade level, and tenure. We also continue to advance transparency in our pay and representation data by complying with all applicable statutory filing requirements.

#### ***Communication and Engagement***

We strongly believe that Meridian’s success depends on employees understanding how their work contributes to the Company’s overall strategy. To this end, we utilize a variety of channels to facilitate open and direct communication, including: (i) quarterly CEO update videos; (ii) open forums or town hall meetings with executives; (iii) regular ongoing update communications; and (iv) employee engagement surveys.

### ***Health, Wellness and Safety***

We are committed to the safety of our employees and communities, from operations to product development to supplier partnerships. Our ultimate goal is to achieve zero serious injuries through continued investment in and focus on our core safety programs and injury-reduction initiatives. We provide access to a variety of innovative, flexible, and convenient health and wellness tools.

## ITEM 1A.

### **RISK FACTORS**

In addition to the other information set forth in this report, you should carefully consider the following factors, which could materially affect our business, financial condition, cash flows or future results. Any one of these factors could cause our actual results to vary materially from recent results or from anticipated future results. The risks described below are not the only risks facing our company. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may materially adversely affect our business, financial condition and/or operating results.

#### **Risks Affecting Growth and Profitability of our Business**

##### ***Our financial condition, results of operations and cash flows could be adversely affected by the ongoing coronavirus (COVID-19) outbreak.***

Any outbreak of contagious diseases, such as COVID-19, or other adverse public health developments, could have material and adverse effects on our business operations. Such adverse effects could include diversion or prioritization of health care resources away from the conduct of diagnostic testing, disruptions of or restrictions on the ability of laboratories to process our tests, and delays with respect to or difficulties in patients accessing our tests, including those resulting from an inability to travel as a result of quarantines or other restrictions resulting from COVID-19. As COVID-19 continues to affect individuals and businesses around the globe, we may experience disruptions that could severely impact our business, including:

- decreased volume of testing and related sales of certain of our Diagnostics products as a result of disruptions to health care providers and limitations on the ability of providers to administer tests;
- disruptions or restrictions on the ability of the Company's, our collaborators', or our suppliers' personnel to travel, and temporary closures of our facilities, or the facilities of our collaborators or suppliers;
- limitations on employee resources that would otherwise be focused on the development of our products, the processing of our diagnostic tests, and/or the conduct of our clinical trials, because of illness of employees or their families, or requirements imposed on employees to avoid contact with large groups of people; and
- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

In addition, the continued spread of COVID-19 globally could adversely affect our manufacturing and supply chains. Parts of our direct and indirect supply chains are located overseas, including in China, and may accordingly be subject to disruption. Additionally, our results of operations could be adversely affected to the extent that COVID-19 or any other epidemic harms our business or the economy in general either domestically or in any other region in which we do business. The extent to which COVID-19 affects our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of COVID-19, and the actions to contain COVID-19 or treat its impact, among others, which could have an adverse effect on our business, results of operations and financial condition. To date, we are seeing that the outbreak has slowed our assay instrument placements and sales of related test kits as diagnostic testing sites have turned their attention to critical care testing. We are unable to predict when expected sales volume levels for our instruments and related test kits will return. Also, as a result of the pandemic, certain clinical trials related to our products which were underway or scheduled

to begin have been temporarily placed on hold. Such delays will 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 pandemic could 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.

***If our essential employees who are unable to telework become ill or otherwise incapacitated, our operations may be adversely impacted.***

Consistent with rapidly changing federal, state and local governmental orders and recommendations, we have implemented telework policies wherever possible for appropriate categories of our employees. Employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering mandates, temperature checking, and increased sanitation standards in an attempt to maintain the health and safety of our workforce. We are following guidance from the Center for Disease Control (“CDC”) and the Occupational Safety and Health Administration (“OSHA”) regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and wellbeing of our employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may not otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

***We may be unable to develop new products and services or acquire products and services on favorable terms.***

The medical diagnostic and life science industries are characterized by ongoing technological developments and changing customer requirements. As such, our results of operations and continued growth depend, in part, on our ability in a timely manner to develop or acquire rights to, and successfully introduce into the marketplace, enhancements of existing products and services, or new products and services that incorporate technological advances, meet customer requirements and/or respond to products developed by our competition. We cannot provide any assurance that we will be successful in developing or acquiring such rights to products and services on a timely basis, or that such products and services will adequately address the changing needs of the marketplace, either of which could adversely affect our results of operations.

In addition, we must regularly allocate considerable resources to research and development of new or acquired products, services and technologies, and protecting intellectual property. The research and development process generally takes a significant amount of time from research to product launch. This process is conducted in various stages. During each stage, there is a risk that we will not achieve our goals on a timely basis, or at all, and we may have to abandon a project in which we have invested substantial resources, any of which could adversely affect our results of operations.

***We may be unable to successfully integrate operations or to achieve expected cost savings from acquisitions we make.***

One of our growth strategies is the acquisition of companies and/or products. Although additional acquisitions of companies and products may enhance the opportunity to increase net earnings over time, such acquisitions could result in greater administrative burdens, increased exposure to the uncertainties inherent in marketing new products, financial risks of additional operating costs, disrupted operations, challenges in employee retention, and increased risk of asset impairments if future revenues and cash flows are deficient. The principal benefits expected to result from any acquisitions we make will not be achieved fully unless we are able to successfully integrate the operations of the acquired entities with our operations and realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses into our existing businesses. We cannot provide assurance that we will be able to identify and complete additional acquisitions on terms we consider favorable or that, if completed, will be successfully integrated into our operations. Furthermore, we cannot predict the outcome of goodwill impairment testing and the impact of goodwill impairments on the Company’s earnings and financial results.

***Revenues for our Diagnostics segment may be impacted by our reliance upon two key distributors in North America, seasonal factors and sporadic outbreaks, and changing diagnostic market conditions.***

#### *Key Distributors*

Our Diagnostics segment's revenues from sales through two U.S. distributors were approximately 23% and 26% of the Diagnostics segment's total revenues for fiscal 2020 and fiscal 2019, respectively, or approximately 12% and 18%, respectively, of each fiscal year's consolidated revenues. These parties distribute our products and other laboratory products to end-user customers. The loss of either of these distributors could negatively impact our revenues and results of operations unless suitable alternatives were timely found or lost sales to one distributor were absorbed by another distributor. Finding a suitable alternative on satisfactory terms may pose challenges in our industry's competitive environment. As an alternative, we could expand our efforts to distribute and market our products directly. This alternative, however, would require substantial investment in additional sales, marketing and logistics resources, including hiring additional sales and customer service personnel, which would significantly increase our future selling, general and administrative expenses.

In addition, buying patterns of these two distributors may fluctuate from quarter to quarter, potentially leading to uneven concentration levels on a quarterly basis.

#### *Seasonal Factors and Sporadic Outbreaks*

Our principal business is the sale of a broad range of diagnostic test kits for common gastrointestinal and respiratory infectious diseases, and elevated blood lead levels. Certain infectious diseases may be seasonal in nature, while others may be associated with sporadic outbreaks, such as foodborne illnesses or pandemics such as an influenza outbreak or the current COVID-19 pandemic. While we believe that the breadth of our diagnostic product lines normally reduces the risk that infections subject to seasonality and sporadic outbreaks will cause significant variability in diagnostic revenues, the current COVID-19 pandemic did result in a significant decline in our Diagnostics revenues during the second half of fiscal 2020. Accordingly, we can make no assurance that revenues will not be negatively impacted period over period by such factors.

#### *Changing Diagnostic Market Conditions*

Changes in the U.S. health care delivery system have resulted in consolidation among reference laboratories, hospital laboratories being operated by large reference laboratories, and the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. Consolidation in the U.S. health care industry has also led to the creation of group purchasing organizations ("GPOs") and IDNs that aggregate buying power for hospital groups and put pressure on our selling prices. Due to such consolidation, we may not be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with institutional customers, GPOs and/or IDNs, which could adversely affect our results of operations.

#### ***We could be adversely affected by health care reform legislation.***

Third-party payers for medical products and services, including state, federal and foreign governments, are increasingly concerned about escalating health care costs and can indirectly affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement they will provide for diagnostic testing services. Following years of increasing pressure, during 2010 the U.S. government enacted comprehensive health care reform with the enactment of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which made changes that significantly impact the pharmaceutical and medical device industries. The Protecting Access to Medicare Act of 2014 requires applicable laboratories to report all private payor reimbursement rates and the volumes for each test they perform. The statute requires that Medicare establish reimbursement rates based on the weighted median of private insurance reimbursement rates effective January 1, 2017. The new Medicare rates would be subject to a maximum reduction of 10% a year for the initial three-year period and a maximum of 15% a year for the subsequent three-year period. There is no limit on the amount of potential rate increases. As a result, some of our customers in the United States may experience lower Medicare reimbursement rates for our products, which may adversely affect our business, financial condition and results of operations. We are seeing some effect on the reimbursement rates for our products. If reimbursement amounts for diagnostic testing services decrease further in the future, such decreases may reduce the amount that will be reimbursed to hospitals or physicians for such services and consequently, could place constraints on the levels of overall pricing, which could have a material effect on our revenues and/or results of operations.

Additional state and federal health care reform measures may be adopted in the future, any of which could have a material adverse effect on our ability to successfully commercialize our products and on our industry in general. For example, the United States government has in the past considered, is currently considering, and may in the future consider, health care policies and proposals intended to curb rising health care costs, including those that could significantly affect both private and public reimbursement for health care services. Further, state and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Future significant changes in the health care system in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether health care policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future, what effect such policies would have on our business, or the effect that ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

***Efforts to reduce the U.S. federal deficit could adversely affect our results of operations.***

As part of the Budget Control Act passed in August 2011 to extend the federal debt limit and reduce government spending, \$1.2 trillion in automatic spending cuts (known as sequestration) were implemented in 2013. The sequestration requires a 2% cut in Medicare payments for all services, including our diagnostic tests, which, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless Congressional action is otherwise taken. Government research funding has also been reduced as a result of the sequestration. On January 2, 2013, the American Taxpayer Relief Act of 2012 also was signed into law, which, among other things, further reduces Medicare payments to providers such as hospitals, imaging centers and cancer treatment centers, and increases the statute of limitations period for the government to recover overpayments to providers from three to five years.

Such reductions in government health care spending or research funding could result in reduced demand for our products or additional pricing pressure. Further, there is ongoing uncertainty regarding the federal budget and federal spending levels, including the possible impacts of a failure to increase the “debt ceiling.” Any U.S. government default on its debt could have broad macroeconomic effects that could, among other things, raise our borrowing costs. Any future shutdown of the federal government or failure to enact annual appropriations could also have a material adverse impact on our business.

***Revenues for our Life Science segment may be impacted by customer concentrations and buying patterns.***

Our Life Science segment’s revenues from three diagnostic manufacturing customers were 27% and 26% of the Life Science segment’s total revenues for fiscal 2020 and fiscal 2019, respectively, with such percentage for fiscal 2019 being concentrated in two of the customers. Sales to these three diagnostic manufacturing customers comprised 14% and 8% of total consolidated revenues for fiscal 2020 and fiscal 2019, respectively. In addition, in excess of 10% of the segment’s total revenues has historically been concentrated among a number of other significant customers. Any significant alteration of buying patterns from these customers could adversely affect our period over period revenues and results of operations.

***We expect to face increased competition resulting from expiration of our H. pylori patents.***

The patents for our stool antigen *H. pylori* products, owned by us, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our stool antigen *H. pylori* products, high margin products which represent approximately 10% of our total revenues, to continue to increase, as we currently are one of only four companies that market FDA-cleared tests to detect *H. pylori* antigen in stool samples in the U.S. market, one of which is DiaSorin Inc., with whom we have entered a strategic collaboration agreement to sell *H. pylori* tests. At present, we are also aware of at least one other company that has commenced clinical trials of *H. pylori* products in the U.S. Such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. We have executed on a number of measures to address competitive pressures in coming off patent including: (i) in October 2018, we entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests; (ii) we have executed multi-year 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, we launched Curian HpSA, our first assay on the new 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, allowing

physicians a choice in test format from one 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.

***We depend on international revenues, and our financial results may be adversely impacted by foreign currency, regulatory or other developments affecting international markets.***

We sell products and services into approximately 70 countries. For fiscal 2020, approximately one third of our consolidated revenues were transacted in currencies other than the U.S. dollar. We are subject to the risks associated with fluctuations in the exchange rates for the Australian dollar, British pound, Canadian dollar, Chinese yuan, Euro, and New Israeli shekel. We are also subject to other risks associated with international operations, including longer customer payment cycles, trade wars, increased tariffs, requirements for export licenses, instability of foreign governments, and governmental requirements with respect to the importation and distribution of medical devices and immunodiagnostic and molecular biology reagents, all of which may vary by country.

***New tariffs and other trade measures could adversely affect our financial results.***

The current U.S. administration has expressed strong concerns about imports from countries that it perceives as engaging in unfair trade practices, and it is possible the administration could impose import duties or other restrictions on products, components or raw materials sourced from those countries, which may include countries from which we import components or raw materials. We are currently not aware of any new import duties imposed on our products. Any such new import duties or restrictions could have a material adverse effect on our business, results of operations or financial condition. Moreover, these new tariffs, or other changes in U.S. trade policy, could trigger retaliatory actions by affected countries. Certain foreign governments have instituted or are considering imposing trade sanctions on certain U.S. goods.

Other foreign governments are considering the imposition of sanctions that will deny U.S. companies access to critical raw materials. A “trade war” of this nature or other governmental actions related to tariffs or international trade agreements or policies has the potential to adversely impact demand for our products, our costs, customers, manufacturers, suppliers and/or the economic environments in which we operate and, thus may adversely impact our businesses. In addition, there may be changes to existing trade agreements, like the North American Free Trade Agreement (“NAFTA”) and its anticipated successor agreement, the U.S.-Mexico-Canada Agreement (“USMCA”), which is still subject to approval by the United States, Mexico and Canada, greater restrictions on free trade generally, and significant increases in tariffs on goods imported into the United States, particularly tariffs on products manufactured in Mexico, among other possible changes. It remains unclear what the U.S. administration or foreign governments will or will not do with respect to tariffs, NAFTA, USMCA or other international trade agreements and policies. Any changes to NAFTA (or subsequent trade agreements) could impact our operations in countries where we manufacture or sell products, or source components or materials, which could adversely affect our operating results and our business.

## **Risks Affecting our Manufacturing Operations**

***We are subject to comprehensive regulation, and our ability to earn profits may be restricted by these regulations.***

Medical device diagnostics is a highly regulated industry. We cannot provide assurance that we will be able to obtain necessary governmental clearances or approvals, or timely clearances or approvals, to market future products in the United States and other countries. Costs and difficulties in complying with laws and regulations administered by the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Department of Commerce, the U.S. Drug Enforcement Agency, the Centers for Disease Control, or other regulators can result in unanticipated expenses and delays, and interruptions to the sale of new and existing products.

Regulatory approval can be a lengthy, expensive and uncertain process, making the timing and costs of approvals difficult to predict. Failure to comply with these regulations can result in delays in obtaining authorization to sell products, seizure or recall of products, suspension or revocation of authority to manufacture or sell products, and other civil or criminal sanctions.

***If we or our third-party vendors fail to comply with FDA regulations relating to the manufacturing of our products or any component part, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be negatively impacted.***

Our diagnostics manufacturing facilities, and the manufacturing facilities of any of our third-party diagnostic component manufacturers or critical suppliers, are required to comply with the FDA's Quality System Regulation ("QSR"), which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of the products we sell, and related regulations, including Medical Device Reporting ("MDR") regulations regarding reporting of certain malfunctions and adverse events potentially associated with our products. The FDA may evaluate our compliance with the QSR, MDR and other regulations, among other ways, through periodic announced or unannounced inspections which could disrupt our operations and interrupt our manufacturing. If in conducting an inspection of our manufacturing facilities, or the manufacturing facilities of any of our third-party component manufacturers or critical suppliers, an FDA investigator observes conditions or practices believed to violate the QSR, the investigator may document their observations on a Form FDA 483 that is issued at the conclusion of the inspection. A manufacturer that receives an FDA 483 may respond in writing and explain any corrective actions taken in response to the inspectional observations. The FDA will typically review the facility's written response and may re-inspect to determine the facility's compliance with the QSR and other applicable regulatory requirements. Failure to take adequate and timely corrective actions to remedy objectionable conditions listed on an FDA 483 could result in the FDA taking administrative or enforcement actions. Among these may be the FDA's issuance of a Warning Letter to a manufacturer, which informs it that the FDA considers the observed violations to be of "regulatory significance" that, if not corrected, could result in further enforcement action.

FDA enforcement actions, which include seizure, injunction, criminal prosecution, and civil penalties, could result in total or partial suspension of a facility's production and/or distribution, product recalls, fines, suspension of the FDA's review of product applications, and/or the FDA's issuance of adverse publicity. Thus, an adverse inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse inspections could also delay FDA approval of our products and could have an adverse effect on our production, sales and profitability.

We and any of our third-party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction, and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to our facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacture of the product, or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, which could, therefore, have a material adverse effect on our business, financial condition and results of operations.

On June 29, 2017, the FDA, in connection with its Safety Notification related to Magellan (whom we acquired in March 2016) and its lead testing systems for venous blood samples, issued its Form 483, Inspectional Observations, to Magellan. This was followed by the FDA issuing a Warning Letter related to the matter on October 23, 2017. During October 2019, the FDA conducted a follow-up inspection of Magellan's manufacturing facility. In connection with this follow-up inspection, the FDA issued five Form 483 observations. Over the last year, we have submitted a number of written responses to the FDA regarding the five Form 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.

Additionally, as set forth in Item 3. "Legal Proceedings", on April 17, 2018, Magellan received a subpoena from the United States Department of Justice ("DOJ") regarding its LeadCare product line. The subpoena outlines documents to be produced, and we are cooperating with the DOJ in this matter. We maintain rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements, and are working with the DOJ to promptly respond to the subpoena, including responding to additional information requests. We



have executed tolling agreements to extend the statute of limitations. We cannot predict when the investigation will be resolved, the outcome of the investigation, or its potential impact on Meridian.

See a more detailed discussion of these matters within MD&A on page 28.

***Significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results.***

Products and services manufactured at facilities we own or lease comprised a majority of our revenues. Our global supply of these products and services is dependent on the uninterrupted and efficient operation of these facilities. In addition, we currently rely on a small number of third-party manufacturers to produce certain of our diagnostic products and product components. The operations of our facilities or these third-party manufacturing facilities could be adversely affected by power failures, or natural or other disasters such as earthquakes, floods, tornadoes or terrorist threats. Although we carry insurance to protect against certain business interruptions at our facilities, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. Any significant interruption in the Company's or a third-party supplier's manufacturing capabilities could materially and adversely affect our operating results.

***We depend on sole-source suppliers for certain critical raw materials, components and finished products. A supply interruption could adversely affect our business.***

*Raw Materials and Components*

Our diagnostic products are made from a wide variety of raw materials that are biological or chemical in nature, and that generally are available from multiple sources of supply. We sole-source certain raw materials and components, which makes it time consuming and costly to switch raw materials and components in FDA-cleared products. If certain suppliers fail to supply required raw materials or components, we will need to secure other sources which may require us to conduct additional development and testing and obtain regulatory approval. These activities require significant time and resources, and there is no assurance that new sources will be secured or regulatory approvals, if necessary, will be obtained.

We utilize third-party manufacturers for certain of our instrumentation. One third party manufactures our proprietary Alethia Incubator/Reader (instrument), a component of our Alethia molecular system, and an additional third party manufactures our Curian instrument. These instruments are manufactured exclusively for Meridian according to our specifications. While other manufacturers for these types of instruments are available, we source each instrument solely from one manufacturer to limit the costs involved in clearing the system for marketing in the United States. If these third-party manufacturers fail to supply us with instruments, we will need to secure another manufacturer, and it may take as long as 12 months to transfer instrument manufacturing. An interruption in the manufacturing of these instruments could have a material adverse effect on our operating results.

Additionally, one third party manufactures a certain reagent for use with our Alethia assays. While alternative suppliers exist, we elect to utilize this third party exclusively in order to maintain consistency in our materials, which is critical in complying with FDA regulatory requirements. An interruption in the manufacturing of these reagents could have a material adverse effect on our operating results.

*Finished Products*

We outsource the manufacturing for certain finished diagnostic products to third parties. A disruption in the supply of these finished products could have a material adverse effect on our business until we find another supplier or bring manufacturing in-house.

Four products manufactured exclusively for us by two separate and independent companies accounted for 7%, 11% and 11% of consolidated revenues in fiscal 2020, 2019 and 2018, respectively. Meridian owns all rights and title to the FDA 510(k) clearances for these products.

Activities undertaken by Meridian to reduce the risk of these sole-supplier arrangements include maintaining adequate inventory levels, supplier qualification procedures, supplier audits, site visits, and frequent communication. Additionally, we have identified potential alternate suppliers.

***Our ability to meet future customer demand for selected products is dependent upon our ability to successfully manage our manufacturing capacity.***

To manage our anticipated future growth effectively, it may become necessary for us to enhance our manufacturing and supply chain capabilities, infrastructure and operations, information technology infrastructure, and financial and accounting systems and controls. Organizational growth and scale-up of operations could strain our existing managerial, operational, financial, and other resources. If our management is unable to effectively prepare for our expected future growth, our expenses may increase more than anticipated, our revenue could grow more slowly than expected, and we may not be able to achieve our commercialization, profitability, or product development goals. Our failure to effectively implement the necessary processes and procedures and otherwise prepare for our anticipated growth could have a material adverse effect on our future financial results and condition.

**Risks Related to Intellectual Property and Product Liability**

***We may be unable to protect or obtain proprietary rights that we utilize or intend to utilize.***

In developing and manufacturing our products, we employ a variety of proprietary and patented technologies. In addition, we have licensed, and expect to continue to license, various complementary technologies and methods from academic institutions and public and private companies. We cannot provide assurance that the technologies that we own or license provide protection from competitive threats or from challenges to our intellectual property. In addition, we cannot provide assurances that we will be successful in obtaining and retaining licenses, or proprietary or patented technologies, in the future.

***Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.***

Litigation over intellectual property rights is prevalent in the diagnostic industry. As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third party may claim infringement against us. If found to infringe, we may attempt to obtain a license to such intellectual property; however, we may be unable to do so on favorable terms, or at all. Additionally, if our products are found to infringe on third-party intellectual property, we may be required to pay damages for past infringement and lose the ability to sell certain products, causing our revenues to decrease. Any substantial loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

***If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may have to limit or cease sales of our products.***

The testing, manufacturing and marketing of medical diagnostic products involves an inherent risk of product liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease sales of our products. We currently carry product liability insurance at a level we believe is commercially reasonable, although there is no assurance that it will be adequate to cover claims that may arise. In certain customer contracts, we indemnify third parties for certain product liability claims related to our products. These indemnification obligations may cause us to pay significant sums of money for claims that are covered by these indemnifications. In addition, a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injury and otherwise. Any substantial underinsured loss resulting from such a claim could have a material adverse effect on our profitability, and the damage to our reputation in the industry could have a material adverse effect on our business.

**Risks Related to Our Common Stock**

***The authority of our board to issue preferred stock and the effects of certain provisions of Ohio corporation law may discourage takeover bids.***

Our board of directors has the authority to issue up to 1,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions, including voting rights, of such shares without any future vote or action by the shareholders. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing a change in control of our company. Ohio corporation law contains provisions that may discourage takeover bids for our company that have not been negotiated with the board of directors. Such

provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, sales of substantial amounts of shares in the public market could adversely affect the market price of our common stock and our ability to raise additional capital at a price favorable to us.

***The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders and subject us to litigation.***

The market price of our common stock may be subject to significant fluctuations due to numerous factors, including but not limited to the risks described in this “Risk Factors” section. In addition, the stock market in general, the NASDAQ Global Market and the market for diagnostics companies in particular may experience a loss of investor confidence. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class-action litigation. Class-action litigation, even if unsuccessful, could be costly to defend and divert management’s attention and resources, which could further materially harm our financial condition and results of operations.

***Our business could be negatively impacted as a result of shareholder activism, an unsolicited takeover proposal or a proxy contest.***

In recent years, proxy contests and other forms of stockholder activism have been directed against numerous public companies. If a proxy contest or an unsolicited takeover proposal is made with respect to us, we could incur significant costs in defending our company, which would have an adverse effect on our financial results. Shareholder activists may also seek to involve themselves in the governance, strategic direction and operations of our company. Such proposals may disrupt our business and divert the attention of our management and employees, and any perceived uncertainties as to our future direction resulting from such a situation could result in the loss of potential business opportunities, be exploited by our competitors, cause concern to our current or potential customers, and make it more difficult to attract and retain qualified personnel and business partners, all of which could adversely affect our business. In addition, actions of activist stockholders may cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

***There can be no assurance that we will resume the payment of dividends.***

The declaration, amount and timing of the Company’s dividends are subject to capital availability and determinations by our board of directors that cash dividends are in the best interest of our stockholders and are in compliance with all respective laws, including the applicable provisions of Ohio law, and our agreements applicable to the declaration and payment of cash dividends. We suspended the payment of quarterly cash dividends effective during the fiscal 2019 second quarter. Any action to resume the payment of dividends will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, including acquisitions, debt service requirements, results of operations, financial condition and other factors beyond our control that our board of directors may deem relevant. Ongoing suspension of our dividend payments could have a negative effect on our stock price.

## **General Risk Factors**

***Intense competition could adversely affect our profitability.***

The markets for our products and services are characterized by substantial competition and rapid change. Hundreds of companies around the world supply diagnostic tests and immunoassay and molecular reagents. These companies range from multinational health care entities, for which diagnostics is one line of business, to small start-up companies. Many of our competitors have significantly greater financial, technical, manufacturing and marketing resources than we do. We cannot provide assurance that our products and services will be able to compete successfully with the products and services of our competitors.

***We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, and failure to comply with these laws could harm our business and the price of our common stock.***

As a public company listed in the United States, we incur significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure,

including regulations implemented by the SEC, the Public Company Accounting Oversight Board (“PCAOB”) and the NASDAQ Global Select Market, may increase our legal and financial compliance costs and/or make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

***Our business could be negatively affected if we are unable to attract, hire and retain key personnel.***

Our future success depends on our continued ability to attract, hire and retain highly qualified personnel, including our executive officers and scientific, technical, sales and marketing employees, and their ability to manage growth successfully. If such key employees were to leave and we were unable to obtain adequate replacements, our operating results could be adversely affected.

***Our bank credit agreement imposes restrictions with respect to our operations.***

Our bank credit agreement contains a number of financial covenants that require us to meet certain financial ratios and tests. If we fail to comply with the obligations in the credit agreement, we would be in default under the credit agreement. If an event of default is not cured or waived, it could result in acceleration of any indebtedness under our credit agreement, which could have a material adverse effect on our business. At September 30, 2020, we had \$68,824 outstanding on a \$160,000 bank revolving credit facility.

***Changes in the method of determining London Interbank Offered Rate (“LIBOR”), or the replacement of LIBOR with an alternative reference rate, may adversely affect interest expense related to outstanding debt.***

Amounts drawn under our credit facility may bear interest rates in relation to LIBOR, depending on our selection of repayment options. On July 27, 2017, the Financial Conduct Authority (“FCA”) in the U.K. announced that it would phase out LIBOR as a benchmark by the end of 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021. The U.S. Federal Reserve is considering replacing U.S. dollar LIBOR with a newly created index called the Broad Treasury Financing Rate, calculated with a broad set of short-term repurchase agreements backed by treasury securities. If LIBOR ceases to exist, we may need to renegotiate the credit facility and may not be able to do so with terms that are favorable to us. The overall financial market may be disrupted as a result of the phase-out or replacement of LIBOR. Disruption in the financial market or the inability to renegotiate the credit facility with favorable terms could have a material adverse effect on our business, financial position, and operating results.

***We face risks related to global economic conditions.***

We currently generate significant operating cash flows, which combined with access to the credit markets, provides us with discretionary funding capacity for research and development and other strategic activities. However, as an enterprise with global operations and markets, our operations and financial performance are in part dependent upon global economic conditions, and we could be negatively impacted by a global, regional or national economic crisis, including sovereign risk in the event of deterioration in the credit worthiness of or a default by local governments. We are particularly susceptible to the economic conditions in countries where government-sponsored health care systems are the primary payers for health care, including those countries within the European Union that are reducing their public expenditures in an effort to achieve cost savings. The uncertainty in global economic conditions poses a risk to the overall economy that could impact demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. As such, if global economic conditions deteriorate significantly, our business could be negatively impacted, including such areas as reduced demand for our products from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets, and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers. While to-date such factors have not had a significant negative impact on our results or operations, we continue to monitor and plan for the potential impact of these global economic factors.

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. The U.K. is currently in a transition period relating to its exit from the European Union (“Brexit”). In January 2020, the U.K. and the European Union ratified a Withdrawal Agreement that set out the transition period of eleven months, from February 1, 2020 until December 31, 2020, during which the final terms of the U.K.’s departure would be negotiated. Although the Withdrawal Agreement ensures that a “no-deal” or “cliff-edge” Brexit was avoided on January 31, 2020, there is no certainty that a similar effect will be avoided at the end of 2020.

The ongoing uncertainty on the final terms of the withdrawal could lead to economic stagnation until an ultimate resolution with respect to Brexit occurs. If the U.K. and the European Union are unable to negotiate acceptable agreements during the transition period or if other European Union Member States pursue withdrawal, it will likely have an adverse impact on labor and trade in addition to creating further short-term uncertainty and currency volatility. In the absence of future trade deals, the U.K.’s trade with the European Union and the rest of the world may be subject to tariffs and duties set by the World Trade Organization. Additionally, the movement of goods and personnel between the U.K. and the remaining member states of the European Union will be subject to additional inspections and documentation checks, leading to possible delays at ports of entry and departure. Even if final terms of the U.K.’s withdrawal from the European Union are approved, the withdrawal could result in significant changes to the trading relationship between the U.K. and the European Union. These changes to the trading relationship between the U.K. and the European Union would likely result in increased cost of goods imported into and exported from the U.K. and 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. With a range of outcomes still possible, the impact from Brexit remains uncertain and will depend, in part, on the final outcome of tariff, trade, regulatory and other negotiations.

***One or more cybersecurity incidents may adversely impact our financial condition, results of operations and reputation.***

Our operations involve the use of multiple systems that process, store and transmit sensitive information about our customers, suppliers, employees, financial position, operating results and strategies. We face global cybersecurity risks and threats on a continual and ongoing basis, which include, but are not limited to, attempts to access systems and information, computer viruses, or denial-of-service attacks. These risks and threats range from uncoordinated individual attempts to sophisticated and targeted measures. While we are not aware of any material cyber-attacks or breaches of our systems to date, we have and continue to implement measures to safeguard our systems and information and mitigate potential risks, including employee training around phishing, malware and other cyber risks, but there is no assurance that such actions will be sufficient to prevent cyber-attacks or security breaches that manipulate or improperly use our systems, compromise sensitive information, destroy or corrupt data, or otherwise disrupt our operations. The occurrence of such events, including breaches of our security measures or those of our third-party service providers, could negatively impact our reputation and our competitive position and could result in litigation with third parties, regulatory action, loss of business due to disruption of operations and/or reputational damage, potential liability and increased remediation and protection costs, any of which could have a material adverse effect on our financial condition and results of operations. In an effort to mitigate the financial impact such an attack might have on the Company, we maintain cyber liability insurance coverage. However, such coverage may be insufficient to cover the full impact of a cyber-attack. Additionally, as cybersecurity risks become more sophisticated, we may need to increase our investments in security measures which could have a material adverse effect on our financial condition and results of operations.

***Natural disasters, war and other events could adversely affect our future revenues and operating income.***

Natural disasters (including pandemics), war, terrorism, labor disruptions and international conflicts, and actions taken by the United States and other governments or by our customers or suppliers in response to such events, could cause significant economic disruption and political and social instability in the United States and in areas outside of the United States in which we operate. These events could result in decreased demand for our products, adversely affect our manufacturing and distribution capabilities, or increase the costs for, or cause interruptions in, the supply of materials from our suppliers.

ITEM 1B.

UNRESOLVED STAFF COMMENTS

None.

ITEM 2.

PROPERTIES

Our corporate offices, infectious disease Diagnostics manufacturing facility, and infectious disease Diagnostics research and development facility are located in four buildings totaling approximately 117,000 square feet on approximately seven acres of land in the Village of Newtown, a suburb of Cincinnati, Ohio. These properties are owned by us. Our blood-chemistry manufacturing and research and development operations are located in an approximately 30,000 square foot leased facility in Billerica, Massachusetts; our PCR-based molecular manufacturing and research and development operations are located in an approximately 26,000 square foot leased facility in Quebec City, Canada; and our BreathID urea breath test manufacturing and research and development operations are located in an approximately 8,000 square foot leased facility in Modi'in, Israel. We also operate a Diagnostics sales and distribution center near Milan, Italy in an approximately 18,000 square foot building. This facility is owned by our wholly owned Italian subsidiary, Meridian Bioscience Europe s.r.l. We also rent office space in Paris, France and Braine-l'Alleud, Belgium for sales and administrative functions, and space in Manasquan, New Jersey and Changzhou, China to house BreathID technical service and repair functions.

Our Life Science operations are conducted in several facilities in Memphis, Tennessee; Boca Raton, Florida; London, England; Luckenwalde, Germany; Sydney, Australia; and Beijing, China. Our facility in Memphis, Tennessee consists of two buildings totaling approximately 44,000 square feet and is owned by us. Our leased facility in Boca Raton, Florida contains approximately 7,500 square feet of manufacturing space. Following are details of our other Life Science facilities, all of which are leased: London – approximately 19,500 square feet of sales, warehouse, distribution, research and development, manufacturing and administrative office space; Luckenwalde – approximately 13,000 square feet of sales, warehouse and manufacturing space; Sydney – approximately 3,000 square feet of sales and warehouse space; Beijing – less than 1,000 square feet of sales and business development space.

ITEM 3.

LEGAL PROCEEDINGS

We are a party to various litigation matters that we believe are in the normal course of business. Aside from the matters discussed below, the ultimate resolution of these matters is not expected to have a material adverse effect on our financial position, results of operations or cash flows, and no material provision has been made in the accompanying Consolidated Financial Statements for these matters.

On April 17, 2018, Magellan received a subpoena from the United States Department of Justice (“DOJ”) regarding its LeadCare product line. The subpoena outlines documents to be produced, and the Company is cooperating with the DOJ in this matter. The Company maintains rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements and is working with the DOJ to promptly respond to the subpoena, 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 \$2,035, \$1,585 and \$775 of expense for attorneys’ fees related to this matter is included within the accompanying Consolidated Statements of Operations for fiscal 2020, 2019 and 2018, respectively. See “Update on Lead Testing” section within MD&A on page 28.

ITEM 4.

MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5.

MARKET FOR REGISTRANT'S COMMON  
EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

*Refer to "Note About Forward-Looking Statements" following the Index in front of this Form 10-K and Item 1A "Risk Factors" on pages 11 through 21 of this Annual Report.*

***Market Information***

Our common stock trades on the NASDAQ Global Select Market under the symbol VIVO.

***Holders of our Common Stock***

As of September 30, 2020, there were approximately 570 holders of record and approximately 18,280 beneficial owners of our common shares.

***Dividends***

"Quarterly Financial Data (Unaudited)" relating to our dividends in Note 12 of the Consolidated Financial Statements are incorporated herein by reference.

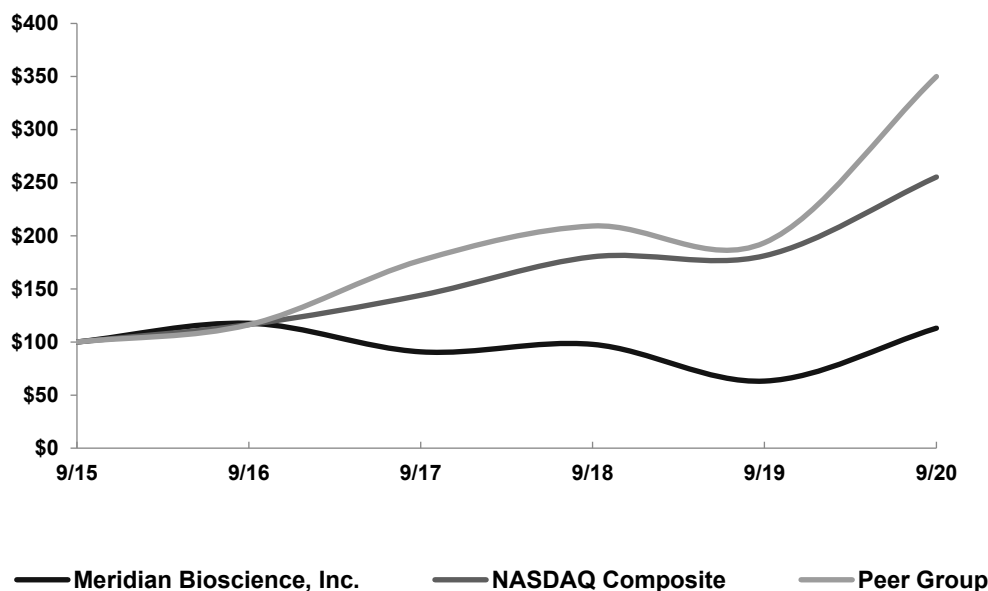
Effective during the second quarter of fiscal 2019, the Company suspended the payment of its quarterly cash dividend, which had previously been established at an indicated annual cash dividend rate of \$0.50 per share for each of fiscal 2019 and 2018. The dividend was suspended as part of the Company's regular evaluation of its capital allocation, with the action taken in order to deploy cash into new product development activities and to preserve capital resources and liquidity for general corporate purposes. Any declaration and amount of dividends will be determined by the board of directors in its discretion based upon its evaluation of earnings, cash flow requirements, business developments and opportunities, and any other factors the board of directors determines are relevant to its evaluation. We paid dividends of \$0.25 and \$0.50 per share in fiscal 2019 and 2018, respectively.

***Stock Total Return Performance***

The graph below matches the cumulative 5-Year total return of holders of Meridian Bioscience, Inc.'s common stock with the cumulative total returns of the NASDAQ Composite index and a customized peer group of eight companies that includes: Bio-Rad Laboratories, Inc., bioMerieux S.A., GenMark Diagnostics, Inc., Luminex Corporation, Myriad Genetics, Inc., OraSure Technologies, Inc., Quidel Corporation and Trinity Biotech Plc. We selected the companies in the customized peer group based on various considerations, including, without limitation, industry classifications, the extent to which certain companies may engage in businesses in which we engage, and the extent to which we and/or our investors consider certain companies to be direct or indirect competitors. The graph assumes that the value of the investment in our common stock, in the index, and in the peer group (including reinvestment of dividends) was \$100 on September 30, 2015 and tracks it through September 30, 2020.

## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Meridian Bioscience, Inc., the NASDAQ Composite Index,  
and a Peer Group



\*\$100 invested on 9/30/15 in stock or index, including reinvestment of dividends.  
Fiscal year ending September 30.

### ITEM 6.

#### SELECTED FINANCIAL DATA

Income Statement Information (Amounts in thousands, except per share data)						
For the Year Ended September 30,	2020	2019	2018	2017	2016	
Net revenues	\$ 253,667	\$ 201,014	\$ 213,571	\$ 200,771	\$ 196,082	
Gross profit	156,248	118,728	131,033	124,833	127,787	
Operating income	61,324	32,699	31,584	37,382	51,378	
Net earnings	46,186	24,382	23,849	21,557	32,229	
Basic earnings per share	\$ 1.08	\$ 0.57	\$ 0.56	\$ 0.51	\$ 0.77	
Diluted earnings per share	\$ 1.07	\$ 0.57	\$ 0.56	\$ 0.51	\$ 0.76	
Cash dividends declared per share	\$ -	\$ 0.250	\$ 0.500	\$ 0.575	\$ 0.800	
Book value per share	\$ 5.75	\$ 4.47	\$ 4.14	\$ 4.02	\$ 3.95	
Balance Sheet Information						
As of September 30,	2020	2019	2018	2017	2016	
Current assets	\$ 162,190	\$ 144,761	\$ 139,053	\$ 133,875	\$ 126,791	
Current liabilities	52,524	20,914	24,173	22,887	22,571	
Total assets	405,261	325,478	251,377	249,777	252,028	
Long-term debt obligations	68,824	75,824	50,180	54,647	58,360	
Shareholders' equity	247,629	190,967	175,418	169,585	166,472	



## ITEM 7.

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Refer to "Note About Forward-Looking Statements" following the Index in front of this Form 10-K and Item 1A "Risk Factors" on pages 11 through 21 of this Annual Report.

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 Meridian's financial condition, changes in financial condition and results of operations. This discussion should be read in conjunction with the financial statements and notes.

#### **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. Governments around the world implemented lockdown and shelter-in-place orders, requiring many non-essential businesses to shut down operations throughout a substantial portion of the last five months of our fiscal year, some 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 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 business could achieve at a much larger scale. Our Diagnostics segment, on the other hand, reported decreased revenues in our third and fourth fiscal quarters as health systems focused on SARS-CoV-2 testing over traditional infectious disease and blood-chemistry testing. However, we did see a significant recovery in our Diagnostics business in our fourth fiscal quarter compared to the third fiscal quarter (up 38%).

#### **Employee Safety**

We have implemented a work-from-home process 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 of 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 United States, and any employees experiencing any symptoms of COVID-19 are required to stay home and 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 of our sites continue to operate without interruption. As the pandemic continues to spread, 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 seeing “re-starts” for such clinical trials, they are at a slower pace than normal. 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. During the last month of our second fiscal quarter and throughout our third fiscal quarter of fiscal 2020, we experienced unprecedented demand for certain of our molecular reagents (e.g., ribonucleic acid (“RNA”) master mixes and nucleotides), and such demand continued throughout our fourth fiscal quarter, albeit at a lower level than the third quarter. Although we are unable to predict when this demand may subside, we expect revenue levels for these products to be materially higher than historical levels during at least the next twelve months. Our products are used in over 100 approved COVID-19 related assays around the world. COVID-related reagent revenues totaled approximately \$71,500 during 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. We expect near-term sales volumes for a number of these assays to continue to be adversely affected by the COVID-19 pandemic 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. However, during our fourth fiscal quarter, we experienced an acceleration in Revogene placements due to the anticipated SARS-CoV-2 assay under the FDA’s emergency use authorization. We notified the FDA on November 13, 2020 of our intent to submit for emergency use authorization and expect to do so in late November or early December. During our fourth fiscal quarter, Diagnostics sales volumes recovered, up 38% over our third fiscal quarter. However, no assurances can be made that this positive trend will continue.

### Asset Impairment Review

Considering the economic impacts of COVID-19, we performed an analysis of our businesses to determine if there were triggering events that would require us to further test our long-lived assets for impairment. Based on our review, we do not believe that a triggering event exists at this time and, therefore, we believe that we will be able to realize the full value of our long-lived assets. As such, no impairments or other write-downs related to COVID-19 have been recorded during fiscal 2020. In addition, we performed our annual test for goodwill impairment as of June 30, 2020 by performing a qualitative assessment pursuant to ASU 2011-08 for each reporting unit. Our qualitative assessment indicated that it is not more likely than not that the fair values of our reporting units are less than their carrying values. Accordingly, a quantitative impairment test for goodwill was not required.

### Access to Capital

The impacts of COVID-19 have adversely affected the ability of many companies to access capital and liquidity on favorable terms or at all. As of September 30, 2020, the outstanding debt balance on the Company’s revolving credit facility was \$68,824, leaving \$91,176 of available borrowing capacity. In addition, positive cash flows from operating activities are expected to be generated over the next twelve months, which will add to cash on hand. We also maintain a shelf registration statement on file with the Securities and Exchange Commission. The Company believes these resources will provide sufficient liquidity and cash flows to meet its operating and debt service

requirements for at least the next twelve months and expects to be in compliance with its financial covenants during this same period. However, given the unusual nature of the COVID-19 pandemic and the rapidly changing environment, we can provide no assurances in this regard and future impacts may materialize that are not currently known.

## **Results of Operations:**

### ***Fourth Quarter***

Net earnings for the fourth quarter of fiscal 2020 increased 58% to \$6,493, or \$0.15 per diluted share, from net earnings for the fourth quarter of fiscal 2019 of \$4,103, or \$0.10 per diluted share. The level of net earnings in the fiscal 2020 fourth quarter were affected by several factors, including most notably the combined effects of the following (amounts presented on a pre-tax basis):

- (i) significantly higher revenue in the Life Science operating segment, due to supplying key molecular components and monoclonal antibodies to diagnostic test manufacturers for use in COVID-19 related PCR and antigen tests (up \$16,905);
- (ii) higher research and development spending in the Diagnostics segment under new product development programs (up \$1,886);
- (iii) increased cash-based incentive compensation tied to higher revenue and profit levels (up \$1,428);
- (iv) an increase in the fair value of the earnout obligation for the acquisition of the GenePOC business (up \$1,135);
- (v) decreased restructuring expenses related to the business realignment and streamlining initiatives commenced in fiscal 2018 and largely completed in the first half of fiscal 2020 (down \$1,071); and
- (vi) lower gains related to foreign currency (down \$1,030).

Consolidated revenues for the fourth quarter of fiscal 2020 totaled \$64,153, an increase of 26% compared to the fourth quarter of fiscal 2019, increasing 25% on a constant-currency basis.

Revenues for the Diagnostics segment for the fourth quarter of fiscal 2020 decreased 11% compared to the fourth quarter of fiscal 2019 (also 11% on a constant-currency basis), comprised of a 23% decrease in molecular assay products and an 8% decrease in non-molecular assay products. During the fourth quarter, we experienced a rebound from the previously noted impact of the COVID-19 pandemic on our placement of molecular assay products. This positive activity resulted in 62 net placements of our Revogene system during the fourth quarter of fiscal 2020 and a total Revogene system install base of 231 systems as of September 30, 2020. With a 294% increase in revenues from molecular reagents products and flat revenues from immunological reagents products, revenues for our Life Science segment increased 97% during the fourth quarter of fiscal 2020 compared to the fourth quarter of fiscal 2019. On a constant-currency basis, revenues for the Life Science segment increased 95%. Life Science 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 record revenue levels during the quarter were sales of recombinant antigens used in COVID-19 antibody tests and monoclonal antibody pairs used in antigen tests.

### ***Fiscal Year***

Net earnings for fiscal 2020 increased 89% to \$46,186, or \$1.07 per diluted share, from net earnings for fiscal 2019 of \$24,382, or \$0.57 per diluted share. The level of net earnings in the fiscal 2020 fourth quarter were affected by several factors, including most notably the combined effects of the following (amounts presented on a pre-tax basis):

- (i) significantly higher revenue in the Life Science operating segment, due to supplying key molecular components, monoclonal antibodies and recombinant antigens to diagnostic test manufacturers for use in COVID-19 related PCR, antigen and antibody tests (up \$68,203);
- (ii) higher research and development spending in the Diagnostics segment under new product development programs (up \$6,909);
- (iii) increased cash-based incentive compensation tied to higher revenue and profit levels (up \$6,325);

- (iv) increased intangible asset amortization, primarily resulting from purchase accounting amortization related to the acquisitions of Exalenz and the GenePOC business in April 2020 and June 2019, respectively (up \$3,413);
- (v) increased acquisition-related costs in connection with the fiscal 2020 Exalenz transaction, as compared to those related to the GenePOC transaction in fiscal 2019 (up \$2,082);
- (vi) a net decrease in the fair value of the earnout obligation for the acquisition of the GenePOC business (down \$6,293); and
- (vii) decreased restructuring expenses related to the business realignment and streamlining initiatives commenced in fiscal 2018 (down \$2,152).

Consolidated revenues for fiscal 2020 totaled \$253,667, an increase of 26% compared to fiscal 2019, increasing 27% on a constant-currency basis.

Revenues for the Diagnostics segment decreased 11% in fiscal 2020 compared to fiscal 2019 (also 11% on a constant-currency basis), comprised of a 17% decrease in molecular assay products and a 10% decrease in non-molecular assay products. Considering the impact of the COVID-19 pandemic on the placement of our molecular assay products throughout the year and the recent rebound in such activity, we placed approximately 170 Revogene systems during fiscal 2020, resulting in a total Revogene system install base of 231 systems as of September 30, 2020. With a 237% increase in revenues from molecular reagents products and a 32% increase in revenues from immunological reagents products, revenues for our Life Science segment increased 106% during fiscal 2020 compared to fiscal 2019. On a constant-currency basis, revenues for the Life Science segment increased 107%. Life Science 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 record revenue levels during the year were sales of recombinant antigens used in COVID-19 antibody tests and monoclonal antibody pairs used in antigen tests.

### **Update on Lead Testing**

As described in Item 3. “Legal Proceedings”, on April 17, 2018, Magellan received a subpoena from the United States Department of Justice (“DOJ”) regarding its LeadCare product line. The subpoena outlines documents to be produced, and we continue to cooperate with the DOJ in this matter, including responding to additional information requests. We have executed tolling agreements to extend the statute of limitations.

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 Centers for Disease Control and Prevention 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 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 revenue, by reportable segment, provided for each of the following:

- By Geographic Region
- By Product Platform/Type

### **Revenue Overview – By Reportable Segment & Geographic Region**

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, 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 further pursue growing revenue opportunities in Asia.

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 \$71,500 of new revenue for our Life Science segment during fiscal 2020.

See the "Revenue Disaggregation" section of Note 1, "*Significant Accounting Policies*" of the accompanying 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 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 are actively converting our existing Alethia install base to the Revogene platform for *C. difficile*, Group A *Streptococcus* ("Group A Strep") and Group B *Streptococcus* ("Group B Strep") assays. As previously noted, the COVID-19 pandemic dramatically slowed the placement of our molecular instruments and related assay products throughout the year, resulting in approximately 170 net placements of our Revogene system during fiscal 2020 and a total Revogene system install base of 231 systems as of September 30, 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 believe the advantages of the Curian analyzer will help protect our existing rapid test accounts.

### Gastrointestinal Assays

During fiscal 2020, revenues from our gastrointestinal products, which include tests for *C. difficile*, *H. pylori* and certain foodborne pathogens, among others, totaled \$55,040. This represents a 20% decrease from fiscal 2019 and follows a 12% decrease during fiscal 2019. We continue to face pricing and volume pressures within this product category that will carry into fiscal 2021 and beyond for our current products. Our acquisition of Exalenz and the BreathID system has strengthened our overall position in non-invasive, active infection testing for *H. pylori*. We continue to believe there are ongoing benefits to be realized from our partnerships with managed care companies in promoting: (i) the health and economic benefits of a test and treat strategy; (ii) changes in policies that discourage the use of traditional serology methods and promote the utilization of active infection testing methods; and (iii) physician behavior movement away from serology-based testing and toward direct antigen testing.

Contributing to the competitive pressures being faced in this product category, the patents for our stool antigen *H. pylori* products, owned by us, expired in May 2016 in the U.S. and in May 2017 in countries outside the U.S. We expect competition with respect to our stool antigen *H. pylori* products to continue to increase, and such competition may have an adverse impact on our selling prices for these products, or our ability to retain business at prices acceptable to us, and consequently, adversely affect our future results of operations and liquidity, including revenues and gross profit. We have executed on a number of measures to address competitive pressures in coming off patent including: (i) in October 2018, we entered into a strategic collaboration with DiaSorin to sell *H. pylori* tests; (ii) we have executed multi-year 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, we launched Curian HpSA, our first assay on the new 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, allowing 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.

### Respiratory Illness Assays

Revenues from sale of our respiratory illness products, which include tests for Group A Strep, Mycoplasma pneumonia, Influenza, and Pertussis, among others, remained relatively flat during fiscal 2020, totaling \$26,694 and primarily reflecting the COVID-19 pandemic's negative effect on demand. These revenue levels follow an 8% decrease in respiratory product revenues in fiscal 2019.

### Blood Chemistry Assays

Revenues from our sale of products to test for elevated levels of lead in blood decreased 6% during fiscal 2020 to \$17,534. Beginning in the latter part of March 2020, we generally experienced lower demand for our blood-lead test as a result of the COVID-19 pandemic. However, since the latter part of June and throughout the fourth fiscal quarter, we have seen shipments to our largest independent distributor return to pre-pandemic levels. During fiscal 2019, revenues from such products decreased 2%.

### **Life Science Products**

During fiscal 2020, revenues from our Life Science segment increased 106%, with revenues from molecular reagent sales increasing 237% compared to fiscal 2019 and revenues from immunological reagent sales increasing 32%. Life Science segment revenues increased 2% in fiscal 2019, with revenues from molecular reagent sales decreasing 5% compared to fiscal 2018 and revenues from immunological reagent sales increasing 6%. Our Life Science segment's growth was nominally impacted by the movement in currency exchange rates since fiscal 2019, with revenues increasing 107% on a constant-currency basis over fiscal 2019. The increase in revenues was primarily attributable to the increased demand for key molecular components such as RNA master mixes and dNTPs from diagnostic test manufacturers for use in COVID-19 related PCR tests, as well as recombinant antigens used in antibody tests and monoclonal antibodies used in antigen tests. Largely as a result of this COVID-19 related demand, revenue from sales into China totaled approximately \$19,000 during fiscal 2020 – representing an increase of approximately 127% over fiscal 2019. COVID-related reagent revenues totaled approximately \$71,500 during fiscal 2020.

### **Foreign Currency**

Fluctuations in foreign currency exchange rates since fiscal 2019 had an approximate \$1,250 unfavorable impact on fiscal 2020 revenues; \$150 within the Diagnostics segment and \$1,100 within the Life Science segment. This compares to year-to-year currency exchange rates having an approximate \$2,200 favorable impact on revenues in fiscal 2019; \$1,150 within the Diagnostics segment and \$1,050 within the Life Science segment.

### **Significant Customers**

Revenue concentrations related to certain customers within our Diagnostics and Life Science segments are set forth in Note 10 of the accompanying Consolidated Financial Statements.

### **Gross Profit:**

	2020	2019	2018	2020 vs. 2019 Inc (Dec)	2019 vs. 2018 Inc (Dec)
Gross Profit	\$ 156,248	\$ 118,728	\$ 131,033	32 %	(9 %)
Gross Profit Margin	62%	59%	61%	3 points	-2 points

The gross profit margin increase experienced in fiscal 2020 results primarily from the positive impacts of a significantly higher percentage of the Life Science segment's revenue relating to sales of molecular products and the segment's manufacturing of larger-than-normal batch sizes for the RNA master mixes, both in response to the COVID-19 pandemic demand, partially offset by the combined effects of: (i) previously-noted pricing changes within our *H. pylori* product line; (ii) mix of products sold, particularly decreased contribution from certain of our higher margin gastrointestinal assays; and (iii) production capacity ramp-up costs for our Quebec facility where Revogene instruments and test devices are made. The overall decrease in the gross profit margin from fiscal 2018 to fiscal 2019 reflects the combined effects of: (i) previously-noted pricing changes within our *H. pylori* product line; (ii) mix of products sold, particularly decreased contribution from certain of our higher margin gastrointestinal assays; (iii) production capacity ramp-up costs for our Quebec facility; and (iv) operating segment mix.

### **Operating Expenses - Segment Detail**

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
Fiscal 2018:					
Diagnostics	\$ 13,579	\$ 24,659	\$ 18,120	\$ 4,032	\$ 60,390
Life Science	3,034	9,367	10,342	1,240	23,983
Corporate	-	-	7,297	7,779	15,076
<b>Total 2018 Expenses</b>	<b>\$ 16,613</b>	<b>\$ 34,026</b>	<b>\$ 35,759</b>	<b>\$ 13,051</b>	<b>\$ 99,449</b>
Fiscal 2019:					
Diagnostics	\$ 14,545	\$ 22,695	\$ 17,081	\$ 3,446	\$ 57,767
Life Science	3,215	5,300	9,186	188	17,889
Corporate	-	-	7,777	2,596	10,373
<b>Total 2019 Expenses</b>	<b>\$ 17,760</b>	<b>\$ 27,995</b>	<b>\$ 34,044</b>	<b>\$ 6,230</b>	<b>\$ 86,029</b>
Fiscal 2020:					
Diagnostics	\$ 21,454	\$ 21,172	\$ 23,233	\$ (1,916)	\$ 63,943
Life Science	2,275	5,314	11,755	200	19,544
Corporate	-	-	9,357	2,080	11,437
<b>Total 2020 Expenses</b>	<b>\$ 23,729</b>	<b>\$ 26,486</b>	<b>\$ 44,345</b>	<b>\$ 364</b>	<b>\$ 94,924</b>

**Operating Expenses -  
Comparisons to Prior Year  
Periods**

	Research & Development	Selling & Marketing	General & Administrative	Other	Total Operating Expenses
<b>2018 Expenses</b>	\$ 16,613	\$ 34,026	\$ 35,759	\$ 13,051	\$ 99,449
% of Revenues	8%	16%	17%	6%	47%
Fiscal 2019 Increases (Decreases):					
Diagnostics	966	(1,964)	(1,039)	(586)	(2,623)
Life Science	181	(4,067)	(1,156)	(1,052)	(6,094)
Corporate	-	-	480	(5,183)	(4,703)
<b>2019 Expenses</b>	\$ 17,760	\$ 27,995	\$ 34,044	\$ 6,230	\$ 86,029
% of Revenues	9%	14%	17%	3%	43%
% Increase (Decrease)	7%	(18%)	(5%)	(52%)	(13%)
Fiscal 2020 Increases (Decreases):					
Diagnostics	6,909	(1,523)	6,152	(5,362)	6,176
Life Science	(940)	14	2,569	12	1,655
Corporate	-	-	1,580	(516)	1,064
<b>2020 Expenses</b>	\$ 23,729	\$ 26,486	\$ 44,345	\$ 364	\$ 94,924
% of Revenues	9%	10%	17%	-%	37%
% Increase (Decrease)	34%	(5%)	30%	(94%)	10%

Total operating expenses fluctuated during fiscal 2020 and fiscal 2019 primarily as a result of the combined effects of the following:

**Fiscal 2020 increase**

- Increased Research & Development costs, primarily reflecting the development of the molecular SARS-CoV-2 assay and molecular GI and RI panel assays for the Diagnostics operating segment, and to a lesser degree, the addition of Exalenz research and development expenses since the April 30, 2020 date of acquisition;
- Decreased Selling & Marketing costs, primarily reflecting the effects of reduced travel from restrictions imposed during the COVID-19 pandemic and the effect such restrictions have had on general sales and marketing activities;
- Increased General & Administrative costs, primarily reflecting additional investment in incentive compensation, along with the purchase accounting amortization from the acquisitions of Exalenz and the GenePOC business; and
- Increased acquisition costs and decreased restructuring costs, along with a net decrease in fair value of the contingent consideration obligation for the GenePOC business, all of which are reflected within “Other” in the above tables.

**Fiscal 2019 decrease**

- Increased Research & Development costs, reflecting the addition of the GenePOC business expenses for the development of the GI and RI panel assays since the June 3, 2019 date of acquisition, partially offset by the decreased expenditures resulting from the timing of product development projects and the clinical trials for our cCMV test in fiscal 2018;
- Decreased Selling & Marketing costs due to: (i) the effects of the fiscal 2018 organization streamlining initiatives; and (ii) lower sales commissions resulting from the decrease in sales levels;



- Decreased General & Administrative costs, reflecting the effects of the fiscal 2018 organization streamlining initiatives and lower Quality System remediation costs related to our blood-lead manufacturing facility, partially offset by the addition of the GenePOC business expenses, including purchase accounting amortization; and
- Decreased restructuring & selected legal costs, along with the effects of the fiscal 2019 acquisition-related costs (reflected within “Other” in the above tables).

### ***Operating Income***

Operating income increased 88% in fiscal 2020, following a 4% increase in fiscal 2019, as a result of the factors discussed above.

### ***Other Income and Expense***

Other income and expense in fiscal 2020, 2019 and 2018 includes interest costs on the Company’s long-term borrowings. The varying levels of the Company’s interest costs reflects the following approximate levels of average debt outstanding and the interest costs thereon, as detailed in Note 6 of the accompanying Consolidated Financial Statements: (i) fiscal 2020 - \$74,560; (ii) fiscal 2019 - \$57,938; and (iii) fiscal 2018 - \$52,500.

### ***Income Taxes***

The effective rate for income taxes was 22%, 23% and 21% for fiscal 2020, 2019 and 2018, respectively. While relatively comparable to the fiscal 2019 and fiscal 2018 rates, the fiscal 2020 tax rate reflects the combined effects of the following: (i) a significantly higher percentage of pretax income being generated in foreign jurisdictions with tax rates lower than the U.S., particularly the United Kingdom; and (ii) the non-deductibility of a significant portion of the acquisition-related costs related to Exalenz.

### ***Impact of Inflation***

To the extent feasible, we have consistently followed the practice of reviewing our prices to consider the impacts of inflation on salaries and fringe benefits for employees and the cost of purchased materials and services. Inflation and changing prices did not have a material adverse impact on our gross margin, revenues or operating income in fiscal 2020, 2019 and 2018.

## **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 approximately \$91,200 as of September 30, 2020. 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 fiscal 2020, we generated a record level of cash flow from operations totaling \$47,976. This level of cash resulted from the achievement of record fiscal year revenues, along with well-managed accounts receivable balances, including the requirement of advance payments in certain instances, as illustrated by an approximate 26% increase in consolidated revenues and only an approximate 5% increase in year-end accounts receivable balances.

Our levels of inventory increased approximately \$21,600 to \$61,264 between September 30, 2019 and September 30, 2020. This increase was attributable to inventory builds in both our Diagnostics and Life Science segments 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 and have BreathID inventory on hand for the first time in fiscal 2020 as a result of the Exalenz acquisition. We are actively managing our inventory levels and are expecting reductions during the first half of fiscal 2021.

As of September 30, 2020, our cash and equivalents balance was \$53,514 or approximately \$8,900 lower than at the end of fiscal 2019. As a result of the cash generated from operations during fiscal 2020 and the financing activities related to the Exalenz acquisition, since the beginning of fiscal 2020, 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 equivalents on-hand) has increased approximately \$6,700 to approximately \$52,300 at September 30, 2020. 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.

The impacts of COVID-19 have adversely affected the capital markets and the ability of many companies to access capital and liquidity on favorable terms or at all. The Company believes it has sufficient liquidity and cash flows to meet its operating and debt service requirements for at least the next twelve months and expects to be in compliance with its financial covenants during this same period. However, given the unusual nature of the COVID-19 pandemic and the rapidly changing environment, we can provide no assurances in this regard and future impacts may materialize that are not currently known.

In April 2019, we suspended the payment of our quarterly cash dividend. The dividend was suspended as part of our regular evaluation of capital allocation, with the action taken in order to deploy cash into new product development activities for the Revogene molecular diagnostic platform, as well as the Curian and PediaSTAT platforms, among other investments, and to preserve capital resources and liquidity for general corporate purposes.

### ***Capital Resources***

As described in Note 6, “*Bank Credit Arrangements*” of the accompanying Consolidated Financial Statements and above, the Company maintains a \$160,000 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 Securities and Exchange Commission.

Our capital expenditures totaled \$3,299 for fiscal 2020 and were largely related to laboratory and manufacturing equipment. During fiscal 2021 our capital expenditures are estimated to range between approximately \$4,000 and \$17,000. Our Diagnostics segment capital expenditures could be as high as \$14,000, depending upon the level of manufacturing scale-up we execute in anticipation of Revogene COVID-19 assay production, 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 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 expansion may possibly be funded by certain grants for which we are applying, none of which we are assured of receiving as of the date of this filing.

**Known Contractual Obligations:**

In addition to the obligations related to the above-noted revolving credit facility and the contingent government grant obligations detailed in Note 6, “*Bank Credit Arrangements*” and Note 9, “*Contingent Obligations and Non-Current Liabilities*” of the accompanying Consolidated Financial Statements, respectively, the Company’s known contractual obligations and their related due dates were as follows as of September 30, 2020:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases <sup>(1)</sup>	\$ 6,968	\$ 2,002	\$ 3,015	\$ 1,669	\$ 282
Purchase obligations <sup>(2)</sup>	27,691	26,315	1,376	-	-
Acquisition price holdback and contingent consideration <sup>(3)</sup>	69,000	5,000	64,000	-	-
Uncertain income tax positions liability and interest <sup>(4)</sup>	706	706	-	-	-
<b>Total</b>	<b>\$ 104,365</b>	<b>\$ 34,023</b>	<b>\$ 68,391</b>	<b>\$ 1,669</b>	<b>\$ 282</b>

- (1) Meridian and its subsidiaries are parties to a number of operating lease agreements around the world, the majority of which relate to office and warehouse building leases expiring at various dates.
- (2) Purchase obligations relate primarily to outstanding purchase orders for inventory, including instruments, service items, and research and development activities. These contractual commitments are not in excess of expected production requirements over the next twelve months.
- (3) Pursuant to the purchase agreement related to the June 3, 2019 acquisition of the business of GenePOC, as amended during fiscal 2020, Meridian’s maximum remaining consideration to be paid totals \$69,000. As noted below and detailed in Note 2, “*Business Combinations*” of the accompanying Consolidated Financial Statements, this amount is comprised of: (i) a \$5,000 purchase price holdback; and (ii) up to \$64,000 of payments contingent upon the achievement of certain product development milestones and financial performance targets, the valuation of which totals approximately \$20,909 as of September 30, 2020.
- (4) Due to inherent uncertainties in the timing of settlement of tax positions, we are unable to estimate the timing of the effective settlement of these obligations.

**Other Commitments and Off-Balance Sheet Arrangements:*****License Agreements***

Meridian has entered into various license agreements that require payment of royalties based on a specified percentage of sales of related products. Approximately 81% of our royalty expenses relate to our Diagnostics operating segment, where the royalty rates range from 3% to 8%. Meridian expects that payments under these agreements will amount to approximately \$1,700 in fiscal 2021.

***Contingent Consideration for Acquisition of Business of GenePOC***

Details of the purchase price holdback and contingent consideration due to be paid pursuant to the purchase agreement related to the June 3, 2019 acquisition of the business of GenePOC are set forth in Note 2, “*Business Combinations*” of the accompanying Consolidated Financial Statements.

***Off-Balance Sheet Arrangements***

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

## **Market Risk Exposure:**

### ***Foreign Currency Risk***

We have market risk exposure related to foreign currency transactions from our operations outside the United States, as well as certain suppliers to our domestic businesses located outside the United States. The foreign currencies where we have market risk exposure are the Australian dollar, British pound, Canadian dollar, Chinese yuan, Euro, and New Israeli shekel. Assessing foreign currency exposures is a component of our overall ongoing risk management process, with such currency risks managed as we deem appropriate.

### ***Concentration of Customers/Products Risk***

Our Diagnostics segment's revenues from sales through two U.S. distributors were 23% of the segment's total revenues or 12% of consolidated revenues for fiscal 2020. Additionally, our three major product families – gastrointestinal, respiratory illnesses and blood chemistry – accounted for 82% of our Diagnostics segment's third-party revenues during fiscal 2020, and 39% of our fiscal 2020 consolidated revenues.

Our Life Science segment's revenues from sales of purified antigens and reagents to three diagnostics manufacturing customers were 27% of the segment's total revenues for fiscal 2020, and 14% of our fiscal 2020 consolidated revenues. Additionally, sales of products related to COVID-19 accounted for 54% of our Life Science segment's third-party revenues during fiscal 2020, and 28% of our 2020 consolidated revenues.

## **Critical Accounting Policies:**

The consolidated financial statements included in this Annual Report on Form 10-K have been prepared in accordance with accounting principles generally accepted in the United States. Such accounting principles require management to make judgments about estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Listed below are the accounting policies management believes to be critical to understanding the accompanying Consolidated Financial Statements, along with reference to location of the policy discussion within the accompanying financial statements. The listed policies are considered critical due to the fact that application of such policies requires the use of significant estimates and assumptions, and the carrying values of related assets and liabilities are material.

<b><u>Accounting Policy</u></b>	<b><u>Location Within Consolidated Financial Statements</u></b>	<b><u>Examples of Key Estimate Assumptions</u></b>
Inventories	Note 1(f)	Slow-moving, excess & obsolete inventories
Intangible Assets	Note 1(h)	Triggering events and impairment conditions
Revenue Recognition	Note 1(i)	Distributor price adjustments and fee accruals
Fair Value Measurements	Note 1(j)	Valuation of interest rate swap agreements and contingent consideration
Income Taxes	Note 1(l) and Note 7	Uncertain tax positions and state apportionment factors

## **Recent Accounting Pronouncements:**

A description of accounting pronouncements recently adopted by the Company, as well as accounting pronouncements issued but not yet adopted by the Company, are set forth in Note 1(q) of the accompanying Consolidated Financial Statements.

ITEM 7A.

## **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

See Market Risk Exposure and Capital Resources under Item 7 above beginning on page 25.

ITEM 8.

FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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All other supplemental schedules are omitted due to the absence of conditions under which they are required or because the information is shown in the Consolidated Financial Statements or Notes thereto.

## MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f).

The Company's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting can only provide reasonable assurance and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2020, based on the framework and criteria in the 2013 *Internal Control – Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on management's evaluation and those criteria, the Company concluded that its system of internal control over financial reporting was effective as of September 30, 2020. The Company's assessment of and conclusion on the effectiveness of its internal control over financial reporting did not include the internal controls of wholly-owned subsidiaries Meridian Bioscience Israel Holding Ltd. and Exalenz Bioscience, Inc. (collectively "Exalenz"), which were acquired during fiscal 2020 and the results of which since the date of acquisition were included in the 2020 consolidated financial statements. Exalenz constituted \$75,551 or 18.64% of the Company's total assets as of September 30, 2020, and \$4,206 or 1.66% of total net revenues, for the year ended September 30, 2020.

The Company's independent registered public accounting firm has issued an attestation report on the registrant's internal control over financial reporting.

/s/ Jack Kenny  
Jack Kenny  
Chief Executive Officer  
November 23, 2020

/s/ Bryan T. Baldasare  
Bryan T. Baldasare  
Executive Vice President and  
Chief Financial Officer  
November 23, 2020

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders  
Meridian Bioscience, Inc.

### **Opinion on the financial statements**

We have audited the accompanying consolidated balance sheets of Meridian Bioscience, Inc. (an Ohio corporation) and subsidiaries (the “Company”) as of September 30, 2020 and 2019, the related consolidated statements of operations, comprehensive income, shareholders’ equity, and cash flows for each of the three years in the period ended September 30, 2020, and the related notes and financial statement schedule listed in the index appearing under Schedule No. II (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2020, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of September 30, 2020, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”), and our report dated November 23, 2020 expressed an unqualified opinion.

### **Adoption of new accounting standard**

As discussed in Note 1 to the consolidated financial statements, the Company has changed its method for accounting for leases in fiscal 2020 due to the adoption of Accounting Standards Codification 842, *Leases*.

### **Basis for opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### **Critical audit matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### *Valuation of Intangible Assets associated with the Exalenz Acquisition*

As described further in Note 2 to the consolidated financial statements, the Company completed its acquisition of Exalenz Bioscience Ltd. (“Exalenz”) for net cash consideration of \$51.3 million, which resulted in the identification and recognition of \$55.2 million of intangible assets. Intangible assets consisted primarily of customer relationships, technology and trade name (collectively “the identifiable intangible assets”), with the remainder allocated to goodwill. The Company used a discounted cash flow model to measure the customer

relationship intangible asset and a relief from royalty model to measure the technology and trade name intangible assets. We identified the valuation of identifiable intangible assets associated with the Exalenz acquisition as a critical audit matter.

The principal consideration for our determination that the valuation of the identifiable intangible assets is a critical audit matter is the complexity associated with auditing the Company's preliminary valuation of identifiable intangible assets due to the high degree of management subjectivity in the related fair value estimates. The high degree of management subjectivity is primarily due to the sensitivity of the respective fair values to underlying assumptions about the future performance of the acquired business. The significant assumptions used to estimate the fair value of the identifiable intangible assets included certain assumptions that form the basis of the future net cash flows (e.g., assumed growth rates, discount rate, economic lives, royalty rates and margin percentages). These significant assumptions are forward looking and consider anticipated market conditions.

Our audit procedures related to the preliminary valuation of intangible assets included the following, among others.

- We tested the design and operating effectiveness of controls relating to the valuation report and allocation of purchase price, which included management's review of the preliminary valuation report for the completeness and mathematical accuracy of the data, and evaluating the reasonableness of assumptions used in the calculations, such as assumed growth rates, discount rate, economic lives, royalty rates and margin percentages, as compared to industry/market data.
- We tested the significant assumptions used within the discounted cash flow model to estimate the fair value of the identifiable intangible assets which included certain assumptions such as assumed growth rates, economic lives, and margin percentages as compared to industry/market data.
- We utilized a valuation specialist to assist in evaluating the appropriateness of the Company's selection of valuation methodology for the identifiable intangible assets and evaluating the reasonableness of certain significant assumptions used, including discount rate, economic lives, and royalty rates.
- We evaluated whether assumptions used were reasonable by considering past performance of similar assets, industry data, current market forecasts, and whether such assumptions were consistent with evidence obtained in other areas of the audit.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2005.

Cincinnati, Ohio  
November 23, 2020



## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders  
Meridian Bioscience, Inc.

### **Opinion on internal control over financial reporting**

We have audited the internal control over financial reporting of Meridian Bioscience, Inc. an Ohio corporation and subsidiaries (the “Company”) as of September 30, 2020, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2020, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated financial statements of the Company as of and for the year ended September 30, 2020, and our report dated November 23, 2020 expressed an unqualified opinion on those financial statements.

### **Basis for opinion**

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control over Financial Reporting (“Management’s Report”). Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Our audit of, and opinion on, the Company’s internal control over financial reporting does not include the internal control over financial reporting of Meridian Bioscience Israel Holding Ltd. and Exalenz Bioscience, Inc., wholly-owned subsidiaries (collectively “Exalenz”), whose financial statements reflect total assets and revenues constituting 18.64% and 1.66%, respectively, of the related consolidated financial statement amounts as of and for the year ended September 30, 2020. As indicated in Management’s Report, Exalenz was acquired during fiscal 2020. Management’s assertion on the effectiveness of the Company’s internal control over financial reporting excluded internal control over financial reporting of Exalenz.

### **Definition and limitations of internal control over financial reporting**

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

Cincinnati, Ohio  
November 23, 2020

**CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data)****Meridian Bioscience, Inc. and Subsidiaries**

For the Year Ended September 30,	2020	2019	2018
Net Revenues	\$ 253,667	\$ 201,014	\$ 213,571
Cost of Sales	97,419	82,286	82,538
Gross Profit	156,248	118,728	131,033
Operating Expenses:			
Research and development	23,729	17,760	16,613
Selling and marketing	26,486	27,995	34,026
General and administrative	44,345	34,044	35,759
Acquisition-related costs	3,890	1,808	-
Change in fair value of contingent consideration obligation	(6,293)	-	-
Restructuring costs	687	2,839	8,706
Selected legal costs	2,080	1,583	4,345
Total operating expenses	94,924	86,029	99,449
Operating Income	61,324	32,699	31,584
Other Income (Expense):			
Interest income	142	681	418
Interest expense	(2,632)	(1,945)	(1,520)
Other, net	459	122	(102)
Total other expense	(2,031)	(1,142)	(1,204)
Earnings Before Income Taxes	59,293	31,557	30,380
Income Tax Provision	13,107	7,175	6,531
Net Earnings	\$ 46,186	\$ 24,382	\$ 23,849
Earnings Per Share Data:			
Basic earnings per common share	\$ 1.08	\$ 0.57	\$ 0.56
Diluted earnings per common share	\$ 1.07	\$ 0.57	\$ 0.56
Common shares used for basic earnings per common share	42,855	42,571	42,325
Effect of dilutive stock options and restricted share units	319	328	429
Common shares used for diluted earnings per common share	43,174	42,899	42,754
Dividends declared per common share	\$ -	\$ 0.250	\$ 0.500
Anti-dilutive Securities:			
Common share options and restricted share units	893	1,129	1,007

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

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (dollar amounts in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

For the Year Ended September 30,	2020	2019	2018
Net Earnings	\$ 46,186	\$ 24,382	\$ 23,849
Other comprehensive income (loss):			
Foreign currency translation adjustment	3,884	(802)	(1,075)
Unrealized gain (loss) on cash flow hedge	(713)	(1,159)	907
Reclassification of amortization of gain on cash flow hedge	(308)	(102)	-
Income taxes related to items of other comprehensive income	252	465	(263)
Other comprehensive income (loss), net of tax	3,115	(1,598)	(431)
Comprehensive Income	\$ 49,301	\$ 22,784	\$ 23,418

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS (dollar amounts in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

For the Year Ended September 30,	2020	2019	2018
<b>Cash Flows From Operating Activities</b>			
Net earnings	\$ 46,186	\$ 24,382	\$ 23,849
Non-cash items included in net earnings:			
Depreciation of property, plant and equipment	5,823	5,433	4,491
Amortization of intangible assets	7,744	4,531	3,433
Amortization of deferred instrument costs	-	-	764
Stock-based compensation	3,802	3,251	3,402
Deferred income taxes	760	(817)	(300)
Losses on dispositions of long-lived assets	64	632	-
Change in accrued contingent consideration	(6,293)	-	-
Change in the following, net of acquisitions:			
Accounts receivable	(971)	(2,215)	(4,370)
Inventories	(18,977)	3,841	(1,142)
Prepaid expenses and other current assets	(153)	(2,143)	246
Accounts payable and accrued expenses	7,248	(2,315)	4,124
Income taxes payable	1,435	1,793	(524)
Other, net	1,308	(198)	814
Net cash provided by operating activities	47,976	36,175	34,787
<b>Cash Flows From Investing Activities</b>			
Purchase of property, plant and equipment	(3,299)	(3,797)	(4,201)
Disposals of property, plant and equipment	-	669	-
Acquisitions, net of cash acquired	(51,299)	(45,324)	-
Net cash used for investing activities	(54,598)	(48,452)	(4,201)
<b>Cash Flows From Financing Activities</b>			
Dividends paid	-	(10,612)	(21,170)
Proceeds from revolving credit facility	50,000	75,824	-
Payment on revolving credit facility	(57,000)	-	-
Payment of debt issuance costs	(116)	(489)	-
Payments on term loan	-	(50,250)	(4,500)
Proceeds from exercises of stock options	3,559	443	183
Payment of acquisition consideration	-	-	(2,110)
Net cash provided by (used for) financing activities	(3,557)	14,916	(27,597)
<b>Effect of Exchange Rate Changes on Cash and Equivalents and Restricted Cash</b>			
	1,296	(1,005)	(298)
<b>Net Increase (Decrease) in Cash and Equivalents and Restricted Cash</b>			
	(8,883)	1,634	2,691
<b>Cash and Equivalents and Restricted Cash at Beginning of Period</b>			
	62,397	60,763	58,072
<b>Cash and Equivalents and Restricted Cash at End of Period</b>			
	\$ 53,514	\$ 62,397	\$ 60,763
Cash and Equivalents	\$ 53,514	\$ 62,397	\$ 59,763
Restricted Cash	-	-	1,000
Cash and Equivalents and Restricted Cash at End of Period	\$ 53,514	\$ 62,397	\$ 60,763

**Supplemental Cash Flow Information:** See Notes 1(g), 2, 5, 6 and 7.

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

**CONSOLIDATED BALANCE SHEETS (dollar amounts in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

As of September 30,	2020	2019
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and equivalents	\$ 53,514	\$ 62,397
Accounts receivable, less allowances of \$513 and \$537, respectively	38,512	36,698
Inventories	61,264	39,617
Prepaid expenses and other current assets	8,900	6,049
Total current assets	162,190	144,761
<b>Property, Plant and Equipment, at Cost:</b>		
Land	991	982
Buildings and improvements	32,188	31,904
Machinery, equipment and furniture	69,854	64,155
Construction in progress	1,200	522
Subtotal	104,233	97,563
Less: accumulated depreciation and amortization	73,113	66,996
Net property, plant and equipment	31,120	30,567
<b>Other Assets:</b>		
Goodwill	114,186	89,241
Other intangible assets, net	83,197	60,243
Right-of-use assets	6,336	-
Deferred income taxes	7,647	156
Other assets	585	510
Total other assets	211,951	150,150
Total assets	\$ 405,261	\$ 325,478

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

**CONSOLIDATED BALANCE SHEETS (dollar amounts in thousands)****Meridian Bioscience, Inc. and Subsidiaries**

As of September 30,	2020	2019
<b>Liabilities and Shareholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 11,969	\$ 7,238
Accrued employee compensation costs	16,661	7,938
Current portion of acquisition consideration	12,619	-
Current operating lease obligations	1,789	-
Current government grant obligations	600	-
Other accrued expenses	5,362	3,758
Income taxes payable	3,524	1,980
Total current liabilities	52,524	20,914
<b>Non-Current Liabilities:</b>		
Acquisition consideration	13,290	32,202
Post-employment benefits	2,493	2,500
Fair value of interest rate swaps	713	-
Long-term operating lease obligations	4,678	-
Long-term debt	68,824	75,824
Government grant obligations	10,524	-
Long-term income taxes payable	549	549
Deferred income taxes	3,804	2,522
Other non-current liabilities	233	-
Total non-current liabilities	105,108	113,597
<b>Commitments and Contingencies</b>		
<b>Shareholders' Equity:</b>		
Preferred stock, no par value; 1,000,000 shares authorized; none issued	-	-
Common shares, no par value; 71,000,000 shares authorized, 43,068,842 and 42,712,296 issued, respectively	-	-
Additional paid-in capital	140,195	132,834
Retained earnings	109,294	63,108
Accumulated other comprehensive loss	(1,860)	(4,975)
Total shareholders' equity	247,629	190,967
Total liabilities and shareholders' equity	\$ 405,261	\$ 325,478

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

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (dollar and share amounts in thousands, except per share data)**

**Meridian Bioscience, Inc. and Subsidiaries**

	Common Shares Issued	Additional Paid-in Capital	Retained Earnings	Accum Other Comp Income (Loss)	Total
<b>Balance at September 30, 2017</b>	42,207	\$ 125,608	\$ 46,923	\$ (2,946)	\$ 169,585
Cash dividends paid - \$0.500 per share	-	-	(21,170)	-	(21,170)
Conversion of restricted share units and exercise of stock options	193	183	-	-	183
Stock compensation expense	-	3,402	-	-	3,402
Net earnings	-	-	23,849	-	23,849
Foreign currency translation adjustment	-	-	-	(1,075)	(1,075)
Hedging activity, net of tax	-	-	-	644	644
<b>Balance at September 30, 2018</b>	42,400	129,193	49,602	(3,377)	175,418
Cash dividends paid - \$0.250 per share	-	-	(10,612)	-	(10,612)
Conversion of restricted share units and exercise of stock options	312	390	-	-	390
Stock compensation expense	-	3,251	-	-	3,251
Net earnings	-	-	24,382	-	24,382
Foreign currency translation adjustment	-	-	-	(802)	(802)
Hedging activity, net of tax	-	-	-	(944)	(944)
Adoption of ASU 2014-09	-	-	(116)	-	(116)
Adoption of ASU 2018-02	-	-	(148)	148	-
<b>Balance at September 30, 2019</b>	42,712	132,834	63,108	(4,975)	190,967
Conversion of restricted share units exercise of stock options	357	3,559	-	-	3,559
Stock compensation expense	-	3,802	-	-	3,802
Net earnings	-	-	46,186	-	46,186
Foreign currency translation adjustment	-	-	-	3,884	3,884
Hedging activity, net of tax	-	-	-	(769)	(769)
<b>Balance at September 30, 2020</b>	43,069	\$ 140,195	\$ 109,294	\$ (1,860)	\$ 247,629

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



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### Meridian Bioscience, Inc. and Subsidiaries

(dollar and share amounts in thousands, except per share data)

#### (1) *Summary of Significant Accounting Policies*

- (a) **Nature of Business** - Meridian is a fully-integrated life science company whose principal businesses are: (i) the development, manufacture and distribution of clinical diagnostic test kits primarily for certain gastrointestinal and respiratory infectious diseases, and elevated blood lead levels; and (ii) the manufacture and distribution of bulk antigens, antibodies, PCR/qPCR reagents, nucleotides, and bioresearch reagents used by other diagnostic manufacturers and researchers.
- (b) **Principles of Consolidation** - The consolidated financial statements include the accounts of Meridian Bioscience, Inc. and its subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. Unless the context requires otherwise, references to “Meridian,” “we,” “us,” “our” or “our company” refer to Meridian Bioscience, Inc. and its subsidiaries.
- (c) **Use of Estimates** - The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.
- (d) **Foreign Currency Translation** - Assets and liabilities of foreign operations are translated using year-end exchange rates with gains or losses resulting from translation included as a separate component of accumulated other comprehensive income or loss. Revenues and expenses are translated using exchange rates prevailing during the year. We also recognize foreign currency transaction gains and losses on certain assets and liabilities that are denominated in the Australian dollar, British pound, Canadian dollar, Chinese yuan, Euro, and New Israeli shekel currencies. These gains and losses are included in other income and expense in the accompanying Consolidated Statements of Operations.
- (e) **Cash, Cash Equivalents and Investments** - The primary objectives of our investment activities are to preserve capital and provide sufficient liquidity to meet operating requirements and fund strategic initiatives such as acquisitions. We maintain a written investment policy that governs the management of our investments in fixed income securities. This policy, among other things, provides that we may purchase only high credit-quality securities that have short-term ratings of at least A-2, P-2 and F-2, and long-term ratings of at least A, Baa1 and A, by Standard & Poor’s, Moody’s and Fitch, respectively, at the time of purchase. We consider short-term investments with original maturities of 90 days or less to be cash equivalents, including institutional money market funds. At times our investments of cash and equivalents with various high credit quality financial institutions may be in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance limit.

As of September 30,	2020	2019
Institutional money market funds	\$ 1,017	\$ 20,913
Cash on hand, unrestricted	52,497	41,484
Total	\$ 53,514	\$ 62,397

- (f) **Inventories** - Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out (FIFO) basis. Testing instruments are carried in inventory until they are sold outright or placed with a customer under the customer reagent rental program, at which time they are transferred to property, plant and equipment.

We establish reserves against cost for excess and obsolete materials, finished goods whose shelf life may expire before sale to customers, and other identified exposures. Such reserves were \$3,629 and \$2,441 at September 30, 2020 and 2019, respectively. We estimate these reserves based on assumptions about future demand and market conditions. If actual demand and market conditions were to be less favorable than such estimates, additional inventory write-downs would be required and recorded in the period known. Such adjustments would negatively affect gross profit margin and overall results of operations.

- (g) **Property, Plant and Equipment** - Property, plant and equipment are stated at cost. Upon retirement or other disposition, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in earnings. Maintenance and repairs are expensed as incurred. Depreciation is computed on the straight-line method in amounts sufficient to write-off the cost over the estimated useful lives, generally as follows:

Buildings and improvements - 18 to 40 years  
Leasehold improvements - life of the lease  
Machinery, equipment and furniture - 3 to 10 years  
Computer equipment and software - 3 to 5 years  
Instruments under customer reagent rental arrangements - 5 years

Supplemental Cash Flow Information (Non-Cash Capital Expenditures)

Additions to property, plant and equipment for which cash remained unpaid at fiscal year-end totaled \$236, \$108 and \$294 in fiscal 2020, 2019 and 2018, respectively.

- (h) **Intangible Assets** - Goodwill is subject to an annual impairment review (or more frequently if impairment indicators arise) at the reporting unit level, which we perform annually as of June 30, the end of our third fiscal quarter. A reporting unit is generally an operating segment or one level below an operating segment that constitutes a business for which discrete financial information is available and regularly reviewed by segment management. At both September 30, 2020 and September 30, 2019, we had two reporting units (Diagnostics and Life Science), both of which contained goodwill. We review our reporting unit structure annually, or more frequently if facts and circumstances warrant. Goodwill is considered impaired if the carrying value of the reporting unit exceeds its fair value. We have no intangible assets with indefinite lives other than goodwill.

During fiscal 2020, the annual impairment review of the Company's goodwill consisted of a qualitative assessment for each of our Diagnostics and Life Science reporting units. A qualitative assessment is first performed to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value using qualitative indicators. In the event that the reporting unit does not pass the qualitative assessment, the reporting unit's carrying value is compared to its fair value, with fair value of the reporting unit estimated using market value and discounted cash flow approaches. Both our Diagnostics and Life Science reporting units satisfied the qualitative assessment for fiscal 2020.

During fiscal 2019 and 2018, we performed quantitative assessments as of June 30 for each of our Diagnostics and Life Science reporting units. As part of this assessment, fair value, as determined through a valuation performed by a third party, was calculated via both market (comparable company) and income (discounted cash flows) approaches. Based upon these approaches, the fair value of each reporting unit exceeded its carrying value; therefore, each of the Diagnostics and Life Science reporting units satisfied the quantitative assessment for each of fiscal 2019 and 2018.

During fiscal 2020, goodwill increased \$24,945, reflecting the addition of \$24,466 in connection with the acquisition of Exalenz, a \$6 decrease from currency translation adjustments on the goodwill associated with the GenePOC business, and a \$485 increase from currency translation adjustments on the goodwill of the Life Science reporting unit. The increase of \$34,604 in fiscal 2019 resulted from the addition of \$34,582 in

connection with the acquisition of the GenePOC business, a \$599 increase from the currency translation adjustments thereon and a \$577 decrease from currency translation adjustments on the goodwill of the Life Science reporting unit.

A summary of Meridian's acquired intangible assets subject to amortization, as of September 30, 2020 and 2019 is as follows.

	2020		2019	
	Gross Carrying Value	Accum. Amort.	Gross Carrying Value	Accum. Amort.
As of September 30,				
Manufacturing technologies, core products and cell lines	\$ 62,363	\$ 18,750	\$ 56,193	\$ 15,096
Tradenames, licenses and patents	18,425	7,801	14,494	6,094
Customer lists, customer relationships and supply agreements	45,071	16,210	24,274	14,110
Government grants	810	810	814	232
Non-compete agreements	110	11	-	-
	<b>\$ 126,779</b>	<b>\$ 43,582</b>	<b>\$ 95,775</b>	<b>\$ 35,532</b>

The actual aggregate amortization expense for these intangible assets for fiscal 2020, 2019 and 2018 was \$7,744, \$4,531 and \$3,433, respectively. The estimated aggregate amortization expense for these intangible assets for each of the five succeeding fiscal years is as follows: fiscal 2021 - \$8,371, fiscal 2022 - \$7,993, fiscal 2023 - \$7,980, fiscal 2024 - \$7,976 and fiscal 2025 - \$7,967.

Long-lived assets, excluding goodwill, are reviewed for impairment when events or circumstances indicate that such assets may not be recoverable at their carrying value. Whether an event or circumstance triggers an impairment is determined by comparing an estimate of the asset's future undiscounted cash flows to its carrying value. If impairment has occurred, it is measured by a fair-value based calculation.

Our ability to recover the carrying value of our intangible assets, both identifiable intangibles and goodwill, is dependent upon the future cash flows of the related acquired businesses and assets. We make judgments and assumptions regarding future cash flows, including sales levels, gross profit margins, operating expense levels, working capital levels, and capital expenditures. With respect to identifiable intangibles and fixed assets, we also make judgments and assumptions regarding useful lives.

We consider the following factors in evaluating events and circumstances for possible impairment: (i) significant under-performance relative to historical or projected operating results; (ii) negative industry trends; (iii) sales levels of specific groups of products (related to specific identifiable intangibles); (iv) changes in overall business strategies; and (v) other factors.

If actual cash flows are less favorable than projections, this could trigger impairment of intangible assets and other long-lived assets. If impairment were to occur, this would negatively affect overall results of operations. No triggering events have been identified by the Company for fiscal 2020, 2019 or 2018.

(i) Revenue Recognition and Accounts Receivable -

Revenue Disaggregation

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

**Revenue by Reportable Segment & Geographic Region**

	2020	2019	2018	2020 vs. 2019 Inc (Dec)	2019 vs. 2018 Inc (Dec)
Diagnostics-					
Americas	\$ 97,228	\$ 110,109	\$ 123,916	(12)%	(11)%
EMEA	21,826	23,888	23,922	(9)%	- %
ROW	2,078	2,685	2,616	(23)%	3 %
Total Diagnostics	121,132	136,682	150,454	(11)%	(9)%
Life Science-					
Americas	37,391	19,441	21,080	92 %	(8)%
EMEA	58,125	28,850	24,715	101 %	17 %
ROW	37,019	16,041	17,322	131 %	(7)%
Total Life Science	132,535	64,332	63,117	106 %	2 %
Consolidated	\$ 253,667	\$ 201,014	\$ 213,571	26 %	(6)%

**Revenue by Product Platform/Type**

	2020	2019	2018	2020 vs. 2019 Inc (Dec)	2019 vs. 2018 Inc (Dec)
Diagnostics-					
Molecular assays	\$ 21,907	\$ 26,283	\$ 33,709	(17)%	(22)%
Non-molecular assays	99,225	110,399	116,745	(10)%	(5)%
Total Diagnostics	\$ 121,132	\$ 136,682	\$ 150,454	(11)%	(9)%
Life Science-					
Molecular reagents	\$ 78,431	\$ 23,261	\$ 24,533	237 %	(5)%
Immunological reagents	54,104	41,071	38,584	32 %	6 %
Total Life Science	\$ 132,535	\$ 64,332	\$ 63,117	106 %	2 %

**Revenue by Disease State (Diagnostics only)**

	2020	2019	2018	2020 vs. 2019 Inc (Dec)	2019 vs. 2018 Inc (Dec)
Diagnostics-					
Gastrointestinal assays	\$ 55,040	\$ 68,982	\$ 78,803	(20)%	(12)%
Respiratory illness assays	26,694	26,622	28,911	- %	(8)%
Blood chemistry assays	17,534	18,639	19,109	(6)%	(2)%
Other	21,864	22,439	23,631	(3)%	(5)%
Total Diagnostics	\$ 121,132	\$ 136,682	\$ 150,454	(11)%	(9)%

## Revenue Policies

### *Product Sales*

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. Management estimates accruals for distributor price adjustments based on local contract terms, sales data provided by distributors, historical statistics, current trends, and other factors. Changes to the accruals are recorded in the period that they become known. Such accruals are netted against accounts receivable.

Shipping and handling costs incurred after control of the product is transferred to our customers are treated as fulfillment costs and not a separate performance obligation.

Our payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 90 days from the date of shipment or satisfaction of the performance obligation. Trade accounts receivable are recorded in the accompanying Condensed Consolidated Balance Sheets at invoiced amounts less provisions for distributor price adjustments under local contracts and doubtful accounts. The allowance for doubtful accounts represents our estimate of probable credit losses and is based on historical write-off experience and known conditions that would likely lead to non-payment. Customer invoices are charged off against the allowance when we believe it is probable that the invoices will not be paid.

### *Practical Expedients and Exemptions*

Revenue is recognized net of any taxes collected from customers (sales tax, value added tax, etc.), which are subsequently remitted to government authorities.

Our diagnostic assay products are generally not subject to a customer right of return except for product recall events under the rules and regulations of the Food and Drug Administration or equivalent agencies outside the United States. In this circumstance, the costs to replace affected products would be accrued at the time a loss was probable and estimable.

We expense as incurred the costs to obtain contracts, as the amortization period would be one year or less. These costs, recorded within selling and marketing expense, include our internal sales force compensation programs and certain partner sales incentive programs, as we have determined that annual compensation is commensurate with annual selling activities.

### *Reagent Rental Arrangements*

Certain of our Diagnostics segment's product platforms require the use of instruments for the tests to be processed. In many cases, a customer is given use of the instrument provided they continue purchasing the associated tests, also referred to as "consumables" or "reagents". If a customer stops purchasing the consumables, the instrument must be returned to us. Such arrangements are common practice in the diagnostics industry and are referred to as "Reagent Rentals". Reagent Rentals may also include instrument related services such as a limited replacement warranty, training and installation. We concluded that the use of the instrument and related services (collectively known as "lease elements") are not within the scope of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* but rather ASC 842, *Leases*. Accordingly, we first allocate the transaction price between the lease elements and the non-lease elements based on estimates of relative standalone selling prices. Lease revenue is derived solely from the sale of consumables and is therefore recognized monthly as earned, which coincides with the transfer of control of the non-lease elements.

For the portion of the transaction price allocated to the non-lease elements, which are principally the test kits, the related revenue is recognized at a point-in-time when control transfers.

Revenue allocated to the lease elements of these Reagent Rental arrangements totaled approximately \$4,600 and \$4,150 in fiscal 2020 and 2019, respectively, and are included as part of net revenues in our Consolidated Statements of Operations.

- (j) **Fair Value Measurements** - Certain assets and liabilities are recorded at fair value in accordance with ASC 820-10, *Fair Value Measurements and Disclosures*. ASC 820-10 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 820-10 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

As indicated in Note 2, we acquired Exalenz and the business of GenePOC in fiscal 2020 and fiscal 2019, respectively. The fair value of the acquired accounts receivable and other current assets and the fair value of the assumed accounts payable and accrued expenses approximated their carrying value at the acquisition date. Inventories, property, plant and equipment, intangible assets and contingent consideration were valued using Level 3 inputs.

In connection with the acquisition of the business of GenePOC and an agreement to amend certain terms of the agreement related to contingent consideration achievement levels and milestone dates, as described in Note 2, 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 payments recognized upon the acquisition as part of the purchase accounting opening balance sheet totaled \$27,202. The fair value of the product development milestone payments was 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. 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 revenue, probability of certain developments, expected expenses and discount rate. The ultimate settlement of contingent consideration could deviate from current estimates based on the actual results of these financial measures. Giving effect to the previously noted amendment to the contingent consideration achievement levels and milestone dates, the contingent consideration obligation is valued at \$20,909 and \$27,202 as of September 30, 2020 and September 30, 2019, respectively.

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

	Carrying Value	Fair Value Measurements Using Inputs Considered as		
		Level 1	Level 2	Level 3
Interest rate swaps (see Note 6) -				
As of September 30, 2020	\$ (713)	\$ -	\$ (713)	\$ -
As of September 30, 2019	\$ -	\$ -	\$ -	\$ -
Contingent consideration -				
As of September 30, 2020	\$ (20,909)	\$ -	\$ -	\$ (20,909)
As of September 30, 2019	\$ (27,202)	\$ -	\$ -	\$ (27,202)

**(k) Research and Development Costs** - Research and development costs are charged to expense as incurred. Research and development costs include, among other things, salaries and wages for research scientists, materials and supplies used in the development of new products, costs for development of instrumentation equipment, costs for clinical trials, and costs for facilities and equipment.

**(l) Income Taxes** - The provision for income taxes includes federal, foreign, state and local income taxes currently payable and those deferred because of temporary differences between income for financial reporting and income for tax purposes. We prepare estimates of permanent and temporary differences between income for financial reporting purposes and income for tax purposes. These differences are adjusted to actual upon filing of our tax returns, typically occurring in the third and fourth quarters of the current fiscal year for the preceding fiscal year's estimates.

We account for uncertain tax positions using a benefit recognition model with a two-step approach: (i) a more-likely-than-not recognition criterion; and (ii) a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being ultimately realized upon ultimate settlement. If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit is recorded. We recognize accrued interest related to unrecognized tax benefits as a portion of our income tax provision in the Consolidated Statements of Operations. See Note 7.

**(m) Stock-Based Compensation** - We recognize compensation expense for all share-based awards made to employees, based upon the fair value of the share-based award on the date of the grant. See Note 8(b).

**(n) Comprehensive Income (Loss)** - Comprehensive income (loss) represents the net change in shareholders' equity during a period from sources other than transactions with shareholders. As reflected in the accompanying Consolidated Statements of Comprehensive Income, our comprehensive income is comprised of net earnings, foreign currency translation, unrecognized gain on termination of our previous cash flow hedge, and the income taxes thereon.

**(o) Shipping and Handling Costs** - Shipping and handling costs invoiced to customers are included in net revenues. Costs to distribute products to customers, including freight costs, warehousing costs, and other shipping and handling activities are included in cost of sales.

**(p) Non-Income Government-Assessed Taxes** - We classify all non-income, government-assessed taxes (sales, use and value-added) collected from customers and remitted by us to appropriate revenue authorities, on a net basis (excluded from net revenues) in the accompanying Consolidated Statements of Operations.

**(q) Recent Accounting Pronouncements** -

Pronouncements Adopted

On October 1, 2019, the Company adopted ASC 842, *Leases*. ASC 842 was issued to increase transparency and comparability among entities by recognizing right-of-use assets ("ROU assets") and lease liabilities on the balance sheet and disclosing key information about lease arrangements. The Company elected to adopt ASC 842 effective October 1, 2019 using the modified retrospective transition method, which was applied to

leases that existed or will be entered into on or after such date, with no adjustment made to prior comparative periods. The comparative periods presented herein reflect the former lease accounting guidance and the required comparative disclosures are included in Note 5, "*Leasing Arrangements*". There was no cumulative-effect adjustment to beginning retained earnings as a result of adopting ASC 842, and additional operating lease ROU assets and obligations of approximately \$5,880 were recognized as of October 1, 2019. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the ROU asset is amortized over the lease term. The Company elected the package of practical expedients permitted under the new guidance to not reassess prior conclusions related to the identification, classification and accounting for initial direct costs for leases that commenced prior to October 1, 2019. Additionally, the elections were made to not use hindsight to determine lease terms and to not separate non-lease components within the lease portfolio. See Note 5 for further information.

#### Pronouncements Issued but Not Yet Adopted as of September 30, 2020

In March 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 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 U.S. 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 plans to apply this guidance to such transactions and modifications of arrangements but does not expect application to have a material impact on financial condition, results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, which changes the impairment model used to measure credit losses for most financial assets. We will be required to use a new forward-looking expected credit loss model that will replace the existing incurred credit loss model for our accounts receivable. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years (fiscal 2021 for the Company), with early adoption permitted. The Company does not anticipate that the adoption of this guidance will have a material impact on its consolidated financial statements.

- (f) **Reclassifications** - Certain reclassifications have been made to the prior fiscal year financial statements to conform to the current year presentation. Such reclassifications had no impact on net earnings or shareholders' equity.

## (2) *Business Combinations*

### Acquisition of Exalenz

On April 30, 2020 ("the acquisition date"), we acquired 100% of the outstanding common shares and voting interest of Exalenz Bioscience Ltd. ("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, we utilized cash and equivalents on hand and proceeds drawn from our revolving credit facility (see Note 6).

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. The settlement of the currency contracts resulted in an \$845 gain, which is reflected within other income in the Consolidated Statement of Operations for the year ended September 30, 2020.



As a result of total consideration exceeding the preliminary fair value of the net assets acquired, goodwill in the amount of \$24,466 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 system through our established customer base and distribution channels. The Consolidated Statement of Operations for the year ended September 30, 2020 included \$3,890 of acquisition-related costs related to the Exalenz acquisition, which are reflected in operating expenses.

The Company's fiscal 2020 consolidated results include \$4,206 of net revenues and \$1,911 of net loss from Exalenz since the date of acquisition. These results, which are reported as part of the Diagnostics segment, include \$1,120 of amortization of specific identifiable assets recorded in the opening balance sheet, 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:

	<b>PRELIMINARY</b>		
	<b>April 30, 2020 (as initially reported)</b>	<b>Measurement Period Adjustments</b>	<b>April 30, 2020 (as adjusted)</b>
Fair value of assets acquired -			
Cash	\$ 5,006	\$ -	\$ 5,006
Accounts receivable	637	-	637
Inventories	4,329	-	4,329
Other current assets	851	1,825	2,676
Property, plant and equipment	544	76	620
Goodwill	29,288	(4,822)	24,466
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	1,151	6,717
	<u>76,199</u>	<u>293</u>	<u>76,492</u>
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
	<u>19,894</u>	<u>293</u>	<u>20,187</u>
Total consideration paid (including \$8,068 to pay off long-term debt)	<u>\$ 56,305</u>	<u>\$ -</u>	<u>\$ 56,305</u>

As indicated, the allocation of the purchase price is preliminary, pending final completion of valuations. 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 from goodwill to deferred taxes, as applicable.

Acquisition of Business of GenePOC

On June 3, 2019, we acquired the business of GenePOC Inc. (“GenePOC”), a Quebec City, Quebec Province, Canada based provider of molecular diagnostic instruments and assays. The purchase agreement originally contemplated a maximum total consideration of up to \$120,000, which was estimated at a total fair value of \$77,526 as of the acquisition date. During fiscal 2020, an agreement was reached to amend certain terms of the original contingent consideration achievement levels and milestone dates, such that the total consideration will be no greater than \$114,000. Pursuant to the purchase agreement, as amended, the maximum consideration is comprised of the following:

- (i) a \$50,000 cash payment on June 3, 2019, subject to a working capital adjustment and a holdback of \$5,000 to secure selling party’s performance of certain post-closing obligations;
- (ii) one \$4,000 installment and one \$10,000 installment contingent upon the achievement of certain product development milestones if achieved by September 30, 2022 (originally two \$10,000 installments contingent upon the achievement of certain product development milestones if achieved by September 30, 2020 and March 31, 2021, respectively); and
- (iii) up to \$50,000 of contingent consideration payable if certain financial performance targets are achieved during the twelve-month period ending September 30, 2022.

As previously noted, the fair value of the contingent consideration identified in (ii) and (iii) above was \$27,202 and \$20,909 as of the acquisition date and September 30, 2020, respectively.

The total of the holdback identified in (i) above and the currently estimated value of the contingent consideration identified in (ii) and (iii) above are reflected within the accompanying Condensed Consolidated Balance Sheets as of September 30, 2020 as follows:

Current liabilities - \$12,619

Reflects anticipated settlement of the holdback amount in the first quarter of fiscal 2021 and the first product milestone payment in the fourth quarter of fiscal 2021.

Non-current liabilities - \$13,290

Reflects anticipated settlement of the second product milestone payment in the first quarter of fiscal 2022 and financial performance targets payments in the first quarter of fiscal 2023.

To finance the acquisition, we utilized cash and equivalents on hand and proceeds drawn from our revolving credit facility. As a result of estimated total consideration exceeding the fair value of the net assets acquired, goodwill in the amount of \$34,582 was recorded in connection with this acquisition, most of which will be deductible for U.S. tax purposes ratably over 15 years. The goodwill results largely from our ability to market and sell GenePOC’s technology and instrument platform through our established customer base and distribution channels.

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

Fair value of assets acquired -		
Accounts receivable	\$	57
Inventories		1,511
Other current assets		84
Property, plant and equipment		1,424
Goodwill		34,582
Other intangible assets (estimated useful life):		
License agreement (10 years)		5,990
Technology (15 years)		34,136
Government grant (1.33 years)		800
		78,584
Fair value of liabilities assumed -		
Accounts payable and accrued expenses		1,058
Total consideration paid (including contingent consideration originally estimated at \$27,202)		
	\$	77,526

*Unaudited Pro Forma Information (Exalenz and GenePOC)*

The following table provides the unaudited consolidated pro forma results for the periods presented as if both Exalenz and the business of GenePOC had been acquired as of the beginning of fiscal 2019. Pro forma results do not include the effect of any synergies 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.

Year Ended September 30,	2020	2019
Net Revenues	\$ 261,131	\$ 214,821
Net Earnings	\$ 45,701	\$ 8,173

These pro forma amounts have been calculated by including the results of Exalenz and GenePOC, and adjusting the combined results to give effect to the following, as if the acquisitions had been consummated on October 1, 2018, together with the consequential tax effects thereon:

Year Ended September 30,	2020	2019
<u>Adjustments to Net Revenues</u>		
Exalenz and GenePOC pre-acquisition revenues	\$ 7,464	\$ 13,807
<u>Adjustments to Net Earnings</u>		
Exalenz and GenePOC pre-acquisition net losses	\$ (6,423)	\$ (13,598)
Pro forma adjustments:		
Meridian acquisition-related costs	3,890	-
Exalenz transaction-related costs	4,550	-
Gain on Exalenz purchase price currency contracts	(845)	-
Remove net impact of non-continuing personnel, locations or activities	(305)	3,022
Incremental depreciation and amortization	(1,680)	(5,358)
Incremental interest costs, net	(183)	(1,477)
Tax effects of pro forma adjustments and recognizing benefit on resulting Exalenz losses	511	1,202
Total Adjustments to Net Earnings	\$ (485)	\$ (16,209)

Supplemental Cash Flow Information (Non-Cash Acquisition Consideration)

As noted above, the remaining acquisition consideration obligation related to acquisition of the GenePOC business decreased \$6,293 during fiscal 2020, due in large part to amendment of certain terms of the original contingent consideration achievement levels and milestone dates. As result, such non-cash consideration totaled \$25,909 as of September 30, 2020, down from \$32,202 as of September 30, 2019. No such items existed in fiscal 2018.

**(3) Restructuring**

During the second quarter of fiscal 2018, the Company began implementation of a plan to realign its business structure into two business units, Diagnostics and Life Science, supported by a global corporate team. Since that time and as part of this plan, certain functions and locations within both business units have been streamlined, including: (i) the elimination of certain executive management and commercial sales positions; (ii) the closing of Life Science locations in Taunton, Massachusetts and Singapore, the operations of which were transferred to our existing locations in Memphis, Tennessee and London, England, respectively; and (iii) the transfer of certain functions performed in the Billerica, Massachusetts Diagnostics facility to the corporate headquarters in Cincinnati, Ohio. Further restructuring costs were incurred in fiscal 2019 and fiscal 2020, as refinements to each business unit's cost structure continued to be made and the Company incurred severance payment obligations relating to the transition of its previous chief financial officer.

As a result of these activities, restructuring costs totaling \$687, \$2,839 and \$6,332 were recorded during fiscal 2020, 2019 and fiscal 2018, respectively, the details of which are as follows:

Year Ended September 30,	2020	2019	2018
Severance, other termination benefits and related costs	\$ 601	\$ 2,046	\$ 5,012
Lease and other contract termination fees	86	54	353
Loss on fixed asset disposals and inventory scrap	-	528	225
Other	-	211	742
Total	\$ 687	\$ 2,839	\$ 6,332

The above table does not include \$2,374 of CEO transition costs incurred in fiscal 2018, which primarily represents the compensation and benefits for our previous Executive Chairman and CEO, Mr. John A. Kraeutler, throughout fiscal 2018, the period during which we also had the compensation and benefits of our current CEO, Mr. Jack Kenny, who began employment at the beginning of fiscal 2018. These CEO transition costs and the restructuring costs set forth in the table above comprise the \$8,706 of restructuring costs set forth in the accompanying Consolidated Statement of Operations for fiscal 2018.

A reconciliation of the changes in the liabilities associated with the restructuring charges from September 30, 2018 through September 30, 2020 is as follows:

	Employee Separation and Related Costs	Lease and Other Contract Termination Fees	Other	Total
Balance at September 30, 2018	\$ 987	\$ 33	\$ 6	\$ 1,026
Restructuring charges	2,810	54	211	3,075
Reversal of prior period accruals	(401)	(32)	(61)	(494)
Payments	(2,386)	(43)	(42)	(2,471)
Balance at September 30, 2019	\$ 1,010	\$ 12	114	\$ 1,136
Restructuring charges	642	86	-	728
Reversal of prior period accruals	(41)	-	-	(41)
Payments	(1,565)	(98)	(114)	(1,777)
Balance at September 30, 2020	\$ 46	\$ -	\$ -	\$ 46

**(4) Inventories**

Inventories are comprised of the following:

As of September 30,	2020	2019
Raw materials	\$ 11,966	\$ 7,455
Work-in-process	19,477	11,504
Finished goods - instruments	1,594	935
Finished goods - kits and reagents	28,227	19,723
Total	\$ 61,264	\$ 39,617

**(5) 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, current operating lease obligations and long-term operating lease obligations on the Consolidated Balance Sheet. 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. Our Consolidated Statement of Operations for fiscal 2020 reflects lease costs for these operating leases of \$597 and \$1,286 within cost of sales and operating expenses, respectively. The amounts charged to expense under operating leases in fiscal 2019 and 2018 total \$2,372 and \$2,457, respectively. Right-of-use assets obtained during fiscal 2020 in exchange for operating lease liabilities totaled \$1,600.

In addition, the Company has periodically entered into other short-term operating leases, generally with an initial term of twelve months or less. These leases are not recorded on the balance sheet and the related lease expense is immaterial for fiscal 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 weighted average remaining lease term for our operating leases as of September 30, 2020 was 4.2 years.

The discount rate implicit within our leases is generally not determinable and, therefore, the Company determines the discount rate using its incremental borrowing rate. The weighted average discount rate used to measure our operating leases as of September 30, 2020 was 3.7%.

Maturities of lease liabilities by fiscal year for the Company's operating lease liabilities were as follows as of September 30, 2020:

	September 30, 2020
2021	\$ 2,002
2022	1,744
2023	1,271
2024	978
2025	691
Thereafter	282
Total lease payments	6,968
Less amount of lease payment representing interest	(501)
Total present value of lease payments	\$ 6,467

As of September 30, 2019, future minimum lease payments under noncancelable operating leases were as follows:

	September 30, 2019
2020	\$ 1,528
2021	1,451
2022	1,293
2023	967
2024	712
Thereafter	616
<b>Total</b>	<b>\$ 6,567</b>

Supplemental Cash Flow Information (Cash Paid for Amounts Included in Measurement of Lease Liabilities)

Operating cash flows from operating lease payments totaled \$1,693 in fiscal 2020.

**(6) Bank Credit Arrangements**

In anticipation of the acquisition of the business of GenePOC (see Note 2), 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 2). 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 3.30% and 4.13% on the credit facility during fiscal 2020 and 2019, respectively. Since entering into the credit facility, three draws totaling \$125,824 have been made on the credit facility, with principal repayments in January 2020 and September 2020 of \$27,000 and \$30,000, respectively, resulting in an outstanding principal balance of \$68,824 at September 30, 2020. 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 credit facility at both September 30, 2020 and September 30, 2019 approximates the current carrying value reflected in the accompanying 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 credit facility agreement. As of September 30, 2020, the Company is in compliance with all covenants.

In order to limit exposure to volatility in the LIBOR interest rate, during March 2020 and June 2020 the Company and the commercial bank entered into three interest rate swap agreements that effectively converted the variable interest rate on \$50,000 of the outstanding principal to a fixed rate of 2.16% (at the current credit spread) beginning June 24, 2020, the effective date of the most recent swap agreement. With an initial notional balance of \$50,000, the interest rate swap agreements were established with critical terms identical to borrowings under the credit facility, including: (i) one-month LIBOR settlement rates, as to be elected by the Company throughout the remaining term of the credit facility; (ii) rate reset dates; and (iii) term/maturity. Consequently, the interest rate swaps have been designated as effective cash flow hedges, with changes in fair values reflected as a separate component of other comprehensive income in the accompanying Consolidated Statements of Comprehensive Income. At September 30, 2020, the fair value of the interest rate swaps was reported as a liability of \$713, which is reflected as a non-current liability in the accompanying Consolidated Balance Sheet. This fair value was determined by reference to a third-party valuation and is considered a Level 2 input within the fair value hierarchy of valuation techniques.

In connection with the Company's term loan repayment in May 2019, the Company also settled the interest rate swap that had been entered into to limit exposure to volatility in the term loan's LIBOR interest rate. At the time of settlement, the Company received a cash payment in an amount equal to the \$563 then-current fair value of the interest rate swap. Accordingly, there is no balance for this interest rate swap reflected within assets or liabilities within the accompanying Consolidated Balance Sheets as of September 30, 2020 or September 30, 2019. The fair value of the swap that had been reflected within a separate component of other comprehensive income in the accompanying Consolidated Statements of Comprehensive Income, as a result of the interest rate swap having been designated as an effective cash flow hedge, is being released ratably into income through March 31, 2021, the interest rate swap's original term.

The balance reflected within accumulated other comprehensive income related to the interest rate swap agreements associated with both the current credit facility and the former term loan totaled \$560 and \$461 at September 30, 2020 and September 30, 2019, respectively.

*Supplemental Cash Flow Information (Interest Paid)*

Cash paid for interest totaled \$2,690, \$1,405 and \$1,487 in fiscal 2020, 2019 and 2018, respectively.

**(7) Income Taxes**

(a) Earnings before income taxes, and the related provision for income taxes for the years ended September 30, 2020, 2019 and 2018 were as follows:

Year Ended September 30,	2020	2019	2018
Domestic	\$ 9,068	\$ 23,954	\$ 27,787
Foreign	50,225	7,603	2,593
Total earnings before income taxes	\$ 59,293	\$ 31,557	\$ 30,380
Provision (credit) for income taxes -			
Federal -			
Current	\$ 1,173	\$ 5,001	\$ 6,030
Temporary differences			
Fixed asset basis differences and depreciation	960	288	410
Intangible asset basis differences and amortization	753	(797)	(4,052)
Currently non-deductible expenses and reserves	(1,001)	241	1,206
Stock-based compensation	(41)	(109)	1,379
Net operating loss carryforwards utilized	26	69	61
Tax credit carryforwards utilized	-	-	181
Other, net	47	(169)	(148)
Subtotal	1,917	4,524	5,067
State and local	1,170	834	1,066
Foreign	10,020	1,817	398
Total income tax provision	\$ 13,107	\$ 7,175	\$ 6,531

(b) The following is a reconciliation between the statutory U.S. income tax rate and the effective rate derived by dividing the provision for income taxes by earnings before income taxes:

Year Ended September 30,	2020		2019		2018	
Computed income taxes at statutory rate	\$ 12,452	21.0 %	\$ 6,627	21.0 %	\$ 7,443	24.5 %
Increase (decrease) in taxes resulting from -						
State and local income taxes	773	1.3	577	1.8	982	3.2
U.S. tax law change	-	-	-	-	(2,655)	(8.7)
One-time repatriation tax	-	-	-	-	876	2.9
Foreign-Derived Intangible Income tax	(136)	(0.2)	(294)	(0.9)	-	-
Global Intangible Low Taxed Income tax	4,970	8.4	1,119	3.6	-	-
Foreign tax credit	(4,767)	(8.0)	(990)	(3.1)	(15)	-
Foreign tax rate differences	(534)	(0.9)	46	0.1	(104)	(0.3)
Transaction costs	548	0.9	-	-	-	-
Qualified domestic production incentives	-	-	-	-	(550)	(1.8)
Uncertain tax position activity	62	0.1	126	0.4	(62)	(0.2)
Valuation allowance	(106)	(0.2)	106	0.3	(40)	(0.1)
Stock-based compensation	41	0.1	(33)	(0.1)	447	1.4
Other, net	(196)	(0.4)	(109)	(0.4)	209	0.6
	<b>\$ 13,107</b>	<b>22.1 %</b>	<b>\$ 7,175</b>	<b>22.7 %</b>	<b>\$ 6,531</b>	<b>21.5 %</b>

On December 22, 2017, the United States enacted tax reform legislation commonly known as the Tax Cuts and Jobs Act (the “tax reform act”) including the Global Intangible Low Taxed Income tax (“GILTI”), which requires the Company to include in U.S. income certain foreign earnings that do not exceed a 10% return on foreign investment. For the year ended September 30, 2020, the Company’s U.S. GILTI inclusion was \$23,666, resulting in a permanent tax expense of \$4,970, which is offset by a foreign tax credit benefit of \$4,767. During fiscal 2020, the Internal Revenue Service issued Final Treasury Regulations related to the GILTI tax. Such regulations served to reduce the Company’s fiscal 2019 GILTI inclusion, resulting in an additional \$220 federal tax benefit related to fiscal 2019. For the year ended September 30, 2019, the Company’s U.S. GILTI inclusion totaled \$5,328, resulting in a permanent tax expense and a foreign tax credit benefit of \$1,119 and \$990, respectively. The Company has elected to take the GILTI into account in the year it occurs.

(c) The components of net deferred taxes were as follows:

As of September 30,	2020	2019
Deferred tax assets -		
Valuation reserves and non-deductible expenses	\$ 4,848	\$ 1,253
Stock compensation expense not deductible	1,804	2,158
Net operating loss and tax credit carryforwards	10,164	494
Basis difference in equity-method investee	302	302
Inventory basis differences	382	289
Other	207	125
Subtotal	17,707	4,621
Less valuation allowance	(302)	(408)
Deferred tax assets	17,405	4,213
Deferred tax liabilities -		
Fixed asset basis differences and depreciation	(4,269)	(2,205)
Intangible asset basis differences and amortization	(9,293)	(4,374)
Deferred tax liabilities	(13,562)	(6,579)
Net deferred tax assets (liabilities)	\$ 3,843	\$ (2,366)



For income tax purposes, we have recorded deferred tax assets related to operating loss and tax credit carryforwards in both U.S. and foreign jurisdictions totaling \$205 and \$9,959, respectively, as of September 30, 2020. At September 30, 2019, such deferred tax assets totaled \$231 and \$263, respectively. The operating loss carryforwards in foreign jurisdictions, the majority of which relate to Israel, have no expiration date. The operating loss carryforwards in the U.S. expire in 2023 at the federal level, and in 2036 at the state level. The aggregate amount of federal, state and foreign operating loss carryforwards separately totaled \$243, \$2,432 and \$78,332, respectively, at September 30, 2020. The use of the federal and state losses is limited by the change of ownership provisions of the Internal Revenue Code.

The Company has evaluated its assertion as to whether earnings of foreign subsidiaries are indefinitely reinvested. The Company has removed its indefinite reinvestment assertion on the foreign subsidiary earnings and recognized a deferred tax liability of \$185 to reflect the corporate and withholding tax impact of a presumed repatriation of foreign earnings.

The realization of deferred tax assets is dependent upon the generation of future taxable income in the applicable jurisdictions. We have considered the levels of currently anticipated pre-tax income in U.S. and foreign jurisdictions in assessing the required level of the deferred tax asset valuation allowance including the characterization of the income as ordinary or capital. Taking into consideration historical and current operating results, and other factors, we believe that it is more likely than not that the net deferred tax asset of \$17,405 will be realized. The amount of the net deferred tax asset considered realizable, however, could be reduced in future years if estimates of future taxable income are reduced.

We utilize a comprehensive model for the recognition, measurement, presentation and disclosure of uncertain tax positions, assuming full knowledge of all relevant facts by the applicable tax authorities. The total amount of unrecognized tax benefits at September 30, 2020 and September 30, 2019 related to such positions was \$568 and \$509, respectively, of which \$494 would favorably impact the effective tax rate if recognized. We generally recognize interest and penalties related to uncertain tax positions as a component of our income tax provision. During fiscal 2020 and 2019, such penalties and interest totaled approximately \$20 and \$34, respectively. We had approximately \$138 accrued for the payment of interest and penalties at September 30, 2020 compared to \$118 accrued at September 30, 2019. The amount of our liability for uncertain tax positions expected to be paid or settled in the next 12 months is uncertain.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows:

	2020	2019
Unrecognized income tax benefits at beginning of year	\$ 509	\$ 388
Additions for tax positions of prior years	-	83
Reductions for tax positions of prior years	-	(38)
Additions for tax positions of current year	104	138
Tax examination and other settlements	(45)	(62)
<b>Unrecognized income tax benefits at end of year</b>	<b>\$ 568</b>	<b>\$ 509</b>

We are subject to examination by the tax authorities in the U.S. (both federal and state) and the countries of Australia, Belgium, Canada, China, England, France, Germany, Holland, Israel and Italy. In the U.S., tax years subsequent to fiscal 2016 remain open. In countries outside the U.S., open tax years generally range from fiscal 2015 and forward. However, in Australia and Belgium, the utilization of local net operating loss carryforwards extends the statute of limitations for examination well into the foreseeable future. To the extent that adjustments result from the completion of these examinations or the lapsing of statutes of limitation, they will affect tax liabilities in the period known. We believe that the results of any tax authority examinations would not have a significant adverse impact on our financial condition or results of operations.

Supplemental Cash Flow Information (Income Taxes Paid)

Cash paid for income taxes totaled \$9,816, \$7,840 and \$6,555 in fiscal 2020, 2019 and 2018, respectively.

**(8) Employee Benefits**

- (a) Savings and Investment Plan** - We have a profit sharing and retirement savings plan covering substantially all full-time U.S. employees. Profit sharing contributions to the plan, which are discretionary, are approved by the board of directors. The plan permits participants to contribute to the plan through salary reduction. Under terms of the plan, we match 100% of an employee's contributions, up to a maximum match of 4% of eligible compensation. Our discretionary and matching contributions to the plan amounted to approximately \$2,434, \$1,979 and \$2,118, during fiscal 2020, 2019 and 2018, respectively.
- (b) Stock-Based Compensation Plans** - During fiscal 2020, we had two active stock-based compensation plans, the 2004 Equity Compensation Plan, which became effective December 7, 2004, as amended (the "2004 Plan") and the 2012 Stock Incentive Plan, which became effective January 25, 2012 (the "2012 Plan").

Each of the 2004 Plan and 2012 Plan authorized the granting of new shares for options, restricted shares or restricted share units for up to 3,000 shares, with the non-granted portion of the 2004 Plan permitted to be carried forward and added to the 2012 Plan authorized limit. As of September 30, 2020, we have granted 1,255 and 2,702 shares under the 2004 Plan and 2012 Plan, respectively, thereby resulting in a remaining authorized limit of 2,043 shares. Options may be granted at exercise prices not less than 100% of the closing market value of the underlying common shares on the date of grant and have maximum terms up to ten years. Vesting schedules for options, restricted shares and restricted share units are established at the time of grant and may be set based on future service periods, achievement of performance targets or a combination thereof. All options contain provisions restricting their transferability and limiting their exercise in the event of termination of employment or the disability or death of the optionee. We recognize compensation expense for all share-based payments made to employees, based upon the fair value of the share-based payment on the date of the grant.

During fiscal years 2018 through 2020, we granted, in the aggregate for the three-year period, approximately 1,040 restricted share units (with weighted-average grant date fair values of \$14.65 per share in fiscal 2018, \$18.66 per share in fiscal 2019 and \$10.13 per share in fiscal 2020) to certain employees, including current CEO, Mr. Jack Kenny, as separately detailed below. Aside from those granted to Mr. Kenny, the units granted in fiscal 2020 and 2019 were generally time-vested restricted share units vesting in total on the third anniversary of the grant date. During fiscal 2018, generally half of each employee's grant was time-vested restricted share units vesting in total on the fourth anniversary of the grant date, with the remaining half being subject to attainment of a specified earnings target for each fiscal period. While dividend equivalents were paid on these units throughout fiscal 2018, the targets for fiscal 2018 were not met and the performance-based portion of these restricted share units granted have been cancelled.

During fiscal 2020, in connection with Mr. Kenny's Amended and Restated Employment Agreement effective October 1, 2019, we granted to Mr. Kenny: (i) options to purchase approximately 198 shares of common stock of the Company (with a grant date fair value of \$3.38 per share) vesting on a pro rata basis over the three years ending October 1, 2022; and (ii) approximately 100 restricted share units (with a grant date fair value of \$10.10 per share) vesting 100% on the October 1, 2022, which are included within the restricted share units noted above.

During fiscal 2018 in connection with Mr. Kenny's October 9, 2017 employment, we granted to Mr. Kenny: (i) options to purchase 100 shares of common stock of the Company (with a grant date fair value of \$3.19 per share) vesting on a pro rata basis over four years; and (ii) 13 restricted share units (with a grant date fair value of \$14.50 per share) vesting 100% on the second anniversary of the grant. Also during fiscal 2018 in connection with his Amended and Restated Employment Agreement, we granted to our former Chairman and CEO at that time, Mr. John A. Kraeutler, 25 restricted share units (with a grant date fair value of \$15.30 per share) to be earned only if specified revenue and earnings per share targets were achieved for fiscal 2018. As a result of the fiscal 2018 performance targets related to this grant being achieved, these restricted share units were fully vested and the related shares were paid to Mr. Kraeutler in November 2018.

Giving effect to these grants, cancellations and certain other activities for restricted shares and restricted share units throughout the years, including conversions to common shares, forfeitures, and new hire and employee promotion grants, approximately 603 restricted share units remain outstanding as of September 30, 2020, with

a weighted-average grant date fair value of \$13.27 per share, a weighted-average remaining vesting period of 1.53 years and an aggregate intrinsic value of \$10,237. The weighted-average grant date fair value of the approximate 157 restricted share units that vested during fiscal 2020 was \$16.73 per share.

The amount of stock-based compensation expense reported was \$3,802, \$3,251 and \$3,402 in fiscal 2020, 2019 and 2018, respectively. The fiscal 2020 expense is comprised of \$1,006 related to stock options and \$2,796 related to restricted share units; the fiscal 2019 expense is comprised of \$542 related to stock options and \$2,709 related to restricted share units; and the fiscal 2018 expense is comprised of \$793 related to stock options and \$2,609 related to restricted share units. The total income tax benefit recognized in the income statement for these stock-based compensation arrangements was \$898, \$572 and \$303, for fiscal 2020, 2019 and 2018, respectively. As of September 30, 2020, we expect future stock compensation expense for unvested options and unvested restricted share units to total \$515 and \$3,122, respectively, which will be recognized during fiscal years 2021 through 2023.

We recognize compensation expense only for the portion of shares that we expect to vest. As such, we apply estimated forfeiture rates to our compensation expense calculations. These rates have been derived using historical forfeiture data, stratified by several employee groups. During fiscal 2020, 2019 and 2018, we recorded \$148, \$127 and \$106, respectively, in stock compensation expense to adjust estimated forfeiture rates to actual, noting that total stock compensation expense for each of fiscal 2020, 2019 and 2018 reflects the effect of terminations made in connection with the restructuring activities discussed in Note 3.

We have elected to use the Black-Scholes option pricing model to determine grant-date fair value for stock options, with the following assumptions: (i) expected share price volatility based on the average of Meridian's historical volatility over the options' expected lives and implied volatility based on the value of tradable call options; (ii) expected life of options based on contractual lives, employees' historical exercise behavior and employees' historical post-vesting employment termination behavior; (iii) risk-free interest rates based on treasury rates that correspond to the expected lives of the options; and (iv) dividend yield based on the expected yield on underlying Meridian common stock.

Year ended September 30,	2020	2019	2018
Risk-free interest rates	1.60 %	2.99 %	2.10 %
Dividend yield	0 %	3.3 %	3.3 %
Life of option	6.51 yrs.	6.51 yrs.	6.47 yrs.
Share price volatility	34 %	29 %	30 %
Forfeitures (by employee group)	0%-16%	0%-16%	0%-16%

A summary of the status of our stock option plans as of September 30, 2020 and changes during the year ended September 30, 2020, is presented in the table and narrative below:

	Options	Wtd Avg Exercise Price	Wtd Avg Remaining Life (Yrs)	Aggregate Intrinsic Value
Outstanding beginning of period	990	\$ 17.36		
Grants	367	10.07		
Exercises	(203)	17.83		
Forfeitures	(2)	14.74		
Cancellations	(49)	21.62		
Outstanding end of period	1,103	\$ 14.67	6.89	\$ 3,483
Exercisable end of period	674	\$ 16.86	5.80	\$ 984

A summary of the status of our nonvested options as of September 30, 2020, and changes during the year ended September 30, 2020, is presented below:

	Options	Weighted-Average Grant Date Fair Value
Nonvested beginning of period	209	\$ 3.24
Granted	367	3.54
Vested	(145)	3.64
Forfeitures	(2)	3.11
Nonvested end of period	429	\$ 3.36

The weighted average grant-date fair value of options granted was \$3.54, \$3.61 and \$3.27 for fiscal 2020, 2019 and 2018, respectively. The total intrinsic value of options exercised was \$1,585, \$62 and \$2 for fiscal 2020, 2019 and 2018, respectively. The total grant-date fair value of options that vested during fiscal 2020, 2019 and 2018 was \$528, \$735 and \$580, respectively.

Cash received from options exercised was \$3,559, \$443 and \$183 for fiscal 2020, 2019 and 2018, respectively.

#### **(9) Contingent Obligations and Non-Current Liabilities**

In connection with the acquisition of Exalenz and as disclosed in Note 2, the Company assumed a number of 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. As such, these grant obligations and related accrued interest are considered contingent obligations under ASC 805-20 and, therefore, are measured, recognized and presented in both the September 30, 2020 and preliminary purchase accounting opening balance sheets at their estimated amounts to be paid. These obligation amounts total \$11,124 as of September 30, 2020, which is reflected on the Consolidated Balance Sheet within current liabilities (\$600) and non-current liabilities (\$10,524).

Additionally, the Company has provided certain post-employment benefits to its former CEO, and these obligations total \$1,840 and \$1,917 at September 30, 2020 and 2019, respectively. In addition, we are required by the governments of certain foreign countries in which we operate to maintain a level of accruals for potential future severance indemnity. These reserves total \$814 and \$702 at September 30, 2020 and 2019, respectively.

#### **(10) Reportable Segments and Major Concentration Data**

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.

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.

Two Diagnostics customers accounted for 10% and 11%, respectively, of consolidated net revenues in fiscal 2018, with no individual customers from either reportable segment accounting for 10% or more of consolidated net revenues in either fiscal 2020 or fiscal 2019. However, during fiscal 2020, reportable segment revenues were concentrated as follows:

**Diagnostics Segment**

Two diagnostics distributors: 23% of segment revenues; 12% of consolidated revenues

**Life Science Segment**

Three diagnostic manufacturers: 27% of segment revenues; 14% of consolidated revenues

Accounts receivable from one of the Diagnostics customers accounted for 11% of consolidated accounts receivable at September 30, 2019, while one of the Life Science customers accounted for 15% of consolidated accounts receivable at September 30, 2020.

Revenue generated by the Company outside of the U.S. and its territories totaled approximately \$121,596, \$74,193 and \$71,494 in fiscal 2020, 2019 and 2018, respectively, and our three major product families – gastrointestinal, respiratory illnesses and blood chemistry – accounted for 39%, 57% and 59% of consolidated net revenues in fiscal 2020, 2019 and 2018, respectively. In addition, products related to COVID-19 accounted for approximately 28% of consolidated fiscal 2020 revenues.

We currently purchase on a sole-source basis from a U.S. manufacturer the instruments on which our Alethia molecular testing platform operates, and from an Australian manufacturer the instruments on which our Curian testing platform operates.

Significant revenue information by country for the Diagnostics and Life Science segments is as follows. Revenues are attributed to the geographic area based on the location to which the product is delivered.

Year Ended September 30,	2020	2019	2018
United States and territories	\$ 95,382	\$ 107,890	\$ 121,609
Italy	9,797	10,911	10,398
United Kingdom	2,312	2,396	2,340
France	2,238	2,446	2,353
Belgium	1,440	1,468	1,711
Holland	1,183	1,413	1,454
Japan	848	1,572	1,307
Other countries	7,932	8,586	9,282
<b>Total Diagnostics</b>	<b>\$ 121,132</b>	<b>\$ 136,682</b>	<b>\$ 150,454</b>

Year Ended September 30,	2020	2019	2018
United States and territories	\$ 36,689	\$ 18,931	\$ 20,468
China	19,047	8,464	8,347
United Kingdom	14,765	4,709	5,201
Germany	14,190	12,663	8,108
Spain	7,242	4,414	4,187
Australia	5,957	3,458	3,631
France	5,579	2,200	2,040
Italy	4,067	1,357	971
Japan	3,707	1,624	1,932
Holland	3,212	710	715
Indonesia	3,027	169	162
Turkey	2,819	290	188
Finland	2,518	500	467
India	2,099	143	251
South Korea	1,908	1,134	2,044
Other countries	5,709	3,566	4,405
<b>Total Life Science</b>	<b>\$ 132,535</b>	<b>\$ 64,332</b>	<b>\$ 63,117</b>

In locations outside the U.S., the Company's identifiable assets were concentrated as follows at the end of the most recent fiscal years, with no additional country's total of assets exceeding \$5,000:

As of September 30,	2020	2019
Israel	\$ 70,097	\$ -
United Kingdom	27,373	22,963
Germany	12,877	7,141
Canada	9,865	6,807
Italy	7,858	7,557

Segment information for the interim periods is as follows:

	Diagnostics	Life Science	Corporate <sup>(1)</sup>	Eliminations <sup>(2)</sup>	Total
<b>Fiscal 2020</b>					
Net revenues -					
Third-party	\$ 121,132	\$ 132,535	\$ -	\$ -	\$ 253,667
Inter-segment	326	261	-	(587)	-
Operating income	3,885	68,826	(11,437)	50	61,324
Depreciation and amortization	11,451	2,116	-	-	13,567
Capital expenditures	1,850	1,449	-	-	3,299
Goodwill	94,855	19,331	-	-	114,186
Other intangible assets, net	83,179	18	-	-	83,197
Total assets	306,812	98,483	-	(34)	405,261
<b>Fiscal 2019</b>					
Net revenues -					
Third-party	\$ 136,682	\$ 64,332	\$ -	\$ -	\$ 201,014
Inter-segment	462	361	-	(823)	-
Operating income	25,390	17,581	(10,373)	101	32,699
Depreciation and amortization	7,676	2,288	-	-	9,964
Capital expenditures	2,049	1,748	-	-	3,797
Goodwill	70,395	18,846	-	-	89,241
Other intangible assets, net	59,807	436	-	-	60,243
Total assets	255,169	70,392	-	(83)	325,478
<b>Fiscal 2018</b>					
Net revenues -					
Third-party	\$ 150,454	\$ 63,117	\$ -	\$ -	\$ 213,571
Inter-segment	392	397	-	(789)	-
Operating income	34,603	11,765	(15,076)	292	31,584
Depreciation and amortization	6,557	2,131	-	-	8,688
Capital expenditures	2,477	1,724	-	-	4,201
Goodwill	35,213	19,424	-	-	54,637
Other intangible assets, net	22,068	1,045	-	-	23,113
Total assets	180,978	70,341	-	58	251,377

<sup>(1)</sup> Includes Restructuring and Selected Legal Costs of \$2,080, \$2,596 and \$7,779 in fiscal years 2020, 2019 and 2018, respectively.

<sup>(2)</sup> Eliminations consist of inter-segment transactions.

A reconciliation of segment operating income to consolidated earnings before income taxes for the years ended September 30, 2020, 2019 and 2018 is as follows:

Year Ended September 30,	2020	2019	2018
Segment operating income	\$ 72,761	\$ 43,072	\$ 46,660
Corporate expenses	(11,437)	(10,373)	(15,076)
Interest income	142	681	418
Interest expense	(2,632)	(1,945)	(1,520)
Other, net	459	122	(102)
Consolidated earnings before income taxes	\$ 59,293	\$ 31,557	\$ 30,380

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

**(11) Commitments and Contingent Obligations**

- (a) **Royalty Commitments** - We have entered into various license agreements that require payment of royalties based on a specified percentage of the sales of licensed products. Approximately 81% of our royalty expenses relate to our Diagnostics operating segment, where the royalty rates range from 3% to 8%. These royalty expenses are recognized on an as-earned basis and recorded in the year earned as a component of cost of sales. Annual royalty expenses associated with these agreements were approximately \$1,860, \$2,107 and \$2,579 for the fiscal years ended September 30, 2020, 2019 and 2018, respectively.
- (b) **Purchase Commitments** - Excluding the operating lease commitments reflected in Note 5, we have purchase commitments primarily for inventory and service items as part of the normal course of business. Commitments made under these obligations are \$26,315 for fiscal 2021 and \$1,376 for fiscal 2022 through fiscal 2023. No purchase commitments have been made beyond fiscal 2023.
- (c) **Litigation** - We are a party to various litigation matters from time to time that we believe are in the normal course of business. The ultimate resolution of these routine matters is not expected to have a material adverse effect on our financial position, results of operations or cash flows. Additionally, the Company has also become a party to certain legal matters that are somewhat outside the normal course of business.

On April 17, 2018, Magellan received a subpoena from the United States Department of Justice (“DOJ”) regarding its LeadCare product line. The subpoena outlines documents to be produced, and the Company is cooperating with the DOJ in this matter. The Company maintains rigorous policies and procedures to promote compliance with applicable regulatory agencies and requirements and is working with the DOJ to promptly respond to the subpoena, 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 \$2,035, \$1,585 and \$775 of expense for attorneys’ fees related to this matter is included within the Consolidated Statements of Operations for fiscal 2020, 2019 and 2018, respectively.

- (d) **Indemnifications** - In conjunction with certain contracts and agreements, we provide routine indemnifications related to our performance obligations. The terms of these indemnifications range in duration and in some circumstances are not explicitly defined. The maximum obligation under some such indemnifications is not explicitly stated and, as a result of our having no history of paying such indemnifications, cannot be reasonably estimated. We have not made any payments for these indemnifications and no liability is recorded at September 30, 2020 or September 30, 2019.

**(12) Quarterly Financial Data (Unaudited)**

The sum of the earnings per common share may not equal the corresponding annual amounts due to interim quarter rounding.

<b>For the Quarter Ended in Fiscal 2020</b>	<b>December 31</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>
<b>Net revenues</b>	\$ 47,421	\$ 57,296	\$ 84,797	\$ 64,153
<b>Gross profit</b>	27,557	34,455	55,905	38,331
<b>Net earnings</b>	2,827	9,359	27,507	6,493
<b>Basic earnings per common share</b>	0.07	0.22	0.64	0.15
<b>Diluted earnings per common share</b>	0.07	0.22	0.64	0.15
<b>Cash dividends per common share</b>	-	-	-	-



For the Quarter Ended in Fiscal 2019	December 31	March 31	June 30	September 30
Net revenues	\$ 51,480	\$ 50,248	\$ 48,440	\$ 50,846
Gross profit	31,836	29,406	28,304	29,182
Net earnings	8,106	7,094	5,079	4,103
Basic earnings per common share	0.19	0.17	0.12	0.10
Diluted earnings per common share	0.19	0.17	0.12	0.10
Cash dividends per common share	0.125	0.125	-	-

ITEM 9.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS  
ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A.

CONTROLS AND PROCEDURES

As of September 30, 2020, an evaluation, excluding the internal controls of wholly-owned subsidiaries Meridian Bioscience Israel Holding Ltd. and Exalenz Bioscience, Inc. (collectively “Exalenz”), which were acquired during fiscal 2020, was completed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective as of September 30, 2020. There have been no changes in our internal control over financial reporting identified in connection with the evaluation of internal control that occurred during the fourth fiscal quarter that has materially affected, or is reasonably likely to affect, our internal control over financial reporting, or in other factors that could significantly affect internal control subsequent to September 30, 2020.

Our internal control report is included in this Annual Report on Form 10-K after Item 8, under the caption “Management’s Report on Internal Control over Financial Reporting.”

ITEM 9B.

OTHER INFORMATION

Not applicable.

PART III.

ITEM 10.

DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our directors and officers may be found under the captions “Election of Directors” and “Directors and Executive Officers” in our Proxy Statement for the Annual Meeting of Shareholders to be held January 27, 2021 (the “Proxy Statement”). Information about our Audit Committee may be found under the caption “Committees of the Board of Directors” in the Proxy Statement. That information is incorporated herein by reference.

We have adopted a code of ethics that applies to all of our employees, including our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer, and other finance organization employees. The code of ethics is publicly available on our website at [www.meridianbioscience.com](http://www.meridianbioscience.com). If we make any substantive amendments to the code of ethics or grant any waiver, including any implicit waiver, from a provision of the code to our Chief Executive Officer, Chief Financial Officer, or Chief Accounting Officer, we will disclose the nature of the amendment or waiver on that website or in a report on Form 8-K.

ITEM 11.

EXECUTIVE COMPENSATION

The information in the Proxy Statement set forth under the captions “Director Compensation,” “Compensation Discussion and Analysis,” “Compensation Committee Interlocks and Insider Participation,” and “Compensation Committee Report” is incorporated herein by reference.

ITEM 12.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information in the Proxy Statement set forth under the captions “Security Ownership of Certain Beneficial Owners” and “Equity Compensation Plan Information” is incorporated herein by reference.

ITEM 13.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information set forth in the Proxy Statement under the captions “Corporate Governance” and “Transactions with Related Persons” is incorporated herein by reference.

ITEM 14.

PRINCIPAL ACCOUNTING FEES AND SERVICES

Information concerning principal accountant fees and services appears in the Proxy Statement under the headings “Principal Accounting Firm Fees” and “Committees of the Board of Directors” and is incorporated herein by reference.

ITEM 15.

EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) and (2) FINANCIAL STATEMENTS AND SCHEDULES.

All financial statements and schedules required to be filed by Item 8 of this Form and included in this report have been so identified under Item 8. No additional financial statements or schedules are being filed since the requirements of paragraph (c) under Item 15 are not applicable to Meridian.

(b) (3) EXHIBITS.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
3.1	Amended Articles of Incorporation (Incorporated by reference to Meridian's Form 10-K filed with the Securities and Exchange Commission on November 26, 2019)
3.2	Amended and Restated Code of Regulations (Incorporated by reference to Meridian's Form 10-K filed with the Securities and Exchange Commission on November 26, 2019)
4.1	Description of Securities (Incorporated by reference to Meridian's Form 10-K filed with the Securities and Exchange Commission on November 26, 2019)
10.1*	Amendment No. 1 to Supplemental Benefit Agreement Dated September 23, 2014 between Meridian and John A. Kraeutler (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on September 25, 2014)
10.2*	Third Amended and Restated Employment Agreement Dated October 3, 2016 between Meridian and John A. Kraeutler (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on October 5, 2016)
10.3*	Amended and Restated Employment Agreement dated effective October 1, 2019 between Meridian and John P. Kenny (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on November 7, 2019)
10.4*	Dividend Reinvestment Plan (Incorporated by reference to Meridian's Annual Report on Form 10-K for the Fiscal Year Ended September 30, 1999)
10.5*	2012 Stock Incentive Plan, effective January 25, 2012 (Incorporated by reference to Meridian's Quarterly Report on Form 10-Q for the Quarterly Period Ended December 31, 2011)
10.6*	Israeli Appendix to the Meridian Bioscience, Inc. 2012 Stock Incentive Plan dated effective July 10, 2020 (Filed herewith)
10.7*	Form of Time-Based Restricted Share Unit Award Agreement (Filed herewith)
10.8*	Form of Nonqualified Stock Option Agreement (Filed herewith)
10.9*	Cash-Based Incentive Compensation Plan for Fiscal 2020 (Incorporated by reference to Meridian's Quarterly Report on Form 10-Q for the Quarterly Period Ended December 31, 2019)
10.10*	Form of Meridian Bioscience, Inc. Change in Control Agreement dated August 4, 2016 (Incorporated by reference to Meridian's Quarterly Report on Form 10-Q for the Quarterly Period Ended June 30, 2016)

10.11**	Share Purchase Agreement dated as of April 29, 2019 by and among GenePOC Inc., Meridian Bioscience Canada Inc., the shareholders of GenePOC Inc., Apres-Demain Holding SA, as Shareholders' Representative, and Meridian Bioscience, Inc. (Incorporated by reference to Meridian's Quarterly Report on Form 10-Q for the Quarterly Period Ended March 31, 2019)
10.12**	Credit Agreement, dated May 24, 2019 between Meridian Bioscience, Inc., as borrower, the Guarantors from time to time party thereto, the Lenders from time to time party thereto, and PNC Bank, National Association, as administrative agent (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on May 31, 2019)
10.13	First Amendment and Consent, dated as of February 19, 2020, by and among Meridian Bioscience, Inc., the Guarantors from time to time party thereto, the Lenders from time to time party thereto, and PNC Bank, National Association (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on February 20, 2020)
10.14**	Promissory Note dated June 3, 2019 between Meridian Bioscience Canada Inc. and GenePOC Inc. (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on June 3, 2019)
10.15	Agreement and Plan of Merger, dated as of February 19, 2020, by and among Meridian Bioscience, Inc., APM Trust Shelf 14 Ltd. and Exalenz Bioscience Ltd. (Incorporated by reference to Meridian's Form 8-K filed with the Securities and Exchange Commission on February 20, 2020)
10.16	Amendment No. 2 to Share Purchase Agreement dated as of September 29, 2020, between Apres-Demain Inc. (formerly known as GenePOC Inc.), Meridian Bioscience Canada, Inc., Apres-Demain SA in its capacity of Shareholders' Representative, and Meridian (Filed herewith)
21	List of Subsidiaries of the Registrant (Filed herewith)
23	Consent of Independent Registered Public Accounting Firm (Filed herewith)
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) (Filed herewith)
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) (Filed herewith)
32***	Section 1350 Certification of Chief Executive Officer and Chief Financial Officer (Furnished herewith)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\* Management Compensatory Contracts

\*\* Schedules to and certain portions of these exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the Registrant if publicly disclosed. The Registrant hereby agrees to furnish a copy of any omitted schedule or other portion to the SEC upon request.

\*\*\* Furnished, not filed.

Meridian will provide shareholders with any exhibit upon the payment of a specified reasonable fee, which fee shall be limited to Meridian's reasonable expenses in furnishing such exhibit.

ITEM 16.

FORM 10-K SUMMARY

None.

## SIGNATURES

Pursuant to the requirements of Sections 13 or 15(d) 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.

By: /s/ Jack Kenny  
Date: November 23, 2020  
Jack Kenny  
Chief Executive Officer

We, the undersigned directors and officers of the Registrant, hereby severally constitute Jack Kenny and Bryan T. Baldasare, and each of them singly, our true and lawful attorneys with full power to them and each of them to sign for us, in our names in the capacities indicated below, any and all amendments to the Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Jack Kenny</u> Jack Kenny	Chief Executive Officer and Director	November 23, 2020
<u>/s/ Bryan T. Baldasare</u> Bryan T. Baldasare	Executive Vice President, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	November 23, 2020
<u>/s/ David C. Phillips</u> David C. Phillips	Chairman of the Board	November 23, 2020
<u>/s/ James M. Anderson</u> James M. Anderson	Director	November 23, 2020
<u>/s/ Anthony P. Bihl III</u> Anthony P. Bihl III	Director	November 23, 2020
<u>/s/ Dwight E. Ellingwood</u> Dwight E. Ellingwood	Director	November 23, 2020
<u>/s/ John C. McIlwraith</u> John C. McIlwraith	Director	November 23, 2020
<u>/s/ John M. Rice, Jr.</u> John M. Rice, Jr.	Director	November 23, 2020
<u>/s/ Catherine A. Sazdanoff</u> Catherine A. Sazdanoff	Director	November 23, 2020
<u>/s/ Felicia Williams</u> Felicia Williams	Director	November 23, 2020

SCHEDULE II  
Meridian Bioscience, Inc.  
and Subsidiaries

Valuation and Qualifying Accounts  
(Dollars in thousands)  
Years Ended September 30, 2020, 2019 and 2018

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Deductions	Other (a)	Balance at End of Period
<b>Year Ended September 30, 2020:</b>					
Allowance for doubtful accounts	\$ 537	\$ 34	\$ (75)	\$ 17	\$ 513
Inventory realizability reserves	2,441	1,775	(564)	(23)	3,629
Valuation allowances – deferred taxes	408	-	(106)	-	302
<b>Year Ended September 30, 2019:</b>					
Allowance for doubtful accounts	\$ 310	\$ 347	\$ (100)	\$ (20)	\$ 537
Inventory realizability reserves	1,971	930	(448)	(12)	2,441
Valuation allowances – deferred taxes	302	106	-	-	408
<b>Year Ended September 30, 2018:</b>					
Allowance for doubtful accounts	\$ 307	\$ 39	\$ (32)	\$ (4)	\$ 310
Inventory realizability reserves	2,059	321	(405)	(4)	1,971
Valuation allowances – deferred taxes	342	-	(40)	-	302

(a) Balances reflect the effects of currency translation.

